PFSCM
Partnership for Supply Chain Management

Non-Pharmaceutical Products Prequalification Guide for Suppliers

Approved 10-15-2024, PFSCM QA&R unit

Definitions

Product dossier screening	Systematic process to ensure that all required documents of the product dossier are submitted.
Product dossier review	Review and assessment of documentation including data, protocols, reports, procedures, etc., to support the quality, safety, and performance of a product for the purpose of PFSCM QA&R non-pharmaceuticals prequalification.
Manufacturing catalog code or reference	Refers to a specific / unique product.
Regulatory approval or registration	Refers to and relates to all the information and documentation associated with a submission for approval of a product by a regulatory authority (e.g., United States Food and Drug Administration, Health Canada, a Notified Body for CE marking, Japanese Pharmaceuticals and Medical Devices Agency, Australian Therapeutic Goods Administration). The regulatory approval / registration is provided for a specific manufacturing catalog code / reference product.
Risk classification	GHTF/IMDRF has stipulated a series of principles and rules that allow a medical device (Including IVD) to be assigned to one of four classes based on its intended use (the risk for the user/patient).

Abbreviations

CE	“Conformité Européenne” = European conformity
GHTF	Global Harmonization Task Force
IFU	Instructions for use
IMDRF	International Medical Device Regulators Forum
ISO	International Organization for Standardization
IVD	In-Vitro Diagnostics
MSDS	Material Safety Data Sheets
RUO	Research Use Only
WHO	World Health Organization

Introduction

The Partnership for Supply Chain Management (PFSCM) prequalification of non-pharmaceutical products is coordinated through the PFSCM Quality Assurance & Regulatory (QA&R) unit. This quality and regulatory assessment of non-pharmaceutical products through a standardized procedure in compliance with the World Health Organization (WHO) model quality assurance system (MQAS) for procurement agencies aimed at determining whether a product meets PFSCM prequalification requirements and can be procured.

The full prequalification assessment process includes the review of a full product dossier according to the quality and regulatory requirements defined for each product risk class.[1]

The duration of the validity of the prequalification status of a product is dependent on the manufacturer's continuous fulfillment with PFSCM's quality and regulatory requirements.

The findings of PFSCM QA&R prequalification is used to assess the regulatory and quality compliance of a product commercially available for procurement on behalf of PFSCM clients.

Intended audience

This document provides suppliers with an overview of the PFSCM QA&R unit process for the prequalification assessment of non-pharmaceuticals.

NOTE: Suppliers / Vendors wishing to make their products available through PFSCM should read this document before sending their product dossier, in order to be aware of requirements and prepare for the prequalification assessment process.

NOTE: For product dossiers submitted during an RFP, the product dossier content and eligibility criteria can differ from the content of this guide. If you are submitting a product dossier under an RFP, please refer to the RFP proposal and RFP language for criteria instead of this guide.

[1] https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf

Product dossier submission and screening

For a full prequalification assessment, PFSCM QA&R invites the suppliers to submit a full product dossier. Before the prequalification assessment may commence, the manufacturer must compile and submit to PFSCM the relevant product dossier as described in this guide. Incomplete product dossiers submitted will not be reviewed.

NOTE: All provided documentation must be in English; no other language will be accepted unless it is requested by PFSCM.

Product dossier content and eligibility criteria

All product dossiers for non-pharmaceutical products must contain a properly completed *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire*. **All the relevant fields must be carefully completed with accurate data for the PFSCM QA&R unit to be able to assess the supporting documentation.**

The above mentioned required data are essential for the creation of each product/item in the PFSCM ERP system. The PFSCM ERP system is the system used to place Purchase Orders and to manage/track shipments. **Without this information, the creation of an item in the PFSCM ERP system and, consequently, the procurement of the product, is not possible.**

According to the risk classification defined in the ***Definitions section*** of this document, supporting documents are requested to ensure that the product meets PFSCM QA&R requirements. The supporting documents are part of the product dossier and need to be submitted with *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire*.

A full and detailed description can be found below for each document requested per risk class. A checklist is also available at the end of the document to guide and support the supplier in the compilation of the product dossier. Kindly refer to ***Attachment 1***.

Class A

A copy of a valid ISO 9001 or ISO 13485 certificate (must provide last updated version, as requested, certifying the manufacturing site manufacturing the product). The manufacturing site (name and address) mentioned in *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire,* must be the same in the ISO 9001 or ISO 13485 certificate provided (i.e., the name with the address needs to match perfectly with both documents). The "product scope" of the certificate has to cover all the products included in *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire*.

Instructions for the completion of the-*F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire* are indicated at the top of the questionnaire.

