

Title:	Instructions for Creating and Submitting Technical Documentation to FHI 360
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1.0 PURPOSE

Regulatory and Compliance staff in FHI 360's Product Quality and Compliance (PQC) department recommend that technical documentation submitted for technical evaluations be uploaded to the FHI 360 SharePoint site. The purpose of this work instruction (WI) is to provide step-by-step instructions on how to create and submit technical documents to the FHI 360 SharePoint site.

2.0 SCOPE

This WI applies to all clients who respond to a request for information (RFI), request for proposal (RFP), request for quotes (RFQ); or who provide additional supporting information for a variance, special request, files exceeding size limit for email, or to provide documentation to support a product quality incident investigation or recall.

Note 1: This WI replaces QA.WI.GEN-03 under the USAID Global Health Supply Chain-Quality Assurance Program (GHSC-QA) directives system.

3.0 REFERENCE DOCUMENTS

- None specified

4.0 DEFINITIONS

- **SharePoint:** A web-based collaborative platform that integrates with Microsoft Office. SharePoint is primarily a document management and storage system.
- **Bookmark:** A type of link with representative text in the bookmarks panel in the navigation pane. Each bookmark goes to a different view or page in the document.

5.0 INSTRUCTIONS

5.1 General Instructions

- 5.1.1 The FHI 360 technical files and appendices for each offered product shall be submitted in a single PDF document. The following are the instructions to prepare the submission, request access to the FHI 360 PQC SharePoint site, and upload the submission.
- 5.1.2 All RFI, RFP, and RFQ documentation should be combined and uploaded as a single pdf per product (per manufacturing site). This should include the completed technical questionnaire with all supporting documentation included as appendices. The technical questionnaire and the appendices should be bookmarked.
- 5.1.3 A SharePoint document library will be created for each company to upload the technical files and documentation relevant to the request.

5.2 Create a PDF Version of Each Document

5.2.1 From a software program (e.g., Microsoft Word, Excel, or PowerPoint):

5.2.1.1 Open the document file and click file and then save as.

5.2.1.2 In the document style option pull-down menu, select PDF.

5.2.1.3 Select the folder where the document will be stored and click save.

5.2.2 Scanned from a paper copy:

5.2.2.1 Choose scan a document using the software and scanner available to your organization and save the file to an appropriate location. Refer to the user manual for your scanner and use the following settings:

- Scan resolution: minimum 200 dpi
- If color coded material: scan in color; otherwise use black and white and annotate color information.
- Scan document as a pdf – if available with optical character recognition (OCR).

5.2.2.2 Review the scanned document and correct unreadable material and/or mistakes generated as part of the OCR recognition.

5.3 Combine Multiple PDF Files into a Single PDF

5.3.1 Combine all documentation into a single pdf document per product. This should include the completed technical questionnaire with all supporting documentation included as appendices (e.g., product formulation, finished pharmaceutical product [FPP] specifications and test methods, FPP packaging and labeling, stability data, licensing status, Certificate of Pharmaceutical Product, registration status).

Note 2: There are multiple desktop publishing options and multiple ways to combine files within each program. Refer to the user manual or help instructions for specific instructions.

5.4 Create Bookmarks

5.4.1 Define bookmarks for each document uploaded. Each bookmark should go to a different view or page in the document.

Note 3: There are multiple desktop publishing options and multiple ways to create bookmarks within each program. Bookmarks may be generated automatically during PDF creation. Refer to the user manual or help instructions for specific instructions.

