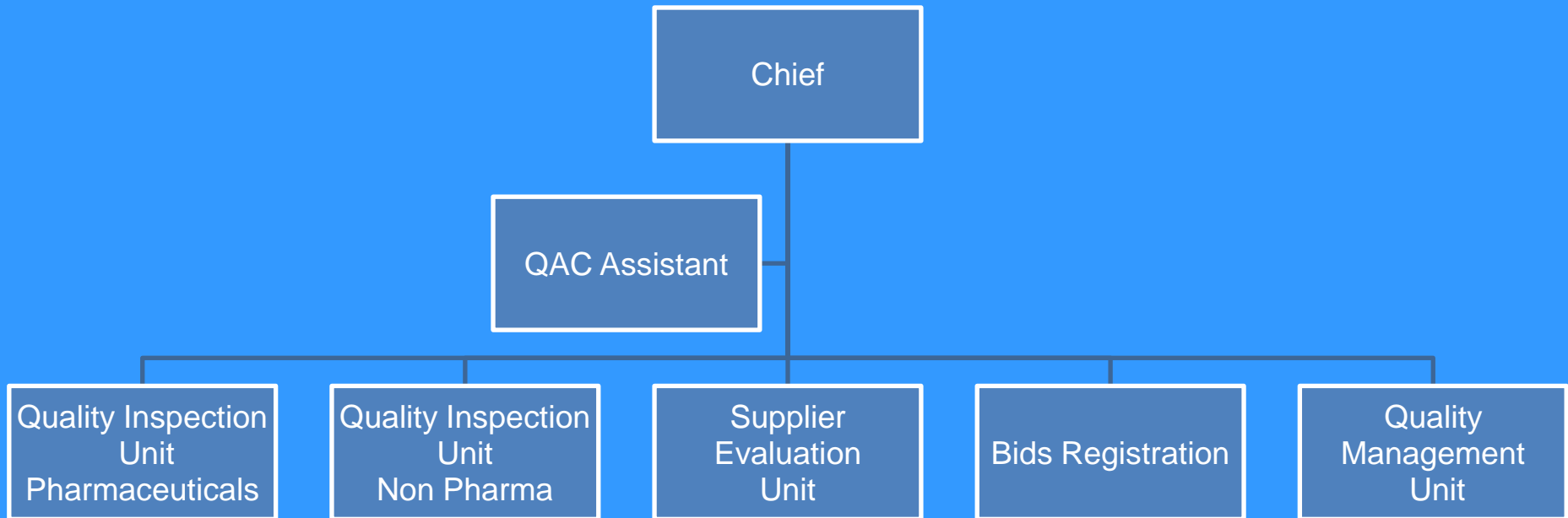


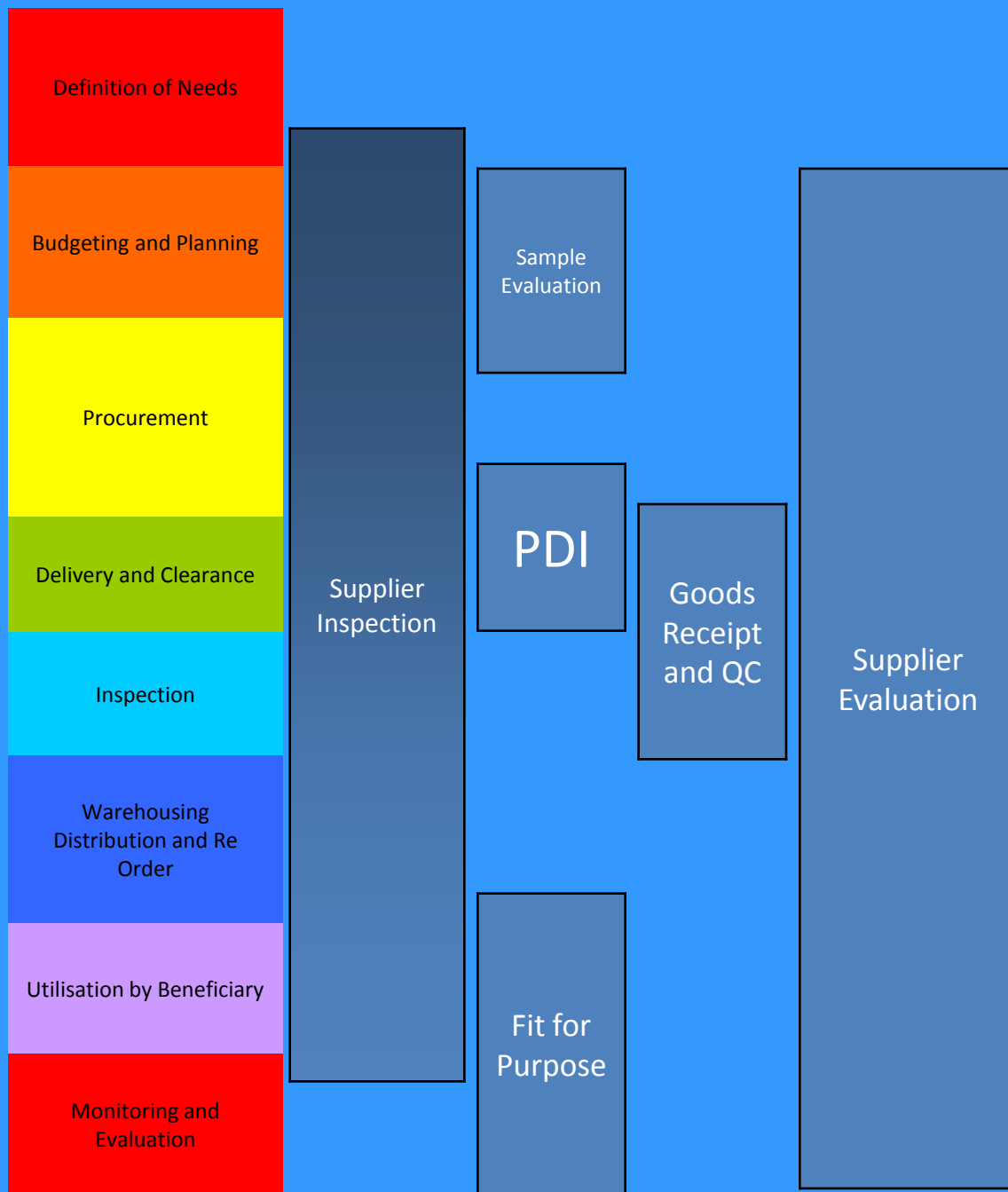
UNICEF Supply Division Copenhagen

Quality Assurance

Quality Assurance Centre



The Supply Chain Where QA fits In



Quality Inspection Unit – Non Pharma

Testing

- Mechanical
- Chemical
- **Inspections**
 - Bid Sample Evaluation
 - Pre Delivery Inspection (PDI)
 - Goods Receipt (Post-Delivery Inspection)
 - Factory and Laboratory Inspection
 - Suppliers and Manufacturers of Bed Nets
 - Master Batch/Raw Materials
- **In House Laboratory**

Testing

- Mechanical
 - Fabrication - ISO 8388:1998
 - Number of filaments in yarn - physical counting
 - Determination of linear density of components in warp knitted fabrics - BS 5441:1998, Clause 15
 - Mesh size - ISO 7211/2:1984
 - Dimensional stability to domestic washing, 1 wash cycle, wash procedure according to PO specification, flat dry - BS EN ISO 6330:2001/ ISO 3759:1994/ ISO 5077:1984
 - Bursting strength of net and seam using pneumatic method - ISO 13938-2:1999
 - Flammability test, before and after dry cleaning - 16 CFR 1610-CS191-53

Testing

- Chemical
 - Fibre analysis - ISO 1833:1977, FTIR
 - Polythene or Polyester
 - Total Insecticide Content before washing (5 samples) WHO/SIT/24.R2-1999 as reference
- Use Selected Laboratories who are ISO 17025:2005 Certified (General requirements for the competence of testing and calibration laboratories)

