GMP COMPLIANCE OVERVIEW

Supply Division | Supply Chains for Children

RUTF PRE-TENDER INDUSTRY CONSULTATION MEETING
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MAJOR FOCUS AREA THIS YEAR…..

1. **Change Control (CC) Management**

2. **Evaluation of raw materials supplier**

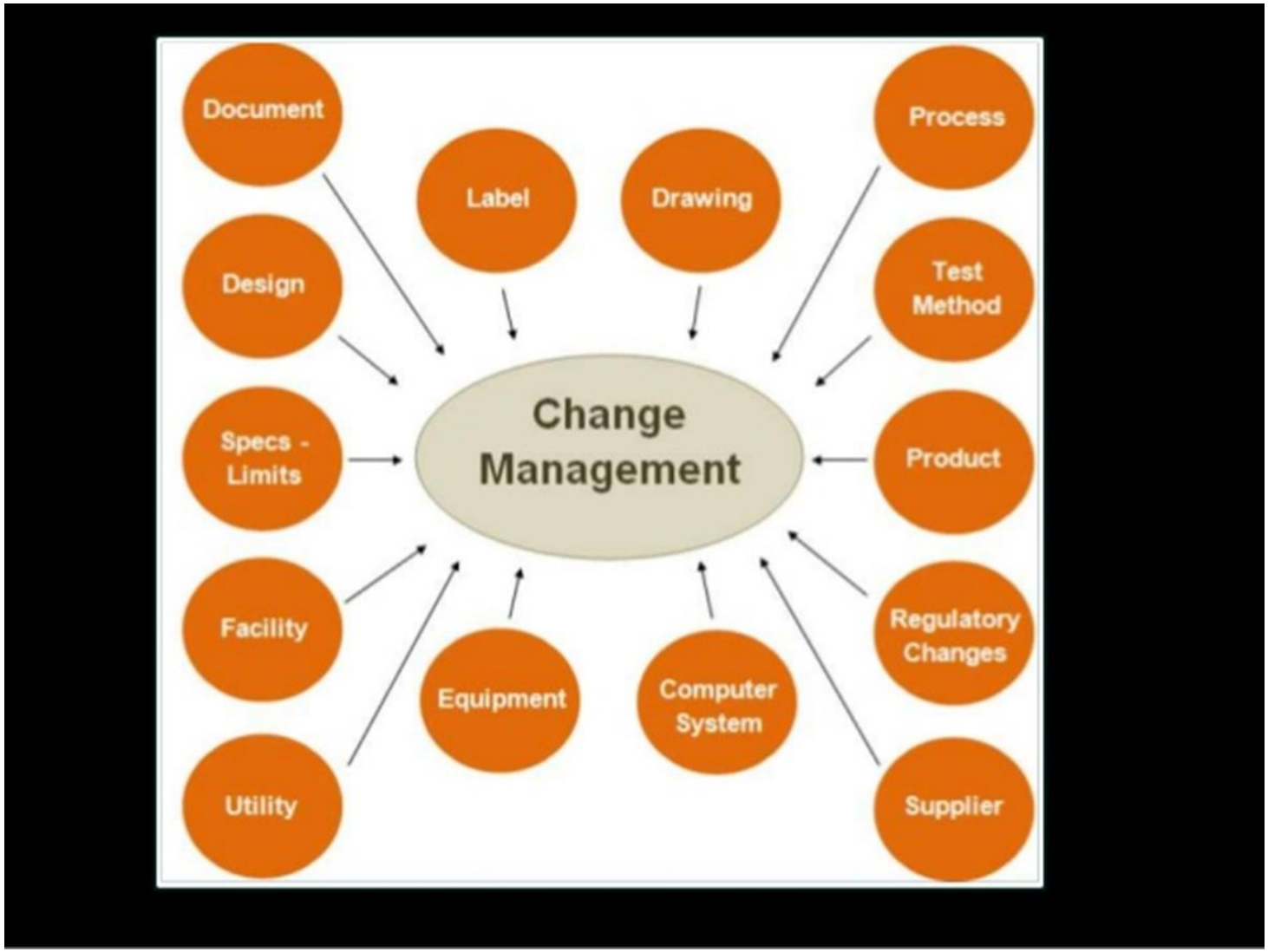
PART I

CHANGE AND CHANGE CONTROL

DEFINITIONS (CHANGE AND CHANGE CONTROL)

- Change refers to any modification in equipment, manufacturing materials, facilities, utilities, design, formulations, processes, packaging/labeling, computer systems and all associated documents (SOPs, quality manual etc.)

