ePQS and eCTD – Inspection Services

Kim Richards
Technical Officer (Inspector)
Inspection services, Prequalification Unit
Regulation and Prequalification Department
Access to Medicines and Health Products Division
WORLD HEALTH ORGANIZATION

What is ePQS?

ePQS is a platform for the processing of prequalification information for -

- Medicines,
- Diagnostics,
- Vector control products,
- Vaccines,
- Immunization devices,
- Quality control laboratories and
- Inspections.

ePQS consists of several integrated packages

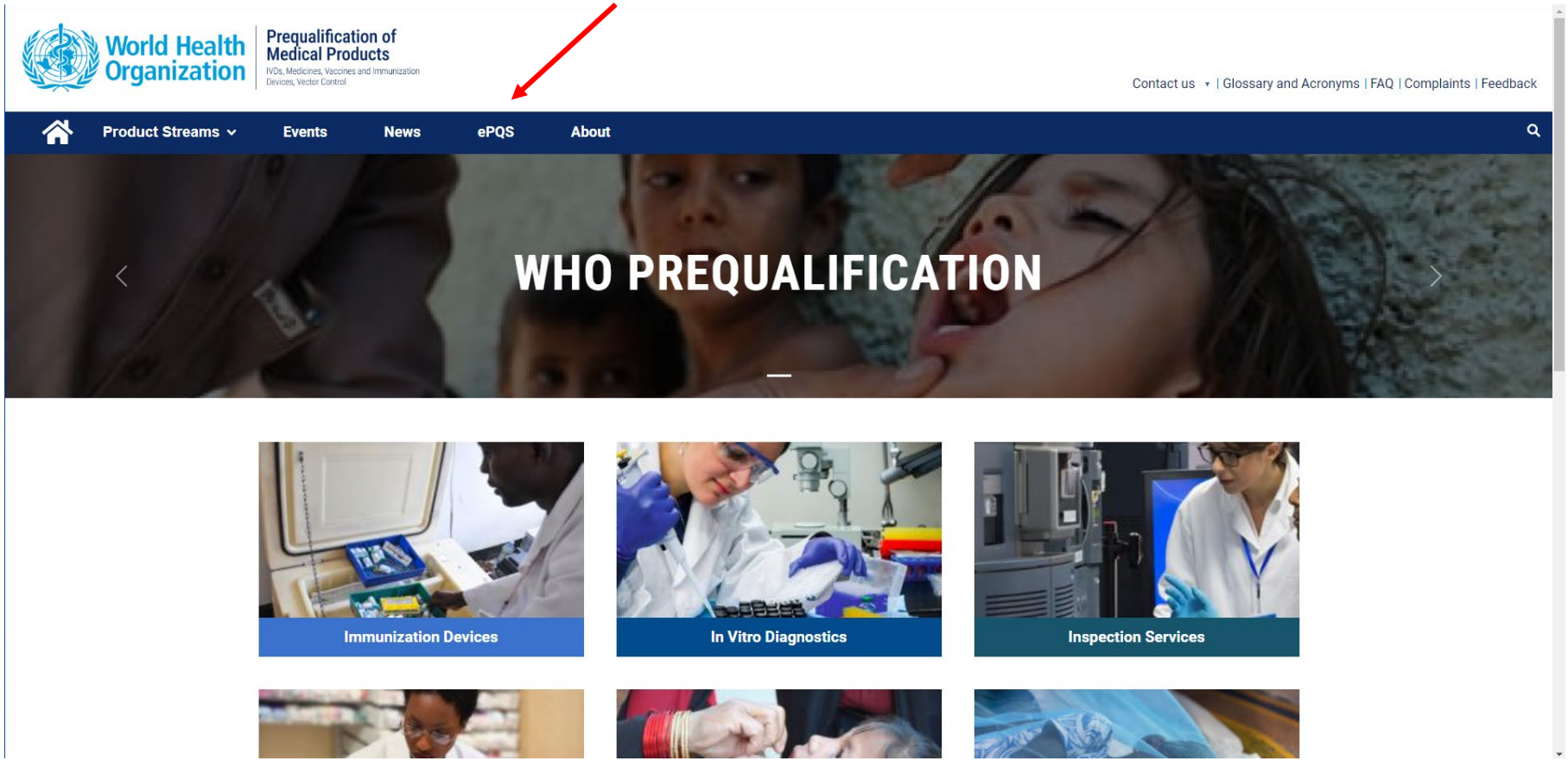
ePQS consists of several integrated software packages.