5.5 File Naming Convention

5.5.1 Use the product and supplier name in the file name whenever possible, per the following examples:

- Example 1: Product Code_Supplier.pdf (012345_NEWCO.pdf)
- Example 2: Product Name_Supplier.pdf (NEWPRODUCT_NEWCO.pdf)

5.5.2 Verify that the file name follows the following formatting requirements:

- File names should run no longer than 20 characters
- File names should not include special characters (only use letters, numbers, periods, underscores, or dashes)
- File names should use underscores instead of spaces between words (e.g. “File_Name” not “File Name”)

5.6 Request Access to FHI 360 SharePoint

5.6.1 Request access to a FHI 360 Product Documentation SharePoint document library by sending an email to Hien Dinh at hdinh@fhi360.org. In the email request, provide:

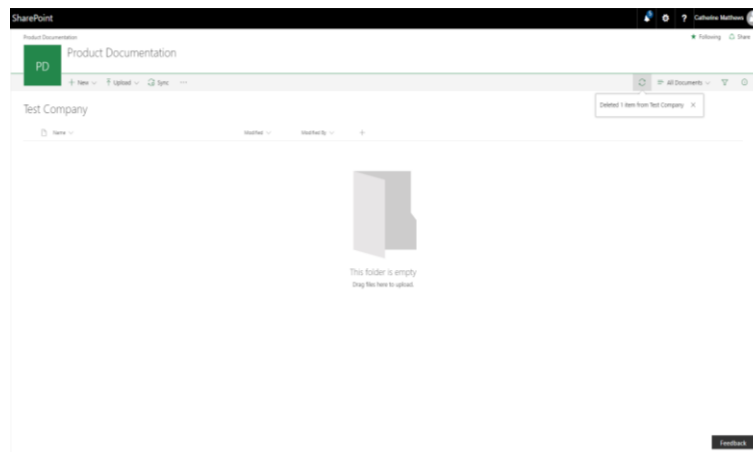
- the name, company, and contact information (including email address) for the person who will be responsible for uploading the product documentation to the SharePoint site.
- product name
- reference RFX (when applicable)

Note 4: The document library for your organization will be accessible only to the point of contact you specifically designate. Please do not share access with others.

5.6.2 For assistance accessing SharePoint, please contact Hien Dinh (hdinh@fhi360.org).

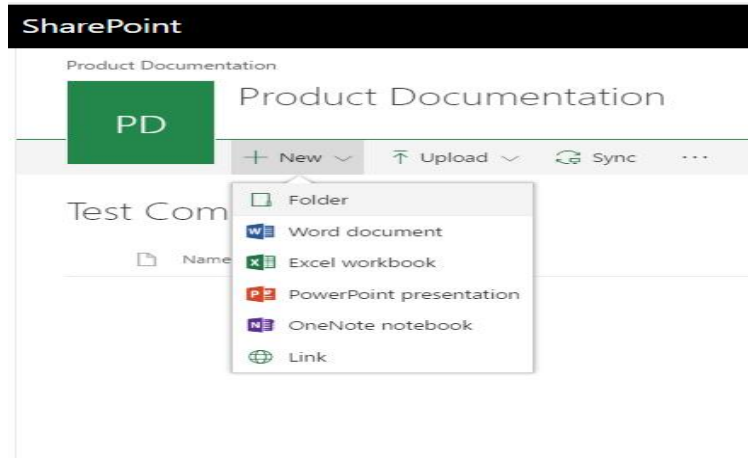
5.7 Instructions for Uploading Documents to FHI 360 SharePoint

5.7.1 Follow the link provided to the product-specific SharePoint library. When you first open the SharePoint document library, it should look like the figure below:

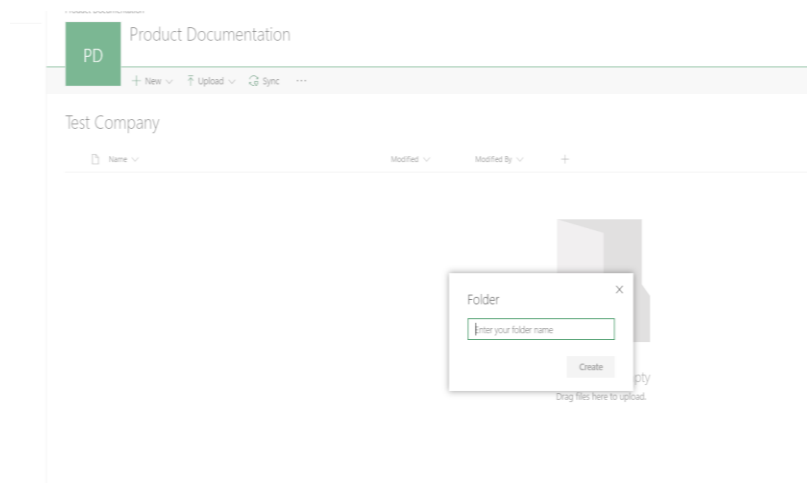


5.7.2 Create folders for each product for which you are uploading files

5.7.2.1 To create a folder, click on the "+New" drop down menu below your document library name (in this case, Test Company) and select "Folder."

