“Strengthening capacity for safe biotechnology management in Sub-Saharan Africa (SABIMA)”

Stewardship Course – Module 3

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PERSEUS
Biosafety and Biotechnology Regulatory Services

SABIMA Project

Module 1

- Introduction
- Policy, processes & procedures
- Critical control points

Module 2

- Implementation review/ Policy
- Training/communication
- Incident response

Module 3

- Implementation review
- Verification/audits

Module 3

1. **Introduction**
2. **Success indicators and expected spin-off benefits of SABIMA Project**
3. **Implementation Review**
4. **Verification and audits**
5. **Summary of training: Stewardship Key Messages**
6. **Taking Stewardship Forward**

6 Verification & audits

Why are verifications important?

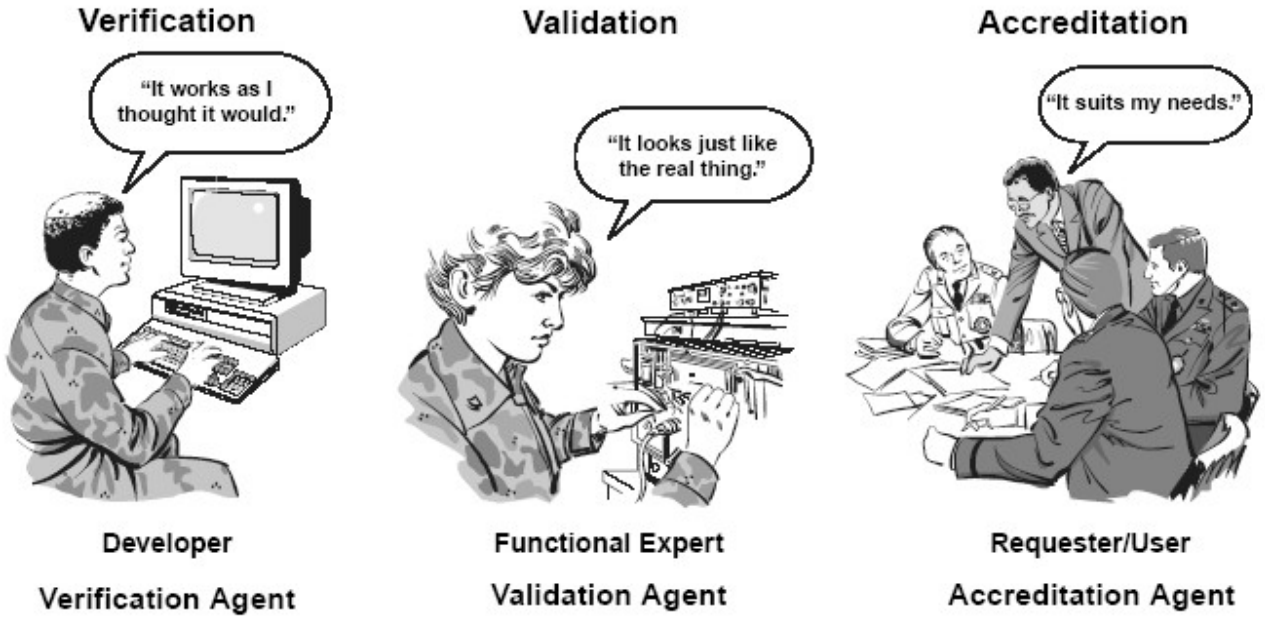
- To be sure that measures we intend to implement will contribute to achieving our objectives .
- To confirm that everything is going according to plan.
- To demonstrate that we achieve our objectives.
- To identify areas for further improvement.

Prerequisite: objectives need to be well defined

6.1 Types

Verification & audit types

- Validation, Monitoring control functions, Verification, Audit, Inspection



6.1 Types

Validation

Validation means the process of confirming that something (an application, an experiment, a piece of equipment, etc) consistently fulfils the requirements for a specific use.

- Mapping all the process steps
- Design steps so that the chance for an unwanted event will be limited.
- In order to guarantee that the methods contribute effectively to the intended goal, formal validation may be required.

