FEED THE FUTURE
The U.S. Government's Global Hunger & Food Security Initiative

FEED THE FUTURE INNOVATION LAB FOR LIVESTOCK SYSTEMS

Good Laboratory Management

Training Manual for Trainers

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Sustainably intensifying smallholder livestock systems to improve human nutrition, health, and incomes

Disclaimer

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Table of Contents

Notes from the Author to the Trainers

This Good Laboratory Management Practices training manual for trainers has been designed as an introductory course in Good Laboratory Management Practices (GLP). During development, the Feed the Future Innovation Lab for Livestock Systems conducted GLP training workshops in Niger and Burkina Faso as part of its technology transfer and capacity building program in the area of laboratory management to support country-specific research priorities in all areas, but particularly in forage and animal nutrition research. The participants of these workshops expressed the need for additional training. The training manual has been compiled by Richard Fethiere, from the University of Florida, based on the materials that were used in the actual workshops. This training manual will serve as a tool for training and promoting GLP concepts in the laboratories that support livestock-related research.

Comments and suggestions on all aspects of these manuals are welcome for consideration in future revisions.

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Training Goals and Objectives

Goals:
The goal of this training is to address gaps in the effectiveness of laboratory management practices. This includes:

- The promotion of good laboratory practices
- The establishment of laboratory practices that promote the quality and validity of test data
- The establishment of proper reporting practices, including final reporting and archives
- Helping scientists obtain results that are reliable, repeatable, and recognized by scientists worldwide
- Promoting conditions in which analyses are planned, performed successfully, recorded, reported, archived, and monitored
- Promoting conditions in which laboratories function in a safe and environmentally conscious manner.

Objectives:
In order to accomplish these goals, this manual will focus on the following objectives:

1. Discuss the fundamentals of good science and good organization in laboratories, including relevant international standards and regulations.
2. Assess challenges in existing labs to conduct research aimed at improving animal health and production.
3. Assess gaps in organizational proficiency of laboratories.
4. Assess gaps in technical proficiency of laboratory management.
5. Assess gaps in technical proficiency of laboratory personnel, scientists, academics, and students.
6. Identify and discuss the roles and responsibilities of laboratory personnel including the lab director, lab manager, scientists, academics, lab staff, and students.
7. Identify and discuss how laboratory practices impact the quality of research and the quality and validity of test data.
8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.
9. Discuss laboratory safety and analyze a laboratory to determine the needs for improving laboratory safety.

Agenda

Day 1

Obj. #	Time	Activity/Lecture Title	Page
--	08:00 – 08:30	Registration	--
--	08:30 – 09:00	Activity: Welcome/Introductions	10
--	09:00 – 09:50	Activity: Norms and Expectations	11
1	09:50 – 10:20	Lecture: Introduction to Good Lab Practices	11
--	10:20 – 10:40	Coffee/Tea break	--
1	10:40 – 11:00	Activity: Brainstorm Good Science/Good Organization	16
3,6,8	11:00 – 11:45	Lecture: Good Lab Practices – Master Schedule and Personnel	16
3,6	11:45 – 12:30	Activity: Developing Job Descriptions and Responsibilities	17
--	12:30 – 13:30	Lunch Break	--
3,8	13:30 – 13:45	Lecture: Good Lab Practices – Master Schedule and Personnel, Continued	18
2,7	13:45 – 14:15	Activity: Discussion on Study Contamination	19
5,7	14:15 – 14:45	Activity: Dose Mixing Unit	20
2	14:45 – 15:00	Lecture: Barrier Systems and Alternatives	21
--	15:00 – 15:20	Coffee/Tea break	--
2,7,8	15:20 – 16:10	Activity: Case Study on Contamination/Disturbance	21
2,3,7,8	16:10 – 16:40	Activity: Discussion on GLP Building Compliance	22
--	16:40 – 17:00	Activity: End of Day Reflection	23

Day 2

Obj. #	Time	Activity/Lecture Title	Page
--	08:30 – 09:00	Activity: Review of Previous Day	23
3,8	09:00 – 09:40	Lecture: Good Lab Practice – Documentation	24
2,3,4,6,7,8	09:40 – 10:10	Activity: Discussion on Good Lab Practice Protocols	25
--	10:10 – 10:30	Coffee/Tea break	--
2,3,4,6,7,8	10:30 – 12:00	Lecture: Good Lab Practice – Study Protocols	26
--	12:00 – 13:00	Lunch Break	--
2,3,4,6,7,8	13:00 – 13:30	Lecture: Good Lab Practice – Study Protocols Part 2	28
2,3,4,6,7,8	13:30 – 14:00	Lecture: Good Lab Practice – Study Protocols Part 2, Continued	29
--	14:00 – 14:20	Coffee/Tea break	--
3,7,8	14:20 – 15:05	Activity: Brainstorm and Discuss SOPs	31
2,3,4,6,7,8	15:05 – 15:35	Lecture: Good Lab Practice – Study Protocols Part 3	32
4,7	15:35 – 15:45	Activity: List Test Systems	33
1,2	15:45 – 16:30	Lecture: Ethics and Rights	34
--	16:30 – 17:00	Activity: End of Day Reflection	35

Day 3

Obj. #	Time	Activity/Lecture Title	Page
--	08:30 – 09:00	Activity: Review of Previous Day	36
8	09:00 – 09:30	Lecture: Raw Data Collection and Audit Trails	36
7	09:30 – 10:30	Activity: Raw Data Collection Case Study	38
--	10:30 – 10:50	Coffee/Tea break	--
8	10:50 – 12:00	Lecture: Final Reporting and Archiving	39
--	12:00 – 13:00	Lunch Break	--
1,3,6,8	13:00 – 13:20	Lecture: Objectives of Good Lab Management	42
8	13:20 – 13:50	Activity: Lab Mission Statement	43
8	13:50 – 14:35	Activity: Promoting the Lab	44
--	14:35 – 14:55	Coffee/Tea break	--
8	14:55 – 15:40	Activity: Lab Intake Forms	44
8	15:40 – 16:00	Lecture: Processing the Intake of Samples	45
8	16:00 – 16:40	Activity: Developing a Lab Workbook	46
--	16:40 – 17:00	Activity: End of Day Reflection	46

Day 4

Obj. #	Time	Activity/Lecture Title	Page
--	08:30 – 09:00	Activity: Review of Previous Day	47
8,9	09:00 – 10:00	Lecture: Laboratory Safety and Equipment Maintenance	47
3,4,8,9	10:00 – 10:30	Activity: Laboratory Toolbox	49
--	10:30 – 10:50	Coffee/Tea break	--
9	10:50 – 12:00	Lecture: Personal Protective Equipment (PPEs)	50
--	12:00 – 13:00	Lunch Break	--
1,2,3,4,5 6,7,8,9	13:00 – 15:30	Practical: Laboratory Visit	51
--	15:30 – 15:20	Coffee/Tea break	--
--	15:20 – 16:00	Activity: Final Reflection	52
--	16:00 – 17:00	Activity: Training Closure	53

Day 5 – Joint Laboratory/Administrator Training and Strategic Planning

Note: Day 5 is intended to be flexible and can be moved to other days (for example, Day 4). It is highly suggested that this day of training takes place in addition to the training of laboratory staff and users. Day 5 focuses on decision-makers and administrators and the importance of their support of the laboratory.

Obj. #	Time	Activity/Lecture Title	Page
--	08:30 – 09:00	Activity: Welcome and Introductions	53
1,6,7	09:00 – 09:30	Lecture: How Laboratories Work	53
1,6,7	09:30 – 10:30	Discussion: The Role of Administrators and Decision-Makers in Laboratory Management	54
--	10:30 – 10:50	Coffee/Tea break	--
1,6,7	10:50 – 12:30	Activity: Laboratory Tour and Evaluation	55
--	12:30 – 13:30	Lunch Break	--
1,6,7,8	13:30 – 15:30	Activity: Strategic Planning	55
--	15:30 – 15:50	Coffee/Tea break	--

1,6,7,8	15:50 – 16:30	Activity: Strategic Planning	55
--	16:00 – 17:00	Activity: Closure	57

Tips for Trainers

Where possible, the trainer is encouraged to replace US-based examples (such as through the US-based Food and Drug Administration) with local agencies, processes, and laws.

This manual was developed as a general laboratory management training for the Livestock Systems Innovation Lab (LSIL) target countries. Depending on the cultural circumstances, the trainer may need to adapt the materials per the context. For example, in Burkina Faso and Niger, where this manual was piloted, laboratories face challenges in finding personal protective equipment (PPE) that is appropriate for the cultural clothing. In these countries, the clothing is loose fitting and covers most of the body. This presents a challenge for laboratory safety within the cultural context. It is recommended that the trainer have sufficient knowledge of the cultural context to appropriately adapt the activities, as needed.

Note: Within this manual, Lecture Notes and "slides" refer to presentations. These slides may become available in the future.

Session Plans: Day 1

Activity: Welcome/Introductions

Time	30 minutes	File Name(s)	Attendance Sheet Handout: Welcome Activity Body Map
Objectives	Introductions and getting to know one another		
Materials	• Markers, colored pencils, or crayons • Masking tape • Nametags (if available) • Sign-In Sheet • **Option 1:** Blank sheets of paper • **Option 2:** Handout: Welcome Activity Body Map Prior to participants arriving, place nametags and a blank sheet of paper or the body map outlines at each seat. Place an array of colored writing tools on the tables for participants to access.		
Process	1. Ask participants to sign in upon arrival. Use the Livestock Lab approved Sign-In Sheet. 2. Welcome participants to the training. Make any relevant announcements to begin the training. **Option 1:** 3. Show the participants that there are blank sheets of paper and markers on the tables. 4. Ask the participants to draw a schematic of their lab and within the schematic to draw their role in the laboratory. 5. Ask the participants to label their drawing with their name and title. 6. Give the participants 10-15 minutes to make their drawings. 7. Ask the participants to stand in a circle. 8. One-by-one ask the participants to show their drawing and explain their role in the laboratory. After each person shares their drawing, ask them to tape it onto a wall. **Option 2:** 3. Show the participants that there are sheets of paper with the outline of a body and markers on the tables. 4. Ask the participants to draw: a. INSIDE the body, their thoughts, feelings, worries, and other internal ideas about their laboratory and their role in it b. OUTSIDE the body, the characteristics of the lab, their role in the lab, and other external ideas about their laboratory and their role in it. 5. Ask the participants to label their drawing with their name and title. 6. Give the participants 10-15 minutes to make their drawings. 7. Ask the participants to stand in a circle. 8. One-by-one ask the participants to show their drawing and explain their role in the laboratory. After each person shares their drawing, ask them to tape it onto a wall.		
Discussion Points	**Discussion options:** • What are the similarities and differences between the drawings? • How are the roles and responsibilities depicted? • How are the physical characteristics of the laboratories depicted? • Did the drawings reveal any new or interesting information about the laboratories or the participants?		

Activity: Norms and Expectations

Time	20 minutes	File Name(s)	None
Objectives	Set norms and expectations for participants during the 3-day workshop		
Materials	• Flipchart paper • Markers		
Process	1. Explain to the participants that the group will determine the norms and expectations for participant behavior over the next three days of the workshop. **Option 1 (recommended):** 2. Ask for two volunteers (or choose two participants) to facilitate a discussion on norms and expectations during the workshop. Encourage the participants to think about expectations for participation, discussion, cell-phone use, timeliness, and other relevant issues. 3. Give the facilitators blank sheets of flipcharts and markers. 4. Explain that everyone must agree on the norms and expectations. All disagreement should be discussed until the group reaches consensus. 5. Explain that you will not participate in the discussion as the norms and expectations must be agreed upon by the participants without the influence of the instructor. 6. Step out of the room or move to the back of the room outside of the immediate line of vision. Give the participants 15 minutes to discuss. 7. After 15 minutes, ask if the group has come to consensus. If they have, ask the facilitators to share the norms and expectations that were addressed. Discuss any issues that you may have as a facilitator. 8. Keep the flipchart with the norms and expectations visible during the training. Refer back to this flipchart if there are any issues during the training. **Option 2:** 2. As the instructor, facilitate a discussion on the key points that you wish to be a part of the norms and expectations. Note that Option 1 is recommended as it will lead to greater participant buy-in. 3. During the discussion, write the key agreed-upon norms and expectations onto the flipchart. It is recommended that the facilitator ensure the consensus of the group during this process. 4. Keep the flipchart with the norms and expectations visible during the training. Refer back to this flipchart if there are any issues during the training.		

Lecture: Introduction to Good Lab Practices

Time	30 minutes	File Name(s)	Lecture: Introduction to Good Lab Practices (Intro)
Objectives	1. Discuss the fundamentals of good science and good organization in laboratories including relevant international standards and regulations.		
Notes to Facilitator	This module first examines management responsibilities and then looks at the topic of personnel. Physical resources have been divided into buildings and equipment. Where possible, the trainer is encouraged to replace US-based examples (such as through the US-based Food and Drug Administration (FDA)) with local agencies, processes, and laws. If no relevant resources exist, explain why it is important for the participants to follow internationally agreed-upon standards such as those in the US, Europe, and the OECD.		
Lecture Notes	Intro-Slide 1-2 This short introduction explains why GLP was a necessary regulation. The history of the development of the GLP regulations is explained and the five fundamental points of GLP are		

provided. The participants should be told at this point that the training course is based upon the OECD Principles of GLP and the five fundamental points which will be dealt with in turn.

Day 1 of the training covers most of the basic points through a series of structured presentations. Day 2 focuses on protocols with workshop sessions. Day 3 deals with Standard Operating Procedures (SOP), again with workshop sessions. During the final part of the training, participants are asked to work on a series of practical case studies.

Intro-Slide 3-4
In the 1970's the U.S. Food and Drug Administration (FDA) was alerted to cases of poor practice in certain laboratories, in some cases by disgruntled employees, in some cases directly by FDA inspectors. The FDA decided that it was necessary to perform an in-depth investigation throughout the whole of the USA. The investigation was performed in about 40 toxicology laboratories. At the end of the investigation, the FDA published their findings. These are summarized on the next slide. Some cases of fraud were detected, and the laboratories concerned were severely dealt with. One called Industrial BioTest was closed, and the directors were given long prison sentences. But most of the poor practice was not fraud and could be dealt with by implementing a system of quality management.

Intro-Slide 5
The findings of the FDA were all available under the Freedom of Information Act. In this slide and the next one, a selection of the FDA findings is listed. These findings do not include the rare cases of fraud or falsification of results. The instructor should explain the importance of each point for the integrity and credibility of studies, with the emphasis on the need to control study variables and standardize procedures. It is important to demonstrate that the need for quality management is not primarily to combat fraud, but to impose a sensible and documented organization of studies.

Intro-Slide 6
In 1976 the FDA published a draft regulation on GLP and requested comment from interested parties. After the consultation period, the final regulation was published in 1978. This came into force in 1979. It is an American regulation but had a wide impact world-wide because non-US companies wishing to register medicines in the USA now had to perform safety studies in compliance with FDA GLP. Don't forget that about 30% of the world's pharmaceutical trade occurs in the USA; it is a market that cannot be ignored! Many countries introduced their own GLP regulations, and the OECD produced GLP Principles in 1981 that have now become the international standard in the domain.

Intro-Slide 7
GLP is a regulation covering the quality management of non-clinical safety studies. The aim of the regulation is to encourage scientists to organize the performance of their studies in a way that promotes the quality and validity of the test data.

Intro-Slide 8
Studies that are organized under GLP promote reliability of test data because the study staff must carefully document any deviations from fixed standards and because the GLP organization encourages the scientist to document all variables. GLP studies must be fully documented (methods, procedures, deviations), which means that they can be accurately repeated at any time in the future by any researcher anywhere. The full documentation of the studies, from planning activities right through to the production of reports, means that all the activities of the study are

traceable and therefore the study may be audited by third parties. Since GLP is an internationally accepted standard for the organization of studies, performing such experiments to GLP promotes their acceptance world-wide.

Intro-Slide 9
Point out the important difference between the "science" of a study and the "organization" of a study. GLP does not tell scientists what tests to perform, or what the scientific contents of a study plan (protocol) should be. There are other regulations for this aspect of studies (scientific guidelines). What GLP requires is that the scientists responsible for the organization of studies implement clear organizational structures in compliance with GLP so that the test data are more reliable.

Intro-Slide 10
GLP will help scientists avoid getting false negatives from their studies because the studies are standardized where they can be and because the variables are well documented. A false negative for a toxicity study is a set of results that falsely makes the scientist believe that a test item is not toxic when it is toxic. Taken to its extreme, this could be dangerous if the test item (believed wrongly to be inoffensive) is administered to man. However, such a situation rarely occurs because there are many studies to perform before getting to man and the chances of them all turning in false negative results is not great. But all false negative results are costly, time consuming and present ethical problems (animals used to no good purpose) and should, therefore, be avoided.

In the same way that GLP helps avoid false negatives, GLP also helps scientists avoid false positives. In the case of a non-clinical safety study, these are results which wrongly lead the scientists to believe that their test item is toxic, when it really is not. In this case, the test item is likely to be discarded, excluded as a candidate medicine. The test item might well be a compound that could be a useful addition in the fight against disease, but because of wrong interpretation, the compound is eliminated and never reaches the patients that it might have been able to help.

Intro-Slide 11
GLP also promotes international recognition of study data. When studies are performed to OECD GLP Principles, 30 countries of the world must recognize that the data have been generated under acceptable organizational standards. So, provided that the scientific aspects of the studies are reasonable, the data will be accepted as reliable and the studies as valid. For the purposes of the registration of studies in foreign countries, this is a fundamental advance over the time prior to GLP where many countries insisted that the studies from a foreign state be repeated in their own country because the confidence in the original data was very limited.

Intro-Slide 12
In the introduction to the European Directives on GLP, the four points mentioned in this slide are cited as the reasons for requiring GLP for the organization of safety studies. Limiting waste of resources is particularly aimed at limiting the use of animals. Ensuring high quality of results concerns the validity of test data described above. Ensuring comparability means that better information can be obtained in order to allow registration authorities to decide between candidate medicines. International acceptance of results refers to the fact that GLP is an internationally accepted set of regulations for the conduct of studies.

Intro-Slide 13
This sentence is one of the key phrases that can be in the introductory text to the OECD GLP Principles (upon which this course is based), GLP defines the working environment under which studies are:

- PLANNED – which is why great emphasis is given to the study plan (protocol) and to possible planned changes throughout the study
- PERFORMED – this refers to the Standard Operating Procedures (SOPs). which are a GLP requirement
- RECORDED – the collection of raw data and the recording of deviations during the study are dealt with in the regulations
- REPORTED – one of the problems pre-GLP was that study reports did not always accurately reflect the study data, so assuring accuracy in the report has become an essential part of GLP
- ARCHIVED – as studies may be inspected many years after their completion, it is important that the study data, specimens, samples and reports are correctly stored after the study
- MONITORED – monitoring by study staff, Quality Assurance personnel and national inspectors helps assure GLP compliance.