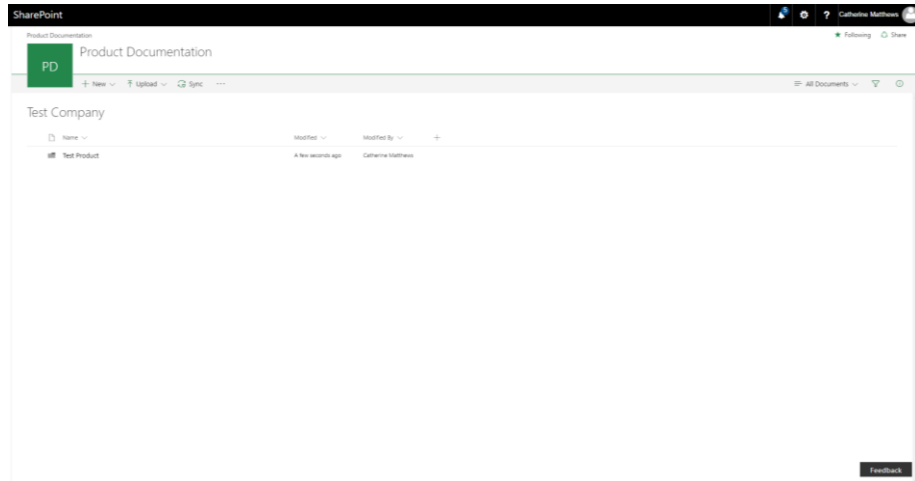


5.7.2.2 Name the new folder after the product for which you will be uploading documents.



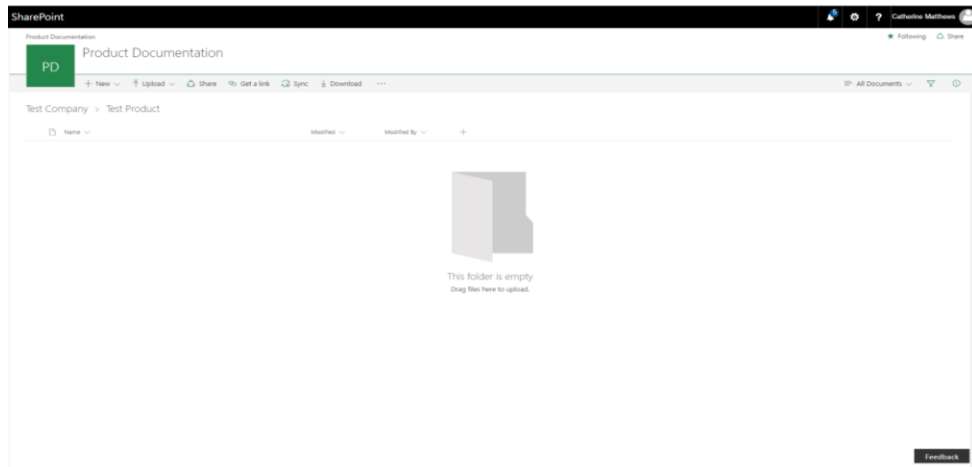
5.7.2.3 Click "Create."

