Joint UNICEF-UNFPA-WHO Meeting with Manufacturers and Suppliers

unicef
for every child

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BECOMING A SUPPLIER TO UNICEF: TECHNICAL REQUIREMENTS FOR PHARMACEUTICAL PRODUCTS

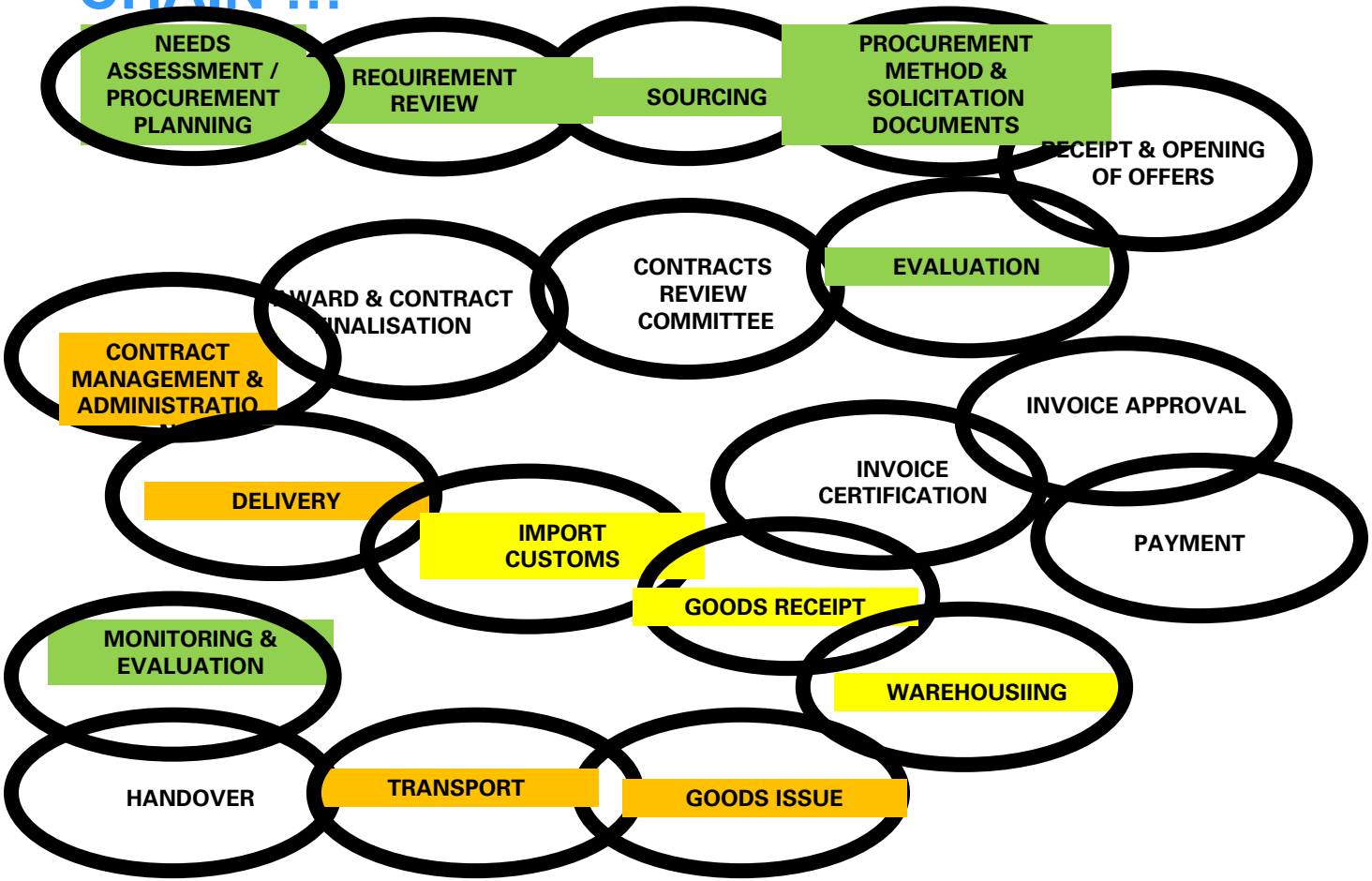



Guiding principles

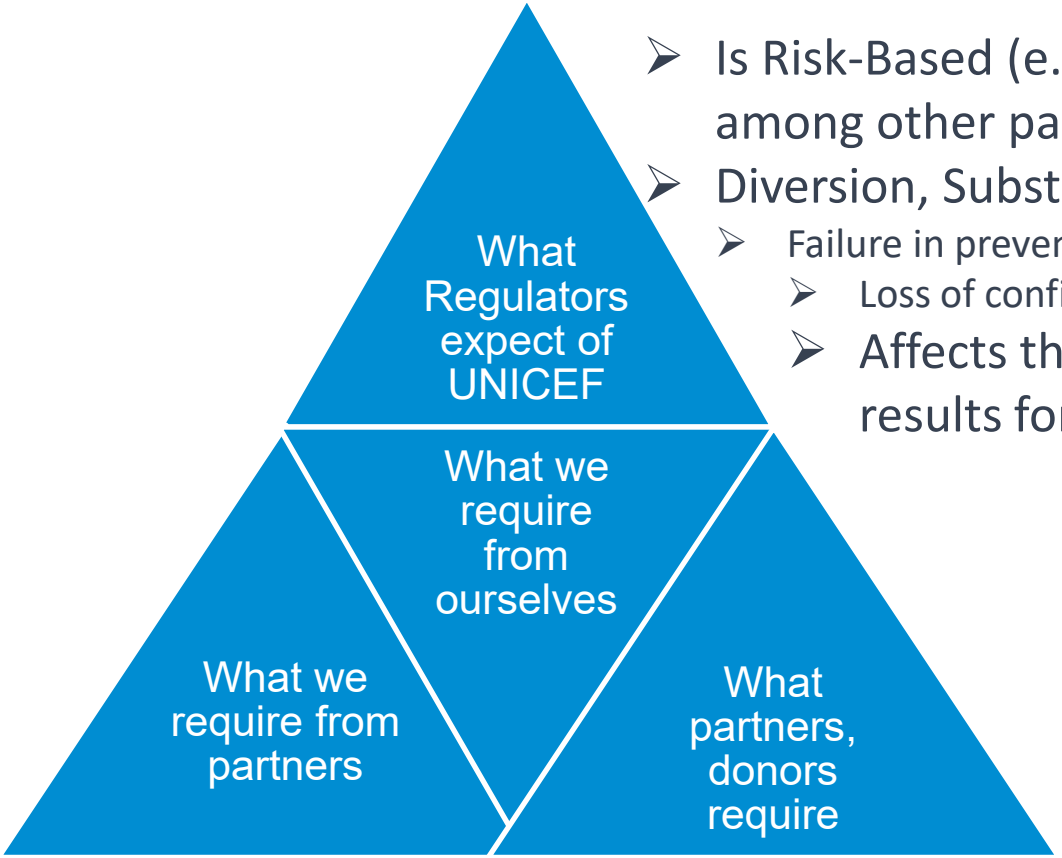
Quality Risk Management




Technical &Quality roles in the SUPPLY CHAIN …



Guiding principles
UNICEF Quality assurance in (Pharmaceutical) Supply Chains….