DEFINITIONS (CHANGE AND CHANGE CONTROL)



CHANGE CONTROL (within a Quality Management System – QMS)

- Change control within a QMS is a formal process to ensure that a change to a system is introduced in a controlled and coordinated manner

TASKS OF CHANGE CONTROL (CC)

- CC minimizes the risk that changes can have on the quality or process characteristics
- Review the changes to keep the system in its original state of “proven suitability”
- Formal CC guarantees that all changes are evaluated for their effect on product quality

PRINCIPLES OF CC

- It is logical the person responsible is from QA
- CC is not department-specific, rather the task of the whole company
- The CC monitors all types of changes which can influence the process or product quality

REQUIREMENTS

- Any changes in the production and processes must be controlled – meaning recorded, reviewed and approved by the QA.

- All changes should be made according to approved written company policies and SOP

- CC procedures have to be written as a way of standardizing instructions.

ELEMENTS OF CC

- INITIATOR

  Change is typically introduced by a initiator or originator.

- CC COMMITTEE

  May be a single entity for the whole company or may be one for the company's manufacturing site. Depending on the size of the company, may be advisable to create a CC committee.

- CHANGE ADMINISTRATOR

  A role usually assumed by QA.

STEP OF CHANGE CONTROL

- Record / classify: filling a change request form, record and categorize i.e. minor/major
- Assess: make a risk analysis by answering a set of questions concerning risk
- Plan: the planning team plans the change in detail
- Build / test: team then proposes solutions which will then be tested
- Implement: in this phase, finalized solutions or changes are implemented
- Evaluation: after change has been implemented, it should be evaluated, it should be monitored after implementation in order to allow the identification of unintended impacts
- Close: when change is implemented correctly then it will be closed

CLASSIFICATION OF CHANGES

- A classification procedure may help in determining the level of testing, validation and documentation needed
- Changes may be classified as Major or Minor, depending on the nature and extent of the changes
- They can also be categorized as specification changes, raw material changes, equipment changes etc.

EXAMPLES OF CHANGES

	Major change	Minor change	No requiring control
Significance change	Influences product quality or process reliability	Influencing a unit requiring control	No relevance to GMP or authorization
Examples	Changes of raw materials supplier Move of processes to other site Change in the product composition Change to the process parameters	Replacement of apparatus part of the same design Change of cleaning agent Change of laundry for work clothes	Change to working times Installation of AC in admin. area Change in non-GMP relevant procedure

EXAMPLES OF CHANGES

- Changes to the cleaning procedure (dry/wet cleaning)

  Use of a new cleaning agent, in concentration/volumes, cleaning process etc.

- Changes to the production equipment

  Replacement of equipment parts, process parameters, implementation of heat treatment

- Changes to the product

  Composition (re-formulation with different ingredients), manufacturing process

  There is a difference between changes in product development phases and changes in already established products

- Changes to the Utilities

  HVAC system, water units etc.

- Change in lay-out (design)

  Implementation of a pass-box etc.

PART II

EVALUATION OF RAW MATERIALS SUPPLIER

What does the Guidelines say?

Codex Alimentarius (CAC/RCP 75-2015)

- A supplier approval and verification program should be developed for sensitive ingredients
- The supplier's food safety program should be evaluated and audited with respect to the recommendations outlined in this document before approval.
- Periodic raw material and/or ingredient testing should be conducted upon receipt to verify supplier control.

Periodic means, every time if critical ingredients and less if supplier is audited. Risk approach identification can be used.

What does the Guidelines say?

ISO 22000:2005

(requirements for a food safety management system)

- … to effectively communicate food safety issues to their suppliers, costumers and relevant interested parties in the food chain.

REQUIREMENTS

- Changes in the raw materials supplier's production and processes must be controlled – meaning recorded, reviewed and approved by the QA.

- Approval of the supplier should be made according to approved written company policies and SOP

STEP OF THE SUPPLIER EVALUATION

- Use of the questionnaire to get basic information of the manufacturing risk

- Certificate of the manufacturing site

  i.e. ISO 22000 would be a logical requirement for most suppliers (roasted peanuts, milk powder, sugar, oil, and mineral premix)

- Manufacturing license from local authorities (if any)

- Evaluation of information

STEP OF THE SUPPLIER EVALUATION

- Need for on-site audit of the supplier. Recommended the company performs it but if not possible, 3rd party audit report available. The 3rd party audit report should be assessed.
- Trial order – which quality documents to be received
- Receipt of goods / testing of the samples to ensure compliance with the specification
- Raw material manufaturer should sign the raw material specifications
- Formal approval by QC/QA for supply.
- Regular re-evaluation.


Q&A


Thank
you !!!