6.1 Types

Validation

- Example:

  Use of an autoclave to destroy plant material produced in the lab that needs to be destroyed before disposal.

6.1 Types

Validation

- Typically validation is done only once and before the actual use. Validation should be repeated whenever a change in the process or equipment is envisaged (*e.g.* changing the pressure settings).

- Validation should be properly documented.

6.1 Types

Monitoring control functions

- Control functions should allow adjustments to be made before the situation becomes unacceptable.
- Some pieces of equipment allow permanent registration of control functions, whereas others may only indicate extreme values.
- They should reflect the critical limits determined in the CACCP analysis.

6.1 Types

Control functions

- Example:

  What is critical?
  Temperature? Pressure?
  Period?

6.1 Types

Monitoring control functions

- If the process didn't run as planned, then the possible impact as well as the cause for the deviation need to be evaluated.

- Full records must be kept of all monitoring data for management, audits, trend analysis and scrutiny by inspectors.

6.1 Types

Verification

Process to establish the correctness of a theory, fact, etc.

- The activity to establish that by implementing the actions required in the CACCP plan (*are we doing what we planned to do?*) the intended quality, purity, safety, containment and compliance are met (*did we meet our objectives? can things be improved?*).
- A very important element of CACCP and should always be included.
- It may help to identify areas for further improvement.

6.1 Types

Verification

- Example:

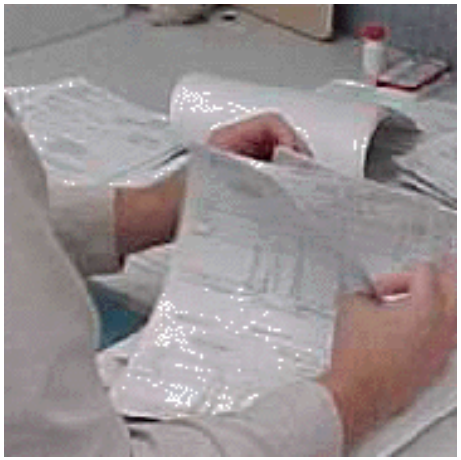
  Verify regularly that no viable material can be recovered.

6.1 Types

Audit

a methodical examination and review of a person, organization, system, process, enterprise, project or product.

a systematic effort to verify the implementation of a stewardship management system.



6.1 Types

Audit

- To verify the existence of objective evidence of processes
- To assess how successfully processes have been implemented
- To judge the effectiveness of achieving any defined target levels,
- To provide evidence concerning reduction and elimination of problem areas
- To provide a hands-on management tool for achieving continual improvement in an organization.