Intro-Slide 14
This slide shows the fundamental points of GLP. They are arranged under five convenient headings. Take about 20 minutes to discuss this slide with the participants, providing basic information about the meaning of each of the five items. Explain that each of the sections is dealt with in the GLP Principles, but that the Principles are organized under a more complicated set of chapter headings. You will find a brief summary of the importance of the 5 points in the introductory text accompanying, these slides

Intro-Slide 15
The OECD GLP Principles are the only truly international GLP texts. This section explains that the OECD GLPs have been agreed to by all 30 member states of the OECD and as such they represent a single acceptable set of rules for performing GLP studies.

Intro-Slide 16
The first regulatory document about GLP was the USA-FDA regulation in 1978. This concerns safety studies performed in non-clinical studies on FDA regulated products. The USA's Environmental Protection Agency (EPA) GLP regulations relate to pesticides used in the field and other substances which could be spread into the environment during, for example, agricultural practices. The OECD GLP Principles were adopted as the GLP directives of the European Union and are, therefore, the same. They concern pharmaceuticals for human and veterinary use, cosmetics, food additives industrial chemicals and agrochemicals. Once again, the emphasis is on non-clinical safety tests. The Japanese have developed separate GLP regulations that apply to different disciplines and are controlled by different ministries (health, industry, agriculture, employment, etc.). Fortunately, there are very few differences between all these GLP regulations, and the OECD Principles are accepted internationally.

Intro-Slide 17
Experts from all member states represent the views of each state. The member states agree to abide by the various rules and recommendations negotiated through the OECD. Negotiated rules and agreements are binding on the signatories of the OECD.

	Intro-Slide 18 All member states have signed up to the MAD agreement: Mutual Acceptance of Data. Thus, all the 30 member states agree to adopt OECD GLP Principles as a baseline for the conduct of safety studies. The validity of data from studies that are OECD GLP compliant must be accepted by all member states. Of course, they may still be refused for scientific reasons. Intro-Slide 19 At the heart of the OECD GLP organization is the "GLP Group". This group is composed of the heads of each national GLP monitoring authority. There is obviously a minimum of 30 chief GLP inspectors (one for each state's monitoring authority). In fact, there are many more than 30, as some states have divided their GLP monitoring activities between different organizations, e.g., USA FDA and USA EPA. The group meets regularly and plans how to promote GLP compliance throughout all the OECD member states. The GLP activities organized through the OECD include special training sessions for inspectors and the performance of joint inspections designed to help harmonize the inspection approach throughout the OECD member states. Intro-Slide 20 The OECD GLP Principles have been completely revised since their first publication. This revision was in 1997 and the complete document was published in 1998. The first part, and the part which interests us, is the GLP Principles. The second part concerns the way in which the inspectors monitor GLP compliance. Intro-Slide 21 This slide lists the seven interpretative or consensus documents issued by the OECD to help people implement the GLP Principles. The consensus documents are not strictly speaking part of the GLP Principles. But they are a considerable help to organizations wishing to set up GLP as they explain in more detail some GLP points which would otherwise be rather obscure. The inspectors use these documents as references during their inspections. They are considered as "state of the art" in the domain covered by the document. Most people adhere to the advice given by these consensus documents as if they had the same status as the GLP Principles. In this training course the OECD consensus documents are considered as serious recommendations on GLP implementation. Intro-Slide 22-23 Any scientific inquiry requires proper resources. GLP regulations state that management must provide proper resources. These are either personnel resources (people) or physical resources such as buildings and equipment. GLP requires that all resources are adequate for the task in hand. Management takes overall responsibility for both the conduct and interpretation of the study. This means that management has a responsibility for both the scientific and organizational aspects of the study. Intro-Slide 24: Review slide
Discussion Points	Respond to any participant questions and comments.

Activity: Brainstorm Good Science/Good Organization

Time	20 minutes	File Name(s)	Lecture: Introduction to Good Lab Practices
Objectives	1. Discuss the fundamentals of good science and good organization in laboratories including relevant international standards and regulations.		
Materials	• Scrap paper or flipchart paper • Pencils or markers		
Process	1. Divide participants into pairs or groups. 2. Provide the participants with scrap paper or flipchart paper and markers. 3. Ask the participants to list the points which are covered by good science on the one side of the paper, and good organization on the other side of the paper. 4. Give the participants 5-10 minutes to list their ideas.		
Discussion Points	Intro-Slide 26 Discuss the lists that the participants have made and compare with the points on this slide. Good science is about the thought process behind the experimental design which underscores the validity of the study. Good organization is about (but may well not be limited to) the items listed in this slide.		

Lecture: Good Lab Practices – Master Schedule and Personnel

Time	45 minutes	File Name(s)	Lecture: Master Schedule and Personnel (MS&P)
Objectives	3. Assess gaps in organizational proficiency of laboratories. 6. Identify and discuss the roles and responsibilities of laboratory personnel including the lab director, lab manager, scientists, academics, and students. 8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.		
Lecture Notes	MS&P-Slide 2-3 The master schedule should contain information that is useful for the planning aspects of studies performed in your institution. There are no hard and fast rules about the form the schedule should take. The information included should be used by management to assure the appropriate use of resources and as a document that demonstrates (for example at the time of an inspection by an authority) that sufficient resources were (are) available at all times that studies were (are) being performed. The schedule can be a tabulated document or may be implemented by using a database or project management tool. Management is the ultimate author of the master schedule, but the task of authorship is often delegated to a specialist group like project management. Your Quality Assurance team must be provided with a current copy of the schedule. Other GLP points are outlined on the slide. MS&P-Slide 4 To document the way in which the resource "personnel" is organized, management must implement the four types of documents mentioned. Management must provide an up-to-date organizational chart. This is used to explain very rapidly to any non-member of the institution where you work, the way in which you are organized and who reports to whom. Many facilities add the number of staff present in each department or service unit as a way of illustrating the size of the organization. In very small organizations it is common to find the names of all staff on the organizational chart. MS&P-Slide 5 Management must provide an up-to-date organizational chart. This is used to explain very rapidly to any non-member of the institution where you work, the way in which you are organized and		

	who reports to whom. Many facilities add the number of staff present in each department or service unit as a way of illustrating the size of the organization. In very small organizations it is common to find the names of all staff on the organizational chart. MS&P-Slide 6 Everyone needs a job description. The job description details the day-to-day tasks of the person concerned. Many laboratories include the relevant part of the organizational chart. It is recommended that it be signed both by the person concerned (n) and by the person's immediate superior (n+1). This is not a GLP requirement, but it is a good way of ensuring that both parties understand their responsibilities, which is a GLP requirement. MS&P-Slide 7 These are the kind of sections that one often sees in job descriptions, but the actual content is left to the discretion of management.
Discussion Points	Respond to any participant questions and comments.

Activity: Developing Job Descriptions and Responsibilities

Time	45 minutes	File Name(s)	Handout: Developing Job Descriptions and Responsibilities
Objectives	3. Assess gaps in organizational proficiency of laboratories. 6. Identify and discuss the roles and responsibilities of laboratory personnel including the lab director, lab manager, scientists, academics, and students.		
Materials	• Pens or pencils • Handout: Developing Job Descriptions and Responsibilities, copies sufficient for each group to have one, or each person to have one if working individually.		
Note to Facilitator	If the organization already has developed job descriptions and responsibilities, this activity can be replaced by: 1. A critique and revision of existing job descriptions and responsibilities 2. A discussion on and development of CVs in place of job descriptions and responsibilities (See MS&P-Slide 9) 3. This activity can be removed, and the time can be used for additional discussion on the other lecture and activity topics throughout the day.		
Process	1. Break the participants into groups. Consider grouping participants by job category or level of responsibility, if possible. 2. Provide the participants with pens or pencils and the "Developing Job Descriptions and Responsibilities" handout. 3. Refer back to MS&P-Slide 7 in the PowerPoint presentation, as needed. 4. Explain to the participants that they will be developing job descriptions and responsibilities as appropriate for their laboratory. All job descriptions should include *at least*: a. The position's title b. The direct supervisor for the position c. The job duties, tasks, responsibilities 5. Give each group of participants a different position to develop. If the lab is run by a single individual, ask each group to independently develop the job descriptions and responsibilities of that individual. Compare the results during the discussion and discuss any differences. Adapt the following suggestions per the needs of the specific laboratory: a. Laboratory Manager – single individual running the lab b. Laboratory Manager – supervisor of a multiple-person lab		

	c. Laboratory Technician d. Researcher e. Students 6. Give the participants 30 minutes to brainstorm the job descriptions and responsibilities. 7. During the last 15 minutes, ask the participants to share what they wrote and troubleshoot any questions they may have. *If there is additional time in the schedule:* 8. Collect the job description worksheets from each group and move them to a different group. 9. Ask the group to review the job description per what the previous group wrote and continue to add/modify. 10. Repeat 8-9 until all groups have seen all job descriptions.
Discussion Points	Respond to any participant questions and comments.

Lecture: Good Lab Practices – Master Schedule and Personnel, Continued

Time	15 minutes	File Name(s)	Lecture: Master Schedule and Personnel (MS&P)
Objectives	3. Assess gaps in organizational proficiency of laboratories. 8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.		
Notes to Facilitator	For this lecture you will also need: • A whiteboard, chalkboard, or flipchart paper • Whiteboard markers, chalk, or flipchart markers		
Lecture Notes	Ask the participants to brainstorm what topics should be in a CV and write them on the board or flipchart paper. After brainstorming, refer to MS&P-Slide 9 It is usual to put the following information in CVs: • Name, contact information, education, including all diplomas and qualifications awarded by recognized institutions • Professional experience both within the institution and before joining it • Any publications • Membership of associations • Languages spoken Even a member of staff without formal qualifications needs to have a CV. This will contain details of the professional experience that qualifies them for their task. Training that does not lead to a diploma is not normally included in a CV but in the person's training records. MS&P-Slide 10 Training records should include information of all training not included in the CV. (There is no need to repeat here the formal education and qualifications of personnel.). Include systematic training which qualifies you for the job you are doing. This should be based on the laboratory SOPs and on practice. Include all courses attended both internal to your laboratory and those attended outside your institution. (Include this course!). You may include attendance to seminars and congresses.		

Activity: Discussion on Study Contamination

Time	30 minutes	File Name(s)	Lecture Slides: Barrier Systems and Alternatives (BS&A)
Objectives	2. Assess challenges in existing labs to conduct research aimed at improving animal health and production. 7. Identify and discuss how laboratory practices impact the quality of research and the quality and validity of test data.		
Materials	None		
Process	BS&A-Slide 2 The GLP regulations do not stipulate exactly how buildings should be constructed. It is up to management and study staff to satisfy the authorities that the buildings are of adequate design and that they function properly. Obviously, the exact type of structure depends upon the kind of work to be performed in the building. However, it is required that buildings are adequate for the study, with assurance that studies are free from interference, disturbance and contamination. 1. Divide the participants into small groups or ask the participants to turn to someone next to them. 2. Ask the participants to read BS&A-Slide 3 and use the keywords to discuss what they consider to be adequate ways in which to divide the work area to best perform research, with respect to the different kinds of studies they perform. 3. Give the participants 10 minutes to discuss. 4. Ask the participants to share what they discussed and reflect on BS&A-Slide 3 a. BS&A-Slide 3: The key point to prevent studies from contamination, disturbance or interference is to ensure separation between studies, test systems, operations and test items. 5. Explain Slide 4 a. BS&A-Slide 4: Sometimes it is necessary to separate studies from one another physically. This may mean having separate rooms for studies, having the test systems in cabinets or even isolators, or assuring that areas are separated by efficient air systems with filters. Physical separation is not always necessary. There are other ways of preventing interference between studies. Some are mentioned here under the heading "Separation by Organization". 6. Ask participants to return to their groups. 7. Ask participants to discuss contamination other than study-to-study (10 minutes maximum). 8. Ask participants to share their thoughts. Ask if they have thought about: cleaning materials, pathogens brought in by staff, storage conditions of test items, feed, equipment, etc.		
Discussion Points	Respond to any participant questions and comments.		

Activity: Dose Mixing Unit

Time	30 minutes	File Name(s)	Lecture Slides: Barrier Systems and Alternatives (BS&A)
Objectives	5. Assess gaps in technical proficiency of laboratory personnel, scientists, academics, and students. 7. Identify and discuss how laboratory practices impact the quality of research and the quality and validity of test data.		

Materials	• Markers
	• Masking tape
	• Strips of paper (about 10 for each group)
	• Papers with headings:
	  ○ Size
	  ○ Construction
	  ○ Location/Separation
	
	Instructions: Tape the papers with headings to a wall.		

Process	1. First, discuss BS&A-Slides 5-6
	  a. BS&A-Slide 5: The points indicated here are some of the factors which would be taken into consideration either when judging whether a building is adequate for the job, or when designing a new building.
	  b. BS&A-Slide 6: Two different examples will be used to stimulate discussion on the important factors in the design of buildings. The first concerns a pharmacy and dose mixing unit, the second an animal facility.
	2. Divide the participants into groups of 4-5.
	3. Ask the participants to brainstorm (in their group) a list of the major functions carried out in a dose mixing unit and write the list on a single piece of paper.
	4. Give the participants 5-10 minutes to compile their list.
	5. Once participants are finished show BS&A-Slide 8.
	6. Ask the participants how to share how their list was similar to the list on the slide.
	7. Ask the participants to share how their list was different then the list on the slide.
	8. Discuss with participants any questions they may have about the similarities and differences in the lists.
	9. Ask the participants to return to their group and write down the important points to consider when evaluating the physical adequacy of a Dose Mixing Unit. Tell the participants to write ONE point per piece of paper.
	10. When the participants have finished writing their papers, ask them to go to the wall and tape their responses under the appropriate headings of Size, Construction, or Location/separation.
	11. Ask the participants to compare their list to the suggestions in BS&A-Slides 9-10.		

Discussion Points	Respond to any participant questions and comments.		

Lecture: Barrier Systems and Alternatives

Time	15 minutes	File Name(s)	Lecture Slides: Barrier Systems and Alternatives (BS&A)
Objectives	2. Assess challenges in existing labs to conduct research aimed at improving animal health and production.		
Notes to Facilitator	Animal facilities must also be designed to separate activities so that there is a very low incidence of interference between studies. Barrier systems are often promoted as the best answer to ensuring minimal disturbance. But this "state of the art" situation is very costly and by no means always necessary.		
Lecture Notes	BS&A-Slides 11-15 There are several procedures that can be implemented to help keep contamination and other interference at a minimum even if you don't have a barrier system. Some of these procedures are indicated on this slide.		

Activity: Case Study on Contamination/Disturbance

Time	50 minutes	File Name(s)	Activity: Case Study on Study Disturbance and Contamination
Objectives	2. Assess challenges in existing labs to conduct research aimed at improving animal health and production. 7. Identify and discuss how laboratory practices impact the quality of research and the quality and validity of test data. 8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.		
Materials	• Handouts sufficient for each group: Activity: Case Study on Study Disturbance and Contamination. Note that the trainer should edit the case study to include the appropriate country name as well as other cultural considerations that you wish to include in the case study.		

Process	1. Divide the participants into groups of 3-5.
	2. Hand out the Case Study.
	3. Give the participants 30 minutes to read and analyze the case, including their responses to the questions posed:
	  1. What are the points in this case study that the samples could have been contaminated or disturbed?
	  2. How does the process that was used by the laboratory technician contribute to the contamination/disturbance of the study?
	  3. How does the equipment that is used in the lab contribute to the contamination/disturbance of the study?
	  4. How might the use of these data influence the results of the study? What are the implications of this?
	  5. What should the laboratory technician do differently, and why?
	4. After the participants have discussed the case, reconvene them into the larger group. Ask each group to provide their response to the questions. Alternatively, each group can respond to one of the questions.
	5. After the participants have shared their responses, proceed to the discussion questions.		

Discussion Points	Case points to consider: • Desiccant in the samples will affect dry matter determination and the calculations expressed • Precision balance may not be leveled affecting weight data • Dryer door not adequately sealing leading to temperature variability		

	• Lack of adequate temperature gauge in the dryer • Assumption of adequate dryness by touch • Lack of manuals for conducting repairs and maintenance • Low temperature freezer temperature gauge is lacking • Assumption that the lowest possible temperature in the low temperature freeze is adequate and does not affect the samples • Cracked rubber seal on the low temperature freezer means there is likely variability in the temperature • The motor of the low temperature freezer is struggling but the technician dismisses the issue • Maintenance of the equipment including repairs, finding online resources to replace the missing manuals, air filters, bulbs, fuses, and other issues that are hinted at by the struggling motor. Also consider: • Importance of establishing a detailed calendar BEFORE starting the study • Importance of following procedures and SOPs • Importance of verifying reliability of balances, pipettes and personnel training with these instruments particularly the ability to measure accurately liquids and solids. • Select representative samples for analysis • ID Samples accurately throughout the process • ID Test item • Record reagent and chemicals used (date received, expiration date, batch number, etc.).

Activity: Discussion on GLP Building Compliance

Time	30 minutes	File Name(s)	Lecture Slides: Barrier Systems and Alternatives (BS&A)
Objectives	2. Assess challenges in existing labs to conduct research aimed at improving animal health and production. 3. Assess gaps in organizational proficiency of laboratories. 7. Identify and discuss how laboratory practices impact the quality of research and the quality and validity of test data. 8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.		
Materials	None		
Process	1. BS&A Slide 17: This slide summarizes the different sorts of document that you will expect to have if you wish to claim GLP compliance for the buildings at your facility. 2. Divide participants into groups. If possible, ensure that at least one leader or decision-maker is in each group. 3. Ask the participants discuss: a. What areas do the lab need to address in order to claim GLP compliance for the building(s)? b. Which documents and forms does the lab already have? c. What documents and forms does the lab need? d. How can these documents assist in ensuring that the lab is properly addressing compliance? 4. Give the groups 20 minutes to discuss. After discussion ask the groups to share their responses.		
Discussion Points	Respond to any participant questions and comments.		

Activity: End of Day Reflection

Time	20 minutes	File Name(s)	
Objectives	Review and reflection		
Materials	None		
Process	1. Ask the participants to turn to somebody next to them. 2. Ask the participants to discuss the day's activities and identify the three most interesting/relevant/or important things they learned during the day. 3. Give the participants 5-10 minutes to discuss. 4. Ask the participants to stand in a circle. 5. Ask the participants to go around and share the 3 things that they identified in their group. 6. Give the participants any information or announcements they need for the next day.		
Discussion Points	Respond to any participant questions and comments.		

Session Plans: Day 2

Activity: Review of Previous Day

Time	30 minutes	File Name(s)	Attendance Sheet
Objectives	Review of Day 1 information and activities		
Materials	• Sign-In Sheet		
Process	1. Ask participants to sign in upon arrival. Use the Livestock Lab approved Sign-In Sheet 2. Welcome the participants to Day 2 of the training. 3. Make any relevant announcements. 4. Remind the participants of the Norms and Expectations that were decided on the previous day and briefly explain each. 5. Ask the participants to turn to somebody next to them. 6. Ask the participants to discuss what information was covered during the previous day 7. Give the participants 5-10 minutes to discuss. 8. Ask the participants to go around and share one thing that they learned the previous day. Explain to the participants that each person must give a different response.		
Discussion Points	Respond to any participant questions and comments.		

