Performance, Quality & Safety

World Health Organization

WHO IMD-PQS Annual Review 2024
APPLICANTS – GENERAL INTRODUCTION

OVERVIEW

The IMD-PQS Annual Review is an annual activity aimed at collecting information on changes in prequalified products and manufacturers as well as data on performance.

IMD-PQS has widened its focus from a qualification process based on certificate and licence reviews, towards the improvement of products through manufacturing change transparency, CAPAs with more detailed failure reports and risk mitigation and certificate verification.

A **Pre-review** of submissions take place four weeks before the Annual Review (on, or shortly after the submission deadline). Should the manufacturer be required to provide further information or to complete documentation, they will be advised two-to-three weeks prior to the Annual Review.

GENERAL INSTRUCTIONS

"Applicant" refers to any product manufacturer or reseller of an IMD-PQS Prequalified Product.
The 2024 IMD-PQS Annual Review provides **two separate submission packages:**

1. **Manufacturer Submission Package** ("Manufacturer" is: meant in this context "Legal manufacturer", the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or product before it is placed on the market under their own name, regardless of whether these operations are carried out by that person themselves or on their behalf by a third party[1]).

OR

2. **Reseller Submission Package** ("Reseller" is: a commercial entity, licensed to act on behalf of a legal manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the legal manufacturer.)

Please carefully select the correct submission package that corresponds to your relationship with the prequalified product.

Both submission packages (for product resellers AND manufacturers) require the applicant to complete and submit a IMD-PQS **Company Review Form A** (CRF) and a IMD-PQS **Product Review Form(s) B** (PRF), as well as submit certified copies of requested mandatory documents by 15 March, 2024.

Reseller responsibility for manufacturer information: A product reseller is required to submit information and documents regarding the original product manufacturer. **The reseller is responsible** for contacting the product manufacturer to obtain the relevant information and documents.

[1] Definition derived from Article 1 2(f) of the EU Medical Device Directives

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Scope of submissions: Please **ONLY** submit the specific forms and documentation that is requested, and no additional documentation; submitting additional documentation slows down the review.

File naming conventions: All files must be provided with the following file name conventions : <Form name> <Category Number Product Number> For example: "**Form A E008_113**". Submissions provided with incorrect file naming will be returned.

IMPORTANT REMINDERS

Confidentiality:	All information provided by the manufacturer will be treated in the strictest confidence.
Completeness:	Applicants are reminded that incomplete submissions cannot be revalidated and will be pending further action. A checklist of required submission documents is included in the Applicant Declaration.
Licence/certificate renewal:	Applicants are requested to ensure business licences and manufacturing certificates are valid, are accompanied by a notarised translation and, when renewal is required, to ensure that valid documents are provided to the IMD-PQS Secretariat in line with the AR submission deadline.
Certification validation:	Applicants are reminded that they are obliged to provide a specific web-link to a certificate authentication page for each mandatory certificate. (A general web link is not sufficient.)
Applicant declaration:	Applicants are reminded of the requirement to sign and date the *Applicant Declaration* form in order to validate their submission. Products cannot be recommended for re-validation in the absence of this signature.
Taxonomy (E003):	Applicants are reminded that IMD-PQS requires that the product performance *Taxonomy* (released 2020) be used to report all performance failures of IMD-PQS prequalified products in category E003 – including as a part of the Annual Review requirement.
Fees payment:	Payment of the previous year's fee is also required for an Applicant to have its products re-validated in the subsequent AR. Payment of fees is verified.