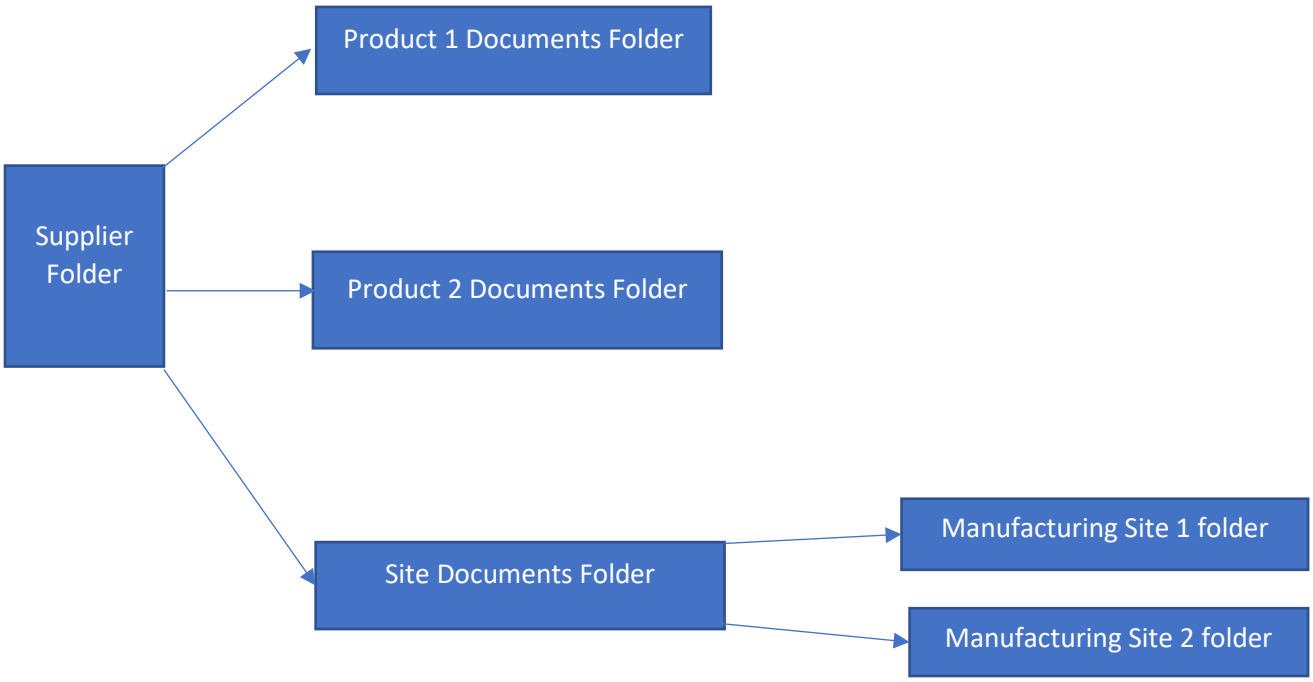
ANNEX 3 INSTRUCTIONS FOR UPLOADING TECHNICAL DOCUMENTS TO SHAREPOINT

1. For a link to the UNICEF Supplier Document Library on SharePoint send a request to Martina Tonin Podobnikar (email: mpodobnikar@unicef.org);
   Include:
   - full name and address of bidder,
   - INN descriptions, strength and dosage form of products of interest and
   - their respective manufacturing sites (name, physical address, city & country).
   - email addresses of (bidder) team members that would require access to SharePoint.
2. The Product **(Annex 2c Interagency Pharmaceutical Product Questionnaire (IAFPPQ)-Automated pdf version)** and the Manufacturer **(Annex 2a UNICEF Technical Questionnaire for manufacturers)** questionnaires are the basis of the UNICEF technical evaluation.
3. Please ensure you upload the Product and Manufacturers questionnaires in their original format. i.e. please DO NOT upload printed/scanned versions. The forms are automated hence cannot be processed if a scanned version is uploaded.
4. In the UNICEF Supplier Document library, each supplier has its own folder, which contains Named Product folders (for each INN, strength and dosage form) and Site documents folder. Only one Site Documents folder is allocated to each supplier and it contains a Product Mfg. Site Locator (excel file) and Manufacturing site folders 1,2...etc.) as depicted in figure 1 below.

