GMP Inspections: new trends and major observations

General Principles of Food Hygiene CAC/RCP 1-1969, Rev. 4-2003
ISO 22000:2018 - Food safety management systems

• Dedicated facilities for low moisture foods
• HVAC system – positive pressure
• Clear zoning system
• Dry cleaning
• Environmental Monitoring Program
• Change Control system
• Handling of deviations / CAPA
Personnel

• Staff needs to know they enter core production area
• Hygiene rules adapted to local conditions and to zone sensitivity. E.g. shower before entry
• Foot wash – risk?
• Do not wear production uniform outside controlled area
• Contract staff clean core production area
• Effectiveness of Training assessed
Quality Management System

• 3rd party certification of quality system is expected in cases where regulatory oversight does not exist
• Handling of non-conforming materials needs improvement – potential impact on other batches
• Investigation reports have generally been good for companies where pathogens are identified. Identification of the root cause is still an issue
• Handling of corrective and preventive actions still needs improvement
• Complaint file do not always give a clear “audit trail”
• Internal audit performed by properly trained internal auditors
Facilities

- Dedicated areas are needed
  - F75 and F100 – infant formula standards
  - RUF – low moisture foods
- HVAC and a good zoning system needed
- Logical flow of materials and staff
- Surfaces smooth and easy to clean (with special focus on dry cleaning). Exclude water and drains from area
- Pipes and wires need to be covered to facilitate dry cleaning
- Sampling should not take place in the warehouse
- No hidden areas allowed. For transparency all areas needs to appear on drawings!
- For peanuts separate raw and roasted side
Equipment

• Sanitary design is important
• Heat treatment (fully or partial)
• Validation of equipment and process parameters
• Facilitate dry cleaning
• Protect against contamination (exposed foil)
• Foreign matter detection on final RUTF sachet (validation needed and production then needs to follow in accordance with the selected parameters)
• Change control
• Updated drawings of all utilities
Assess impact on product quality:

- Facility
- Equipment
- Formula changes / updates
- Changes from established processes

Procedure
Minor / Major Changes
Operation

• Dry cleaning is required
• Limited controlled wet cleaning (no production should take place when water is introduced)
• Environmental monitoring (EMP) is implemented by most companies
• Is it designed to detect contamination? Add random sampling
• Remember is for you – not the inspector/auditor
• Pest control: corrective action in case of higher activity
• Maintenance: clear procedure / formal assessment before restart of production
• Rework of filled sachets is not allowed.
Documentation

• Procedures need to be reviewed, updated and approved at regular intervals
• Control of changes in formulation and production processes. Remember to use approved procedure
• Various reports such as validation reports need to:
  – Have a conclusion based on obtained results
  – Be authorized
• Development versus product improvement should be clearly separated
• Raw material specifications should be signed by the manufacturer
Batch documentation

- Information should not be pre-filled by operators!
- Independent verification by another person needed for all weighing (when applicable) and dispensing
- The various operating parameters need to be documented
- CCP monitoring – e.g. print out, when a “kill step” is used
Quality Assurance

• Evaluation of suppliers (and distributors) needs to be improved. Complete information of the raw material manufacturer needs to be present
• Only approved suppliers should be used
• Audit of key suppliers are needed (e.g. peanuts or peanut paste, milk powders, vitamin and mineral premix, oil mixtures), but audit of all suppliers are highly recommended
Quality Control

- More analysis (number of nutrients and mixes) needed for RUTF and RUSF (companies can still improve their knowledge on compliance with the finished product specification). 1 tracer per shift / shift
- Trend analysis
- Internal specifications e.g. Vit. C
- Appropriate qualification of analytical equipment
- Documentation in microbiological laboratories needs improvement
- Laboratory testing for Salmonella in finished products needs to be done in accredited laboratories
- Proficiency testing needed
UNICEF QC testing / complaints in 2018 - 2019

- 3 cases of salmonella in 2018
- EB detected in high levels in 2019
- Leaking sachets
- Poor shipper cantons
- Cartons do not contain 150 sachets