- Is Risk-Based (e.g. Reliance vis a vis full assessment among other parameters)
- Diversion, Substandard, Falsified products cause harm
  - Failure in preventing/managing the diseases
    - Loss of confidence in medicines, vital health systems..
  - Affects the way we work together to obtain results for children

Processes influencing
RELIANCE

Who can we rely on ?
Whose data can be used ?
Risk based approach per Product…
Risk based approach per Supplier…

Technical Requirements for Pharmaceutical Products

Link to the 6th edition (July 2024):
https://www.unicef.org/supply/documents/technical-requirements-pharmaceutical-and-nutrition-products

This document contains detailed requirements for pharmaceutical and nutrition products procured by UNICEF in relation to, but not limited to:

- marketing Authorization in the country of origin
- WHO-certificate “Certificate of Pharmaceutical Product”
- product specification reference to international recognized Pharmacopoeias
- labels and packaging inserts
- stability
- shelf life and storage
- pharmaceutical equivalence
- active pharmaceutical ingredients and excipients.

Technical Requirements for Pharmaceutical Products

IAFPQ	ICH's CTD (common Technical document)
Annex 2C Interagency Finished Pharmaceutical Product Questionnaire (below annexes under 2c-for Non-SRA)	
Annex A-Batch Formula	Section 3.2.P.3.2 (and 3.2.P.3.1)
Annex AA-Graphic Summary of BE results	Module 5
Annex AB-BE Study report	Module 5
Annex B-Primary Packaging	Section 3.2.P.7
Annex C-Secondary Packaging	Section 3.2.P.7
Annex D-Manufacturing licence	Section 3.2.P.1
Annex-E-CPP	Module 1
Annex G-WHO prequalification letter	Module 1
Annex I-Labelling	Module 1 and Module 3
Annex J-SmPC and PIL	Module 1 and Module 3
Annex K-API Gmp Certficate	Section 3.2.S and Module 1
Annex L-API specification	Section 3.2.S.4.1
Annex M-Method Validation	Sections 3.2.P.5.2 and 3.2.P.5.3
Annex O-API COA	Section 3.2.S.4.4
Annex P1-CEP certificate	Section 3.2.S
Annex P2-Technical File (DMF)	Section 3.2.S (open part of the DMF)
Annex Q-FPP GMP certificate	Section 3.2.p.1 & module 1
Annex R-FPP specifications	Section 3.2.P.5.1
Annex S-FPP COA	Section 3.2.P.5.4
Annex T-Process flow chart	Section 3.2.P.3.1
Annex V-Stability data	Section 3.2.P.8
Annex W-Stability Declaration	Section 3.2.P.8
Annex X-Status ongoing Stability	Section 3.2.P.8.3
API declaration form, annex 2d (commitment and signature)	Module 1

Technical Requirements for Pharmaceutical Products

Abridged procedure (for SRA/WLA/WHO PQ approved):-

a) Annex 2f-UNICEF offer form
b) Annex 2g-UNICEF Technical commitment declaration form
c) Annex 2j-Declaration of similarity; SRA approved product released in Non-SRA country
d) Annex 2k-Declaration of Equivalence (differences in product information language)
e) Certificates of analysis
f) Artworks, SmPC/PILs

COLLABORATION ON QUALITY

- ✓**Interagency Pharmacists Group (IAPG)**
  - ✓ Membership by application
  - ✓ Minimum requirement- agency has implemented MQAS, duly qualified assessors
  - ✓ Exchange of information between the Interagency pharmacists group, joint inspections
- ✓**UN Quality Assurance Group- in formative stages**
- ✓**UNICEF is PIC/s observer member**

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Interagency Finished Pharmaceutical Product Questionnaire

- Annexed to WHO MQAS

Finished Pharmaceutical Product questionnaire for biotherapeutics*

- Done by WHO PQ, IAPG reviewing it, recently used in UNICEF tender for bio-oncology products