Figure 1: Supplier folder structure



Please note that product folders are created for each product strength (for e.g., Amoxicillin 250mg tabs and Amoxicillin 500mg tabs) and you need to upload documents into respective Product documents and Site documents folders even if they are similar or have been already uploaded in the other product folder having different strengths e.g., you need to again upload the same documents (if applicable) in each

strengths folder for e.g., Amoxicillin 250 mg and Amoxicillin 500 mg for e.g. even if API, mfg. site is same for both the strengths.

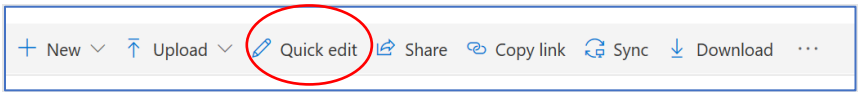
5. *For each* Named Product folders (*for each INN, strength and dosage form) please upload the required documents as mentioned in the Table 1 below in the section "Product Documents".*
6. *Product Mfg. Site Locator (excel file located in Site Documents folder) needs to be completed. This file is used for locating specific Manufacturing Site (e.g., 1 or 2 or 3) for a specific product and its strength. The product and its mfg. site must match with the details mentioned in the Product Questionnaire (Annex 2c Interagency Pharmaceutical Product Questionnaire (IAFPPQ)-Automated pdf version).*
7. *For each manufacturing site – please upload the required documents as mentioned in Table 1 below in the section "Site Documents (for each mfg. Site)".*
8. Please upload only pdf or Word doc or Jpeg (for pictures/ Images) files in Product documents and Site documents folder. Do not upload any "zip folders" and/or do not create additional "folders" in Product documents and Site documents folder. (e.g., CoA's or stability reports for 3 batches should be scanned as one file). Scanned files for the Annexes of the IAFPPQ can be uploaded.
9. If you do not have any Annex (for product or site or other documents) to upload for any reason, please mention the specific reason for the same on a word /pdf file and upload the same with respective Annex name, e.g. Not Applicable or Will submit the document later (by XXXX date) or Document cannot be provided or Not available or any other reason as applicable.

Table 1: Documents to be provided by Suppliers (All files should be named as below)

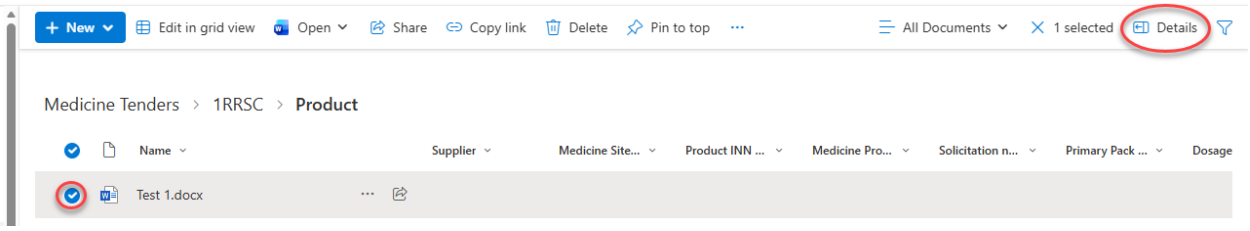
Site Documents (for each mfg. Site) (for a specific manufacturing site where the product is produced)	**Product Documents (Annex 2c and related Annexes)** (refers to product specific documents)
Annex 2a UNICEF Technical Questionnaire for manufacturers	**Annex 2c Interagency Pharmaceutical Product Questionnaire (IAFPPQ)-Automated pdf version**
Site Master File (pdf or word document)	**Annex 2d IAFPPQ Commitment and signature - Section 5**
Manufacturing License from your National Regulatory Authority.	Annex A Batch Formula
Copy of the latest inspection report.	Annex B Primary Packaging
Most recent GMP Certificate(s).	Annex C Secondary Packaging
List of all the recent GMP inspections performed at the site.	Annex D CPP
Copy of relevant closing letters from the GMP inspections.	Annex E MA issued & approval history
List of products currently supplied to UNICEF.	Annex F Acceptance letter issued by WHO PQ/SRA/WLA
List of products submitted for tender.	Annex G Product Photos
	Annex H Label-Primary
For Wholesalers Only	Annex I Label-Secondary
Annex 2b UNICEF Technical Questionnaire for wholesalers (required only for wholesalers)	Annex J SmPC and PIL
Evidence from wholesaler that they are authorized by manufacturer to distribute the product.	Annex K API GMP certificate and Manufacturing License