5.7.2.4 Repeat this process for each product for which you will be uploading documents.

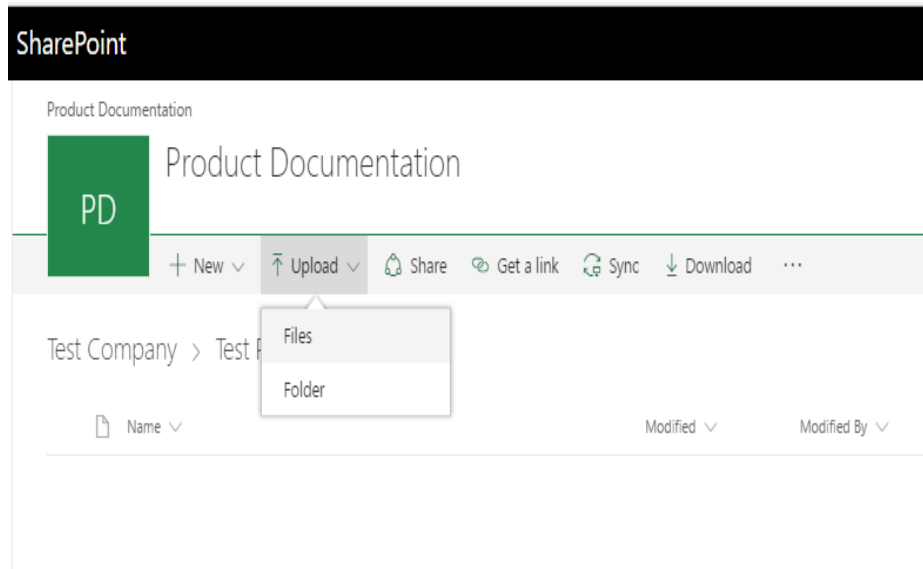


5.7.3 Upload a new document

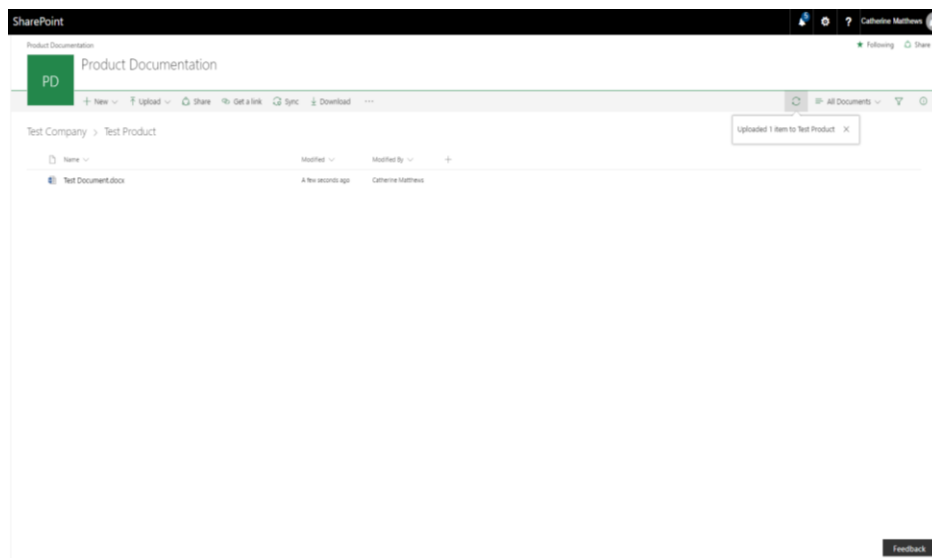
5.7.3.1 To upload a new document, navigate into the relevant product folder.



5.7.3.2 Click the “Upload” button (next to “New”) and select “Files.”



5.7.3.3 Select the files you wish to upload from File Explorer and click “Open.” Once the document has uploaded, you should see a notification in the top right corner of the document library.



5.7.3.4 If you wish to upload multiple documents at once, you can drag and drop files directly from File Explorer on your computer. For further instructions, reference [“Upload a folder or files to a document library”](#) from Microsoft.

5.7.3.5 Once you have uploaded all the documents you plan to submit, notify Hien Dinh at (hdinh@fhi360.org).

6.0 DOCUMENT HISTORY

Version	Author/Signature	Approver/Signature	Action	Summary of changes
00			New	Migrated from GHSC-QA QMS (replaces QA.WI.GEN-03)