The Instructions For Use (IFU) or the User Manual (if applicable) of the product(s) included in *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire* must be provided. These documents are needed for the PFSCM QA&R unit to understand the intended use of the product as well as for the PFSCM Product Information Management (PIM) unit to determine the product name description in PFSCM's ERP system.

A respective Material Safety Data Sheet (MSDS) for all chemicals and hazardous products must be submitted. Information indicated in these documents are used for the proper handling of the products during the shipment and to determine shipment planning.

Proof or evidence of sterilization such as a sterility report, Certificate of Analysis (CoA), or other proof of sterility, must be submitted for all sterile products in order for PFSCM QA&R unit to verify that the sterilization is done in compliance with recognized sterilization standards.

Note: For WHO prequalified products, the reference of the product must be the exact same reference in the WHO prequalified product report and must match the product reference included in F-QA&R-015-004 Non-Pharmaceutical Technical Questionnaire.

Class B

A copy of a valid ISO 13485 certificate (must provide last updated version, as requested, certifying the manufacturing site manufacturing the product). The manufacturing site (name and address) mentioned in *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire* must be the same in the ISO 9001 or ISO 13485 certificate provided (i.e., the name with the address needs to match perfectly with both documents). The "product scope" of the certificate has to cover all the products included in *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire*.

Instructions for the completion of *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire* are indicated at the top of the questionnaire.

The IFU or the User Manual (if applicable) of the product(s) included in *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire* must be provided. These documents are needed for the PFSCM QA&R unit to understand the intended use of the product as well as for the PFSCM PIM unit to determine the product name description in the PFSCM's ERP system.

A respective MSDS for all chemicals and hazardous products must be submitted. Information indicated in these documents are used for the proper handling of the products during the shipment and determine shipment planning.

A proof or evidence of sterilization (sterility report, CoA, other proof of sterility) for all sterile products must be submitted in order for the PFSCM QA&R unit to verify that the sterilization is done in compliance with recognized sterilization standards.

A proof or evidence of regulatory approval / registration (kindly refer to ***Definitions section***) must be provided. A valid regulatory approval / registration ensures that the product is regulatory controlled and quality, efficacy, and safety have been assessed and confirmed.

Note: For WHO prequalified products, the reference of the product must be the exact same reference in the WHO prequalified product report and must match the product reference included in F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire.

Class C

A copy of a valid ISO 13485 certificate (must provide last updated version, as requested, certifying the manufacturing site manufacturing the product). The manufacturing site (name and address) mentioned in *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire* must be the same in the ISO 9001 or ISO 13485 certificate provided (i.e., the name with the address needs to match perfectly with both documents). The "'product scope" of the certificate has to cover all the products included in *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire*.

Instructions for the completion of *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire* are indicated at the top of the questionnaire.

The IFU or the User Manual (if applicable) of the product(s) included in *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire* must be provided. These documents are needed for the PFSCM QA&R unit to understand the intended use of the product as well as for the PFSCM PIM unit to determine the product name description in the PFSCM ERP system.

A respective MSDS for all chemicals and hazardous products must be submitted. Information indicated in these documents are used for the proper handling of the products during the shipment and determine shipment planning.

Proof or evidence of sterilization (sterility report, CoA, other proof of sterility) for all sterile products must be submitted in order for the PFSCM QA&R unit to verify that the sterilization is done in compliance with recognized sterilization standards.

A proof of evidence of regulatory approval / registration (kindly refer to ***Definitions section***) must be provided. A valid regulatory approval / registration ensures that the product is regulatory controlled and quality, efficacy, and safety have been assessed and confirmed.

The Label of the product must be provided for the PFSCM QA&R unit to ensure that the labelling is in compliance with applicable ISO or other standard(s).

Note: For WHO prequalified products, the reference of the product must be the exact same reference in the WHO prequalified product report and must match the product reference included in F-QA&R-015-004 -Non-Pharmaceutical Technical Questionnaire.

Note: For products approved by the Global Fund, the reference of the product must be the exact same reference as in the corresponding Global Fund List, [2]&[3] and to match the product reference included in F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire.

Class D

A copy of a valid ISO 13485 certificate (must provide last updated version, as requested, certifying the manufacturing site manufacturing the product). The manufacturing site (name and address) mentioned in *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire* must be the same in the ISO 9001 or ISO 13485 certificate provided (i.e., the name with the address needs to match perfectly with both documents). The '"product scope" of the certificate has to cover all the products included in *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire*.

Instructions for the completion of *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire* are indicated at the top of the questionnaire.

The IFU or the User Manual (if applicable) of the product(s) included in *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire* must be provided. These documents are needed for the PFSCM QA&R unit to understand the intended use of the product as well as for the PFSCM PIM unit to determine the product name description in the PFSCM ERP system.