6.1 Types

Audit

- Self-audit
- Internal audit
- Third party audit

Auditors need to be trained and qualified

6.1 Types

Inspection

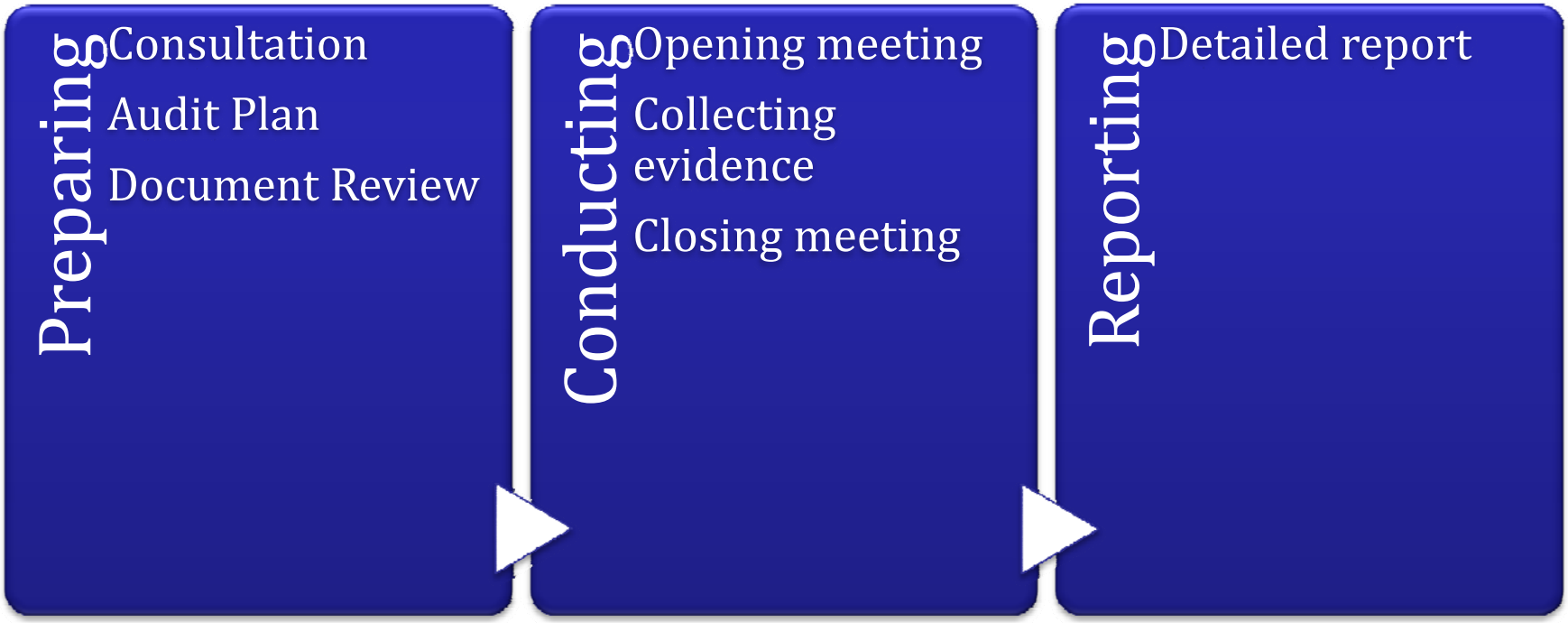
- Commonly used to refer to verifications made by officials.
- Main objective: to verify if the activities are performed in compliance with the legal conditions.
- Stewardship programmes include complete compliance with all legal requirements. An organization will:
  - cooperate with inspectors
  - make sure that any indication is properly documented and addressed.

6 Verification and audits

Types

- Validation
- Monitoring control functions
- Verification
- Audit
- Inspection

6.2 Audit Process



6.2 Audit Process: Preparing

- Pre-audit consultation between auditor and auditee

Purpose: to achieve a common understanding of the audit process and to jointly determine the specific scope and objectives of the audit.

6.2 Audit Process: Preparing

- **Pre-audit consultation**
  - Establish communication channels
  - Confirm the authority to conduct the audit
  - Provide information on the proposed timing and people
  - Request access to relevant documents, including records
  - Make arrangements for the audit
  - Agree on the attendance of observers and the need for guides for the auditor

6.2 Audit Process: Preparing

- Audit plan: The auditor should prepare an audit plan that provides the basis of the agreement between the auditor and the auditee.

6.2 Audit Process: Preparing

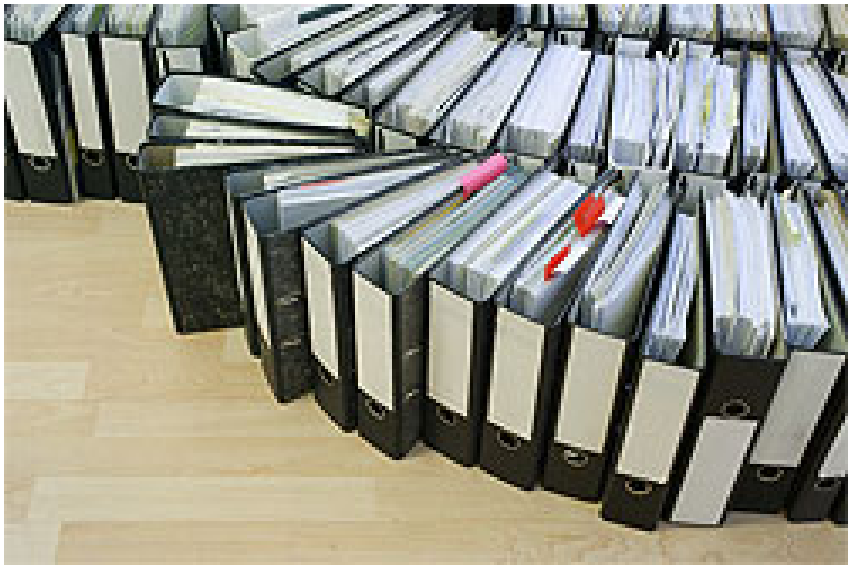
- **Document review**
  - Documentation identified during the initial meeting may be reviewed before on-site audit begins
  - Document review may also be completed on-site
  - Auditor reviews and manages auditee documents in accordance with agreements specifying document confidentiality, retention and destruction

