Sample Evaluations and Inspections of Non Pharma Items

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Quality Inspection Unit
Discussion Today...

• Quality Assurance
  – What we expect from Suppliers
  – What Suppliers can expect from UNICEF, QA

• QA Inspections
  – When to Expect Inspections
  – Type
Quality Assurance

• Bid Evaluation includes QA evaluation of submitted QA documentation, product samples, etc.

• We Expect Suppliers to be responsible for proving, by submitted bid documentation, that the products offered meet the specifications.
Quality Assurance

• This documentation should clearly demonstrate assurance that the product meets the specs...
  – ISO Certificates relevant to the bid
  – CE Certificates relevant to the product
  – WHO Pre Qualification Documentation
  – Internal (or External) Product testing results
Quality Assurance

• Suppliers will receive feedback from QA inspections and evaluations – if requested.
  – Feedback from...
    • Any Sample Evaluations...
    • Any Inspection of goods...
    • Any inspection of Factory Premises.
  – Feedback will be constructive
    • Feedback is given to drive improvements in products offered or specifications (ISO 9001 concepts of continual improvement)
Quality Inspection Unit

• Inspections Conducted by QIU

  – Sample Evaluation
  – Factory\Supplier Visits
  – Pre Delivery Inspection (PDI)
  – Goods Receipt Inspection

  – Container Stuffing, Post delivery Inspections
The Supply Chain and where QA Inspections Fit In
Quality Assurance

• Assurance of Product
  – Sample Evaluation conducted in house
    • Physical Check that product is to specification
    • Quality and workmanship
    • Durability and functionality
    • Compatibility of products
    • Results of evaluation are available to suppliers.
      – Rejected items will be notified so improvements in product or specs can be discussed
Inspections

• **Factory\Supplier Inspection**
  – Used to determine several criteria
  – Option to use Questionnaire before visit
  – Assurance that QMS system is in place
  – Assurance QMS is Working
  – Provide Advice and Guidance on Quality Assurance
  – Reduces Risk to SD Business Units

• **Goods Receipt**
  – conducted at receiving warehouse or destination
Inspections

• Pre Delivery Inspection (PDI)
  • Managed by the QIU
  • Normally Conducted by Third Party Agents
  • More efficient to remedy any identified problems at this time
  • Conducted using ISO 2859-1, Sampling procedures for inspection by attributes, (Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection is used as a criterion for inspection.)
  • May include in-process sample
  • Value Added Activity

• Levels of Inspection
  • Determination of Sample Size
    • Statistical Method - ISO
    • Experience Method – Past Performance

• Change of Inspection Levels
  • Based on past performance of supplier
  • Tightened or loosened
Inspections

- Currently SD has 4 LTA’s with Inspection Agencies for worldwide PDI requests – these can be used by country offices if suitable
  - Baltic Control
  - Crown Agents
  - Intertek
  - SGS

- It is important to understand that passing a PDI does not absolve suppliers from their liability if product quality is not acceptable under designed use
Inspections

• **Outsourced Testing**
  – Mechanical
  – Chemical

• **In House Laboratory Testing**

• **Supervision of loading**
  – Can be done together with PDI

• **Post Delivery Inspection (Goods Receipt)**
  – Sample Check
  – Can Result in 100% Rejection of Consignment
Thank You