- A central Salesforce-based database
- An externally facing Salesforce-based community portal
- An integrated Document Management System
- And a related eCTD repository

The external Salesforce-based community portal has been designed to allow users to –

- View records related to their application/site/product,
- Submit applications,
- Upload and download documents in a secure environment,
- View and monitor notifications for pending activities.

https://extranet.who.int/prequal/



World Health Organization | Prequalification of Medical Products
IVDs, Medicines, Vaccines and Immunization Devices, Vector Control

Contact us | Glossary and Acronyms | FAQ | Complaints | Feedback

Product Streams | Events | News | ePQS | About

ePQS Portal

The **ePQS Portal** is the externally-facing Salesforce Community site of the WHO Prequalification Unit's new ePQS system. ePQS is a platform for the processing of Prequalification Information for medicines, diagnostics, vector control products, vaccines, immunization devices, quality control laboratories and inspections.

Within the portal, users will have the ability to:

General user information can be found here -

https://extranet.who.int/prequal/epqs-portal

Within the portal, users will have the ability to:

- View Salesforce records relevant to the user
- Submit applications
- Upload and download documents securely
- View and monitor notifications for pending activities

Registration to open early 2024

Registered users will be able to access the Portal at this link: https://who.my.site.com/ePQS/s/login/

Guidance notes related to the features of the portal, processes around applications, document submissions, and many other topics will be progressively posted to this webpage.

Webinars will be announced soon and regular clinics will be held post-go live to support users, answer questions, and identify issues in order to make continuous improvements.

NOTE: The portal will be opened from January 2024 and commence with user registrations thereon.

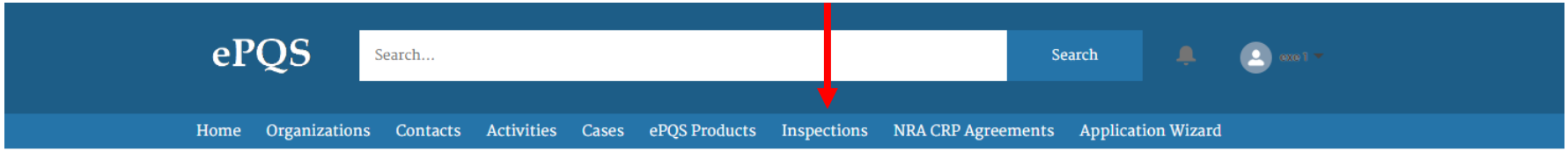
General Portal Information

ePQS - Accounts Contacts Users and Record Visibility
ePQS - Creating or editing a Contact or Account
ePQS - Portal Introduction and Features
ePQS - Terms and Conditions of use (4 October 2023)
ePQS - User Registration and accessing the ePQS Portal

What will be visible -

- Accounts/records to which you are directly related to,
- Contacts,
- Product records – related to accounts that are listed under the applicatants orgainsation,
- Activity records assigned,
- Completed inspection records.


ePQS
Search...
Search
Home
Organizations
Contacts
Activities
Cases
ePQS Products
Inspections
NRA CRP Agreements
Application Wizard
Submit an application
Create Account or Contact
Edit an Account or Contact
Change a Record Contact
World Health Organization
COMMONLY USED LISTS
Medicine Storage Conditions
WHO Vaccine Names
Medicines Pharmaceutical Ingredients
VC Active Ingredients/Synergist Name
QCLm Generic Name (INN)
Post-Prequalification Changes
View ePQS Registered Accounts
FEATURED
FAQs
Prequalification Information
EPQS Training Material