6.2 Audit Process: Conducting

- **Opening meeting**
  - Confirm the audit plan, scope and timelines
  - Summarize how the audit activities will be undertaken
  - Provide an opportunity for auditee to provide relevant site and/or organizational overviews

6.2 Audit Process: Performing

- **Collecting information**
  - Information relevant to the audit objectives, scope and criteria should be collected by appropriate sampling
    - Verified
    - Recorded
  - Sources of information chosen may vary according to the complexity of the audit
  - Checklists



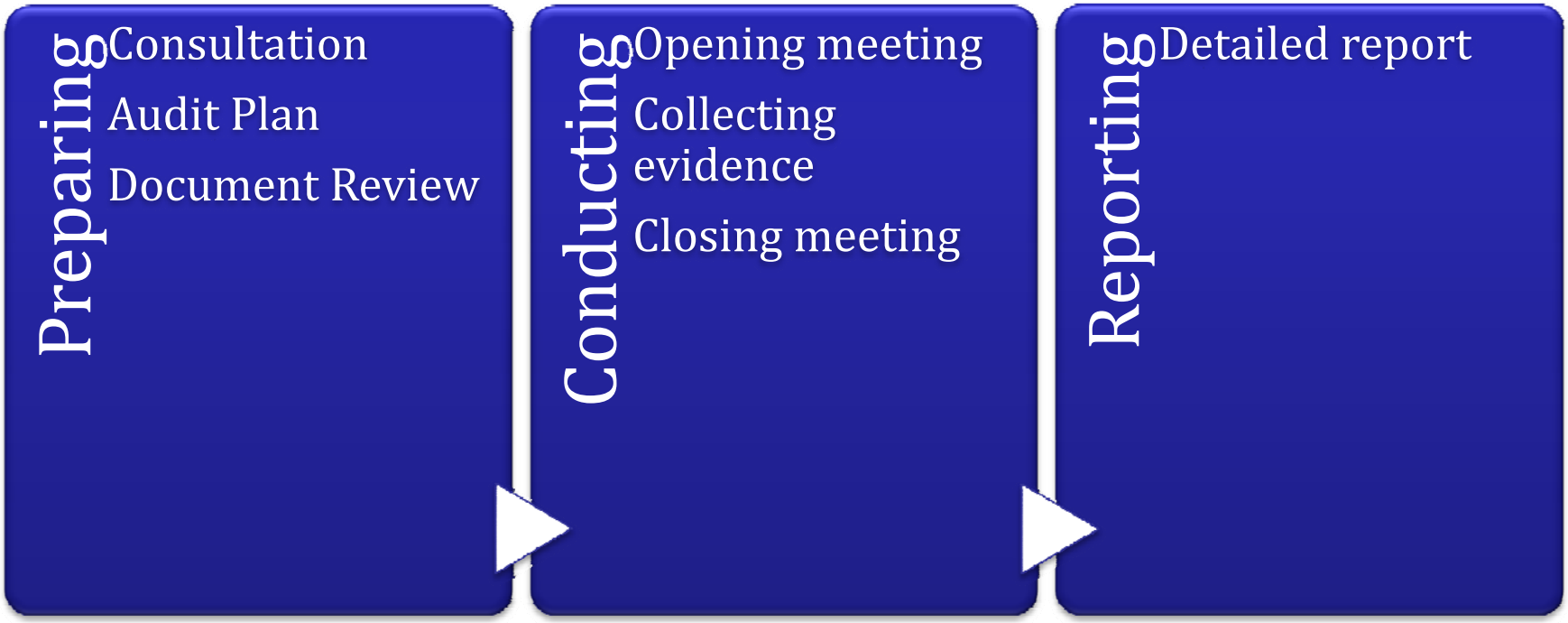
6.2 Audit Process: Conducting

- **Closing meeting**
  - Daily closing meeting (if applicable)
  - Present audit findings and conclusions
  - Keep minutes of the meeting, including records of attendance
  - Discuss -and if possible resolve- differences of opinion regarding the audit findings and/or conclusions
  - Opportunity for auditee to ask for clarification
  - Opportunity to provide additional objective evidence
  - Record any differences of opinion
  - Indicate when the detailed audit report will be prepared and sent to the auditee

6.2 Audit Process: Reporting

- Detailed audit report is a confidential matter between auditor and auditee
- Auditee needs to ensure (and document) appropriate follow-up!

6.2 Audit Process



6.3 Feedback

- Not a formal audit!
- Limited time and subjective evidence review!
- Consider feedback as first impression at the end of the training.

6.3 Feedback

- Nice facilities
- Well thought through procedures
- Motivated, trained & enthusiastic staff
- Compliance oriented
- Many of the elements are established
  - *E.g.* note taking, archiving, material accounting, labeling

6.3 Feedback

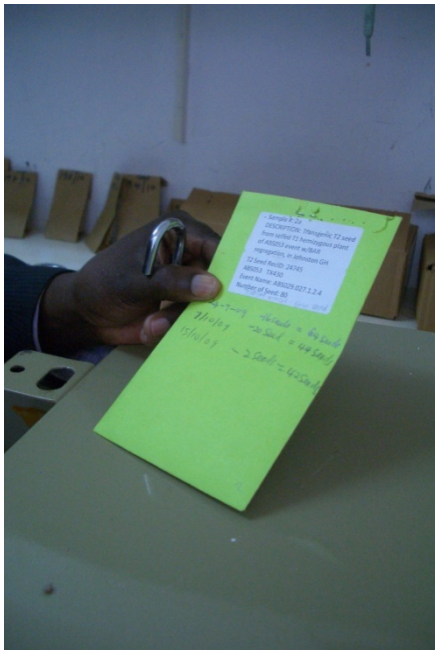
- Stewardship
  - Policy ?
  - Structure ?
  - Written procedures (except safety/compliance manual)?
  - Continuous improvement?

6.3 Feedback

- Beyond compliance
  - Why L2 greenhouse?
  - Why certain isolation distance?
  - Critical Control Points? Standard Operating Procedures?
  - Next regulatory steps? Product Launch? IRM?

6.3 Feedback

- Beyond the single event!
  - Seed storage (capacity)
  - Traceback?
  - Molecular controls?
  - Production of material



6.3 Feedback

- On the right track!
- No major deviations.
- Further integration of information.