Product Documents (Annexes-continuation) (refers to product specific documents)	Annex L API specification (FPP Mfg. Internal spec)
Annex 2d IAFPPQ Commitment and signature - Section 5	Annex M Method Validation for API
Annex 2e UNICEF API Declaration form	Annex N CEP/WHO PQ certificate
Annex 2f UNICEF Technical Offer form	Annex O Technical file (DMF)
Annex 2g UNICEF Technical commitment declaration form	Annex P Data on validation of sterile API
Annex 2i Letter of Authorization permitting UNICEF access to information from WHO, ERP, MSF etc.	Annex Q API COA (API Mfg. & FPP Mfg.)
	Annex R API source comparison
	Annex S FPP GMP certificate and Manufacturing License
	Annex T FPP Specifications (release & shelf life)
	Annex U FPP CoA (3 Batches)
	Annex V Process Flow Diagram (FPP mfg. process)
	Annex W Process validation report
	Annex X Data on validation of sterile aspects for sterile FPP
	Annex Y Nitrosamines risk assessment
	Annex Z Stability Data
	Annex Z1 Status of On-going Stability
	Annex AA Stability Declaration (API used)
	Annex AB In-use Stability Data
	Annex AC Summary of pharmacology, toxicology and efficacy of the product
	Annex AD Graphic summary of BE results
	Annex AE BE study report/CDP study report
	Annex AF CRO inspection outcome evidence and certificate of Accreditation of Facility/Laboratory
	Annex AG Schematic representation of BE study design
	Annex AH Study protocol summary
	Annex AI Latest Periodic Safety report
	Annex AJ Power of Attorney

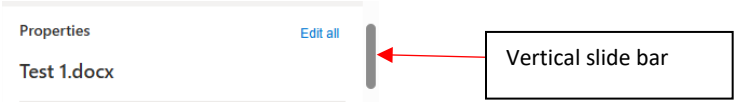
10. To upload files on our SharePoint:
    i. Click on the link provided. It will take you to your supplier folder.
    ii. Click on the appropriate type of folder for the document to be uploaded (Site Documents or Product Documents)
    iii. Click on “Upload”.



    iv. Select “Files” and choose the file/files you would like to upload.
    v. Once the file is uploaded, select the file/files by ticking the circle that appears on the left when you mouse over the files. Then click on the “Details” icon on the top right corner.



vi. Using the vertical slide bar at the far right, scroll down to "Properties" and click on "Edit All".



vii. Complete the relevant fields by entering value or choosing a relevant term from a drop-down menu.

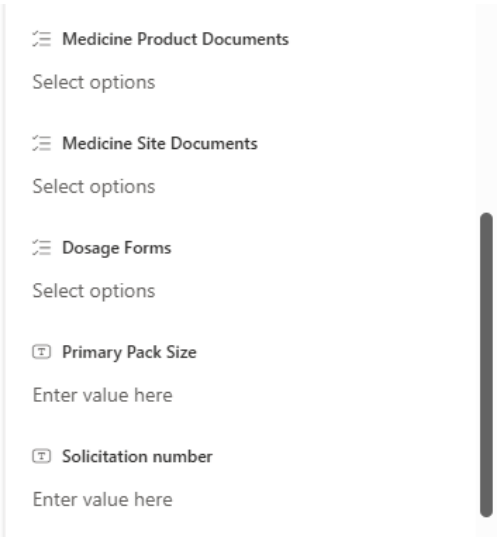
For the *Medicine Product Documents* tag the following fields only:

1. Dosage forms (select options from the drop-down menu)
2. Primary pack (enter value[1])
3. Solicitation number (enter value)

[1]When entering the Primary pack value, the following format must be used; for blister packs e.g. 10 x 10, 5 x 10 etc. & loose or bulk packs e.g. 100, 1000 etc. Also indicate a dosage form e.g. a vial, ampoule, bag etc.

For the *Medicine Site Documents* tag the following fields only:

1. Medicine Site Documents (select options from the drop-down menu)
2. Solicitation number (enter value)



viii. Click on "✓" or press Enter to save

ix. Repeat the steps for all the documents. These will be secured for future tenders, so the documents uploaded will remain in folders for each tender unless amended. Updates can be made if needed.

x. When uploading documents for more than one product, please ensure that you upload the files in the correct product folder.

Updated November 2025-general form