


# UNICEF

## Quality Assurance in the procurement of Therapeutic Food

Peter S. Jakobsen – September 2009  
Quality Assurance Centre  
SUPPLY DIVISION  
[pjakobsen@unicef.org](mailto:pjakobsen@unicef.org)

For every child  
Health, Education, Equality, Protection  
ADVANCE HUMANITY

unicef 



# RUTF – Ready to Use Therapeutic Food

---

- 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

# 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 market so it is important that manufacturers know our expectations

# UNICEF reference doc. for QA/QC - 1

---

- Purpose is to provide a baseline for UNICEF inspections
- Applicable to
  - RUTF
  - F-75
  - F-100
  - BP-100

# UNICEF reference doc. for QA/QC - 2

---

## Manufacturing standards

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

Manufacturing License for food

# UNICEF reference doc. for QA/QC - 3

---

## Quality management system

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

# UNICEF reference doc. for QA/QC – 4

---

## Personnel

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

# UNICEF reference doc. for QA/QC – 5

---

## 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

# UNICEF reference doc. for QA/QC – 6

---

## 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

# UNICEF reference doc. for QA/QC – 7

---

Documentation system must be in place

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

# UNICEF reference doc. for QA/QC – 8

---

## 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

# UNICEF reference doc. for QA/QC – 9

---

## 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

---

- Staff have little technical background to perform duties assigned to them
- Limited separation between production and quality control
- Training is poorly documented
- Health check do not cover all staff
- Entry procedures to production is too weak

# Observations from GMP inspections

## Quality Management

---

- No quality system implemented
- 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
- 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

# 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
- 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