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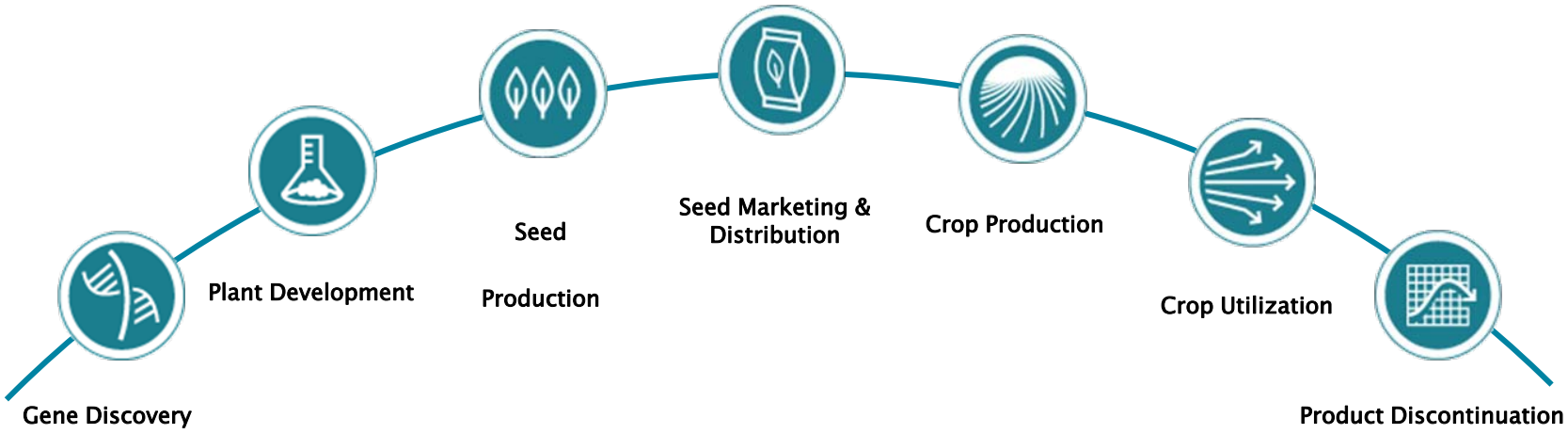
Key messages

Stewardship in plant biotechnology

- **is the responsible management of a product from its inception through to its use and discontinuation.**
- applies across the life cycle of a plant product and includes careful attention to the responsible introduction and use of products.
- Objectives of a Stewardship plan should include:
  - Fully comply with applicable regulatory requirements,
  - Seek to achieve and maintain plant product integrity, and
  - Work to prevent trade disruptions in order to facilitate the flow of goods in commerce