Lecture: Good Lab Practice – Documentation

Time	40 minutes	File Name(s)	Lecture Slides: Documentation (Doc)
Objectives	3. Assess gaps in organizational proficiency of laboratories. 8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.		
Lecture Notes	Doc-Slide 2 The second part of the section on facilities concerns the equipment used during the GLP studies. The GLP regulations require you to make certain that the equipment used in studies: 1. Is suitable for the task in hand, 2. Is properly calibrated and maintained, and 3. Has good documentation relating to each piece of equipment. Doc-Slide 3 The question, "Is your equipment suitable for the job?" is one directed to the person responsible for the science of the study, the study director. Study staff must be able to justify the use of their equipment and demonstrate that it is suitable for the work being performed. Some equipment, when used in certain methods, will require proof of suitability by formal testing or even formal qualification. This may be the case in the analytical or clinical pathology laboratory. Only the study staff can decide whether there is a need for formal commissioning and qualification. Doc-Slide 4 All equipment used must be calibrated to demonstrate that it is working within the limits fixed by the manufacturer and scientist and is producing reliable data. It is highly recommended to maintain a link between the working standard of the laboratory, say a standard weight used to check balances, and a certified standard kept at an international or national level. This is usually achieved by purchasing a primary standard, which has a certificate from the national weights and measures authority. This is used to calibrate a secondary standard for routine use in the laboratory. The scientist must decide what is the appropriate frequency of calibration for each instrument and this should be documented, normally in an SOP. Doc-Slide 5 Maintenance is necessary for all equipment. Maintenance is particularly important for instruments that impact all raw data collected (e.g., precision balances, drying ovens, incubators, furnaces, pipettes). This is usually divided into maintenance that is performed as a preventive measure (e.g., changing the ultraviolet lamps in some equipment as their efficiency is known to decline over time) and curative maintenance which consists of repair work on broken apparatus. In the case of equipment that breaks, it is necessary to have either back-up equipment or a back-up procedure so that the work can continue. This is the case when a computer system goes down, but you still must collect data. Most institutions also have maintenance contracts with external service companies (sometimes the vendors of specific pieces of equipment). This work should be described in detail and traceable (contract, date, equipment number, technician, etc.). If your equipment requires an alarm, make sure that it is in working order, that it is regularly checked (part of the maintenance plan) and that, when the alarm operates, there is an emergency procedure for dealing with the problem. Doc-Slide 6 This slide reminds us of the need for Standard Operating Procedures (SOP) for all equipment. Records must be kept for all interventions involving equipment.		

	Doc-Slide 7 This table is an example of the kind of service plan the maintenance department should keep. It concerns the planned interventions on an air conditioning system. Letters in lower case represent actions (d = daily, m = monthly, x = periodic) which are planned throughout the year. Letters change to UPPER CASE when the actions have been completed. Each completed action would be accompanied by a record of the action, signed and dated by the responsible person. Doc-Slide 8 This is the kind of information needed to show that the equipment has been properly serviced. Often the information is on a label attached to the equipment. It is important not to use a piece of equipment if it is no longer covered by the service. Therefore, the information "Next service due" is important. Doc-Slide 9 When equipment needs servicing or repairing, records must be kept of who did the repair, when and what was the outcome. This is called a fault action report. It is important that, after repair, a responsible person signs to state that the equipment can be used again. Doc-Slide 10 This slide summarizes in diagrammatic form the different sorts of document that you will expect to have if you wish to claim GLP compliance for the equipment at your facility.
Discussion Points	Respond to any participant questions and comments.

Activity: Discussion on Good Lab Practice Protocols

Time	30 minutes	File Name(s)	Lecture Slides: Study Protocols Part 1 (SPP1)
Objectives	1. Discuss the fundamentals of good science and good organization in laboratories including relevant international standards and regulations. 2. Assess challenges in existing labs to conduct research aimed at improving animal health and production. 3. Assess gaps in organizational proficiency of laboratories. 4. Assess gaps in technical proficiency of laboratory management. 6. Identify and discuss the roles and responsibilities of laboratory personnel including the lab director, lab manager, scientists, academics, and students. 7. Identify and discuss how laboratory practices impact the quality of research and the quality and validity of test data. 8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.		
Notes for Instructor	The importance of the protocol as a formal document for communication or for contractual reasons is explained drawing on examples from the instructor's experience to illustrate the importance of this communication document.		
Process	1. In a whole group setting, ask the participants to share the problems they have had in the design, approval and use of protocols or similar non-GLP study plans. 2. Compare the participants' stories to SPP1-Slide 3 a. SPP1-Slide 5: The protocol covers both scientific aspects of the study and organizational aspects of the study. b. Only the organizational/GLP aspects are covered in these slides.		

	3. Ask the participants which scientific aspects they consider should be included in the kind of studies they perform. 4. Compare the participants' responses to SPP-Slide 6. a. SPP-Slide 6: The protocol is a multi-function document. Some of the functions are mentioned here. 5. Ask the participants to list other possible functions of the protocol (such as a formal document for communication or for contractual reasons).
Discussion Points	Respond to any participant questions and comments.

Lecture: Good Lab Practice – Study Protocols Part I

Time	90 minutes	File Name(s)	Lecture Slides: Study Protocols Part I (SPPI)
Objectives	2. Assess challenges in existing labs to conduct research aimed at improving animal health and production. 3. Assess gaps in organizational proficiency of laboratories. 4. Assess gaps in technical proficiency of laboratory management. 6. Identify and discuss the roles and responsibilities of laboratory personnel including the lab director, lab manager, scientists, academics, and students. 7. Identify and discuss how laboratory practices impact the quality of research and the quality and validity of test data. 8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.		
Lecture Notes	SPP1-Slides 2-3 It is important to distinguish between these three types of rules. In GLP, the Study Plan or protocol and the SOPs are the most important documents and will form the major part of this section. SPP1-Slide 4 Guidelines provide information on the scientific methods which are recommended for specific studies. They define the scientific methods which are recommended for certain studies. The OECD has published many scientific guidelines for the performance of specific studies, ranging from toxicology to physio-chemical analyses. All these tests can be performed in compliance with GLP. GLP studies do not have to be performed to guidelines. However, when guidelines are used, they should be referenced in the protocol. SPP1-Slide 5 Guidelines provide information on the scientific methods which are recommended for specific studies. They define the scientific methods which are recommended for certain studies. The OECD has published many scientific guidelines for the performance of specific studies, ranging from toxicology to physio-chemical analyses. All these tests can be performed in compliance with GLP. GLP studies do not have to be performed to guidelines. However, when guidelines are used, they should be referenced in the protocol. SPP1-Slide 6 The protocol is the pivotal scientific document for GLP studies. It should provide enough information to describe to the reader (who may be a member of a receiving authority or a member of the study staff) the basic methods involved in performing the study. The protocol need not follow international guidelines where this is inappropriate. The protocol provides a description of the important parameters of the study and the timelines. In this sense, the		

	protocol is a Master Plan for the study. The protocol must be approved by the study director even if the study is sponsored by another organization. SPP1-Slide 7 GLP requires that each study has a separate protocol, individually identified. From the protocol number, it is usually possible to trace all study data and other items of interest as shown in the slide. SPP1-Slide 8 GLP requires a clear title and statement of purpose for each study. The points that it is usual to address are those in the slide. However, very often the title is sufficiently explicit to indicate the purpose of the study too: e.g., study of the short-term toxicity of compound X when administered orally to the rat as a single administration, followed by a two-week observation period. SPP1-Slide 9 GLP requires that the test and control items be identified, and any reference items too. Usually, test items are identified by the points shown in the slide. The test item may only be identified by a code number or name. This is often the case when a CRO is performing the studies on behalf of a sponsor. It is preferable to use a single batch throughout the study as this eliminates possible batch to batch variability. Specifications of test items may not be known for items in early development phases. SPP1-Slide 10 GLP requires you to identify all the partners participating in the study. In some multi-site studies, there can be many such partners. SPP1-Slide 11 Although GLP only requires you to identify the study director in a protocol (and principal investigators if it is a multi-site study) it is highly recommended to identify other significant personnel here. This is good for communications and to clarify responsibilities. The study monitor is the person who will follow the study on behalf of the Sponsor when the study is being performed by a contract research organization (CRO). SPP1-Slide 12 The dates required by the GLP regulations are: – The date of approval and signature of the study director (and management and the sponsor if required by individual national regulatory authorities) – The proposed start and finish dates for the study o Start = date study director signs the protocol o Finish = date study director signs the final report. SPP1-Slide 13 This slide indicates the information required for the adequate description of a test system. In this case, as the most usual example, the test system is a mammal.
Discussion Points	SPP1-Slides 7-12: Discuss with participants that a good protocol will include a more extensive time plan for the whole study. It is useful to include dates that will help the scientists working in different areas to co-ordinate various activities. The instructor should underline the importance of using the draft protocol with its draft proposed dates as a planning document so that all scientists involved in

	the study can agree to the overall time plan. For instance, it is important that the Study Director has the agreement of the clinical pathologist concerning the dates of sending blood samples to that laboratory for analysis. SPP1-Slide 13: Ask the participants how they would adequately describe the test systems they use. These may be plants, bacteria, cell lines, isolated organs or even analytical apparatus.

Lecture: Good Lab Practice – Study Protocols Part 2

Time	30 minutes	File Name(s)	Lecture Slides: Study Protocols Part 2 (SPP2)
Objectives	2. Assess challenges in existing labs to conduct research aimed at improving animal health and production. 3. Assess gaps in organizational proficiency of laboratories. 4. Assess gaps in technical proficiency of laboratory management. 6. Identify and discuss the roles and responsibilities of laboratory personnel including the lab director, lab manager, scientists, academics, and students. 7. Identify and discuss how laboratory practices impact the quality of research and the quality and validity of test data. 8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.		
Notes to Facilitator	This lecture will include a reading and discussion component. 1. If the participants do not have laptops or access to the internet, provide a handout of the Reading: OECD Good Lab Practice Regulations, Excerpt of Sections 8.1-8.2. 2. Provide the participants with the Reading Guide: OECD Regulations.		
Lecture Notes	SPP2-Slide 2-3 This slide and the next give some of the points that would normally be mentioned in a typical animal toxicity study. The experimental design depends on the kind of study being performed. The items listed are given as examples only. The participants will be faced with the detailed examination of a protocol later in the course. Points which could be commented on include: • The preparation of the dose mix will be covered in more detail in the SOPs for the study and need not be given in detail in the protocol. • It is usual in a long-term toxicology study to perform analytical work on the dose mix (QC) at the start of the study, often in the first week, to make sure that the desired concentrations are being correctly prepared, and at the end of the study to ensure that there has been no deviation of preparation during the study. For very long studies, it is customary to do QC every three months at least. • The method of randomization of animals is important since it reduces group-to-group variability. You should also distribute the animals in the cages/racks in a way which reduces the effect of environmental variables. Further items covered in the protocol are given here as examples. The statistical methods that will be used at the end of the study should be mentioned but additional tests can, of course, be performed if necessary. Mention where the archives of the study will be kept. Most GLP protocols also indicate the extent to which Quality Assurance (QA) will cover the study in its program of inspections/audits.		
Discussion Points	**Reading:** After this SSP2-Slide 3, participants should all read sections 8.1 and 8.2 of the OECD regulations where the full list of GLP protocol requirements are. If the instructor prefers, this reading can be done immediately prior to the workshop on protocols.		

	Provide the participants with the following guiding questions for the reading: 1. What is the title of the study? 2. What is the purpose of the study? 3. What are the test methods to be used? 4. Who is the study Director? 5. What is the list of records to be retained? After the participants have completed the question guide and the reading, respond to any participant questions or concerns.

Lecture: Good Lab Practice – Study Protocols Part 2, Continued

Time	30 minutes	File Name(s)	Lecture Slides: Study Protocols Part 2 (SPP2)
Objectives	2. Assess challenges in existing labs to conduct research aimed at improving animal health and production. 3. Assess gaps in organizational proficiency of laboratories. 4. Assess gaps in technical proficiency of laboratory management. 6. Identify and discuss the roles and responsibilities of laboratory personnel including the lab director, lab manager, scientists, academics, and students. 7. Identify and discuss how laboratory practices impact the quality of research and the quality and validity of test data. 8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.		
Lecture Notes	SSP2-Slide 5 As stated earlier, the study director signs and dates the protocol to approve it. In some countries, the protocol must also be signed by management. It is also often a requirement that the sponsor signs the protocol to indicate his approval. Usually, the draft protocol is reviewed by QA before the final signature of the study director. This is done before the signature in order to avoid having to write an amendment if QA finds something wrong. The most frequent criticism regarding the writing of protocols is that the Study Director does not allow enough time before the start of the study for everyone to read and comment on the protocol. SSP2-Slide 6 Amendments are only used for planned changes to the study. This may include extending the study period, changes in study staff mentioned in the protocol, adding experimental parameters to be studied, etc. The amendment must be signed by the study director. The amendment will be reviewed, but as some of the changes need to be immediate, it is accepted that the review may be retrospective. Under no circumstances must amendments be issued for "unplanned changes" which are deviations to the study plan. These are noted in the study file and reported in the final report. SSP2-Slide 7 Amendments must have all the attributes of traceability necessary to identify the study concerned, the change planned (the part of the protocol affected), and the reasons for the change. All personnel having received the original protocol should get all the amendments even if they are not directly concerned. SSP2-Slide 8 To ensure that all staff concerned receive the protocol and to provide traceability of that distribution, most laboratories implement a protocol distribution list like the one in this		

example. Staff sign to indicate that they have received the protocol. The same kind of distribution/receipt form is used for the amendments to protocols.

SSP2-Slide 9
This document is not a GLP requirement but is a very useful document for the persons performing the operations that are detailed in the protocol or study plan shown here. It is quite simply a time plan showing, day by day, what phase of the study is to be performed.

SSP2-Slide 10
Standard Operating Procedures (SOPs) describe in detail the routine operations of your laboratory. They are a necessary addition to the protocol if you wish to exactly repeat a study. In most cases you will find SOPs reply to the following questions:

- Who performs the operation?
- What is the operation being performed?
- When is it being performed?
- Where is it done?
- How is it being done?

SSP2-Slide 11
It is pointless trying to implement GLP if there is no management support. As SOPs are an integral part of GLP, they too must have full management support. Management must be convinced of the advantages that a good SOP system can bring to the institution. SOPs should be used as a tool for education and training of staff. People who perform a technique for a GLP study must do so in compliance with the SOP. There must be good correspondence between what the SOP says and what happens on the ground. Up-to-date SOPs always need to be available for consultation, otherwise operations will be performed which are not in compliance with SOPs and standardization will be lost and, as a result, the experiment will be vulnerable to false positives and false negatives. Therefore, a good SOP management system is essential.

SSP2-Slide 12
With management support, SOPs become an integral part of the documentation of the organization. You will need to write SOPs to cover all the technical aspects of your studies. These are probably the most important SOPs. But in addition, you will need SOPs on some administrative aspects of your activities, especially where the activity impinges on the conduct of the study (e.g., SOP on the transfer of data to the archives, SOP on the management of documents such as SOPs), and you will need to have SOPs covering aspects of safety and hygiene (e.g., SOP on the handling of dangerous chemicals, SOP on the elimination of waste, SOP on the protective clothing needed for entry into an animal room). It is pointless having SOPs that are not easy to understand or to read. This is one reason why an independent, but informed, person from Quality Assurance will review the SOP before it is distributed for use. The SOP must be followed, otherwise there is increased test-to-test variability, no traceability and no possibility to audit. This is one reason why Quality Assurance will inspect certain activities of the study to ensure that SOPs are complied with.

SSP2-Slide 13
To facilitate the management of SOPs, particularly updating, it is a good idea to nominate a person responsible for each SOP. This person ensures that the SOP corresponds to the needs of the laboratory, that it is kept up to date, and that persons using it are trained to use it. Any changes you make to SOPs must be done following a standard method, described in an SOP. This is called change control. A central organization dealing with the management of SOPs is

	helpful, but not mandatory – each department or unit can control their own SOPs – since this makes sure that the SOPs used on a site are harmonized. In some laboratories, the Quality Assurance Unit (QAU) undertakes this responsibility. SSP2-Slide 14 In this slide some of the roles of a centrally organized management system for SOPs are mentioned. SSP2-Slide 15 This is the kind of header you usually see on organizations' SOPs. There is no mandatory way for the presentation of SOPs. It is important to stipulate which is the date when the SOP came into force. This is necessary for traceability of operations. There is no need for the QAU to sign SOPs. But this is frequently done in Europe to signify that the SOP has been reviewed. It is not a way of underwriting the technical aspects of the SOP. If you can avoid it, it is recommended not to refer to other SOPs in the SOP concerned. This is because when you change the number of one you must change the reference in the other. Most organizations have a standard approach as to how to deal with the various chapters that should be included in SOPs. This is one example.
Discussion Points	Respond to any participant questions and comments.

Activity: Brainstorm and Discuss SOPs

Time	45 minutes	File Name(s)	Lecture Slides: Study Protocols Part 2 (SPP2)
Objectives	3. Assess gaps in organizational proficiency of laboratories. 7. Identify and discuss how laboratory practices impact the quality of research and the quality and validity of test data. 8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.		
Materials	**Option 1** (recommended, 45 minutes): • Half-sheets of paper, two colors if available • Markers • Two colors of sticker dots cut into strips of 3 (found in most office supply stores). If colored dots are not available, withhold two colors of marker from the participants. • Masking Tape For Option 1, prepare two of the half-sheets of paper (one of each color) with a heading. One colored paper should have the heading, "Advantages of a well-managed SOP system." The other colored paper should have the heading, "Issues that arise from not having an SOP system." If colored sheets of paper are not available, plain white paper will suffice. **Option 2** (20 minutes): • Flipchart paper • Markers		
Process	Option 1 is recommended per the suggested agenda. Option 2 is recommended if you are running low on time or have limited time in your agenda. **Option 1** 1. Tape on the wall the two prepared papers with the prompts: a. Advantages of a well-managed SOP system b. Issues that arise from not having an SOP system		

	2. Divide the participants into two groups. Provide each group with one stack of colored paper (if available) and markers. 3. Give each group one of the prompts to brainstorm. 4. Ask each group to brainstorm their responses to the prompt. Explain to the participants that each piece of paper should have a single response. Also explain that the group does not need to come to consensus on the responses, rather they should brainstorm quickly and write as many ideas as they can. 5. After 10 minutes ask the groups to tape their responses under their respective heading 6. Give the participants one color of sticky dots. If no dots are available, provide the participants with one color of marker that was withheld. 7. Ask the participants to place their 3 stickers on three of the papers posted under "Advantages of a well-managed SOP system" that they think would be of the *most immediate* benefit to their lab(s). 8. Give the participants the second color of stick dots. If no dots are available, provide the participants with the second color of marker that was withheld. 9. Ask the participants to place their 3 stickers on three of the papers posted under "Issues that arise from not having an SOP system" that they think are *the most important* for their lab(s) to address. 10. Proceed to discussion. **Option 2:** 1. Divide the participants into two groups. Provide the groups with a flipchart paper and markers. 2. Give each group one of the prompts: a. Advantages of a well-managed SOP system b. Issues that arise from not having an SOP system 3. Ask the groups to identify one person who will write on the flipchart. 4. Ask the groups to discuss their prompt and brainstorm their responses. 5. Give the groups 10 minutes to brainstorm. 6. After 10 minutes, bring the groups back together and ask each group to share their brainstorm.
Discussion Points	• Where do you see connections between the two different brainstorming questions (advantages of a well-managed SOP compared to the issues that arise from not having an SOP)? • What does this tell you about the important of SOPs? • Compare the points made by the participants with SSP2-Slides 17-19. • What SOPs do you currently have in operation in your lab? • What SOPs need revision or are missing?