A respective MSDS for all chemicals and hazardous products must be submitted. Information indicated in these documents are used for the proper handling of the products during the shipment and determine shipment planning.

Proof or evidence of sterilization (sterility report, CoA, other proof of sterility) for all sterile products must be submitted in order for the PFSCM QA&R unit to verify that the sterilization is done in compliance with recognized sterilization standards.

A proof or evidence of regulatory approval / registration (kindly refer to ***Definitions section***) must be provided. A valid regulatory approval / registration ensures that the

[2]Malaria: https://www.theglobalfund.org/media/5891/psm_qadiagnosticsmalaria_list_en.pdf
[3]Tuberculosis:https://www.theglobalfund.org/media/9461/psm_productsdiagnosticstb_list_en.pdf?u=63720569058000000

product is regulatory controlled and quality, efficacy and safety have been assessed and confirmed.

Note: For WHO prequalified products, the reference of the product must be the exact same reference in the WHO prequalified product report and must match the product reference included in F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire.

Note: For products approved by the Global Fund, the reference of the product must be the exact same reference as in the corresponding Global Fund list[4]&[5], and must match with the product reference included in F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire.

RUO

If applicable: A copy of a valid ISO 9001 or ISO 13485 certificate (must provide last updated version, as requested, certifying the manufacturing site manufacturing the product). The manufacturing site (name and address) mentioned in *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire* must be the same in the ISO 9001 or ISO 13485 certificate provided (i.e., the name with the address needs to match perfectly with both documents). The "product scope" of the certificate has to cover all the products included in *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire*.

Instructions for the completion of *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire* are indicated at the top of the questionnaire.

The IFU or the User Manual (if applicable) of the product(s) included in *F-QA&R-015-004-Non-Pharmaceutical Technical Questionnaire* must be provided. These documents are needed for the PFSCM QA&R unit to understand the intended use of the product as well as for the PFSCM PIM unit to determine the product name description in the PFSCM ERP system.

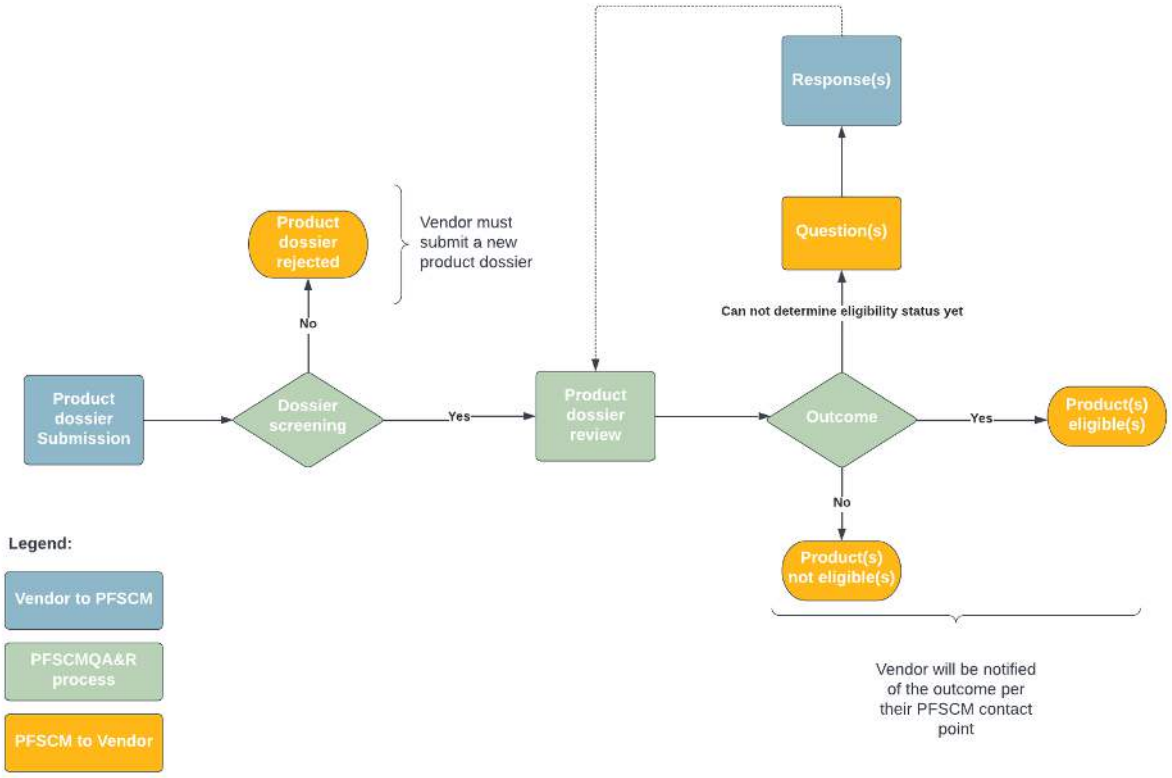
A respective SDS for all chemicals and hazardous products must be submitted. Information indicated in these documents are used for the proper handling of the products during the shipment and determine shipment planning.