Key messages

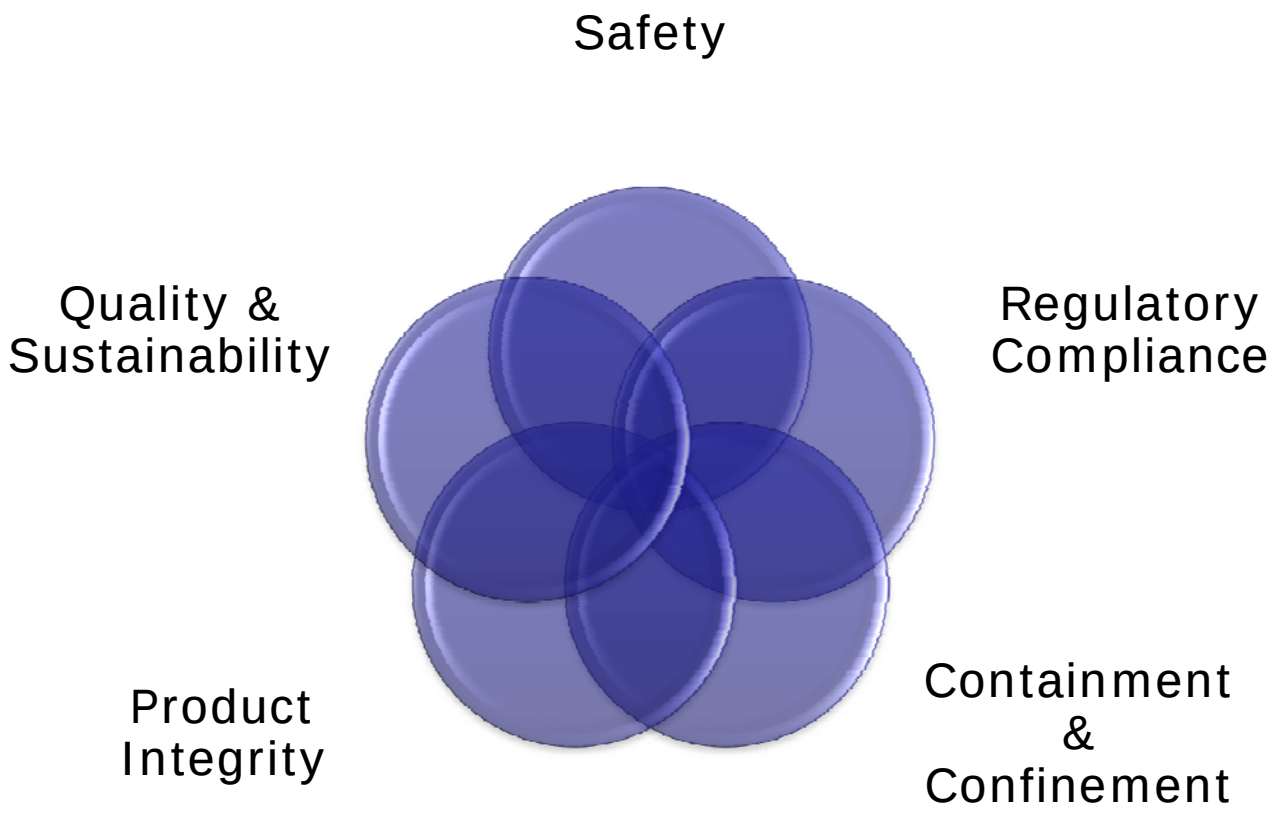


modelled after the

Guide for Stewardship of Biotechnology-Derived Plant Products

***(March* 2009 Excellence Through Stewardship)**

Key messages



Key messages

- **Policy**
  - a definite course or method of action selected from among alternatives and in light of given conditions to guide and determine present and future decisions.
- **Process**
  - a series of actions or operations that results in an end product
- **Procedure**
  - a particular way of accomplishing something or of acting.
  - **Standard Operating Procedures** (SOPs) are established or prescribed methods to be followed routinely for the performance of designated operations or in designated situations.

Key messages

- A Critical Control Point (CCP)
  - **a step at which control can be applied and is essential to prevent, eliminate, or reduce to an acceptable level an activity that may compromise one of the life cycle themes.**

(Note that the term control as used here means "to have/to bring under control," and should not be confused with testing, checking or verification).

Key messages

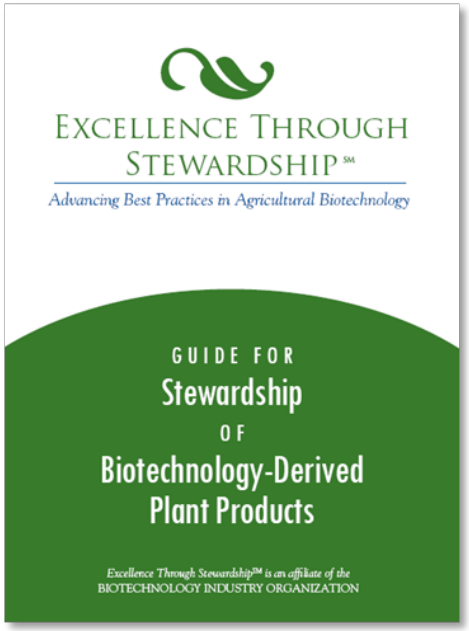
Internal organization

Top Management	Stewardship Leaders	Functional Responsible
• Endorse Product Stewardship • Set the objectives • Identify necessary resources • Take note of the regular reports • Communicate	• Trained and mandated by their management to steer the implementation of Product Stewardship in their organisation	• Involved in daily operations and are key in communication with the involved personnel and in the implementation of the proper practices

Key messages

Reference documents

- Excellence Through Stewardship[SM] Guides
  - Stewardship of Biotechnology Derived Plants
  - Maintaining Plant Product Integrity of Biotechnology Derived Plants
  - Product Launch of Biotechnology Derived Plants
  - Discontinuation of Biotechnology Derived Plant Products
  - Incident Response Management of Biotechnology Derived Plants



Key messages

Incident response

Be prepared !

- Roles and accountabilities
- Cascade of contacts
- Processes are in place
- Tools are available
- People are trained

Key messages

Incident Response Process

Key messages

Stewardship & communication

- Stewardship requires that training and communication occurs in an organised and planned way.
- There are no preset indications on transparency or obligations to share information beyond what would be required for achieving the stewardship objectives.
  - Product Launch Stewardship, regulatory requirements, ...
- Beyond these obligations, each organisation has the freedom to decide which information to share or to keep confidential.
- Stewardship only requires an organisation to consider how this information shall be handled ideally in advance of the request.

