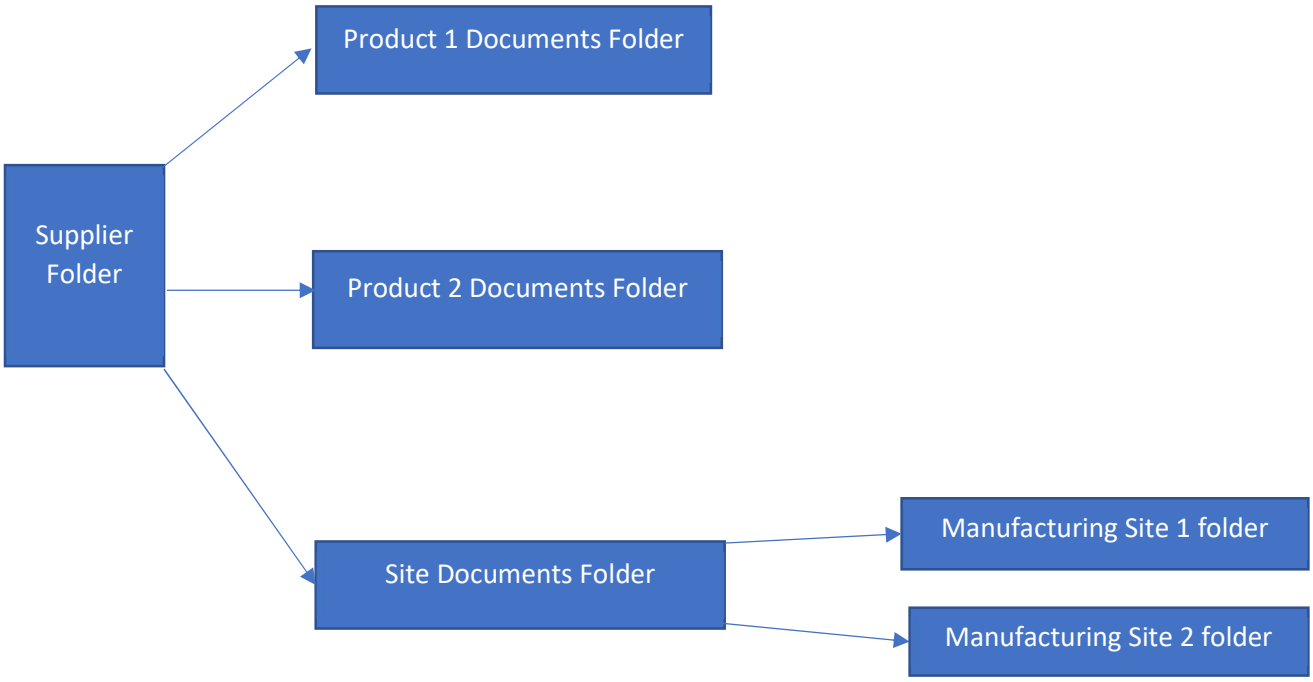
# ANNEX 3 INSTRUCTIONS FOR UPLOADING TECHNICAL DOCUMENTS TO SHAREPOINT

1. For a link to the UNICEF Supplier Document Library on SharePoint send a request to Rennie Shonhiwa-Chikwanha at rshonhiwa@unicef.org include:
    - full name and address of proposer,
    - INN descriptions, strength and dosage form of products of interest and
    - their respective manufacturing sites (name, physical address, city & country).
    - Email address(es) of the company contact person(s) who will access the SharePoint folder.
2. For this tender, the technical proposal is primarily composed of either the Interagency Questionnaire (Annex 2c) or the abridged Technical Offer Form (Annex 2f), depending on the product offered.
3. Where applicable, ensure you upload the Interagency Questionnaire (Annex 2c) in its original format. DO NOT upload printed or scanned versions. The forms are automated and 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 a Site Documents folder. Only one Site Documents folder is allocated to each supplier, and it contains a Product Manufacturing Site Locator (Excel file) and Manufacturing Site folders (1, 2, etc.), as shown 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. *The Product Manufacturing Site Locator (Excel file located in the Site Documents folder) needs to be completed. This file is used to identify the specific manufacturing site (e.g., 1, 2, or 3) for a given product and its strength. The product and its manufacturing site must match the details provided in the Product Questionnaire (Annex 2c Interagency Questionnaire or Annex 2f technical Offer form).*
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, Word, or JPEG (for pictures/images) files in the Product Documents and Site Documents folders. **Do not** upload any zip folders or create additional folders in the Product Documents and Site Documents folders. For example, CoAs or stability reports for three 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, site, or other documents) to upload for any reason, please state the specific reason in a Word or PDF file and upload it with the respective annex name. For example: Not Applicable, Will submit the document later (by XXXX date), Document cannot be provided, Not available, or any other applicable reason.

