

## eCTD Implementation at WHO (World Health Organization) PQT

The World Health Organization's (WHO) Prequalification Unit (PQT) is dedicated to ensure that medicines, vaccines, medical devices, vector control, and in vitro diagnostic products meet global quality, safety, and efficacy standards.

### Transition to eCTD

The introduction of eCTD aims to ease the burden of document lifecycle management while also streamlining the review process for assessors. The transition to eCTD will occur in phases:

Phase	APIMF/API-PQ Products   FPP Products   FVP Products
<b>Phase 1</b> April 2025	<ul style="list-style-type: none"> <li>Companies may voluntarily submit applications for new products in eCTD format.</li> <li>Companies may voluntarily submit Post-PQ Change applications to convert existing prequalified Product dossiers to eCTD.</li> </ul>
<b>Phase 2</b> April 2026	<ul style="list-style-type: none"> <li>Companies must submit applications for new products in eCTD format.</li> <li>Companies should submit Post-PQ Change applications to convert existing prequalified Product dossiers to eCTD.</li> <li>In addition, the FPP Requalification procedure will now be used as an opportunity to request a conversion of prequalified Product dossiers to eCTD.</li> </ul>
<b>Phase 3</b> April 2027	<ul style="list-style-type: none"> <li>Both new and legacy product dossiers must be in eCTD format for APIMFs, API-PQs and FVPs.</li> <li>Companies must submit applications for new FPP products in eCTD format. The FPP Requalification procedure will continue to be used to convert any remaining legacy Product dossiers to eCTD.</li> </ul>

- Applications undergoing assessment that are in non-eCTD format, should remain in non-eCTD format and be converted after the assessment has concluded.
- The Product must first be converted to eCTD format.
- Once a Product Dossier has been converted to eCTD, all future application documents must be in eCTD format.
- Conversion of a legacy Product dossier can be requested by filing a Post-PQ change application of type Conversion.

### ePQS Submission Portal

Submission of eCTD-based applications will occur via the 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