Lecture: Good Lab Practice – Study Protocols Part 3

Time	30 minutes	File Name(s)	Lecture Slides: Study Protocols Part 3 (SPP3)
Objectives	2. Assess challenges in existing labs to conduct research aimed at improving animal health and production. 3. Assess gaps in organizational proficiency of laboratories. 4. Assess gaps in technical proficiency of laboratory management. 6. Identify and discuss the roles and responsibilities of laboratory personnel including the lab director, lab manager, scientists, academics, and students. 7. Identify and discuss how laboratory practices impact the quality of research and the quality and validity of test data.		

	8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.
Lecture Notes	SSP3-Slide 2 The test items that are used in preclinical safety studies can be very varied. The trainer should ask the participants to suggest test items other than chemical substances that might be tested preclinically. However, most are chemical compounds, and this example is the one chosen for consideration here. The GLP regulations consider the above three topics related to the test items used in studies. SSP3-Slide 3 There is often confusion about whether good manufacturing practice (GMP) is needed to produce batches used in GLP studies. GMP is only required for clinical studies performed in man. But authorities do require that you demonstrate that your test item is of a constant quality and fit for use. Using a single batch of compound throughout the whole of a study reduces variability and makes it easier to interpret the results of the study. SSP3-Slide 4 See discussion question below. SSP3-Slide 5 GLP requires you to put procedures into place that guarantee that the dose form is made up with the right test item, in the right concentration and in the same way each time. You must also be able to show that you have complete traceability of the custody, preparation and use of the bulk test item and the dose-form. SSP3-Slide 6 The analytical laboratory provides results that are used to assess the quality of the bulk test element when compared to dose formulation. Unless test elements in bulk or in dose are reliable, the whole study is worthless. Therefore, the GLP regulations require that these data be generated under GLP.
Discussion Points	• Discuss with the participants the points they consider to be important for their studies about the quality of the BULK or DOSED ingredient. What difficulties do they have when it comes to the characterization of the active ingredient?

Activity: List Test Systems

Time	10 minutes	File Name(s)	Lecture Slides: Study Protocols Part 3 (SPP3)
Objectives	4. Assess gaps in technical proficiency of laboratory management. 7. Identify and discuss how laboratory practices impact the quality of research and the quality and validity of test data.		
Materials	• Flipchart paper, whiteboard, or chalkboard • Flipchart markers, whiteboard markers, or chalk		
Process	1. SSP3-Slide 7: Test systems are not necessarily animals, though this is usually the case in preclinical studies. Here is a list of various test systems. 2. Ask the participants to complete the list from their own studies. 3. Write down the results on a flipchart, whiteboard, or chalkboard		
Discussion Points	1. What test items do you trainees work with in your laboratory? Test items can be fertilizers, plants varieties, pesticides, pharmaceuticals, veterinary drugs, food additives, chemicals, and so on. The purpose of testing these test items is to obtain data on their impact on crop		

	yield, weight gain, milk production egg production in animals, on their properties, and their safety with respect to human health and environment. 2. What is the test site for this study (i.e., the location where the test is conducted)?

Lecture: Ethics and Rights

Time	45 minutes	File Name(s)	Lecture Slides: Ethics and Rights (Ethics)
Objectives	1. Discuss the fundamentals of good science and good organization in laboratories including relevant international standards and regulations. 2. Assess challenges in existing labs to conduct research aimed at improving animal health and production.		
Notes to Facilitator	This lecture will also include a discussion component.		
Lecture Notes	Ethics-Slide 2 Because it is impossible to deal with all kinds of test systems, and because it is the most common situation, the case of animals is chosen here. The way in which the test system is dealt with must comply with the GLP regulations and with the national animal welfare rules. You could be asked to show that you do respect welfare legislation during a GLP inspection. Ethics-Slide 3 It is the responsibility of the study director to select the right animal for his/her study. There are many reasons for choosing one type or strain of animal rather than another. These reasons may depend on the kind of things listed in this slide. Remember that the quantity of animals put on a study, neither too few nor too many, is also a responsibility of the study director. GLP requires you to explain why the test system has been chosen for the study in hand; this should be set out in the protocol. Ethics-Slide 4 You will need to keep a careful check on the status of the animals you use, the way in which they are handled and the conditions under which they are housed, both during the experimental phase and during the pre-study phases including acclimatization. Many organizations have separate units that keep track of environmental factors in the animal rooms. These data are often supplied to the study director when he/she is writing the final report for his/her study. Ethics-Slide 5 Regular checks on the documents filled in by the animal care staff should be made (e.g., cage changes, washing of racks, treatment of ill animals, etc.). This should be done by responsible staff and by the QAU during audits. When there is a deviation from normal procedure, this should be noted, and the study director must be informed because he/she will need to assess the impact of the deviation and it may have to be commented on in the final study report. Ethics-Slide 6 The items shown on this slide are some of the documents you will need to keep in order to show how the animals were assigned to groups. It is important to be able to demonstrate that no bias was introduced in the study by the way the animals are divided into groups and the way that they are caged and their location in the animal room. Any animal eliminated from the groups for whatever reason must be accounted for and the reason for elimination recorded. It should be remembered that one of the reasons that GLP came into existence was the malpractice of replacing ill animals for healthy ones during an experiment. Inspectors are, therefore, very sensitive about this kind of issue.		

	Ethics-Slide 7 *See discussion prompt below.* Ethics-Slide 8 The acclimatization period obviously depends on the species and on the type of study being performed. During the acclimatization period it is necessary to maintain full documentation on the procedures performed and on the identity of the animals. Usually when the animals are ready for the study, the study room is prepared (cleaned, disinfected, supplied with feed, etc.) these activities should also be recorded. Ethics-Slide 9 Animal receipt is an important phase in the activity of the laboratory. Organizations must have SOPs covering this part of the laboratory activity as shown in this slide. Ethics-Slide 10 It is important to build up a "partnership" relationship with the animal supplier. Most organizations audit the suppliers of important goods like animals, feed, bedding. It is important to investigate the conditions under which the animals are transported. Transport stress can introduce important variables into the study and have a significant effect on the health of the animals. In some countries the national QA society performs regular audits. Keep letters, invoices, supply and delivery notes from the suppliers as raw data. Ethics-Slide 11 When the study director writes the final report, he/she must consider the environmental conditions, particularly deviations from target values, that the animals have been kept in. Deviations from specifications should be reported and, in some cases, commented on in the study report.
Discussion Points	Ethics-Slide 7 Discuss with participants the different ways in which animals can be identified, drawing on their own experience. During the discussion draw attention to the fact that some SOPs (e.g., "Never have two cages open at once in an animal room") can help reduce the possibility of mistaking one animal for another and jeopardizing the study. All data referring to animals should contain full animal identity. Even though it is always necessary to identify animals now of dosing, it is also good practice to have regular identity checks on the animals in each room to make sure that there is no problem of identity.

Activity: End of Day Reflection

Time	30 minutes	File Name(s)	
Objectives	Review and reflection.		
Materials	**Option 1:** None **Option 2:** Something to throw such as a soft ball		
Process	**Option 1:** Repeat the End of Day Activity from Day 1 **Option 2:** 1. Ask the participants to stand in a circle. 2. Explain to the participants that you will throw the ball to somebody, and that person needs to share one thing that they learned during the day's session. 3. Explain that after that person responds, they will throw the ball to another person.		

	4. Repeat until all participants have provided a response, or until the time for the activity has passed. 5. Give the participants any information or announcements they need for the next day.
Discussion Points	Respond to any participant questions and comments.

Session Plans: Day 3

Activity: Review of Previous Day

Time	30 minutes	File Name(s)	Attendance Sheet
Objectives	Review of Day 2 information and activities		
Materials	• Sign-In Sheet		
Process	1. Ask participants to sign in upon arrival. Use the Livestock Lab approved Sign-In Sheet. 2. Welcome the participants to Day 2 of the training. 3. Make any relevant announcements. 4. Remind the participants of the Norms and Expectations, if needed. Option 1: 1. Repeat the review of previous day activity from Day 2. Option 2: 1. Ask participants to find a single partner. 2. Ask the participants to identify who will be "Partner 1" and who will be "Partner 2". 3. Ask those who are Partner 1 to form a circle in the middle of the room. 4. Ask those who are Partner 1 to turn around 180 degrees so that they are facing outside of the circle rather than inside. 5. Ask Partner 2 to go stand facing their partner. 6. This should result in two concentric circles, with Partner 1 forming the inside circle and Partner 2 forming the outside circle. 7. Ask the Partners to discuss what was covered during the previous day. 8. After 2-3 minutes, ask Partner 2 to point the person on their left. Ask Partner 2 to move to stand where the person on their left is standing. Person 1 should NOT move. This will result in new partners. 9. Repeat steps 7-9 until 10-15 minutes have passed or until you feel that the participants have adequately discussed the content from the previous day. 10. Ask the participants to go around and provide one thing they learned from the previous day. Each participant should be encouraged to give a different response.		
Discussion Points	Respond to any participant questions and comments.		

Lecture: Raw Data Collection and Audit Trails

Time	30 minutes	File Name(s)	(Data)
Objectives	8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.		
Lecture Notes	Data-Slide 2 This section deals with raw data collection. Stress the importance of data as being "WHAT IS LEFT AT THE END OF THE STUDY". In a sense it is the only tangible result of the scientific inquiry. The data will be reported in a FINAL REPORT. The FINAL REPORT and the DATA will		

be removed to the archives for safekeeping at the end of the study. For some long-term studies it is wise to archive bit-by-bit during the study.

Data-Slide 3
The GLP definition of RAW DATA is two-fold, as shown in this slide. It is useful to explain the way in which raw data are defined by using the image of a set of individual values recorded from a series of weights, and the mean value. Each individual weight is a raw datum, needed to reconstruct the weighing series. The mean is not a raw datum (though important); it can be regenerated by a simple calculation.

Data-Slide 4
This slide is about the preparation that is needed before an experiment starts. The organization is ultimately the responsibility of the study director, but he/she may well delegate this to a senior technician. Draw attention to the important last line, that when the study is on-going, data are generated, and it is important to be ready to collect them in an organized way. Therefore, most laboratories prepare data collection forms prior to beginning the study.

Data-Slide 5
Some raw data are so vital that losing any of them would invalidate the whole study. Discuss with the participants what they consider to be the most important data for their studies. You can use the analogy of the series of weights to underline the fact that one piece of lost data (a weight) can never be regenerated.

Data-Slide 6
The collection of data must be done in such a way as to enable another person afterwards to find out who did what, when, where and how. This is called auditability. Having data which can survive an audit gives the study credibility and makes the acceptance of data by other scientists or authorities much easier. The reputation of your organization depends in great part on the auditability of your data.

Data-Slide 6
The collected data, on data sheets or in a laboratory notebook, should clearly identify WHAT the process was and that it was performed according to plans (protocol) and procedures (SOPs).

Data-Slide 7
Not all procedures will go exactly according to plan. All deviations from the planned method should be recorded carefully in the raw data. The impact of deviations must be assessed by the study director and will be commented on in the study report.

Data-Slide 8
The requirements with respect to recording of the times that operations occurred depend upon the type of experiment performed. In some studies, timing must be to the nearest minute. In others it is enough to say for example that "the clinical observations were carried out in the morning and again in the afternoon".

Data-Slide 9
Everyone who is concerned with the collection, recording or verification of the data should be identified and the dates (at least) of their interventions, and what they did, should also be recorded.

	Data-Slide 10 These are the general rules for data collection. Never use pencil, never use "white out", never correct data if you do not explain why, and sign and date every change. This correction method applies also to computerized data. It is called leaving an AUDIT TRAIL.
Discussion Points	Respond to any participant questions and comments.

Activity: Raw Data Collection Case Study

Time	45 minutes	File Name(s)	Lecture Slides: Raw Data Collection (Data) Activity: Raw Data Collection Case Study
Objectives	7. Identify and discuss how laboratory practices impact the quality of research and the quality and validity of test data.		
Materials	• Pen or pencil • Paper • Folder or binder • Activity: Raw Data Collection Case Study		
Process	1. Divide the participants into groups of 3-5. 2. Hand out the Case Study. 3. Give the participants 25 minutes to read and analyze the case, including their responses to the questions posed: • What are the errors made in each scenario? • How can these errors result in data contamination? • What would you do differently, and why? 4. After the participants have discussed the case, reconvene them into the larger group. Ask each group to provide their response to the questions. Alternatively, each group can respond to one of the questions. After the participants have shared their responses, proceed to the discussion questions.		
Discussion Points	Scenario 1: • First thing to do is go back to your main reference point is Submission Form 2 that lists all the samples in sequential order. The sample bags should have more information on it describing the species, plant tissue, treatment, date of harvest, etc. • The information on the Form 2 and the information on the sample bag should match. Even if the sequential number on the bag is repeated by mistake the additional info should help catch the mistake BEFORE the sample is processed for analysis. • It is important to observe if the error was compounded by mislabeling other samples that follow the mislabeled number. Poor organization of your lab space can result in mistakes in labeling samples. • Info in the lab logbook should never be changed once entered accurately. Raw data can be edited but careful record should be kept as to what caused the discrepancy • Researcher cannot finish collecting raw data by handing it to his/her assistant. One must verify that raw data transcription is accurate, or better, one has to enter the data accurately just once to avoid having to reenter it. • Improper labeling of samples will result in attributing the wrong raw data to the wrong sample. • Recording data by hand and then retyping into Excel for example can lead to typing errors that will affect results. • Every change in the records should be signed and dated with an explanation provided.		

	• In all scenarios the best practice is to first stop what you are doing. The second one is to talk to the study director about the issue so he/she knows there is a problem. Hiding such a problem from the study director or delaying telling him/her will only compound the problem and make it worst and make the study less reliable. The third is to try to understand the nature of the problem and exactly where the problem started. The last thing to do is to decide on the best solution to apply to fix the problem and ensure we have accurate data recording.

Lecture: Final Reporting and Archiving

Time	70 minutes	File Name(s)	• Lecture Slides: Final Report and Archiving (Archive) • Reading: OECD Good Lab Practice Regulations, Excerpt of Sections 9.2 • Reading: OECD Good Lab Practice Regulations, Excerpt of Sections 9.1 • Reading: OECD Good Lab Practice Regulations, Excerpt of Sections 2 • Reading: OECD Consensus Document #4, Excerpt on Quality Assurance Inspections
Objectives	8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.		
Notes to Facilitator	• This lecture will include a reading and discussion component. • If the participants do not have laptops or access to the internet, provide a handout of ○ Reading: OECD Good Lab Practice Regulations, Excerpt of Sections 9.2 ○ Reading: OECD Good Lab Practice Regulations, Excerpt of Sections 9.1 ○ Reading: OECD Good Lab Practice Regulations, Excerpt of Sections 2 ○ Reading: OECD Consensus Document #4, Excerpt on Quality Assurance Inspections		
Lecture Notes	Archive-Slide 2 1. **Reading:** Ask the participants to look at the GLP regulations concerning the requirements for final reports (section 9.2 of the OECD GLP Principles, page 28). They will note that the requirements include a list of contents for the final report. Most of these are mentioned in this slide and the next one. 2. Ask if there are any questions or comments relating to these requirements. 3. Discuss what should be considered as the "Experimental start and completion dates". Archive-Slide 3 These are the items that should be included in the final report. Archive-Slide 4 Once a final report has been signed by the study director, it cannot be changed. If there is a need to correct or amplify the report, this must be done by issuing a separate amendment to the report. The amendment must indicate what is being changed, or what is being added to the report. The amendment must be signed by the study director and must be audited by the QAU. Archive-Slide 5 **Reading**: This approach to report amendments is explained in section 9.1 of the OECD GLP Principles. Ask the participants to read this section. Archive-Slides 6-7		

All that is left at the end of the study is needed to demonstrate the validity and traceability of the scientific results. Therefore, the archives are so important. The kind of things that you would find in the archives are listed here, but there may be other things to archive, depending on the type of study performed. These items may not all be archived together in the same place. It is not usual, for example, to archive paper and specimens in the same place because they often need different storage conditions. QA documents should be stored separately (can be in the same room) from the study archives. The function of the archive is to store important items over a long period under secure conditions.

Archive-Slide 8
When the study director or other staff submit a document to the archives, it should be carefully logged in. There is a hand-over of responsibility at this point. The responsibility for the integrity of the data is transferred from the study director to the archivist. It is important to guarantee that all the data are transferred and that there is a record of what is transferred. Most organizations use a transfer form like the one in this slide. It is completed now of transfer and the form is signed by the study director and the archivists, who both attest to the material being handed over to the safekeeping of the archives.

Archive-Slide 9
Whenever documents are taken out of the archives, split up or otherwise interfered with, full records of these events must be kept. This is usually done by using an Events Form like the one on this slide. In this way a complete history of the movement of archived material is established. This will help you limit the loss of material.

Archive-Slide 10
The archived materials must be protected from interference (particularly unauthorized removal that will lead to loss) and from disasters like fire and flooding and deliberate vandalism. Therefore, entry to the archives should be restricted. You need an SOP to describe the conditions of entry (sign in and out) and a list of persons who are allowed access. If possible, do not let anybody remove articles from the archives, allow them instead to consult the documents in the archives and if necessary, give them a photocopy if they need to have the data with them.

Archive-Slide 11
The GLP regulations require you to store archives under conditions which minimize possible damage and loss.

Archive-Slide 12
In order to be able to rapidly find archived material, it is essential to fix criteria for the indexing of the material. Most organizations use a combination of the criteria listed in this slide.

Archive-Slide 13
This is the last of the five Fundamental Points of GLP. The Quality Assurance Unit (QAU) is the subject of an important chapter of GLP regulations, and the OECD has published a consensus document to help the interpretation of the QAU section in the main text. You will need to have this consensus document at hand because it will be referred to often during this presentation: OECD Series on Principles of GLP Compliance Monitoring Number 4 (revised) Consensus Document Quality Assurance and GLP.

Archive-Slide 14

To understand the work of the QAU it should be remembered that GLP is a standard for the organization of studies. Remember that GLP is not a set of rules that judges the scientific value of studies. The QAU works in the area of compliance with GLP and in the area of study organization. GLP is concerned with the organization of studies and the way in which they are:

- PLANNED: This is why the protocol is important
- PERFORMED: This is why respecting SOPs is important
- RECORDED: This is why GLP gives such importance to raw data
- REPORTED: This is why the study director is requested to make a final report including his scientific judgement
- MONITORED: Continuous monitoring of the study is done by the study director and his team, and by the QAU.

