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**

<table>
<thead>
<tr>
<th></th>
<th>Major change</th>
<th>Minor change</th>
<th>No requiring control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Significance change</strong></td>
<td>Influences product quality or process reliability</td>
<td>Influencing a unit requiring control</td>
<td>No relevance to GMP or authorization</td>
</tr>
<tr>
<td><strong>Examples</strong></td>
<td>Changes of raw materials supplier</td>
<td>Replacement of apparatus part of the same design</td>
<td>Change to working times</td>
</tr>
<tr>
<td></td>
<td>Move of processes to other site</td>
<td>Change of cleaning agent</td>
<td>Installation of AC in admin. area</td>
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<tr>
<td></td>
<td>Change in the product composition</td>
<td>Change of laundry for work clothes</td>
<td>Change in non-GMP relevant procedure</td>
</tr>
<tr>
<td></td>
<td>Change to the process parameters</td>
<td></td>
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</tr>
</tbody>
</table>
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, customers 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 manufacturer should sign the raw material specifications

• Formal approval by QC/QA for supply.

• Regular re-evaluation.
Thank you !!!