Proof or evidence of sterilization (sterility report, CoA, other proof of sterility) for all sterile products must be submitted in order for the PFSCM QA&R unit to verify that the sterilization is done in compliance with recognized sterilization standards.

[4]HIV: https://www.theglobalfund.org/media/5878/psm_productshiv-who_list_en.pdf
[5]Covid: https://www.theglobalfund.org/media/9629/covid19_diagnosticproducts_list_en.pdf?u=637261896210000000

For RUO, additional standards may be requested given that there is no regulatory control. This will be communicated to the vendor by PFSCM during the product dossier review if not done prior to the dossier submission.

Product Prequalification assessment



Successful prequalification

Once prequalification assessment for the relevant product dossier is completed to the satisfaction of PFSCM QA&R and product(s)* meet(s) PFSCM prequalification requirements, the product will be included in the PFSCM ERP system.

***Note: The product bears a specific product name, product code(s), and regulatory approval (when requested), as manufactured at the specific manufacturing site(s)**

Duration of validity of the prequalification status

Products included in the PFSCM ERP system and their associated manufacturing sites will be reassessed by PFSCM QA&R at intervals determined by PFSCM QA&R. If the result of this reassessment shows that a product and/or specified manufacturing site(s) no longer meets

PFSCM requirements, such products will be deactivated / suspended from the PFSCM ERP system and no further POs will be allowed. Failure of a manufacturer to participate in the reassessment procedure will also lead to deactivation / suspension of the product(s) from the PFSCM ERP system.

Submission of changes for a prequalified product

Kindly update PFSCM of any changes.

Conclusion

For any further questions related to this guide, please send an email to productquality@pfscm.org. PFSCM QA&R team will try to respond to you as soon as possible.

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Attachments

Attachment 1 - Checklists

Class A

- ✔ ☐Copy of ISO 9001 or ISO 13485 certificate, certifying the manufacturing site manufacturing the product
- ✔ ☐IFU or the User Manual
- ✔ ☐MSDS for all chemical products and hazardous products
- ✔ ☐Proof of evidence of sterilization (sterility report, CoA, other proof of sterility) for all sterile products
- ✔ ☐For WHO prequalified product, the reference of the product matching the reference of the WHO prequalified product.

Class B

- ✔ ☐Copy of ISO 13485 certificate, certifying the manufacturing site manufacturing the product
  IFU or the User Manual
- ✔ ☐MSDS for all chemical products and hazardous products
- ✔ ☐Proof of evidence of sterilization (sterility report, CoA, other proof of sterility) for all sterile products
- ✔ ☐Proof of evidence of regulatory approval / registration
- ✔ ☐For WHO prequalified product, the reference of the product matching the reference of the WHO prequalified product.

Class C

- ✔ ☐Copy of ISO 13485 certificate, certifying the manufacturing site manufacturing the product
- ✔ ☐IFU or the User Manual
- ✔ ☐MSDS for all chemical products and hazardous products

- ✔ ☐Proof of evidence of sterilization (sterility report, CoA, other proof of sterility) for all sterile products
- ✔ ☐Proof of evidence of regulatory approval / registration
- ✔ ☐For WHO prequalified product, the reference of the product matching the reference of the WHO prequalified product.
- ✔ ☐For product approved by The Global Fund, the reference of the product must be the exact same reference of the corresponding global fund list.
- ✔ ☐Label

Class D

- ✔ ☐Copy ISO 13485 certificate, certifying the manufacturing site manufacturing the product
- ✔ ☐IFU or the User Manual
- ✔ ☐MSDS for all chemicals products and hazardous products
- ✔ ☐Proof of evidence of sterilization (sterility report, CoA, other proof of sterility) for all sterile products
- ✔ ☐Proof of evidence of regulatory approval / registration
- ✔ ☐For WHO prequalified product, the reference of the product matching the reference of the WHO prequalified product.
- ✔ ☐For product approved by The Global Fund, the reference of the product must be the exact same reference of the corresponding global fund list.
- ✔ ☐Label

RUO

- ✔ ☐Copy of ISO 9001 or ISO 13485 certificate, certifying the manufacturing site manufacturing the product (if applicable)
- ✔ ☐IFU or the User Manual
- ✔ ☐MSDS for all chemical products and hazardous products
- ✔ ☐Proof of evidence of sterilization (sterility report, CoA, other proof of sterility) for all sterile products

✔ ☐Additional standards requested / documents requested