Archive-Slide 15
Reading: Ask the participants to read the section on Qualifications of QA personnel from the OECD Consensus document Quality Assurance and GLP page 7. Discuss with the group.

Archive-Slide 16
The GLP regulations require that the QAU has a documented program. This means that the QAU must have its own SOPs on how it operates and must record what it does.
QAU personnel must be familiar with the studies they are auditing. Note that the GLP regulations do not require QAU personnel to be scientific experts in these studies, the expert is the study director. QAU personnel should, however, be experts in their own field, which is GLP, quality and organizational issues. QAU personnel must be independent of the study personnel. They report directly to the facility management, never to the study staff. This allows them to be as objective as possible during audits and inspections. The QAU must have a copy of the Master Schedule. They need this to plan their own inspection/audit program.

Archive-Slide 17
Reading: Ask all the participants to read Section 2 of the OECD GLG Principles.

Archive-Slide 18
What follows highlights some of the aspects that are detailed in this section. The GLP Principles require QAU to check that all personnel have protocols and SOPs available for their work and that these documents are followed during the performance of their work. This is achieved by audit or inspection. It is this program of audits/ inspection that should be defined in the QAU SOPs.

Archive-Slide 19
When the QAU performs an audit/inspection it must be recorded in writing. Any findings resulting from the investigation must be reported to the appropriate person in management and the study director if the finding is about a specific study. QAU responsibilities with respect to the final report are to audit it against raw data and make sure that the results in the report represent exactly the raw data. QAU will add a statement to the study report detailing the dates and the nature of the investigations performed during the study.

Archive-Slide 20
Although the OECD GLP Principles clearly state that the QAU must verify (review) the protocol, the same is not clearly stated for SOPs. However, the OECD Consensus document on QAU responsibilities recommends this.

	Archive-Slide 21 The OECD GLP Principles recommend that the QAU performs three types of inspections/audits. These are explained in the following slides. Archive-Slide 22 Study-based inspections are those that investigate specific studies. They are performed on the protocol, the phases of the study that are in process or on going, and on the final report. Typically, the QAU identifies important study phases known as critical phases, which are then inspected during the actual performance of operations by study staff. Archive-Slide 23 Facility-based inspections cover wider aspects of the laboratory's operations than those relating to a single study. This slide shows some examples of the type of facility inspections that QAU could do within a laboratory. Archive-Slide 24 **Reading:** Read the definition of facility inspections, in the OECD consensus document Quality Assurance and GLP: Section on QA inspections. Archive-Slide 25 The QA Unit is a team responsible as defined by the GLP to ensure that the laboratory is in compliance with GLP Rules. This team is organized to work independently from the personnel in charge of study operations and functions as witnesses to the pre-clinical research process. Archive-Slide 26 This slide demonstrates what should be included in a QA statement.
Discussion Points	Discuss with the participants other possible archive conditions applicable in their studies.

Lecture: Objectives of Good Lab Management

Time	20 minutes	File Name(s)	Lecture Slides: Objectives of Good Lab Management (GLM)
Objectives	1. Discuss the fundamentals of good science and good organization in laboratories including relevant international standards and regulations. 3. Assess gaps in organizational proficiency of laboratories 6. Identify and discuss the roles and responsibilities of laboratory personnel including the lab director, lab manager, scientists, academics, and students. 8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.		
Lecture Notes	GLM-Slide 2 This presentation in lab management teaches the trainee the objectives of good lab management: 1. His/her main job is to obtain help scientists/customers/patients obtain results that are reliable, credible and repeatable. A dependable lab is the main focus of a good lab manager. 2. In order to reach the above objective, the lab manager must constantly promote good lab practices in his laboratory. He/she must constantly validate the tests data for quality. 3. A good lab manager must produce professional final report for the analyses. He/she must ensure that the results are archived to be consulted later if needs be. Researchers rely on		

	these for their scientific publications. Other researchers rely on the archived data for validating conclusions of other publications. GLM-Slide 3 The lab manager must promote conditions where each analysis is planned, performed successfully, recorded, reported, archived, and monitored: • Planned: each analysis must be planned. The manager must have decided ahead of time what standard operating procedure will be followed for that analysis. He must ensure that all reagents are available, in the needed quantity, that all glassware and instruments are available, in sufficient quantity and in working order. A calendar must be established to ensure that there will be enough personnel to execute the SOP. • Performed successfully: the lab manager must make sure that the SOP is followed to the letter. • Recorded: that all data and all steps conducted are conducted at the time they are performed. • Reported: the lab manager is responsible for reporting the results to the researchers/clients when the analyses are completed. • Archived: the lab manager must archive all results obtained. It is also the job of the lab manager to ensure that all these analyses are performed in a safe manner and environmentally conscious manner as requested by OSHA, EPA, CDC and Environmental Health and Safety. GLM-Slide 4 At times the lab manager is not only a scientist, but he/she is also the face of the laboratory. He/She is the public relation in charge of representing the lab with clients and researchers. Some of these duties include: 1. Writing an information sheet, a web page, a link that summarizes what the lab offers 2. Information that will advertise the services offered at this lab. GLM-Slide 5 The lab manager must clearly understand the lab's mission and the users that will depend on the results generated by the facility. He/She needs to know what analyses they perform and for whom. GLM-Slide 6 In this slide we are using the mission of the University of Florida, Forage Evaluation Support Laboratory as an example: • It clearly states that they provide forage nutritive value analysis. • It clearly states who the users are: IFAS researchers throughout the state of Florida, i.e., this lab is a service lab to support in-house research. • The lab also provides DNA content to plant breeders. • The lab provides hands-on training and experience to UF students.
Discussion Points	Respond to any participant questions and comments.

Activity: Lab Mission Statement

Time	30 minutes	File Name(s)	None
Objectives	8. Identify and discuss essential laboratory reporting practices including logging and processing		

	samples, keeping records, final reporting, and archives.
Materials	1. Blank or lined paper 2. Pens or pencils
Process	1. Divide the participants into groups. 2. Pass out blank or lined paper and pens or pencils to the participants. 3. Ask the participants to elect one person to be the writer. 4. Ask the participants to discuss what should be included in a laboratory statement for their own lab(s). 5. Ask the participants to write their mission statement. 6. After 20 minutes, ask each group to share their mission statement.
Discussion Points	• Ask participants which mission statement they liked the best and why. • Respond to any participant questions and comments.

Activity: Promoting the Lab

Time	45 minutes	File Name(s)	• Lecture Slides: Objectives of Good Lab Management (GLM) • Activity: Web Page Worksheet • Activity: Form Worksheet
Objectives	8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.		
Materials	• Handout: Web Page Worksheet, sufficient copies for each group • Handout: Form Worksheet, sufficient copies for each group		
Process	1. Divide the participants into groups or ask them to return to their previous group. 2. GLM-Slide 8: Explain that it is important to have all info about the lab in one location for lab employees to consult and for potential clients to learn about services and procedures offered at the laboratory. 3. If the institution is web-capable, hand out the Web Page Worksheet to each group. If the institution does not have a web presence, hand out the Form Worksheet to each group. 4. Ask each group to elect one person to be the writer. 5. Ask the participants to discuss what should be included in their Web Page or Form. 6. Ask the participants to design their Web Page or Form. 7. After 30 minutes ask each group to share their Web Page or Form with the group.		
Discussion Points	• Ask participants which Web Page or Form they liked the best and why. • Respond to any participant questions and comments.		

Activity: Lab Intake Forms

Time	45 minutes	File Name(s)	Lecture Slides: Processing the Intake of Samples Activity: Lab Submission from Worksheet
Objectives	8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.		
Materials	• Lab Submission Form Worksheet, copies sufficient for each group • *Optional:* UF FESL Submission Form 1 Handout, copies sufficient for each participant. This form can be found at the following links: ○ https://agronomy.ifas.ufl.edu/media/agronomyifasufledu/documents/FESL-Form-1.pdf ○ https://agronomy.ifas.ufl.edu/media/agronomyifasufledu/documents/NIRS-Form-1.pdf		

Process	1. Divide the participants into groups or ask them to return to their previous group. 2. PIS-Slide 2: Explain how to receive and organize submissions to the laboratory. It is important to be clear what kind of information to give to the potential clients and what kind of information we must receive from the potential client regarding their incoming samples. 3. PIS-Slide 3: Explain how the UF FESL Submission Form 1 works. Explain how the form serves all these functions of gathering necessary information on number of samples submitted, number of analyses requested, type of analyses requested, and payment options. 4. Provide each group with the Submission Form Worksheet Handout and the UF FESL Submission Form 1 Handout (*if providing*). 5. Ask the participants to discuss what should be included in their Submission Form 1. 6. Ask the participants to design their Submission Form 1. 7. After 30 minutes ask each group to share their Submission Form 1.
Discussion Points	• Ask participants which Submission Form they liked the best and why. • Ask the participants which items should be required to be included on the Submission Form 1 for their own lab(s). • Respond to any participant questions and comments.

Lecture: Processing the Intake of Samples

Time	20 minutes	File Name(s)	Lecture Slides: Processing the Intake of Samples (PIS)
Objectives	8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.		
Lecture Notes	PIS-Slide 4 This sample preparation is for samples to be submitted to the UF Forage Lab. All samples are collected into brown paper bags that are labeled with a black marker (Sharpie). The checklist directs the researcher/student who collected the forage leaf ,stem and/or root to first dry all the samples at 60C for 72 hours. After drying the samples, they then must be ground using a mill to 1mm particle size. The ground-up samples are then placed into a 7 ounce polyethylene bags (such as Whirl-Pak brand). Each bag is numbered and labeled according to the study plan. All the samples in the set destined to this lab must be numbered from 1 to N. PIS-Slide 5 Explain how the UF FESL Form 2 works to collect information on the samples themselves, their type, origin, treatment. The Form 2 also allows the laboratory to organize the samples in a sequential order. PIS-Slide 6 Explain the Form 2 and how to use the Form 2. PIS-Slide 7 Explain the analyses offered by the laboratory at UF Agronomy Department. PIS-Slide 8 Explain the analyses offered. In this case the Nitrogen determination. PIS-Slide 9 Explain sample processing as the samples are either: • Brought to the laboratory • Mailed to the laboratory • And organized in the laboratory BEFORE processing.		

	PIS-Slide 10 Explain a sample of a simple laboratory workbook to keep track of: • When samples arrive at the laboratory and returned to the researcher/client • What type of samples, plant tissue • What analyses are requested • When samples are started, processed for an analysis, when results are calculated. PIS-Slide 11 Explain same as previous slide but in Excel form.
Discussion Points	Respond to any participant questions and comments.

Activity: Developing a Lab Workbook

Time	30 minutes	File Name(s)	Handout: Example Logbook
Objectives	8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.		
Materials	• Blank or lined sheets of paper • Pens or pencils • Handout: Example Logbook, copies sufficient for each group		
Process	1. Divide the participants into groups or ask them to return to their previous group. 2. Handout out blank or lined sheets of paper and pens or pencils to the groups. 3. Ask each group to elect one person to be the writer. 4. Ask the participants to think of their own laboratory and write or design a functioning workbook that will work for their lab(s). 5. Give the participants 20 minutes to create their workbook. 6. Ask each group to present their workbook to the participants.		
Discussion Points	• Compare the trainee's submission and discuss different logbooks for different types of laboratories. What are the similarities and differences? Are there items that must be on a logbook for it to be effective?		

Activity: End of Day Reflection

Time	20 minutes	File Name(s)	
Objectives	Review and reflection.		
Materials	• Strips of scrap paper (must be blank on one side) sufficient for each participant to have one paper • Pencils or pens		
Process	**Option 1:** Repeat the end of day reflection from Day 1 **Option 2:** Repeat the end of day reflection from Day 2 **Option 3:** 1. Pass out strips of paper so that each participant has one paper. 2. Ask the participants to write one sentence about what they believe is the most important thing that they learned during Day 3. 3. Give the participants 5 minutes to think of their response and write it on the scrap paper. 4. After the participants are finished writing, instruct them to crumple their paper into a ball.		

	5. Explain that you will have a "snowball fight." If snow does not occur in the country where the training is taking place, first ask participants if they are familiar with snow. Then explain the idea of a "snowball fight." 6. Instruct the participants to throw their "snowballs" at one another. They can pick up and continue throwing until you tell them to stop (1-2 minutes). Note that you may need to demonstrate this. 7. After a couple of minutes, ask each participant to pick up one "snowball". 8. Ask the participants to unwrap their snowball. 9. Go around the circle and ask each person to read what is written on the snowball that they picked up. 10. Give the participants any information or announcements they need for the next day.
Discussion Points	Respond to any participant questions and comments.

Session Plans: Day 4

Activity: Review of Previous Day

Time	30 minutes	File Name(s)	Attendance Sheet
Objectives	Review of Day 2 information and activities		
Materials	Sign-In Sheet		
Process	1. Ask participants to sign in upon arrival. Use the Livestock Lab approved Sign-In Sheet. 2. Welcome the participants to Day 3 of the training. 3. Make any relevant announcements. 4. Remind the participants of the Norms and Expectations, if needed. **Option 1:** Repeat the review activity from Day 2 **Option 2:** Repeat the review activity from Day 3 **Option 3:** 1. Ask participants to find a single partner. 2. Ask the pairs to link together with another pair to form groups of four. 3. Ask the groups to discuss what material was covered during Day 3 of the workshop. 4. Explain to the participants that they each will share one thing that they learned from the previous day but using no more than 3 words. 5. Give the participants 15 minutes to discuss. 6. Ask the participants to stand in a circle. 7. Ask the participants to go around and share what they learned during the last day in only 3 words.		
Discussion Points	Respond to any participant questions and comments.		

Lecture: Laboratory Safety and Equipment Maintenance

Time	60 minutes	File Name(s)	Lecture: Laboratory Safety and Equipment Maintenance (Safety)
Objectives	8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives. 9. Discuss laboratory safety and analyze a laboratory to determine the needs for improving		

Lecture Notes	laboratory safety. Safety-Slide 2 This is an activity to show the thought process behind lab management: Who is the target clientele, what test item, what protocol, and how to receive samples and ship results. Keeping a chemical inventory is crucial. The inventory must record the following: • Date chemical is purchased • Building where chemical is kept • Room where chemical is kept • Name of Study Director using the chemical • Primary chemical name • Chemical Abstracts Service (CAS) Number for chemical • Quantity of chemical on hand • Unit (g, kg, ml, L) • Link Material Safety Data Sheet (MSDS). Safety-Slide 3 Explain the importance of the Material Safety Data Sheet (MSDS) and how to use them. Explain that the information contained in the MSDS is most useful before one start using the product or chemical. MSDS list the different existing names for the chemical, the dangers one is exposed to when handling the by the chemical, the possible treatment is one is harmed by the chemical, the contact information if there is an emergency involving said chemical. Safety-Slide 4 Explain same as slide 21 Safety-Slide 5 Explain Personal Protective Equipment (PPE) and their importance in laboratories. PPEs include and are not limited to lab coats, gloves, goggles, footwear, respirators, etc. Safety-Slide 6 Explain the process of equipment acquisition: • What to buy? • Why buy it? • What options offered with said equipment if any? • What about the warranty? • What about service offered/provided? • Will you be buying from the company directly or from a distributor? It is necessary to keep a list of current suppliers as businesses come and go. Or circumstances like these days with the coronavirus creates new suppliers of new products: https://www.thomasnet.com/articles/top-suppliers/medical-testing-kits-suppliers/ Safety-Slide 7 Explain the importance of regular preventive maintenance in the efficient operation of any laboratory. How do you know what part of the equipment requires maintenance? How often? What tools are required to execute the operation?

	Safety-Slide 8 Explain more about maintenance and the importance of the equipment manual. How to use the manuals? Where to keep them? Safety-Slide 9 Explain the need for redundancy in skills. Safety-Slide 10-14 Explain what to look for when using a manual.
Discussion Points	• Ask the participants to talk about specific problems they encounter, and discuss the procedures that will mitigate them • Respond to any participant questions and comments

Activity: Laboratory Toolbox

Time	20 minutes	File Name(s)	• Lecture Slides: Laboratory Safety and Equipment Maintenance • Example Manual 1: Electronic Balance • Example Manual 2: Microscope • Example Manual 3: Incubator • Example Manual 4: Fiber Analyzer
Objectives	3. Assess gaps in organizational proficiency of laboratories. 4. Assess gaps in technical proficiency of laboratory management. 8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives. 9. Discuss laboratory safety and analyze a laboratory to determine the needs for improving laboratory safety.		
Materials	• Flipchart paper, whiteboard, or chalkboard • Flipchart markers, whiteboard markers, or chalk • 4-5 Equipment Operation Manuals or Handouts. Four operations manuals are available in the manual resources folder. They include: ○ Example Manual 1: Electronic Balance (Also available at: https://www.shimadzu.com/an/products/analyzer-and-balances) ○ Example Manual 2: Microscope (Also available at: http://www.alanwood.net/downloads/olympus-bh-2-bht-manual.pdf) ○ Example Manual 3: Incubator (Also available at: https://www.ankom.com/analytical-methods-support/daisy-incubators) ○ Example Manual 4: Fiber Analyzer (Also available at: https://www.ankom.com/product-catalog/ankom-delta-automated-fiber-analyzer)		
Process	1. Safety-Slide 32: Explain the need for a laboratory toolbox. What tools should be kept in the laboratory to help with maintenance? Explain how one can use the equipment operation manuals to establish a list of mandatory tools. 2. Ask the participants to list the tools that they should have available in their lab(s). 3. Write the responses on the flipchart paper, whiteboard, or chalkboard. 4. After 5 minutes, hand out a copy of the equipment operation manuals, or provide an electronic file for the participants to view. 5. Give the participants 5 minutes to read the handout and determine which tools are needed. 6. After 5 minutes, ask the participants to continue listing the tools and add them to the list.		
Discussion Points	• What tools does the lab currently have? • What tools are missing?		

	• How can the lab acquire the tools and toolbox they need? • How can the lab ensure that the tools and toolbox are kept safely in the lab and only accessed for lab use? • Respond to any participant questions and comments.

Lecture: Personal Protective Equipment (PPEs)

Time	70 minutes	File Name(s)	Lecture Slides: Personal Protective Equipment (PPE)
Objectives	9. Discuss laboratory safety and analyze a laboratory to determine the needs for improving laboratory safety.		
Notes to Facilitator	Additional resources for the facilitator: • Labeling waste (Slide 38) poster available in the files and at: https://www.ehs.ufl.edu/departments/research-safety-services/hazardous-waste-management/chemical-waste/laboratory-waste/ • Personal Protective Equipment (Slide 39) Plan example available in the files and at: http://webfiles.ehs.ufl.edu/CHPAppE_PPE.pdf • PPE (Slide 41) examples available in the files and at: https://ehs.ucmerced.edu/researchers-labs/ppe/selection • Respirator and Mask (Slide 43) examples available in the files and at: https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks		
Lecture Notes	PPE-Slide 2 Explain the importance of keeping a record of procedures used in the laboratory. PPE-Slide 3 Explain the importance of laboratory safety and how to make sure employees and students are always protected. PPE-Slide 4 Explain: • Who is responsible for lab safety? • Who is responsible for safety education? • Who is responsible to ensure rules are followed? • Hierarchy? • Individual responsibility? PPE-Slide 5 Explain more about safety as above. PPE-Slide 6 Explain the importance of labeling in laboratory. How to label chemicals? How to recognize and label waste? PPE-Slide 7 Explain PPEs particularly gloves What kind for what danger? What size?		

