



**PERFORMANCE, QUALITY & SAFETY (PQS)
STANDARD OPERATING PROCEDURE**

SOP N°: MHP/RPQ/PQT/VAX/PQS/009

Version n°: 01.06

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**HOW TO EVALUATE APPLICATIONS FOR PRODUCT
PREQUALIFICATION**

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Prequalification Team (PQT)		



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1. Purpose

All immunization-related [products](#) or [devices](#) in the following categories must *prequalified* before they can be added to the PQS database:

- E001: [Cold rooms, freezer rooms, and related equipment](#)
- E002: [Refrigerated vehicles](#)
- E003: [Refrigerators and freezers](#)
- E004: [Cold boxes and vaccine carriers](#)
- E005: [Coolant-packs](#)
- E006: [Temperature monitoring devices](#)
- E007: [Cold chain accessories](#)
- E010: [Waste management equipment](#)

A product can only be prequalified if it complies with the relevant PQS performance specification and with the related PQS product [verification protocol](#). This SOP describes the procedure for reviewing prequalification applications.

The procedures set out in this SOP will be followed by the *PQS Secretariat* (Secretariat), the *PQS Working Group* (WG) and by all *Technical Specialists* (TS) commissioned by the Secretariat.

2. Scope

This SOP is applicable to any product or device offered for prequalification through the PQS initiative.

3. Responsibility

Responsibilities and tasks will be assigned as follows.

The *PQS Working Group* (WG)¹ (at the direction of the *PQS Secretariat*):

- Reviews product application dossiers; and
- Makes recommendations to Secretariat.

¹ The PQS Working Group (WG) is comprised of the WHO (PQS and Expanded Programme on Immunization), the United Nations Children's Fund (UNICEF) Supply and Programme Divisions, the Gavi, the Vaccine Alliance Secretariat, specialist agencies, partner organizations and other key stakeholders. In an advisory capacity through the WG structure, these actors offer a wide range of programmatic and technical expertise that supports the development, introduction and advancement of technologies that will meet countries' EPI needs for high-quality cold chain equipment and devices.



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The *PQS Secretariat* (Secretariat)²:

- Receives dossiers from applicants, establishes and maintains a register that records the details of all applications for product prequalification;
- Convenes Working Group (WG) members and/or Technical Specialists (TS) to review dossiers;
- Reviews product application dossiers;
- Corresponds with applicants should any clarifications related to the application be required;
- Takes the final decision to approve or reject prequalified status for a product;
- Informs applicants (product manufacturers) of their decision; and
- Publishes approved products on the PQS website and circulates it to the relevant members of staff of WHO, UNICEF and manufacturers.

A *Technical Specialist* (TS):

- Reviews product application dossiers as directed by the Secretariat; and
- Makes recommendations to Secretariat.

4. Associated reference documentation

- WHO/BCT/03.09: Procedure for assessing the acceptability, in principle, of single-use injection devices for procurement by United Nations agencies.
- SOP No MHP/RPQ/PQT/VAX/PQS/010: How to re-evaluate a prequalified PQS product.
- SOP No MHP/RPQ/PQT/VAX/PQS/011: How to remove a prequalified product from the PQS database.
- SOP No MHP/RPQ/PQT/VAX/PQS/001: How to develop and publish a PQS product performance specification.
- SOP No MHP/RPQ/PQT/VAX/PQS/002: How to review and revise a PQS product performance specification.
- SOP No MHP/RPQ/PQT/VAX/PQS/003: How to withdraw a PQS product performance specification.
- SOP No MHP/RPQ/PQT/VAX/PQS/004: How to develop and publish a PQS product verification protocol.
- SOP No MHP/RPQ/PQT/VAX/PQS/005: How to review and revise a PQS product verification protocol.
- SOP No MHP/RPQ/PQT/VAX/PQS/006: How to withdraw a PQS product performance specification.

² The WHO PQS Secretariat is responsible for sharing up-to-date information on prequalified immunization devices and products, as well as product alerts. It ensures that the standards that apply to equipment maintenance, manufacturing and product testing are current. The Secretariat also coordinates product feedback reports and learnings from product field monitoring. The Secretariat holds ultimate responsibility for the PQS process and takes all final PQS decisions.