Key messages

Roles and accountabilities

- **Communication plan manager**
- **Communication content responsible(s)**
- **Communicator(s)**
  - the individual or group of people selected to convey the messages.
  - As a prerequisite the communicator should have received sufficient information and training to fulfil this task.
  - An organisation must establish a system to transfers inquiries, *e.g.* by third parties such as media, to the assigned spokesperson.

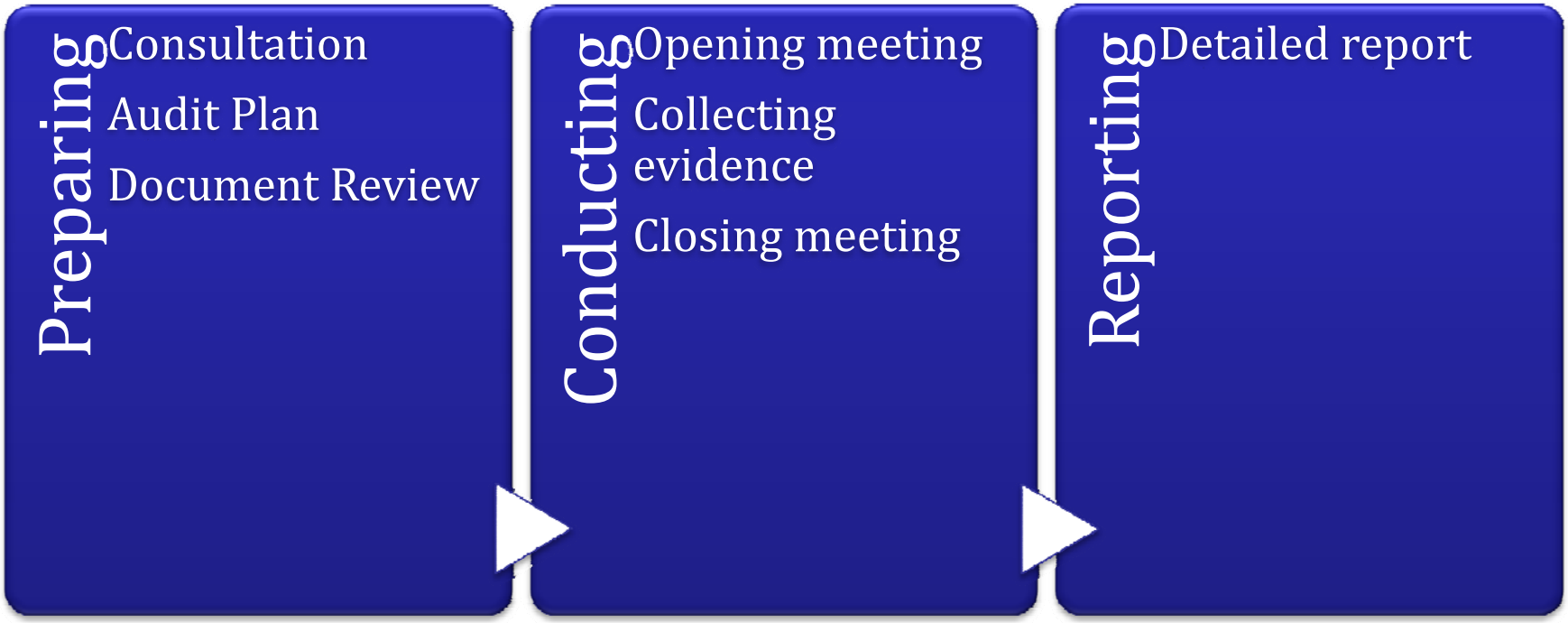
Key messages

Verification & audit types

- Validation
- Monitoring control functions
- Verification
- Audit
- Inspection

Key messages

Audit process



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Module 3

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- Verification/audits

Thank you for your attention!

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