Inspections

- Bid Sample Evaluation – Conducted in house to ensure that technically compliant bids meet all the detailed specifications
- Goods Receipt – conducted at receiving warehouse or destination

Inspections

- Pre Delivery Inspection (PDI)
 - Managed by QIU-NP
 - Normally Conducted by Third Party Agents
 - We specify what has to be inspected and to what level
 - Can be as basic as a physical count or a 100% check against the PO specifications
 - Use of Sampling Plans
 - Mechanical Testing – Burst Strength, Dimensional Stability, Fireproofing
 - More efficient to remedy any identified problems at this time
- Post Delivery Inspection (Goods Receipt)
 - Sample Check
 - Can Result in 100% Rejection of Consignment
- 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

PDI Requests Completed on Bed Nets

- 2007 – 54 conducted at 3 Suppliers
- 2008 – 92 conducted at 7 Suppliers
- 2009 – 53 conducted to date at 7 Suppliers

- 2007 – 5 Rejected Lots at 2 Suppliers
- 2008 – 6 Rejected Lots at 4 Suppliers
- 2009 – 7 Rejected Lots to date at 4 Suppliers

Main Issues Resulting from Rejected Lots

- Holes
- Stains\Contamination
- Dimensional Stability
- Split Seams
- Extra Panels\Lge Patch
- Hanging Loops
- Labelling
- Trimmings\Threads
- Dirty
- Colour

Major defects – AQL 1% applies

Minor defects – AQL 2.5% applies

Inspections

- Factory Inspection
 - Used to determine several criteria
 - Detailed Questionnaire completed 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
- Very useful information gathering exercise for SD. A major positive...
 - Discovered some suppliers are setting up ISO 17025 Certified labs for internal and external testing of bed nets and Master Batch.

Inspection Visits

- 2005/6
 - 7 Manufacturing Site Visits
- 2008
 - 4 Manufacturing Site Visits
- 2009
 - 9 Manufacturing Sites visited
 - 2 Master Batch Manufacturers Visited
 - Visit Reports are made available to Suppliers
- 2010
 - Resources now in place to complete outstanding visits to suppliers and Master Batch Producers

Concerns from factory inspections

1. Lack of in-house QA/QC programmes including having suitable equipment, testing procedures etc.
2. Maintain manufacturing records and product specifications in English (or any other UN Language)
3. Use labels which contain accurate information.
4. Develop a formal QMS in compliance with the current revision of QMS requirements in ISO 9001: 2008 and seek certification

Concerns from factory inspections

Insufficient tests in house and maintenance of records. e.g.

- Test results by a third party
- Specific quality plan for each manufacturing site
- Adequate info on the quality of the raw materials
- Criteria for selection of outside labs for required tests
- Calibration of test and inspection equipment
- Analysis of the causes of problems, leading to CAPA
- Handling of complaints, their analysis with CAPA taken
- Training plans
- Analysis of the records maintained
- Clear responsibilities (Who does what)

Way Ahead

- Guidelines agreed with all Suppliers detailing clear Acceptance (and Rejection) Criteria
- Regular meetings at Supply Division with suppliers
- Structured Common approach to Factory Visits
 - Questionnaire
 - Risk Based Criteria
 - Standardised Internal Reporting
 - Supplier Rating System

Way Ahead

- SMART Future Engagement with Inspection and Testing Agencies.
 - More effective LTA's with testing agencies reducing our costs.
 - Improvements in Reporting from Inspection Agencies.
- Seek ISO 9001:2008 Certification of all Suppliers
 - Most issues raised at factory visits could be resolved by proper application of a QMS
 - Reduce our costs by reduction of 100% Lot inspection at present if evidence suggests QMS is effective.
- Formulate UNICEF Quality Assurance Centre Relationships with Suppliers not engaged in direct manufacture of bed nets

Summary

- WHOPES Phase II Recommendation Required
- Inspection and Test are Critical Activities in the Procurement Process.
- UNICEF Desire for all Suppliers to have as a minimum ISO 9000:2008 Certification.
- We will continue to engage Suppliers to ensure Continual Improvement of Product

Thank You