	Explain that not all gloves can be worn for all hazards in a laboratory. Explain which gloves to use when. PPE-Slide 8 Explain PPEs as above. PPE-Slide 9 Explain PPEs as above (eye protection). PPE-Slide 10 Explain PPEs as above (lab coats and skin protection). PPE-Slide 11 Explain PPEs as they relate to protection against smoke, vapors, fumes. PPE-Slide 12 Explain generation, collection and disposal of hazardous waste. PPE-Slide 13 Explain a well-organized waste collection area.
Discussion Points	Respond to any participant questions and comments.

Practical: Laboratory Visit

Time	2 hours, 30 minutes	File Name(s)	Use Lab Practical Activity (page 126)
Objectives	1. Discuss the fundamentals of good science and good organization in laboratories including relevant international standards and regulations. 2. Assess challenges in existing labs to conduct research aimed at improving animal health and production. 3. Assess gaps in organizational proficiency of laboratories. 4. Assess gaps in technical proficiency of laboratory management. 5. Assess gaps in technical proficiency of laboratory personnel, scientists, academics, and students. 6. Identify and discuss the roles and responsibilities of laboratory personnel including the lab director, lab manager, scientists, academics, and students. 7. Identify and discuss how laboratory practices impact the quality of research and the quality and validity of test data. 8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives. 9. Discuss laboratory safety and analyze a laboratory to determine the needs for improving laboratory safety.		
Materials	• Strips of scrap paper (must be blank on one side) sufficient for each participant to have one paper • Create one page checklists using information on (page 125) and print to provide sufficient checklists for each participant to have • Pencils or pens		
Process	1. Ask the participants to go around the lab and randomly interview one of the lab personnel focusing on the roles and responsibilities of the laboratory personnel, on laboratory		

	practices and on laboratory safety measures. Encourage participants to write down observations of what they see in the lab before they interview the lab personnel. 2. Ask participants to complete checklists provided.
Discussion Points	Discuss in groups the following questions: 1. What equipment and instruments does the lab currently have? 2. What equipment and instruments are missing? 3. Are the equipment and instruments in working order? 4. Are the manuals in a location where they can be easily accessed? If not, how can the manuals be found? 5. Are the samples properly logged? 6. Are there sufficient reagents? 7. Are the reagents properly inventoried and stored? Respond to any participant questions and comments.

Activity: Final Reflection

Time	40 minutes	File Name(s)	
Objectives	Review and reflection.		
Materials	• Flipchart paper • Colored Markers (withhold the black markers) • Black Markers		
Process	1. Divide the participants into groups of 4-5. If there are less than 15 participants, divide the participants so that there are at least 3 groups. 2. Give each group a flipchart paper and colored markers (withhold the black markers). 3. Ask the participants to brainstorm everything they have learned during the training. Explain that they do not need to reach consensus. Every person should have a marker and they will write at the same time. The flipchart does not need to be neat, in fact, it is encouraged to write all over the paper. 4. Give the participants 10 minutes to write as much as they can about what they have learned. 5. After 10 minutes, ask the participants to put their markers down. 6. Ask the participants to rotate one group to the left. It is helpful for the facilitator to point to where each group should move to. 7. Give the participants another 5-7 minutes to read the flipchart and continue adding to it. 8. Repeat steps 6-7 until the groups have been to every flipchart and then have returned to their original. 9. Hand out the black markers to the groups. 10. Explain to the participants that each person should use the black marker to circle the ONE thing that they found the most useful during the training. 11. After each person has circled their item, ask the participants to form a circle, placing the flipcharts in the center of the circle. 12. Take a moment with the participants to reflect on how much material was covered during the training. 13. Ask the participants to go around the room and one-by-one to share what the circled and why.		
Discussion Points	Respond to any participant questions and comments.		

Activity: Training Closure

Time	60 minutes	File Name(s)	• Certificate of Completion • Training Evaluation
Objectives	Training closure and evaluation.		
Materials	• Certificates of Completion, one for each participant • Training Evaluations, copies sufficient for each participant • Pens or pencils		
Process	1. Pass out the certificates of completion. Follow the appropriate cultural methods for this process. In most cases, this will involve a formal acknowledgement of each participant inclusive of a handshake and a photo. Other cultural contexts may have other processes, as well. 2. Pass out the Training Evaluations. Ask each participant to fill out the training evaluation prior to leaving the training. 3. Thank the participants for their time and participation. Provide any end-of-training information that is needed.		
Discussion	Respond to any participant questions and comments.		

Session Plans: Day 5 - Joint Laboratory/Administrator Training & Strategic Planning

Activity: Welcome and Introductions

Time	30 minutes	File Name(s)	Attendance Sheet
Objectives	Welcome and introductions		
Materials	Sign-In Sheet		
Process	1. Ask participants to sign in upon arrival. Use the Livestock Lab approved Sign-In Sheet 2. Welcome the participants to Day 5 of the training. 3. Make any relevant announcements. 4. Show the Norms and Expectations developed during the beginning of the training, explain for the new participants. Introductions 1. Show PowerPoint slide (page 93) with line drawings of common laboratory instruments (e.g., microscope, beaker, test tube, pipette, Bunsen burner, scale, graduated cylinder, thermometer, mortar and pestle, safety goggles, dropper). 2. Ask the participants to look at the line drawings and choose which one best represents their personality. 3. Ask the participants to share their name, role at the institution, which laboratory instrument best represents their personality, and why.		
Discussion Points	Respond to any participant questions and comments.		

Lecture: How Laboratories Work

Time	30 minutes	File Name(s)	Lecture Slides: Role of Lab Administrators – How laboratories work per the interests of administration
Objectives	1. Discuss the fundamentals of good science and good organization in laboratories including relevant international standards and regulations.		

	6. Identify and discuss the roles and responsibilities of laboratory personnel including the lab director, lab manager, scientists, academics, lab staff, and students. 7. Identify and discuss how laboratory practices impact the quality of research and the quality and validity of test data.
Notes to Facilitator	This lecture will also include a discussion component.
Lecture Notes	RLA-Slide 2 Explain the mission of the lab but relating to objectives of having a lab in the organization. RLA-Slide 3 Explain the role of lab administration. This is the first set of roles. RLA-Slide 4 Continue expanding on the role of lab administration. This is the second set of roles. RLA-Slide 5 Explain how a lab can elevate or demote the reputation of the institution RLA-Slide 6 Includes a few questions that can be used for discussion purposes after lecture.
Discussion Points	Respond to any participant questions and comments.

Discussion: The Role of Administrators and Decision-Makers in Laboratory Management

Time	60 minutes	File Name(s)	Attendance Sheet
Objectives	1. Discuss the fundamentals of good science and good organization in laboratories including relevant international standards and regulations. 6. Identify and discuss the roles and responsibilities of laboratory personnel including the lab director, lab manager, scientists, academics, lab staff, and students. 7. Identify and discuss how laboratory practices impact the quality of research and the quality and validity of test data.		
Materials	• Blank or lined sheets of paper • Pens or pencils		
Process	**Option 1** 1. Pose the questions listed below to the whole group. Note that there may be power dynamics that influences the discussion when conducted as a whole group. 2. Ensure that all participants are able to speak. **Option 2** 1. Divide the participants into groups of 4-5. a. Split administrators among the groups. This will allow all groups to have an in-depth discussion with an administrator. b. Keep administrators and laboratory personnel in different groups. This will allow each group to discuss and problem-solve from their perspectives. 2. Show the discussion questions on RLA-Slide 6 or provide in a handout. 3. After 30 minutes, reconvene to plenary. 4. Ask one of the groups to share their response to Question 1. Open up to discussion from the whole group.		

	5. Repeat #4 for all questions.
Discussion Points	1. What is the mission of the lab? What do the administrators expect of the lab? 2. What are the challenges facing the laboratories at the institution? 3. What is the role of administrators and decision-makers in ensuring the functioning of the laboratory? 4. What are the institutional process/procedures/rules that influence the functioning of the lab? If there are none, how does the lack of process/procedures/rules influence the functioning of the lab? 5. How can the administrators better support the laboratory? 6. How can the laboratory better communicate and engage with the administrators?

Activity: Laboratory Tour and Evaluation

Time	1 hour, 40 minutes	File Name(s)	Attendance Sheet
Objectives	1. Discuss the fundamentals of good science and good organization in laboratories including relevant international standards and regulations. 6. Identify and discuss the roles and responsibilities of laboratory personnel including the lab director, lab manager, scientists, academics, lab staff, and students. 7. Identify and discuss how laboratory practices impact the quality of research and the quality and validity of test data. 8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.		
Materials	• Blank or lined sheets of paper • Laboratory evaluation handouts printed • Pens or pencils		
Process	1. Take the group to a laboratory at the institution, preferably one where the training participants have conducted their lab practical evaluation. 2. Pair the administrators with the laboratory personnel. There should be at least one laboratory personnel in each group. 3. Provide the laboratory evaluation handouts to the participants (one can use the same checklist in the Lab Practical Activity). 4. Ask the laboratory personnel to take the administrators around the lab and point out what is going well and what needs attention, per the laboratory checklists. 5. After the groups have made their evaluations, reconvene in plenary. This can be done in the lab. 6. Proceed to discussion questions.		
Discussion Points	1. What are the areas that you identified where the lab is doing well? 2. What are the areas that you identified that the lab needs improvement on? 3. How are the positives and negatives that you identified related (or not related) to the support and involvement of the administration? 4. What needs to occur at the laboratory level to better engage with the administration? 5. What needs to occur at the administrative level to improve the functioning of the labs?		

Activity: Strategic Planning

Time	2 hour, 40 minutes	File Name(s)	Attendance Sheet
Objectives	1. Discuss the fundamentals of good science and good organization in laboratories including relevant international standards and regulations. 6. Identify and discuss the roles and responsibilities of laboratory personnel including the lab director, lab manager, scientists, academics, lab staff, and students.		

	7. Identify and discuss how laboratory practices impact the quality of research and the quality and validity of test data. 8. Identify and discuss essential laboratory reporting practices including logging and processing samples, keeping records, final reporting, and archives.
Materials	• Blank or lined sheets of paper • Flipchart paper and markers • Pens or pencils
Process	**Part 1: Culture versus Structure, 1 hour** 1. Divide participants into groups of 4-5. 2. Assign each group to conduct a Strengths/Weaknesses/Opportunities/Threats/Challenges (SWOT) analysis of the culture or the structure of the institution, in terms of the laboratory. Find Activity: SWOT analysis handout for this purpose. 3. Give the participants flipchart paper and markers. 4. Give the participants 30 minutes to discuss and create their flipcharts. 5. Ask each group to share their results and open to plenary discussion (30 minutes). **Part 2: Action Plan, 1 hour 40 minutes** 1. Divide the participants into groups of administrators and groups of laboratory personnel. There should be no more than 4-5 people per group. 2. Post the flipcharts from Part 1 on the wall so they can easily be referenced. 3. Provide the participants with flipchart paper and markers, or ask participants to use laptops (one required per group). 4. Ask each group to develop a preliminary action plan to support the development of the lab including: a. Leveraging lab strengths and opportunities b. Addressing lab weaknesses and threats/challenges c. Improving the institutional culture d. Implementing/Modifying/Adapting/Developing the institutional structure i. Roles ii. Responsibilities iii. Processes iv. Procedures v. Rules e. Next steps for the administrators f. Next steps for the laboratory personnel g. Administrator and laboratory personnel who will follow-up with another meeting to continue the process 5. After 1 hour reconvene the groups in plenary. Ask each group to share their plan but to skip any responses that have been stated by a previous group (this will help to save time). a. Trainer/facilitator should compile the ideas presented in questions a-d on a flipchart or PowerPoint slide. b. Trainer/facilitator should compile the ideas presented in questions e-g on another flipchart or PowerPoint slide.
Discussion Points	Respond to any participant questions and comments.

Activity: Closure

Time	1 hour	File Name(s)	• Certificate of Completion • Training Evaluation
Objectives	Training closure and evaluation.		
Materials	• Certificates of Completion, one for each participant • Training Evaluations, copies sufficient for each participant • Pens or pencils		
Process	1. Ask the participants to stand in a circle. 2. Ask each participant to state: a. One new thing that they learned today about the laboratory, institutional culture, institutional structure, or another item b. One thing that they will do to follow-up on the day's activities. 3. Facilitator should compile a list based on question 2 to provide to the participants. 4. Pass out the certificates of completion. Follow the appropriate cultural methods for this process. In most cases, this will involve a formal acknowledgement of each participant inclusive of a handshake and a photo. Other cultural contexts may have other processes, as well. 5. Pass out the Training Evaluations. Ask each participant to fill out the training evaluation prior to leaving the training. 6. Thank the participants for their time and participation. Provide any end-of-training information that is needed.		
Discussion Points	Respond to any participant questions and comments.		

Appendix 1: List of Acronyms

ADF	Acid Detergent Fiber
CDC	Center for Disease Control of the United States
CP	Crude Protein
CRO	Contact Research Organization
CV	Curriculum Vitae
DNA	Deoxyribonucleic Acid
EPA	Environmental Protection Agency of the United States
FDA	Food and Drug Administration of the United States
FESL	Forage Evaluation Support Laboratory at the University of Florida
FL	Forage Lab
MAD	Mutual Acceptance of Data
MSDS	Material Safety Data Sheet
GLP	Good Lab Practices
GMP	Good Management Practices
IFAS	Institute of Food and Agricultural Sciences at the University of Florida
IVOMD	In-Vitro Organic Matter Digestibility
OECD	Organization for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration of the United States
LSIL	Livestock Systems Innovation Lab
NDF	Neutral Detergent Fiber
P	Phosphorus
PPE	Personal Protective Equipment
QA	Quality Assurance
QAU	Quality Assurance Unit
QC	Quality Control
SOP	Standard Operating Procedure
UF	University of Florida

Appendix 2: Activities and Handouts

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FEED THE FUTURE
The U.S. Government's Global Hunger & Food Security Initiative

Attendance Sheet

Feed the Future Innovation Lab for Livestock Systems

Short-term Training Attendance Sheet

Training Information	
Subaward Project Name:	
PI Name:	**PI Institution:**
Training Program Title:	

First and last name(s) of trainers/facilitators and their affiliation (add or remove rows as needed):

First name	Last name	Organization	Position
1.			
2.			
3.			

Training Purpose and Objectives:

USAID FROM THE AMERICAN PEOPLE

BILL & MELINDA GATES foundation

ILRI INTERNATIONAL LIVESTOCK RESEARCH INSTITUTE

CGIAR

UF IFAS UNIVERSITY of FLORIDA

Short-term Training Attendance Sheet: Totals

(Please enter the total number of individuals who attended the training by type of individual)

Training Title: _____
Training Date: _____

TOTAL # OF ATTENDEES	
# Male	
# Female	
Producers (total)	
Male	
Female	
Farmers	
Pastoralists	
Ranchers	
Other (describe)	
People in government (total)	
Male	
Female	
Policy makers	
Extension workers	
Other (describe)	
People in private sector firms (total)	
Male	
Female	
Processors	
Service providers	
Manufactures	
Other (describe)	
People in civil society (total)	
Male	
Female	
NGO workers	
People in research or academic organizations	
People working in civil society organizations	
People working in community-based organizations	
Other (describe)	

Feed the Future Innovation Lab for Livestock Systems

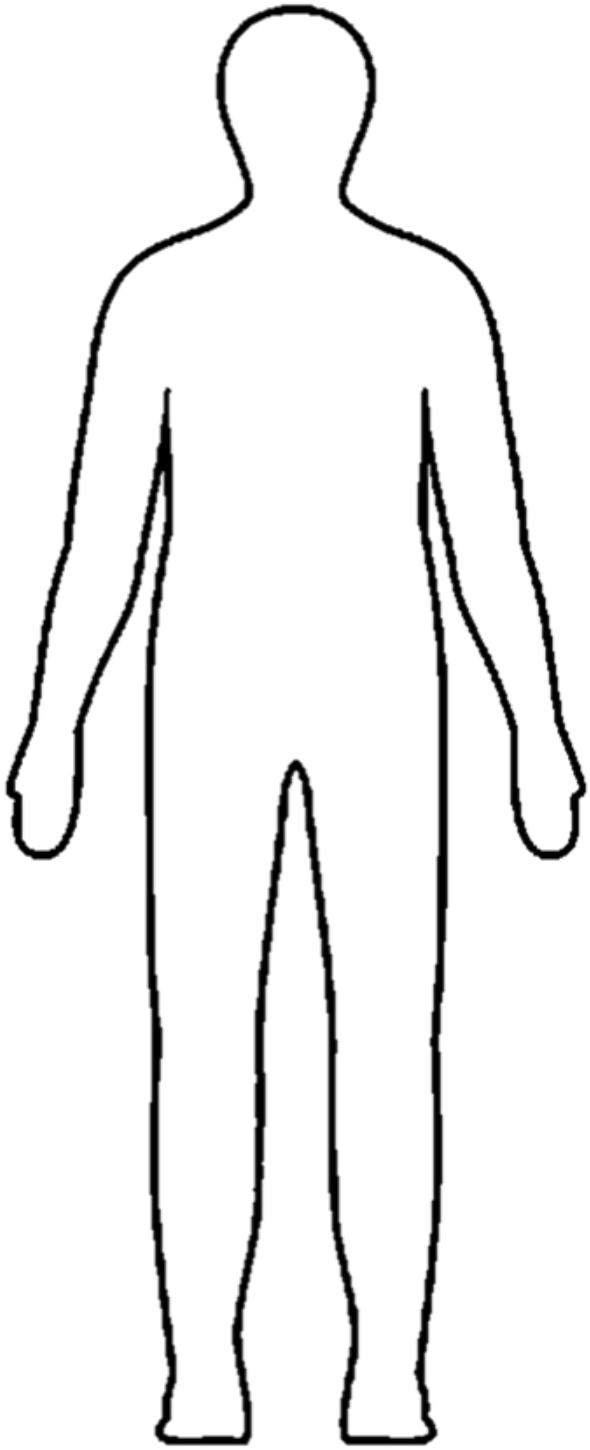
Short-term Training Attendance Sheet

Training Title: _____

Date: _____ **Location:** _____

Attendee Information								
First Name	Last Name	Sex M/F	Age		Address, community/ village	Association/ organization affiliation	Email address / Phone number	Signature
			15-29	30+				

Handout: Welcome Activity Body Map



Handout: Developing Job Descriptions and Responsibilities

Use this worksheet to brainstorm the job descriptions and responsibilities for your laboratory. All job positions should have clearly stated, concrete, measurable tasks and responsibilities. The positions in your lab may be unique to your department, unit, group, or based on the analyses that you conduct. Some of the positions that you should consider include: laboratory manager, research scientist, laboratory technician(s), and graduate/undergraduate students, as appropriate.

General Job Description

What is the job title?	
What is the name of the department, unit, or group?	
What is the level of this position *(if possible, per the structure of the department, unit, or group)?*	
What is the title of the person who will be the direct supervisor?	