UNICEF Technical Requirements for Pharmaceuticals – 6th Edition

Aligned with WHO TRS norms and standards and ICH guidelines

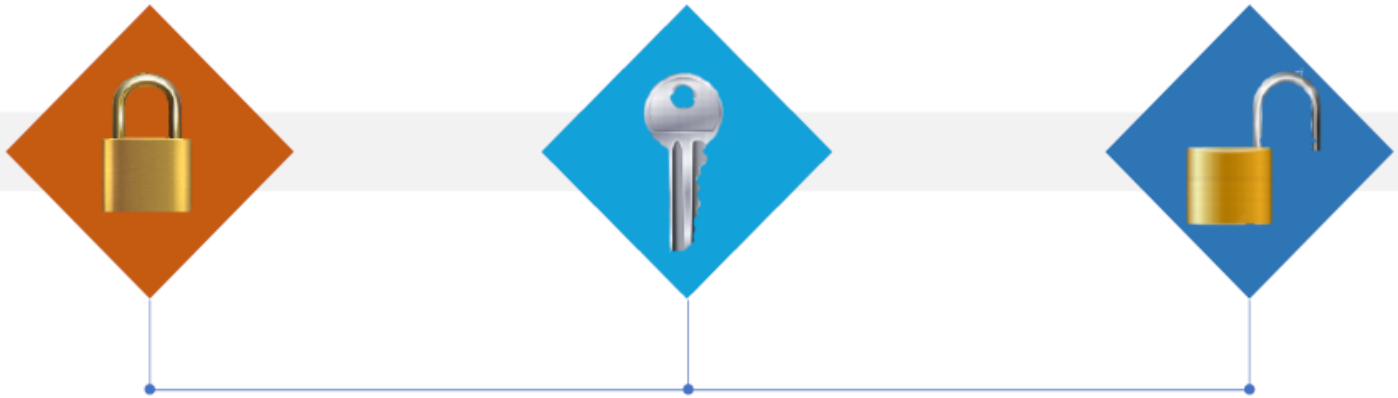
The Future is reliance

WHO Listed Authorities




WHO Listed Authorities

A new concept introduced to replace SRAs



Following ICH structural changes in 2015, need for replacing the term Stringent Regulatory Authority (SRA) and eligibility criteria based on the pre-reform membership to ICH

ICDRA 2016 & 2018 *Recommendations regarding SRAs*

Recommendations from 51st ECSPP in 2017 and 61st ECBS in 2018

Feedback *from international consultations and virtual meetings on developing the GBT*

WLA

Authorities listed by WHO following a **consistent, documented, transparent and accountable** assessment

UNICEF

Supplier Document Management System




Supplier document Management system

SharePoint dossier library overview:
The Suppliers Dossier Library has been in existence since 2020.