**Table 1: Documents to be provided by suppliers (all documents should be named as indicated below)**

| **Site Documents (for each mfg. Site)**<br>(for a specific manufacturing site where the product is produced) | **Product Documents (Annex 2c and related Annexes)**<br>(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)**<br>(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) |

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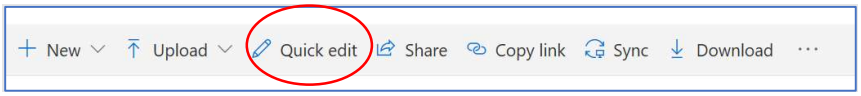
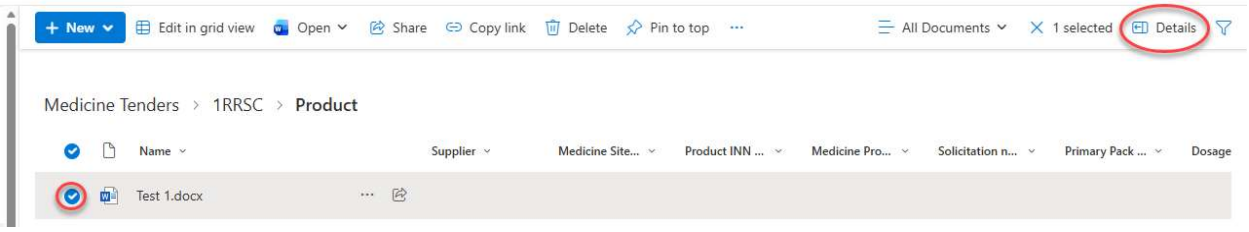
|---|---|
| **Annex 2g UNICEF Technical commitment declaration form** | Annex P Data on validation of sterile API |
| **Annex 2i Letter of Authorization permitting UNICEF access to information from WHO, ERP, MSF etc.** | Annex Q API COA (API Mfg. & FPP Mfg.) |
| | Annex R API source comparison |
| | 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 |

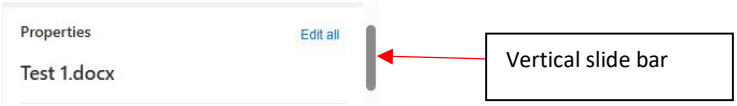
10. To upload files on our SharePoint:
    i. Click on the link provided. It will take you to your supplier folder.
    ii. Click on the appropriate type of folder for the document to be uploaded (Site Documents or Product Documents)
    iii. Click on “Upload”.




    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.

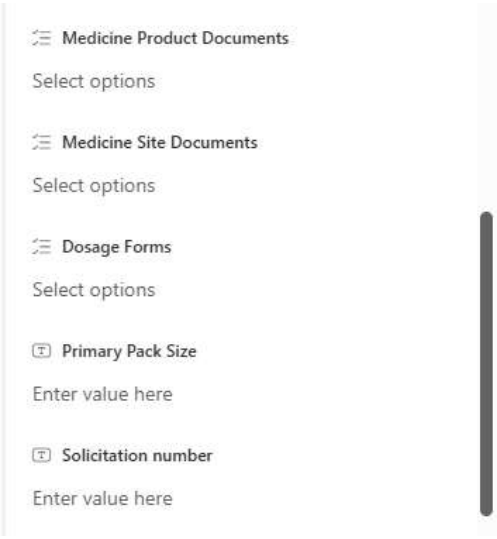
For the *Medicine Product Documents* tag the following fields only:

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.

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