Risk Analysis and Risk Mitigation Plan/
Product and Process Design

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For every child
Health, Education, Equality, Protection
ADVANCE HUMANITY
Strategy to mitigate risks related to supply of nutrition products

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- Strategy
- Risk Analysis
- Risk Mitigation Action Plan
Risk analysis

- Risks identified

A. Product Quality
- Sub-standard product delivery,
- Deterioration of product in supply chain,
- Failure in addressing incidents,

B. Supply
- Product supply shortages,
- Stock-outs,
- Lack of alternative products,
- Incident claims response.
Risk analysis resulted in

- **Risk mitigation plan:**

  1. Gap analysis (WHO QA Model for Procurement Agencies).

  2. Action plan to cover gaps and to address the risks identified.
Risk Mitigation Plan

1. Develop/ improve QMS related to nutrition products area…

…new procedures to address

- product and supplier prequalification,
- how to deal with quality incidents,
- supplier development process…
Risk Mitigation Plan…

2. Improve supplier performance

- Scorecards
- Benchmarking to show best (and worst) performance in the industry around UNICEF (for reference)
- Website to improve interactions/communication with the suppliers?
3. Influence suppliers development (and improve link to the suppliers – communication, responsiveness to complaints and quality incidents)

- influence product/ manufacturing process design and development processes owned by the suppliers.
Risk Mitigation Plan...

Why we want to influence product/ manufacturing process design and development processes owned by the suppliers?

because

During these processes/ stages the QUALITY is created!
UNICEF Specifications = Customer Requirements

- UNICEF provides product specifications which need to be considered as customer requirements for product...

- Suppliers are required to critically assess the specifications provided by UNICEF

- Suppliers are expected to use their expertise to translate the specifications provided by UNICEF into specifications addressing different aspects of quality and safety (quality and safety to be built in to the product):
  
  QUALITY PRODUCT

- Suppliers are expected to design/develop such manufacturing processes which can generate consistent quality of the product required by UNICEF:
  
  QUALITY MANUFACTURING PROCESS
What the industry have in place?

**Recommended processes/ elements to be implemented…**

- **Product Design Process,**
- **Manufacturing Process Design Process,**
- **Risk analysis at early stages of product and process design,**
- **Build quality into product and process in the early stages of products and process design,**
- **If there is something wrong with a product, then to look for improvement via:**
  * revisit product and manufacturing process design records;
  * go to the risk analysis, product specifications and
  * stop to consider extended testing of the product as **the only way** to solve problems! (trial and error method),
- **Product Change Control Process,**
- **Manufacturing Process Change Control Process.**
Product Design/ Manufacturing Process Design processes

Questions:
- Who is the owner of the product we produce?
- Do we have in place product design and development process?
- How we influence product quality in the early stages of product design?
  a) Are all necessary risk assessments done to identify risks and are all necessary actions taken to mitigate the risks?
  b) Specifications – how they are compiled? Are the risks identified adequately addressed? (e.g. via adequate tolerances of the specifications/ parameters)
  c) What are the implications for consumers if particular product is out of specs (e.g. high level of active ingredients/ contaminants )?
  d) Who is the industry expert/ reference person per product?
- Do we have in place manufacturing process design and development process?
- What is the impact of well/ not so well established manufacturing process on the quality of product?
Questions, cont.:

Have we done risk analysis for manufacturing process design?
- Are the risks identified properly addressed via manufacturing process controls (e.g. procedures and work instructions on the shop floor)?

....

etc...
Questions:

- How we deal with product changes? (e.g. required because of unavailability of some ingredients, or determined by unpredictable changes in our manufacturing process)
- How we deal with manufacturing process changes determined by required product changes?
- Do we have the processes of changes adequately documented? Do we collect relevant records when changes take place?
- How we communicate product and process changes to UNICEF?
- …etc.

Important Aspects
- Traceability
- Specifications’ waivers
- Raw materials’ waivers
- Timelines for waivers
- Communication interface with UNICEF on changes…
Final Request/ Reflections:

Please review our questions

Please let us know the status of implementation of the design and change control processes (How they are documented? What records you can present as proof of the implementation?)

Please assess what is realistic and can be implemented

Please assess critically what is applicable to be implemented in the short and long term perspective

Please let us know your feedback next time!

Thank You!