Job Tasks and Responsibilities

In this section, use the boxes below to brainstorm the various job tasks and responsibilities. The tasks and responsibilities should be concrete and measurable. For example, *"The laboratory technician will be responsible for the intake of specimens including promptly labeling specimens, entering them into the intake form, and proper specimen storage."* Use additional pages, or the back of this page, as necessary. Once you have brainstormed the tasks and responsibilities, refine them into an official job position summary.

What are general job tasks and responsibilities?	What are the daily job tasks and responsibilities?
What are the job tasks and responsibilities in terms of health and safety of the lab?	What are the knowledges, skills, and abilities required to do this job?

Activity: Case Study on Study Disturbance and Contamination

You are working in a laboratory in [COUNTRY NAME]. A researcher brings you a set of samples stored in plastic Ziploc bags. The bags include desiccant to aid in drying of the samples. You log the samples indicating who brought them in, the date, the type of sample, and other relevant information.

You weigh each of the samples using a precision balance and note the raw weight into your logbook. You then place the samples into the drying oven and shut the door, using a wire to keep it closed. Unfortunately, the locking mechanism on the door has broken so you have used this temporary replacement, which seems to be working! When you take the samples out of the dryer, you can see that they have adequately dried by looking at the samples. The thermometer is also broken in the dryer, but the samples are dry to the touch when they come out, so you use this as a proxy to a thermometer. In some of the samples, your assistant did not remove the desiccant that was in the Ziploc bags, so you remove it at this point and make a note in your logbook to remind your assistant to remove it in the future.

After you remove the dried samples, you weigh them again using the precision balance and log their dry weight. Finally, you place the samples into your low temperature freezer, which was donated from Europe ten years prior. The freezer didn't come with the manual, but after time, the digital assembly that shows the temperature broke anyway, so you have it turned to as cold as it can go. This way, you can be sure that the samples are as cold as they can be. When you place the samples into the freezer, you notice that the motor seems to be struggling a bit. The rubber seal on the door is cracked in some places due to the age of the freezer, so sometimes the motor has to work extra hard. However, the temperature seems cold enough, so you don't worry about it. You push on the door to be sure it is sealed fairly well, and then move on to your next task.

The researcher returns and thanks you for your work. They take the weights of the samples to use in their calculations for feed formulation.

Questions to Consider:

- What are the points in this case study that the samples could have been contaminated or disturbed?
- How does the process that was used by the laboratory technician contribute to the contamination/disturbance of the study?
- How does the equipment that is used in the lab contribute to the contamination/disturbance of the study?
- How might the use of these data influence the results of the study? What are the implications of this?
- What should the laboratory technician do differently, and why?

Reading: OECD Good Lab Practice Regulations, Excerpt of Sections 8.1-8.2

Excerpt from: OECD. (2019). OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring. Pages 25-27. Available at: http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm

8. Performance of the Study

8.1 Study Plan

1. For each study, a written plan should exist prior to the initiation of the study. The study plan should be approved by dated signature of the Study Director and verified for GLP compliance by Quality Assurance personnel as specified in Section 2.2.1.b., above. The study plan should also be approved by the test facility management and the sponsor, if required by national regulation or legislation in the country where the study is being performed.

2. a) Amendments to the study plan should be justified and approved by dated signature of the Study Director and maintained with the study plan.

   b) Deviations from the study plan should be described, explained, acknowledged and dated in a timely fashion by the Study Director and/or Principal Investigator(s) and maintained with the study raw data.

3. For short-term studies, a general study plan accompanied by a study specific supplement may be used.

8.2 Content of the Study Plan

The study plan should contain, but not be limited to the following information:

1. Identification of the Study, the Test Item and Reference Item
   a) A descriptive title;
   b) A statement which reveals the nature and purpose of the study;
   c) Identification of the test item by code or name (IUPAC; CAS number, biological parameters, etc.);
   d) The reference item to be used.

2. Information Concerning the Sponsor and the Test Facility
   a) Name and address of the sponsor;
   b) Name and address of any test facilities and test sites involved;
   c) Name and address of the Study Director;
   d) Name and address of the Principal Investigator(s), and the phase(s) of the study delegated by the Study Director and under the responsibility of the Principal Investigator(s).

3. Dates
   a. The date of approval of the study plan by signature of the Study Director. The date of approval of the study plan by signature of the test facility management and sponsor if required by national regulation or legislation in the country where the study is being performed.
   b. The proposed experimental starting and completion dates.

4. Test Methods. Reference to the OECD Test Guideline or other test guideline or method to be used. Issues (where applicable).
    a. The justification for selection of the test system;
    b. Characterization of the test system, such as the species, strain, sub-strain, source of supply, number, body weight range, sex, age and other pertinent information;
    c. The method of administration and the reason for its choice;
    d. The dose levels and/or concentration(s), frequency, and duration of administration/application;
    e. Detailed information on the experimental design, including a description of the chronological procedure of the study, all methods, materials and conditions, type and frequency of analysis, measurements, observations and examinations to be performed, and statistical methods to be used (if any).

5. Records

A list of records to be retained.

Reading (*French Version)*: OECD Good Lab Practice Regulations, Excerpt of Sections 8.1-8.2

8. Réalisation de l'étude

8.1 Plan de l'étude

1. Pour chaque étude, il convient d'établir un plan écrit avant le début des travaux. Le plan de l'étude doit être approuvé par le Directeur de l'étude, qui le date et le signe, et sa conformité aux BPL doit être vérifiée par le personnel d'assurance qualité comme indiqué à la section 2.2.1.b ci-dessus. Ce plan doit également être approuvé par la direction de l'installation d'essai et le donneur d'ordre si la réglementation ou la législation du pays où l'étude est réalisée l'impose.

2.
a) Les amendements apportés au plan de l'étude doivent être justifiés et approuvés par le Directeur de l'étude, qui les date et les signe, puis conservés avec le plan de l'étude.
b) Les déviations du plan de l'étude doivent être décrites, expliquées, déclarées et datées en temps utile par le Directeur de l'étude et par le ou les Responsables principaux des essais, puis conservées avec les données brutes de l'étude.

3. Pour les études à court terme, on peut utiliser un plan général d'étude accompagné d'un complément spécifique de l'étude considérée.

8.2 Contenu du plan de l'étude

1. Le plan de l'étude doit comporter les renseignements suivants, dont la liste n'est pas limitative:
    a) Identification de l'étude, de l'élément d'essai et de l'élément de référence
    b) Un titre descriptif ;
    c) Un exposé précisant la nature et l'objet de l'étude ;
    d) L'identification de l'élément d'essai par un code ou par un nom (IUPAC, numéro du CAS, paramètres biologiques, etc.) ;
    e) L'élément de référence à utiliser.

2. Renseignements relatifs au donneur d'ordre et à l'installation d'essai
    a) Le nom et l'adresse du donneur d'ordre ;
    b) b) Le nom et l'adresse de toute installation d'essai et de tout site d'essai concernés ;
    c) c) Le nom et l'adresse du Directeur de l'étude ;
    d) d) Le nom et l'adresse du ou des Responsables principaux des essais, et la ou les phases de l'étude déléguées par le Directeur de l'étude au ou aux Responsables principaux des essais.

3. Dates
    a) La date de l'approbation du plan de l'étude par apposition de la signature du Directeur de l'étude. La date de l'approbation du plan de l'étude par apposition de la signature de la direction de l'installation d'essai et du donneur d'ordre si la réglementation ou la législation du pays où l'étude est effectuée l'impose.
    b) b) Les dates proposées pour le début et la fin de l'expérimentation.

4. Méthodes d'essai: L'indication de la Ligne directrice de l'OCDE pour les essais ou d'une autre ligne directrice ou méthode à utiliser.
    a) La justification du choix du système d'essai;

b) La caractérisation du système d'essai, c'est-à-dire l'espèce, la race, la variété, l'origine, le nombre d'individus, la gamme de poids, le sexe, l'âge et autres informations pertinentes;
c) La méthode d'administration et les raisons de son choix;
d) Les taux de dose et/ou les concentrations, ainsi que la fréquence et la durée de l'administration ou de l'application;
e) Des renseignements détaillés sur la conception de l'expérience, qui comprennent une description du déroulement chronologique de l'étude, de tous les matériaux, méthodes et conditions, de la nature et de la fréquence des analyses, des mesures, des observations et des examens à réaliser, ainsi que des méthodes statistiques à utiliser (le cas échéant).

5. Enregistrements et comptes rendus: La liste des enregistrements et des comptes rendus qu'il faut conserver.

Reading Guide: OECD Regulations

1. What is the title of the study?

2. What is the purpose of the study?

3. What are the test methods to be used?

4. Who is the study Director?

5. What is the list of records to be retained?

Activity: Raw Data Collection Case Study

Scenario 1:
You are a researcher who conducts research in a lab in [COUNTRY NAME]. You realize that you mixed up a few of your samples. You notice that you have two with the same number. You check your work and see that last week you accidentally repeated the number on the last five samples. The samples were sitting together in a box to be moved to the freezer, so you are not sure which ones were labeled first. You grab the duplicated samples and scratch out the label on five of them, relabeling them with the current numbers, also changing the label names in your logbook. When you finish, you give your logbook to your assistant to enter in Excel.

1. What are the errors made in each scenario?
2. How can these errors result in data contamination?
3. What would you do differently, and why?

Scenario 2:
You are a researcher who conducts research in a lab in [COUNTRY NAME]. You realize while weighing in leaf samples to be digested for protein determination you weigh two different samples into the same tube. The assistant decides to continue entering samples into the tubes from that point on by matching sample numbers with tube numbers.

1. What are the errors made in each scenario?
2. How can these errors result in data contamination?
3. What would you do differently, and why?

Scenario 3:
You are a researcher who conducts research in a lab in [COUNTRY NAME]. You realize while weighing samples for processing that the precision balance was not properly calibrated and/or you forgot to re-zero the balance after placing the weighing boat on the balance.

1. What are the errors made in each scenario?
2. How can these errors result in data contamination?
3. What would you do differently, and why?

Reading: OECD Good Lab Practice Regulations, Excerpt of Sections 9.2

Excerpt from: OECD. (2019). OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring. Pages 28-29. Available at: http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm

9.2 Content of the Final Report

The final report should include, but not be limited to, the following information:

1. Identification of the Study, the Test Item and Reference Item
    a. A descriptive title;
    b. Identification of the test item by code or name (IUPAC, CAS number, biological parameters, etc.);
    c. Identification of the reference item by name;
    d. d) Characterization of the test item including purity, stability and homogeneity.

2. Information Concerning the Sponsor and the Test Facility
    a. Name and address of the sponsor;
    b. Name and address of any test facilities and test sites involved;
    c. Name and address of the Study Director;
    d. Name and address of the Principal Investigator(s) and the phase(s) of the study delegated, if applicable;
    e. Name and address of scientists having contributed reports to the final report.

3. Dates: Experimental starting and completion dates.

4. Statement: A Quality Assurance Program statement listing the types of inspections made and their dates, including the phase(s) inspected, and the dates any inspection results were reported to management and to the Study Director and Principal Investigator(s), if applicable. This statement would also serve to confirm that the final report reflects the raw data.

5. Description of Materials and Test Methods
    a. Description of methods and materials used;
    b. Reference to OECD Test Guideline or other test guideline or method.

6. Results
    a. A summary of results;
    b. All information and data required by the study plan;
    c. A presentation of the results, including calculations and determinations of statistical significance;
    d. An evaluation and discussion of the results and, where appropriate, conclusions.

7. Storage: The location(s) where the study plan, samples of test and reference items, specimens, raw data and the final report are to be stored.

Reading (*French Version)*: OECD Good Lab Practice Regulations, Excerpt of Sections 9.2

9.2. Contenu du rapport final

Le rapport final doit donner les renseignements suivants, sans se limiter à ceux-ci :

1. Identification de l'étude et des éléments d'essai et de référence
   a) Un titre descriptif;
   b) L'identification de l'élément d'essai par un code ou par un nom (IUPAC, numéro du CAS, paramètres biologiques, etc.);
   c) L'identification de l'élément de référence par un nom;
   d) d) La caractérisation de l'élément d'essai, notamment sa pureté, sa stabilité et son homogénéité.

2. Renseignements relatifs au donneur d'ordre et à l'installation d'essai
   a) Le nom et l'adresse du donneur d'ordre;
   b) Le nom et l'adresse de chaque installation et site d'essai concernés;
   c) Le nom et l'adresse du Directeur de l'étude;
   d) Le nom et l'adresse du ou des Responsables principaux des essais et les phases de l'étude qui leur sont déléguées, le cas échéant;
   e) Le nom et l'adresse des scientifiques ayant fourni des comptes rendus pour le rapport final.

3. Dates: Les dates de début et d'achèvement de l'expérimentation.

4. Déclaration:
   Une déclaration sur le programme d'assurance qualité énumérant les types d'inspections réalisées et leurs dates, y compris la ou les phases inspectées, ainsi que les dates auxquelles chacun des résultats des inspections a été communiqué à la direction et au Directeur de l'étude, ainsi qu'au ou aux Responsables principaux des essais, le cas échéant. Cette déclaration servira, en outre, à confirmer que le rapport final reflète les données brutes.

5. Description des matériaux et des méthodes d'essai:
   a) Une description des méthodes et des matériaux utilisés;
   b) L'indication de la Ligne directrice de l'OCDE pour les essais, ou d'une autre ligne directrice ou méthode.

6. Résultats
   a) Un résumé des résultats;
   b) Toutes les informations et les données demandées par le plan de l'étude;
   c) Un exposé des résultats, comprenant les calculs et les déterminations d'intérêt statistique;
   d) Une évaluation et un examen des résultats et, s'il y a lieu, des conclusions.

7. Stockage: Le lieu où le plan de l'étude, les échantillons des éléments d'essai et de référence, les spécimens, les données brutes, ainsi que le rapport final doivent être conservés.

Reading: OECD Good Lab Practice Regulations, Excerpt of Section 9.1

Excerpt from: OECD. (2019). OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring. Pages 28. Available at: http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm

9. Reporting of Study Results

9.1 General

1. A final report should be prepared for each study. In the case of short term studies, a standardized final report accompanied by a study specific extension may be prepared.
2. Reports of Principal Investigators or scientists involved in the study should be signed and dated by them.
3. The final report should be signed and dated by the Study Director to indicate acceptance of responsibility for the validity of the data. The extent of compliance with these Principles of Good Laboratory Practice should be indicated.
4. Corrections and additions to a final report should be in the form of amendments. Amendments should clearly specify the reason for the corrections or additions and should be signed and dated by the Study Director.
5. Reformatting of the final report to comply with the submission requirements of a national registration or regulatory authority does not constitute a correction, addition or amendment to the final report.

Reading *(French Version)*: OECD Good Lab Practice Regulations, Excerpt of Section 9.1

9. Etablissement du rapport sur les résultats de l'étude

9.1 Généralités

1. Il faut établir un rapport final pour chaque étude. Pour les études à court terme, un rapport final normalisé pourra être préparé et s'accompagner d'un complement particulier à l'étude.
2. Les Responsables principaux des essais ou les scientifiques participant à l'étude doivent signer et dater leurs rapports.
3. Le Directeur de l'étude doit signer et dater le rapport final afin d'indiquer qu'il assume la responsabilité de la validité des données. Le degré de conformité avec les présents Principes de bonnes pratiques de laboratoire doit être indiqué.
4. Les corrections et additions apportées à un rapport final doivent se présenter sous forme d'amendements. Ces amendements doivent préciser clairement la raison des corrections ou des additions et être signés et datés par le Directeur de l'étude.
5. La remise en forme du rapport final pour se conformer aux conditions de soumission imposées par une autorité nationale réglementaire ou chargée de l'homologation ne constitue pas une correction, une addition ou un amendement à ce rapport final.

Reading: OECD Consensus Document #4, Excerpt on Quality Assurance and GLP

Excerpt from: OECD. (2019). OECD Consensus Document No. 4: Quality Assurance and GLP. Page 7. Available at: http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm

The QA-management link

Management of a test facility has the ultimate responsibility for ensuring that the facility as a whole operates in compliance with GLP Principles. Management may delegate designated control activities through the line management organization, but always retains overall responsibility. An essential management responsibility is the appointment and effective organization of an adequate number of appropriately qualified and experienced staff throughout the facility, including those specifically required to perform QA functions.

The manager ultimately responsible for GLP should be clearly identified. This person's responsibilities include the appointment of appropriately qualified personnel for both the experimental program and for the conduct of an independent QA function. Delegation to QA of tasks which are attributed to management in the GLP Principles must not compromise the independence of the QA operation and must not entail any involvement of QA personnel in the conduct of the study other than in a monitoring role. The person appointed to be responsible for QA must have direct access to the different levels of management, particularly to top level management of the test facility.

Qualifications of QA personnel

QA personnel should have the training, expertise and experience necessary to fulfil their responsibilities. They must be familiar with the test procedures, standards and systems operated at or on behalf of the test facility.

Individuals appointed to QA functions should have the ability to understand the basic concepts underlying the activities being monitored. They should also have a thorough understanding of the Principles of GLP.

In case of lack of specialized knowledge, or the need for a second opinion, it is recommended that the QA operation ask for specialist support. Management should also ensure that there is a documented training program encompassing all aspects of QA work. The training program should, where possible, include on-the-job experience under the supervision of competent and trained staff. Attendance at in-house and external seminars and courses may also be relevant. For example, training in communication techniques and conflict handling is advisable. Training should be continuous and subject to periodic review.

The training of QA personnel must be documented and their competence evaluated. These records should be kept up-to-date and be retained.

Reading *(French Version)*: OECD Consensus Document #4, Excerpt on Quality Assurance and GLP

Relations entre l'assurance qualité et la direction

Il incombe en dernier ressort à la direction d'une installation d'essai de veiller à ce que le fonctionnement de l'ensemble de l'installation soit conforme aux Principes de BPL. La direction peut déléguer par la voie hiérarchique des activités de contrôle désignées, mais n'en garde pas moins en permanence la responsabilité globale. Il lui appartient notamment de nommer et d'organiser efficacement des effectifs suffisants possédant les qualifications et l'expérience requises dans toute l'installation, y compris le personnel spécifiquement attaché aux fonctions d'assurance qualité.

Le directeur responsable en dernier ressort des BPL doit être clairement identifié. Ses responsabilités comprennent la nomination du personnel présentant les qualifications adéquates tant pour le programme expérimental que pour l'exercice d'une fonction d'assurance qualité indépendante. La délégation au service d'AQ des tâches attribuées dans les Principes de BPL à la direction ne doit pas compromettre l'indépendance de cette fonction ni impliquer d'intervention dans la réalisation de l'étude autre qu'au titre de la vérification. La personne nommée responsable de l'AQ doit avoir un accès direct aux différents échelons de la direction, et notamment au niveau hiérarchique le plus élevé de l'installation
d'essai.

Qualifications du personnel d'assurance qualité

Le personnel d'assurance qualité doit avoir la formation, les compétences et l'expérience nécessaires pour assumer ses responsabilités. Il doit être familiarisé avec les procédures d'essai, les norms et les systèmes en usage dans l'installation d'essai ou mis en œuvre pour son compte.