Inspection
I-00056

+ Follow | Printable View | Conga Inspection

Site	Inspection Status	Inspection Type	Final Inspection Outcome
PQT Pharmaceuticals (Site II) - Test	Completed	Routine inspection	Compliant (On-site Inspection)

Details | Related | Preview Documents | Document Download | Document Submission

Comments
APIMF394 , HA742 , WHOAPI-219 , HA516 , HA561 , HA562 , HA498 , HA538 , HA448 , HA549 , APIMF173 , APIMF219 , APIMF258 , WHOAPI-258 , HA611 Routine inspection

Information

ePQS Inspection ID: INSP-API-2015-0291	Previous Inspection Type: Routine inspection
Inspection Status: Completed	Previous Inspection Record Number: I-00054
Is Inspection a Priority:	Previous Final Inspection Outcome: Compliant (On-site Inspection)
Inspection Type: Routine inspection	Revised Inspection Due Date:
Initial Inspection Request:	Reason for Revising Inspection Due Date:
Trigger Reason:	
Joint Inspection:	

Site Detail

Site: PQT Pharmaceuticals (Site II) - Test	Latitude: 0.0000
Site (Legal): PQT Pharmaceuticals - Test	Longitude: 0.0000
Site Address:	Site Contact:

Desk Assessment

Desk Assessment - Basis for Outcome

Date of Last Inspection by NRA

Should Desk Assessment be placed on hold

Reason for hold

Desk Explanation for Hold

Hold Start Date

Hold End Date

Internal Inspection Supporting Decision

External Inspection Supporting Decision

Date of Desk Assessment Completion

Desk Assessment Outcome

Desk Assessment Final Comments

Reference Authority

Onsite

Inspection Start Date - Proposed
22/07/2019

Inspection End Date - Proposed
24/07/2019

Should Onsite Inspec be placed on hold?

Onsite Inspection Reason for Hold

Onsite Inspection Hold Start Date

Onsite Inspection Hold End Date

Inspection Start Date - Agreed

Inspection End Date - Agreed

Start Date Change Justification

Inspection Start Date - Actual
22/07/2019

Inspection End Date - Actual
24/07/2019

Onsite Explanation for Hold

Onsite Inspection Outcome
Compliant (On-site Inspection)

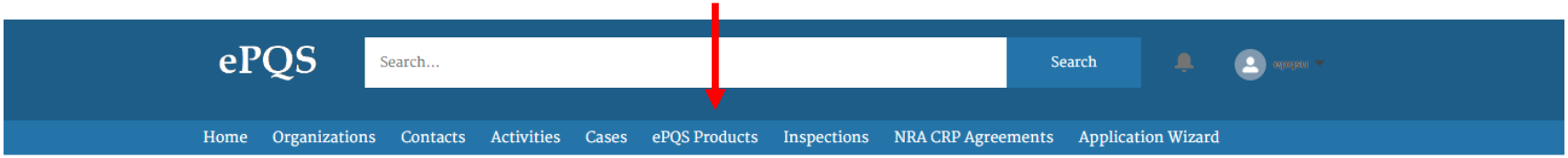
Date Onsite Inspection closed
26/05/2020

Onsite Inspection Comments

Final Inspection Outcome

Date Inspection Completed
26/05/2020

Target Re-inspection Date



ePQS Product
FPP Test Product

+ Follow | Printable View | Publish | Clone

Product Type	Applicant Organization	Date of Prequalification/Acceptance
Finished Pharmaceutical Product	ePQS Test Account 2 - NonStateActor	

Details | Related | Preview Document | Document Download

Information

WHO Product ID: FPP Test Product	Product Status: Prequalified
Product Type: Finished Pharmaceutical Product	Responsible team: Medicines Team
	Applicant Organization: ePQS Test Account 2 - NonStateActor
	Applicant Organization (Legal): ePQS Test Account 2 - NonStateActor
	Primary Contact: ePQS External Applicant 3
	Secondary Contact:
	Alternative Secondary Contact:

