Validation Requirements for Nutrition Products

Supply Division

Supply Chains for Children

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Nutrition Supplier Meeting
14-16 June 2017, Copenhagen
Presentation Overview

• Quality Standards for Nutrition Products
• Validation in Pharma Industry
• Validation in Food Industry
• Validation – Monitoring -Verification
Nutrition Products and Quality Standards

Nutrition Products

Pharmaceutical Facilities
- WHO GMP for pharmaceutical products or equivalent

Nutritional Supplement Facilities
- National Standards
- Codex Alimentarius - HACCP
- ISO 22000: 2005 or equivalent

Food Processing Facilities
- Codex Alimentarius - HACCP
- ISO 22000: 2005 or equivalent
Validation

- **WHO GMP for pharmaceutical products** [TRS 986, Annex 2 - TRS 992, Annex 3]

**Validation**: action of proving, in accordance with the principles of GMP, that any procedure, process, equipment, material, activity or system actually leads to the expected results

**Process Validation**: the collection and evaluation of data, from the process design stage through to commercial production, which establishes scientific evidence that a process is capable of continuously delivering the finished product meeting its predetermined specifications and quality attributes

- **Codex Alimentarius** [CAC/RCP 1-1969 (Rev. 4 - 2003) & CAC/GL 69 – 2008]

**Validation**: Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome

- **ISO 22000: 2005**

**Validation**: obtaining evidence that the control measures managed by the HACCP plan and by the operational PRPs are capable of being effective
Process Validation in Pharma Industry

Objectives of Process Validation

• the process design is evaluated to show that the process is reproducible, reliable and robust;
• the commercial manufacturing process is defined, monitored and controlled;
• ensure on a continuous basis that the process remains in a state of control

Approaches to Process Validation

• Traditional Process Validation (Prospective and Concurrent)
• New Approach (Process design - Process qualification – Continued process verification)
• Combination of Traditional and New Approach
Traditional Approach to Process Validation

- Personnel, premises, utilities, support systems and equipment should be appropriately qualified before manufacturing processes are validated.
- Number of batches (min 3 batches) manufactured and number of samples taken should be based on quality risk management principles.
- A process validation protocol should include as a minimum a short description of the process, the functions and responsibilities, a summary of the Critical Quality Attributes to be investigated, a summary of Critical Process Parameters and their associated limits, a list of analytical methods and method validation, as well as the sampling plan and any additional testing to be carried out.
New Approach to Process Validation

**PROCESS VALIDATION**

- Pilot scale and scale up batches
- Risk assessment to identify critical quality attributes and process control parameters
- Protocols and reports
- Process validation

- Premises, Equipment, Utilities
- Commercial scale batches
- In-line/Online/At-line monitoring
- Defined number of batches

- Periodic Review of trends
- Sampling and Testing
- In-line/Online/At-line monitoring

**RISK MANAGEMENT**

- Process Design
- Process Qualification
- Continued Process Verification

**CHANGE CONTROL**

**PRODUCT LIFE-CYCLE**
Validation in Food Industry

- Validation focuses on the collection and evaluation of scientific, technical and observational information to determine whether control measures are capable of achieving their specified purpose in terms of hazard control.
- Validation involves measuring performance against a desired food safety outcome or target, in respect of a required level of hazard control.
- Validation is performed at the time a control measure or a food safety control system is designed, or when changes indicate the need for re-validation.
- Validation of control measures should normally be performed before their full implementation.
Tasks prior to Validation

- Identify the hazards that are intended to be controlled in the product and/or environment concerned, taking into account all relevant information, including information from a risk assessment.
- Identify the food safety outcome required.
- Identify the measures that are to be validated, taking into account:
  - The importance of the control measure in achieving control of the hazard
  - Prior validation knowledge
  - Priority of validation
  - Scientific and technical feasibility
  - Resources
Approaches for Validating Control Measures

- Reference to scientific or technical literature, previous validation studies or historical knowledge of the performance of the control measure
- Scientifically valid experimental data that demonstrate the adequacy of the control measure
- Collection of data during operating conditions in the whole food operation
- Mathematical modelling
- Surveys

Scale up
Validation Steps

• Decide on the approach or combination of approaches.
• Define the parameters, decision criteria and limits that will demonstrate that a control measure or combination of control measures, is capable of consistently controlling the hazard to the specified outcome.
• Assemble relevant validation information and conduct the studies
• Analyze the results and reach a conclusion
• Consider changes
• Document and review the validation
Validation – Monitoring - Verification

• Validation is performed at the time a control measure or a food safety control system is designed or changed and focuses on the collection and evaluation of information to determine whether control measures are effective.

• Monitoring of control measures is the on-going collection of information (real time) at the step the control measure is applied. The information establishes that the measure is functioning as intended.

• Verification occurs during or after operation of a control measure through a variety of activities, including observation of monitoring activities and review of records to confirm that implementation of control measures is according to design.
Thank you for your attention