Les personnes nommées aux fonctions d'AQ doivent être en mesure d'apprécier les principes de base qui sous-tendent les activités soumises à vérification. Elles doivent également comprendre les Principes de BPL sous tous leurs aspects.

Faute de connaissances spécialisées ou lorsqu'un second avis est nécessaire, il est recommandé au service d'assurance qualité de demander l'assistance d'un spécialiste. La direction doit veiller à l'existence d'un programme de formation documenté et englobant tous les aspects des tâches d'assurance qualité. Le programme de formation doit prévoir, chaque fois que c'est possible, une expérience acquise sur le terrain sous la surveillance d'un personnel compétent et formé. La participation à des séminaires et à des cours, en interne ou à l'extérieur, peut aussi présenter un intérêt. Par exemple, la formation aux techniques de communication et à la gestion des conflits est recommandée. La formation doit être continue et soumise périodiquement à examen.

Le personnel d'AQ doit recevoir une formation attestée par des documents et sa compétence doit être évaluée. Il convient d'assurer la mise à jour de la documentation correspondante et de la conserver.

Reading: OECD Good Lab Practices Regulations, Excerpt of Section 2

Excerpt from: OECD. (2019). OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring. Pages 20-21. Available at: http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm

2. Quality Assurance Program

2.1 General

1. The test facility should have a documented Quality Assurance Program to assure that studies performed are in compliance with these Principles of Good Laboratory Practice.
2. The Quality Assurance Program should be carried out by an individual or by individuals designated by and directly responsible to management and who are familiar with the test procedures.
3. This individual(s) should not be involved in the conduct of the study being assured.

2.2 Responsibilities of the Quality Assurance Personnel

1. The responsibilities of the Quality Assurance personnel include, but are not limited to, the following functions. They should:
    a. maintain copies of all approved study plans and Standard Operating Procedures in use in the test facility and have access to an up-to-date copy of the master schedule;
    b. verify that the study plan contains the information required for compliance with these Principles of Good Laboratory Practice. This verification should be documented;
    c. conduct inspections to determine if all studies are conducted in accordance with these Principles of Good Laboratory Practice. Inspections should also determine that study plans and Standard Operating Procedures have been made available to study personnel and are being followed.

        Inspections can be of three types as specified by Quality Assurance Program Standard Operating Procedures:

        - Study-based inspections,
        - Facility-based inspections,
        - Process-based inspections.

        Records of such inspections should be retained.

    d. inspect the final reports to confirm that the methods, procedures, and observations are accurately and completely described, and that the reported results accurately and completely reflect the raw data of the studies;
    e. promptly report any inspection results in writing to management and to the Study Director, and to the Principal Investigator(s) and the respective management, when applicable;
    f. prepare and sign a statement, to be included with the final report, which specifies types of inspections and their dates, including the phase(s) of the study inspected, and the dates inspection results were reported to management and the Study Director and Principal Investigator(s), if applicable. This statement would also serve to confirm that the final report reflects the raw data.

Reading *(French Version)*: OECD Good Lab Practices Regulations, Excerpt of Section 2

2. Terminologie

2.1 Bonnes pratiques de laboratoire

1. Les bonnes pratiques de laboratoire (BPL) forment un système de garantie de qualité portant sur le mode d'organisation des études de sécurité non cliniques ayant trait à la santé et à l'environnement et sur les conditions dans lesquelles ces études sont planifiées, réalisées, contrôlées, enregistrées, archivées et diffusées.

2.2 Termes relatifs à l'organisation d'une installation d'essai

1. L'installation d'essai comprend les personnes, les locaux et les équipements qui sont nécessaires à la réalisation de l'étude de sécurité non clinique ayant trait à la santé et à l'environnement. Pour les études multi-sites, réalisées sur plusieurs sites, l'installation d'essai comprend le site où se trouve le Directeur de l'étude et tous les autres sites d'essai, qui peuvent être considérés individuellement ou collectivement comme des installations d'essai.

2. Le site d'essai comprend le ou les emplacements sur lesquels une ou des phases d'une étude donnée sont réalisées.

3. La direction de l'installation d'essai comprend la ou les personnes investies de l'autorité et de la responsabilité officielle de l'organisation et du fonctionnement de l'installation d'essai, conformément aux présents Principes de bonnes pratiques de laboratoire.

4. La direction du site d'essai comprend la ou les personnes (si on en a désigné) chargées d'assurer que la ou les phases de l'étude, dont elles sont responsables, se déroulent conformément aux présents Principes de bonnes pratiques de laboratoire.

5. Le donneur d'ordre est la personne morale qui commande, parraine ou soumet une étude de sécurité non clinique ayant trait à la santé et à l'environnement.

6. Le Directeur de l'étude est la personne responsable de la conduite générale de l'étude de sécurité non clinique ayant trait à la santé et à l'environnement.

7. Le Responsable principal des essais est la personne qui, dans le cas d'une étude multi-sites, exerce, au nom du Directeur de l'étude, des responsabilités bien définies pour les phases de l'étude qui lui sont déléguées. Le Directeur de l'étude ne peut déléguer au ou aux Responsables principaux des essais sa responsabilité de la conduite générale de l'étude, s'agissant notamment d'approuver le plan de l'étude, avec ses amendements, et le rapport final, et de veiller au respect de tous les Principes pertinents de bonnes pratiques de laboratoire.

8. Le programme d'assurance qualité est un système précis, englobant le personnel correspondant, qui est indépendant de la conduite de l'étude et vise à donner à la direction de l'installation d'essai l'assurance que les présents Principes de bonnes pratiques de laboratoire sont bien respectés.

9. Les modes opératoires normalisés sont des modes opératoires étayés par des documents qui décrivent la façon de réaliser des essais ou travaux dont le détail ne figure pas normalement dans le plan de l'étude ou dans les lignes directrices pour les essais.

10. Le schéma directeur est une compilation des informations devant aider à l'évaluation de la charge de travail et au suivi des études réalisées dans une installation d'essai.

Reading: OECD Consensus Document #4, Excerpt on Quality Assurance Inspections

Excerpt from: OECD. (2019). OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring. Page 8. Available at: http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm

QA inspections

QA programs are frequently based upon the following types of inspections:

- Study-based inspections: These are scheduled according to the chronology of a given study, usually by first identifying the critical phases of the study.
- Facility-based inspections: These are not based upon specific studies but cover the general facilities and activities within a laboratory (installations, support services, computer system, training, environmental monitoring, maintenance, calibration, etc.).
- Process-based inspections: Again, these are performed independently of specific studies. They are conducted to monitor procedures or processes of a repetitive nature and are generally performed on a random basis. These inspections take place when a process is undertaken very frequently within a laboratory and it is therefore considered inefficient or impractical to undertake study-based inspections. It is recognized that performance of process-based inspections covering phases which occur with a very high frequency may result in some studies not being inspected on an individual basis during their experimental phases.

QA planning and justification of QA activities and methods

QA should plan its work properly and its planning procedures as well as the operation of QA personnel in performing, documenting and reporting inspections should be described in SOPs. A list of studies planned and in progress should be kept. QA should have access to an up-to-date copy of the master schedule. Such a list is necessary for planning QA activities and assessing the QA workload in the laboratory.

As is the case for any other operative procedures covered by the GLP Principles, the QA program of inspections and audits should be subject to management verification. Both the QA staff and management should be able to justify the methods chosen for the performance of their
tasks.

QA inspection reports

National GLP monitoring authorities may request information relating to the types of inspections and their dates, including the phase(s) of the study inspected. However, QA inspection reports should not normally be examined for their contents by national monitoring authorities as this may inhibit QA when preparing inspection reports. Nevertheless, national monitoring authorities may occasionally require access to the contents of inspection reports in order to verify the adequate functioning of QA. They should not inspect such reports merely as an easy way to identify inadequacies in the studies carried out.

Reading *(French Version)*: OECD Consensus Document #4, Excerpt on Quality Assurance Inspections

Inspections d'assurance qualité

Les programmes d'assurance qualité sont souvent fondés sur les types d'inspection suivants :

1. Inspections portant sur les études : elles sont programmées selon le calendrier adopté pour une étude donnée et commencent en général par l'identification des phases critiques de l'étude.

2. Inspections portant sur les installations : elles n'ont pas pour objet des études données, mais couvrent l'ensemble des installations et activités d'un laboratoire (équipements, services logistiques, système informatique, formation, surveillance de l'environnement, maintenance, étalonnage, etc.).

3. Inspections portant sur les procédés : ces inspections sont elles aussi effectuées indépendamment des études. Elles sont destinées à vérifier des procédures ou processus de nature répétitive et sont généralement effectuées de manière aléatoire. Elles ont lieu lorsqu'un procédé est très fréquemment mis en œuvre dans un laboratoire et qu'il n'apparaît ni efficace ni judicieux de procéder à des inspections portant sur les études. Il est entendu que si l'on réalise des inspections portant sur des procédés et couvrant des phases qui se présentent très fréquemment, il peut en résulter que certaines études ne fassent pas en soi l'objet d'une inspection au cours des phases d'expérimentation.

Planification de l'assurance qualité et justification des activités et méthodes mises en œuvre à ce titre

Le service d'AQ doit planifier correctement son travail, et ses procédures de planification ainsi que les activités effectuées par le personnel d'assurance qualité pour réaliser, documenter et rendre compte des inspections doivent être décrites dans des modes opératoires normalisés. Il convient d'établir une liste des études planifiées et en cours. Le service d'AQ doit avoir un exemplaire à jour du schéma directeur. Cette liste est nécessaire à la planification des activités du personnel d'assurance qualité et à l'évaluation de sa charge de travail dans le laboratoire.

De même que pour tout mode opératoire relevant des Principes de BPL, le programme des inspections et audits d'assurance qualité doit être soumis à la direction pour vérification. Le spécialiste de l'assurance qualité comme la direction doivent être en mesure de justifier les méthodes choisies pour effectuer leurs tâches respectives.

Rapports d'inspection d'assurance qualité

Les autorités nationales chargées de la vérification du respect des BPL peuvent demander des informations sur la nature et la date des inspections, y compris la ou les phase(s) de l'étude soumise(s) à inspection. Toutefois, ces autorités nationales n'ont pas normalement à examiner le contenu des rapports d'inspection d'AQ, dans la mesure où elles risqueraient ainsi d'inhiber le personnel d'AQ lors de l'élaboration de ses rapports d'inspection. Les autorités nationales peuvent néanmoins demander l'accès occasionnel au contenu des rapports d'inspection, afin de vérifier le bon fonctionnement de l'assurance qualité. Elles ne sauraient se servir de ces rapports comme d'un moyen leur permettant de repérer aisément les insuffisances des études réalisées.

Activity: Web Page Worksheet

Who is the audience for the Website? *Who do you anticipate will visit and use the Website?*	
What is the message that you want to deliver to the Website users?	
Why will the target audience use your Website?	
What information does the target audience need?	
What services do you offer? (e.g., what tests do you run, and a brief description of each)	
What downloadable files do the target audience need (e.g., forms, instructions, regulations)?	
What contact information do you need to provide?	
How should your Website be organized?	
What resources are available at your institution to help in developing the Website? (*Images, videos, departments that provide assistance, and other resources)*	

Activity: Form Worksheet

Who is the audience for the Form? *Who do you anticipate will request and use the form?*	
What is the message that you want to deliver to the Form users?	
Why will the target audience use your Form?	
What information does the target audience need?	
What services do you offer? (e.g., What tests do you run, and a brief description of each)	
What contact information do you need to provide?	
How should your Form be organized?	
What other Forms or resources do you need to reference in the Form?	

Activity: Lab Submission Form Worksheet

What information do you need about the researcher submitting the sample(s)?	
What instructions do you need to provide to the researcher in terms of how the sample(s) should be submitted? (e.g., Packaging, Labeling, Numbering)	
What requirements do you have for the disposition of the submitted samples? (e.g., Dryness)	
What tests and analyses can the researcher choose from?	
Is there a cost charged to the researcher for the tests? What are the fees? What forms of payment are accepted?	
What contact information do you need to provide to the researcher?	
What other information needs to be requested from or provided to the researcher to ensure transparency, traceability, and logging?	

Handout: Example Logbook

Keeping an accurate Logbook for any lab is paramount in keeping track of daily activities and where we are in processing samples. This Excel sheet is only of example of the type of information that a researcher must keep on samples submitted to the lab.

						Analyses Requested																
Year	FL #	# of Samples	Researcher	Date Received	Description of experiments	Nitrogen / CP			IVOMD			P			Neutral DF (NDF)			Acid DF (ADF)			PAID	DUE
						Start	Calc	Sent	Start	Calc	Sent	Start	Calc	Sent	Start	Calc	Sent	Start	Calc	Sent		

Year: Always log the year for long-term data archiving

FL #: Name of the set number. Each set must have its own number. In this case samples sent to the Forage Lab are called FL for Forage Lab followed by a sequential numeric part. That is the very beginning of identifying your samples.

# of Samples: Enter the number of samples submitted

Researcher: Enter the full name of the researcher who submitted the samples

Date Received: Enter the day and month that the samples were submitted

Description of Experiments: Note any relevant details about the experiment(s) such as: Type of tissue researcher wants analyzed: leaf, stem or roots (rhizomes); date of harvest; treatment (type of fertilizer, animal load, harvest frequency, irrigation, type of pesticide used…)

Nitrogen/CP: Indicates if the researcher wants Nitrogen and Crude protein determined on this set of samples

IVOMD: This indicates if the researcher wants In Vitro Organic Matter Digestibility performed on this set of samples

P: Indicates if researcher wants Phosphorus determined on this set of samples

Neutral DF (NDF): Indicates if researcher wants Neutral Detergent Fiber (NDF) performed on this set of samples

Acid DF (ADF): Indicates if researcher wants Acid Detergent Fiber (ADF) performed on this set of samples

Start: Date this procedure is started on this particular set of samples

Calc: Date procedure is completed, and results calculated for this set of samples

Sent: Date result report is actually sent back to the researcher

Paid: Enter the amount of any payments made

Due: Enter the amount still due

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Activity: Lab Practical

Instrument Evaluation & Repair Checklist (Checklist #1)
When an instrument is not working, check if:
☐ It is plugged in
☐ Electricity is running to the plug
☐ Fuses are working properly
☐ Filters are clean
☐ Doors properly shut and latch

Sample Intake Checklist (Checklist #2)
When samples are brought to the lab:
☐ Confirm that the samples are correctly labeled
☐ Ask the researcher to fill out Form X
☐ Laboratory technician to fill out Form X
☐ Store samples in the proper location
- XX samples are placed in the deep freezer
- XX samples are placed in the refrigerator
- XX samples are placed in X

Problem in the Lab Checklist (Checklist #3)
If you have an issue in the lab and are unsure what to do:
☐ Identify the problem

Is it the equipment?
☐ Check the manual
☐ No manual? Check the internet for a PDF copy of the laboratory manual
☐ Follow the checklist for "When an instrument is not working"
☐ Identify the vendor who supplied equipment and contact them for advice

Is something missing in the lab?
☐ Check with lab supervisor or technician
☐ Fill out Form X for reagents and submit to X

Unsure of what to do?
☐ Did you follow all of the above steps, first?
☐ Did you ask for help from a laboratory technician or lab supervisor?
☐ Contact the laboratory supervisor at phone: _____ email: _____

Reagent (Checklist #4)
Did you use or do you need a reagent?
☐ Are there sufficient reagents remaining (check the reagent inventory list X)?
☐ Are the remaining reagents good to use (check expiration date)?

Laboratory Practical Activity
Provide participants with:
☐ Instrument Evaluation & Repair Checklist
☐ Sample Intake Checklist
☐ Program in the Lab Checklist
☐ Reagent Checklist

Additional questions for the lab practical:

1. Are the instruments in working order?
2. Are the manuals in a location where they can be easily accessed? If not, how can the manuals be found?
3. Are the samples properly logged?
4. Are there sufficient reagents?
5. Are the reagents properly inventoried and stored?

Activity: SWOT Analysis

Use Strengths/Weaknesses/Opportunities/Threats-Challenges (SWOT) table to analyze the culture or the structure of the institution, in terms of the laboratory.

STRENGTH What does the lab do well? What unique resources can the lab draw on? What do others see as lab's strengths?	**WEAKNESS** What could you improve in the lab? Where does the lab have fewer resources than others? What are others likely to see as weaknesses?
OPPORTUNITIES What opportunities are open to the lab? What trends could the lab take advantage of? How can the lab turn its strength into opportunities?	**THREATS/CHALLENGES** What threats or challenges could harm the lab?

Feed the Future Innovation Lab for Livestock Systems

Good Laboratory Management Training Evaluation

LOCATION_____ | DATE_____

Thank you for participating in this evaluation for the Feed the Future Innovation Lab for Livestock Systems. The purpose of this survey is for the participants of the workshop on "Good Laboratory Management" to offer feedback for use in a continuous learning and development process. This survey should take approximately 5 minutes to complete and the answers you provide will remain confidential and anonymous. Thank you for your time!

1. Please describe your involvement in the Livestock Systems Innovation Lab.

☐ Subawardee ☐ Lab Management Entity ☐ Lab Trainee ☐ Other Lab Stakeholder

2. Which one of the following categories best describes your affiliation?

☐ Researcher ☐ Non-governmental Organization ☐ Other Public Sector

☐ Government ☐ Private Sector ☐ Other (describe) _____

3. Please use the scale provided below to indicate your level of agreement or disagreement with each of the following statements. If any statement is not applicable, please mark the box in the column "N/A".

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	N/A
A. Workshop Objectives						
i. The workshop purpose was clearly explained	☐	☐	☐	☐	☐	☐
ii. The specified workshop objectives were met	☐	☐	☐	☐	☐	☐
iii. My expectations of the workshop were met	☐	☐	☐	☐	☐	☐
iv. The main conclusions of this workshop are clear	☐	☐	☐	☐	☐	☐
v. The next steps of this workshop are clear	☐	☐	☐	☐	☐	☐
B. Workshop Design and Logistics						
i. The workshop was well organized	☐	☐	☐	☐	☐	☐
ii. Presentations were audible, clear & informative	☐	☐	☐	☐	☐	☐
iii. Any materials distributed were useful	☐	☐	☐	☐	☐	☐
iv. Participation & interaction were encouraged	☐	☐	☐	☐	☐	☐
v. Adequate time was provided for discussion & feedback	☐	☐	☐	☐	☐	☐
vi. My questions were satisfactorily answered	☐	☐	☐	☐	☐	☐
vii. Group work was well structured & useful	☐	☐	☐	☐	☐	☐
viii. The venue and facilities were appropriate	☐	☐	☐	☐	☐	☐
C. General Lab Communication						
i. I am satisfied with the Lab's website	☐	☐	☐	☐	☐	☐
ii. I am satisfied with the Lab's social media platforms	☐	☐	☐	☐	☐	☐

What was most useful about the workshop?

What was most enjoyable about the workshop?

What could have been done differently to improve the workshop?

Other comments about any aspects of the workshop:

Thank you very much for your feedback

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FEED THE FUTURE
The U.S. Government's Global Hunger & Food Security Initiative

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