1. Upload technical documents

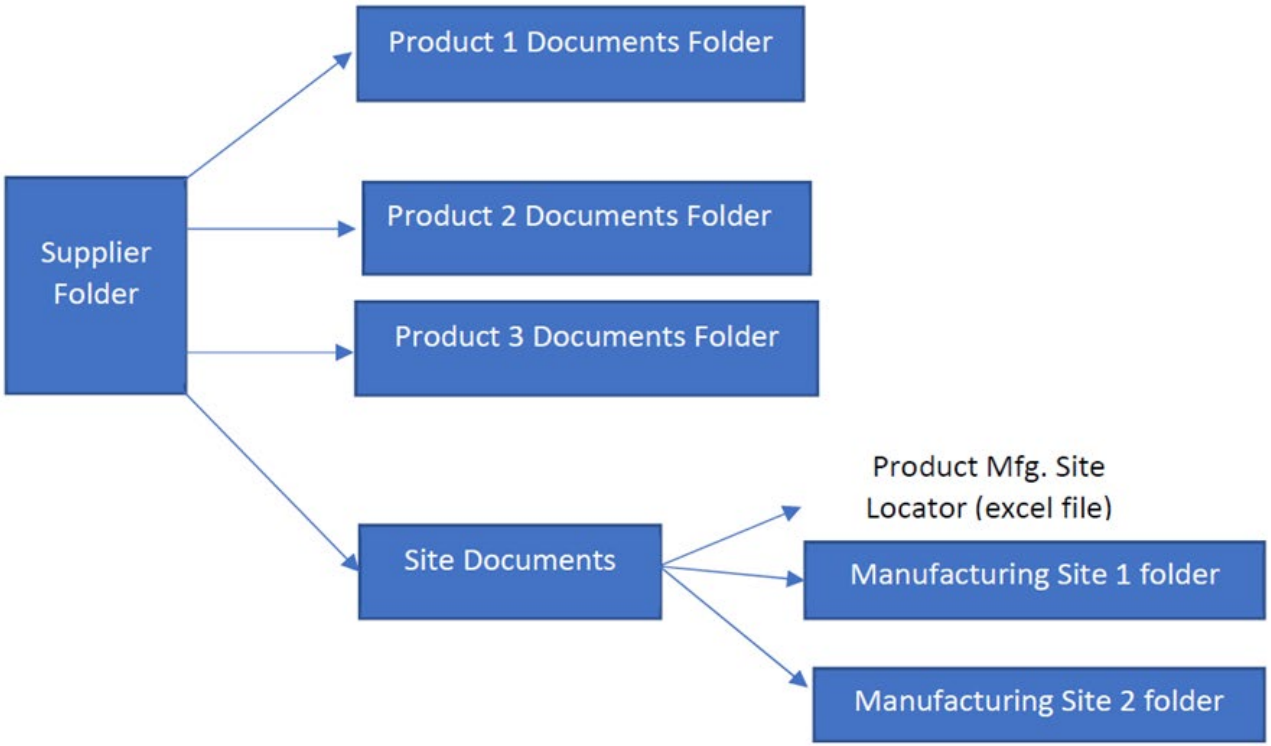
- All technical documents must be uploaded to the designated SharePoint dossier library. Each supplier folder in the supplier dossier library has two main folders:
  - ✓ folders for specific products and
  - ✓ folder for site documents.

2. Access for suppliers

- Each supplier receives a unique link to access their specific folder.
- Access will only be granted if the supplier has expressed an interest in a specific tender.

Supplier document Management system

Supplier Folder Structure:



Supplier document Management system

3. Confidentiality

- The dossier library is highly secured to ensure confidentiality.
- Access to the folders is restricted to the following persons:

The bidder, technical unit and Quality Assurance inspectors.

4. Efficiency and convenience

- The library simplifies the process of re-evaluating future tenders.
- Suppliers can easily update their existing portfolio with new or amended information, reducing the need for duplicate submissions.

Supplier document Management system

Supplier Dossier Library:

- Each supplier will be given their own link to access their own folder only if they have expressed an interest in participating in a specific tender.
- The information in the library is confidential and only accessible to the supplier, the technical unit and the QAC inspectors.
- The advantage of the library is that it facilitates the re-evaluation of future tenders, as suppliers only need to update the information that is already in their folder.

Identified deficiencies in technical submissions

1. Incomplete inter-agency questionnaire
- Annex 2c of the questionnaire was not fully completed.

2. Missing documentation
- API (Active Pharmaceutical Ingredient) declaration forms were not submitted.
- Valid pharmaceutical GMP (Good Manufacturing Practice) certificates for API sources are missing.
- CEP certificates (Certificate of Suitability) or DMF (Drug Master File) for API sources have not been submitted.

3. Inadequate Specifications
- The specifications for the final product (release and shelf life) lack references to specific monographs.

Identified deficiencies in technical submissions

4. Requirements for the stability report
- The stability report must refer to the finished pharmaceutical product (FPP) manufactured at the specified site, unit or workshop.
- The report must indicate the exact address of the site/unit where the FPP was manufactured.

5. Specifications for stability data
- Both accelerated and long-term stability data must be provided.
- The stability data should include results for at least three batches of the product.

6. Communication obligations
- Suppliers must inform UNICEF of any deviations in relation to the following:

API (Active Pharmaceutical Ingredient) sources.
Production sites or locations.

Q&A