Original Application Dates

Date Application Accepted for Assessment: 09/01/2013

Product Dates

Date of Prequalification/Acceptance:

Contact
ePQS External Expert 1

+ Follow | New Note | Make Contact Info Private

Job Title	Account Name	Phone (2)	Email	Contact Owner
	ePQS Test Account 3		epqsuatenvironmentsanitytest@gmail.com	User16184741731295586380

Details | Related | Preview Documents | Download Documents | Preview Mx Documents | Download Mx Documents

Contact Information

Name: ePQS External Expert 1
Job Title:
Status:
Email: epqsuatenvironmentsanitytest@gmail.com
Phone:
Mobile:
Fax:
Gender:

Organization

Account Name: ePQS Test Account 3

Identity

Language:

Address Information

eCTD and PQ (Medicines and Vaccines)

- Electronic Common Technical Document
  - Used for the submitting regulatory information to the health authorities,
  - It provides a harmonized electronic means to submit documents,
  - Purpose to reduce the burden,
  - The Module 1 requirements have been posted on the WHO webpage,
  - The first webinar has occurred, and further webinars and industry clinics are planned as eCTD is implemented.

eCTD Transition phases

- Phase 1 (2024): optional eCTD submissions.
- Phase 2 (+1 year): Mandatory for new product applications.
- Phase 3 (+2 years): Mandatory all applications in eCTD.

The transition timeline to eCTD

We are currently in Phase 0.

Phase	APIMF/API-PQ Products | FPP Products | FVP Products
Phase 0	Companies should take time to familiarize themselves with WHO PQT requirements and prepare legacy dossiers or new product dossiers in this format.
Phase 1	Companies may voluntarily submit applications for new products in eCTD format. Companies may voluntarily submit Post-PQ Change applications to convert existing prequalified Product dossiers to

General user information can be found here -

https://extranet.who.int/prequal/ectd-portal

eCTD Portal

The Medicines and Vaccine assessment teams within the Prequalification Unit (PQT) are introducing an **eCTD facility** as part of the opening of the ePQS Portal

eCTD (electronic Common Technical Document) is a standard format for submitting Regulatory information (such as applications) to the Health Authorities, or in this case the Prequalification Unit. It provides a harmonized electronic means to submit in the Common Technical Document (CTD) of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) – www.ich.org

The purpose of introducing eCTD is to reduce the burden of document lifecycle management upon applicants and PQT, as well facilitating document review by assessors.

Submission of eCTD-based applications will occur via the ePQS portal.

Various reference documents to support companies to create an acceptable eCTD dossier are provided in the links below

Information pertaining to the practical steps aspects of submission are provided on the ePQS webpage

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Validation of eCTD submissions

Prior to the eCTD submission itself, WHO recommends the use of a validator to ensure that the content fully complies with regulatory requirements and is valid. The validator used should be up to date at all times; detailed validation reports also facilitate the creation of a correct submission.

One example of such a tool is EXTEDO's EURSvalidator. You can find more information here: https://www.extedo.com/software/submission-validation/eursvalidator

Links

Webinars

Implementing M1 for eCTD submissions submitted to the WHO Prequalification Unit (PQT) | EXTEDO (Register here)

This webinar will be recorded and posted.

Documents

eCTD - 2023 10 18 PQT Validation Criteria v 1.0
eCTD - FAQ WHO PQT
eCTD - WHO eCTD guidance for Industry
eCTD - WHO PQT eCTD checksums
eCTD - WHO PQT Technical Files
eCTD - WHO PQT Valid Values XML
eCTD - WHOPQT eCTD M1 Specification (Files-Elements-Folders)


Thank you
World Health Organization
WHO
20, Avenue Appia
1211 Geneva
Switzerland
www.who.int