UNICEF
Quality Assurance
in the procurement of Therapeutic Food and other nutrition products

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For every child
Health, Education, Equality, Protection
ADVANCE HUMANITY
Content of presentation

- Background
- UNICEF reference document of manufacturing standards for QA / QC of Therapeutic Food
- Inspection Aid Memoire
- Observations from GMP inspections of manufacturers of therapeutic food
- Complains received on products
Background

• UNICEF is a buyer of Therapeutic Food
• UNICEF is not a normative organisation and we do not want to be seen as one
• UNICEF will use the available international standards for production of therapeutic food
• UNICEF is one of the main buyers in the marked so it is important that manufacturers knows our expectations
Purpose is to provide a baseline for UNICEF inspections

Applicable to
- RUTF
- F-75
- F-100
- BP-100

Partially applicable to CSB+, BP5, HPB
Manufacturing standards

- Codex Alimentarius
- ISO 22000 (food safety management)
- ISO 9001:2000
- Any other applicable standard

Manufacturing License for food
Quality management system

• Quality manual
• Clear organisation chart
• Handling of complaints and recall
• Internal audit
• Handling of deviations/non-conforming materials
• Management reviews
Personnel

- Relevant education
- Training program in place
- Training files
- Job descriptions
- Regular health checks
- Suitable clothes in production
Premises

• Located, designed, constructed and maintained to suit the operations
• Minimize risk for error and mixup
• Permit effective cleaning
• Dedicated to food products
• Ventilation should be adequate
• Lightning
Equipment

• Suitable for intended use
• Product contact surfaces should not be reactive, additive or adsorptive
• Surfaces must be smooth and easy to clean
• Written maintenance program
• Calibration program
Documentation system must be in place

- Written procedures
- Raw material and packaging specification
- Finish product specification
- Batch record for production
Production

• Cleaning of premises and equipment must be documented
• Manufacturing process must be validated to ensure batch to batch consistency
• Full traceability
• Documented in-process control
• HACCP plan
Quality control

- Raw material testing
- Finished product testing – annex 1
- Batch definition
- “Release for sale”
- Justification for assigned shelf life – annex 2
- Reference samples
Inspection aide memoire

- Not a checklist
- Used to ensure that important points not are left out during an inspection
- Current aide memoire is based on Codex Alimentarius and ISO 22000
- Headings in reference document is used as aide memoire
Observations from GMP inspections
Organisation and Personnel

• Health check do not cover all staff
• Entry procedures to production is weak and not exposed at entry.
• Limited signs to ask staff to wash hands prior to entry into production areas.
• Production garments should only be used in production areas
Observations from GMP inspections
Quality Management

• Limited number of written procedures
• No quality manual
• Poor system for handling of corrective actions
Observations from GMP inspections

Premises

• Not designed and constructed to suit operations carried out, but better now!
• Surfaces not smooth and easy to clean
• Design do not facilitate cleaning
• Poor lightning
• Easy access for pests (birds, flies, ants, cockroaches)
• Limited control of temperature in warehouses
• Cleaning facility is in open air
Observations from GMP inspections

Equipment

• Some equipment only suitable for small scale production
• Risk for contamination as “a closed system” not is used
• No documentation for food grade greasing oil
• Limited cleaning of production equipment must be backed by worst case sampling!
Observations from GMP inspections

Production

- Transfer of starting materials in an uncontrolled environment
- Limited validation to provide documentation for a uniform batch
- Batch size is large – one week!
- Limited number of CCP (1 to 7)
- Poor documentation of in-process control (sealing, printing)
- Inadequate control of electronic data
- Insufficient pest control
Observations from GMP inspections
Quality control - 1

• Limited testing of raw materials

• No Certificate of Analysis obtained for raw materials

• Vitamins and minerals purchased from sources not well qualified

• Poor traceability
Observations from GMP inspections
Quality control - 2

- Limited written documentation of production – poor batch record – eg sequence of mixing not defined, lack of verification of weighing of raw materials

- No packaging documentation

- No/poor reconciliation of used materials

- Limited testing of finished product – whole specification not covered at regular intervals

- Out of specification results
Observations from GMP inspections
Quality control - 3

• No formal release

• Limited documentation to justify assigned shelf life / out of specification result

• Oil separation in peanut based products

• Different products supplied in identical packaging
Complaints and other concerns

- High level of aflatoxin contamination
- Leaking sachets / empty sachets
- Poor shipper carton quality
- Ballooning sachets
- Poor bags and sealing of SCB+
- Enterobacter Sakazaki
- Certificates of Analysis with OOS results