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1. Evolving Trends In Seed Quality Management Systems
Evolving trends in seed quality management systems

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OBJECTIVES OF INTERNAL QUALITY CONTROL

– Confirmation we have alignment with business objectives and customer expectations
– Audit/Measurement/Validation

• Managing cost and productivity
• Identification of process improvement opportunities
• Reduction in employee stress
• Possible leveraging opportunities related to regulatory compliance.
What Is Process Management?

• Identification of critical business areas that must be defined, controlled and maintained.
• Critical business actions must be repeatable and measurable
• System design must allow for changing business needs
• Customer requirements must be identified and incorporated into the system.
Documentation in internal quality control

- Quality Manual (50 pages maximum)
- Administrative and Operational Procedures
- Work Instructions (task level detail)
- Records
Management System Structure - Documentation

Quality Manual - Overview of system. 50 pages of less

Operational and Administrative Procedures 4 -6 pages with flow chart includes “what” is to be accomplished

Work Instruction = one person one task includes “how” work is accomplished

Records
Business Process

Procedure/Activity

Inputs

Activity #1

Activity #2

Activity #3

Input Data/Document

Task

Task

Record

Output
Inputs

- Specifications
- Data and/or documents
- Manuals
- Regulations/laws
- Policies and guidelines
- Output from a companion process
Activity

• An action or activity or doing something
• A component of a larger process
• If activity is not initiated, the process will fail
• Typically, made up of several task involving several people
Work Instruction

- An action or activity
- Doing something
- A subcomponent of a procedure
- Typically, one task that involves one person
Work Instruction

• An action or activity
• Doing something
• A subcomponent of a procedure
• Typically, one task that involves one person
Outputs

• Confirmation that an activity has achieved a defined state of completeness

• Includes:
  – Records
  – Documents
  – Forms
  – Data
Key Points of Process Analysis

• Defined purpose and scope
• What is happening?
• Who is responsible for what?
• Who interfaces with whom?
• Timing and measurements
• Viewed from a customer and supplier relationship
Documentation Structure
System Documentation

- Quality Manual (50 pages maximum)
- Administrative and Operational Procedures
- Work Instructions (task level detail)
- Records
Overview of business operations including Quality Policy and reference to support documentation. Quality Manual views management system structure from an introductory point of view.
Procedures

Administrative Procedures
- Document management
- Internal audit
- Corrective action
- Other

Operational Procedures
- What
- When
- Where
- Who
Work Instruction

- Task level detail
- Viewed as one person one task
- Describes “how” work is accomplished
Records

- Provides objective evidence
- Demonstrates compliance
Development Quality Assurance System Documentation

- Obtain data on the actual state of the quality assurance system
- Plan the documentation system
- Collect and compile existing documentation and require additional documentation where necessary
- Review the documentation to ensure clarity, suitability and proper structure
- Develop a distribution policy
- Incorporate pertinent changes
- Communicating the company’s quality policy, procedures and requirements
- Describing the quality system
- Providing documented bases for auditing quality systems
- Providing continuity of the quality system and its requirements during changing circumstances
- Training personnel in the quality system requirements and methods of compliance
- Presenting the quality system for external purposes, such as demonstrating compliance with respective accreditation standards
WHAT TO INCLUDE IN A QUALITY MANUAL

- Scope and field of application
- Table of contents
- Definitions and explanation of abbreviations
- Policy and quality objectives
- Description of the quality system and document control procedures
- Organization and management structure
- Staff and training
- Company premises
- Equipment and calibration
- Process management (work flows)
- Recording and archiving
- Quality control procedures
STANDARD OPERATING PROCEDURES (SOPS) & WORK INSTRUCTIONS

- SOPs serve the staff members as a practical working aid for daily use.
- They should be compiled in such a way that they can be used like a “cooking recipe”.
- SOPs should be kept concise, exact, to the point and represent the reality by using simple wording.
- Where necessary, SOPs may be supplemented by work instructions, describing single aspects even more detailed or giving examples
Why SOPs instead of referring to general regulations/standards

- General regulations do not always describe the activities to be conducted sequentially.
- General regulations provide different options for a specific activity; in the SOP only the information relevant for the particular activity shall be available.
- A SOP shall clearly indicate which specific procedure/method is to be used.
Types of SOPs

- System SOPs
- Technical SOPs

NOTE:
General policy and procedures already described in the quality manual should not be mentioned again in the SOP to avoid redundancy and inconsistency.
System SOPs

- Document Control Procedure
- Training of new and experienced staff including recognition, training of new and experienced staff, procedure of warning, suspension etc
- Internal Audit Procedure
- Dealing with Customer Complaints
- Non conforming work and Corrective Action Procedure
- Preventive Action Procedure
- Purchasing of Services and Supplies
- Management Review Procedure
- Quality Control Procedure (Monitoring)
- Proficiency Testing Procedure
Technical SOPs

- Maintenance, repair, control or internal calibration for each item or group of equipment
- Storage and disposal of samples
- Control and disposal of chemicals
- Maintenance and description of seed collection(s) and how the verification of species is accomplished including a list of seeds
- Testing procedures (separate SOP for each type of test)
Other Quality Documents

- Include working instructions, forms & reports
- Working instructions give details on the standard procedure concerned.
- Working instructions or specimen forms may be directly attached to the respective SOP if applicable.
- Forms, checklists, reports related to a standard procedure should be provided where appropriate.
FLOW CHARTING

- Flow charts help to visualize a process and to represent the essential elements of a given procedure on a single page.
- A flow may be supplemented by explanatory notes or be itself the summary to a textual description.
- By general consensus a very limited number of symbols is used, which facilitates its generic application and makes it a tool that is easily understood.
• Visual representation of each step in the process
• Graphically displays functional activity and provides a visual understanding of interrelated occurrences
• Provides an understanding of the entire process
• Modifications and disconnects can be identified
• Displays a clear relationship between customer and supplier
Flowchart Symbols

- Begin/End/Linkage
- Activity/Process
- Major Review
- Decision
- Data and/or Document
Basic Flowcharting Guidelines

• Start at the top of the page and end at the bottom
• As a general rule do not exceed 20 symbols per page
• Describe activities with same level of process complexity
• Too much detail will defeat the purpose of a flowchart
• Do not develop flowcharts without input from everyone involved in the process
• Use active terms - verb/noun
  – Schedule meeting
  – Develop plan
  – Conduct audit