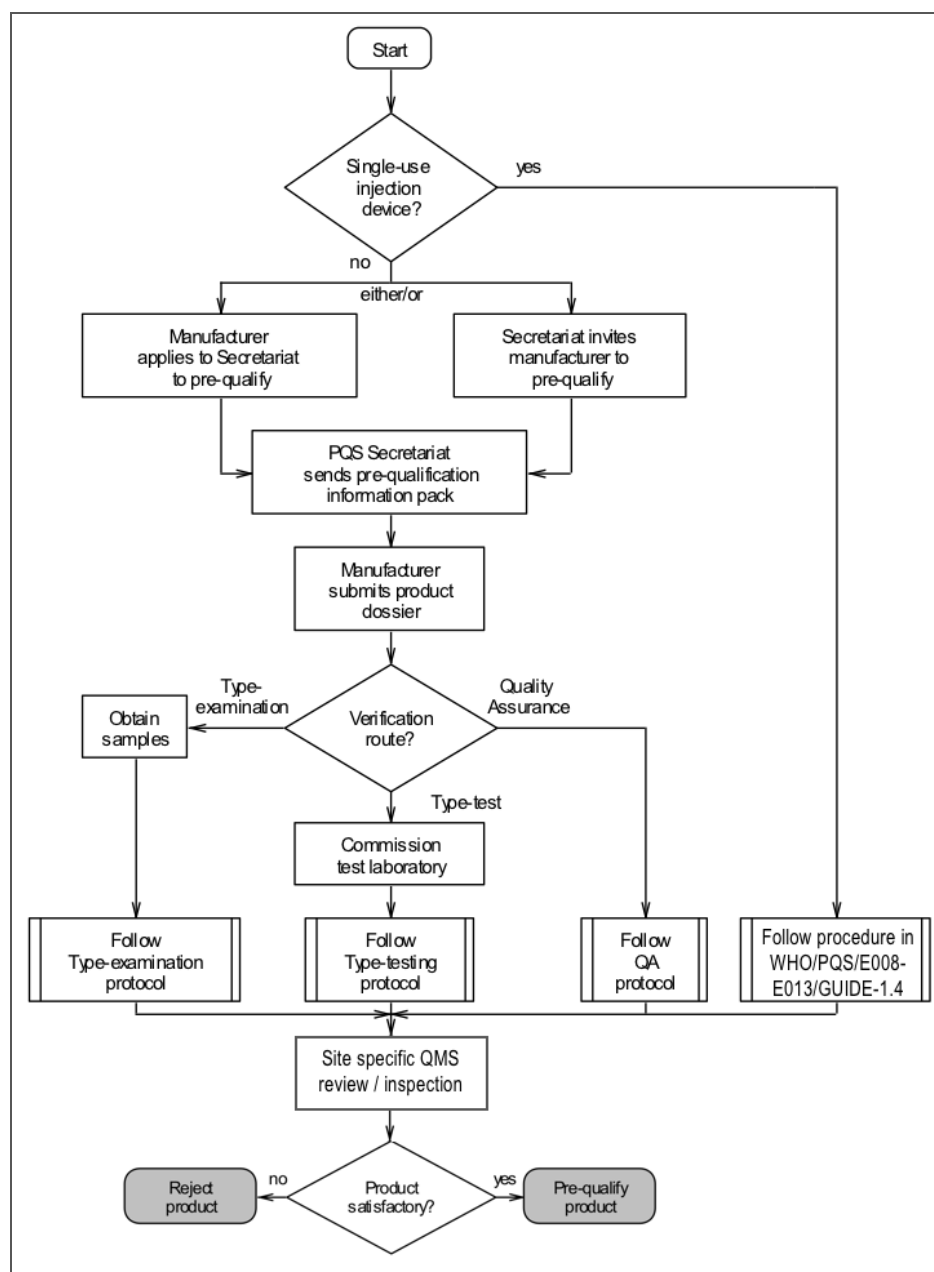


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5. Procedure

Each of the task headings below includes (in brackets) a description of the person or group responsible for the task. Figure 1 summarizes the prequalification process.

Figure 1 – Prequalification process





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5.1 Prequalification register

(Secretariat)

The Secretariat will establish and maintain a register which records details of every application for product prequalification. Copies of all [correspondence](#) with [manufacturers](#) will be kept in the register. The register will be organized according to the following hierarchy:

<PQS product category> : <manufacturer> : <product>

5.2 Cost recovery

(Secretariat)

In general, WHO will charge manufacturers only when products are prequalified. In exceptional circumstances, at the discretion of the Secretariat, a charge may be applied for dossier assessment even in the event of non-prequalification of a product³. The Secretariat will prepare and will maintain an up-to-date schedule of charges for this work, which will be sent out to all applicant manufacturers with the *prequalification information pack* (detailed in Annex 3).

5.3 Confidentiality

(Secretariat, WG, Evaluators)

WHO will treat all information to which they will gain access during the evaluation, or otherwise in connection with the discharge of their responsibilities in regard to the prequalification of PQS products, as confidential. WHO will require [evaluators](#) of product dossiers to likewise treat all information as confidential. In addition, the evaluators of product dossiers will be required to sign a Declaration of Interest. A sample of the confidentiality and Declaration of Interest undertaking for evaluators of product dossiers is attached in Annex 1. If, based on this Declaration of Interest, it is felt that there is no risk of real or perceived conflict of interest and it is thus deemed appropriate for evaluators to undertake this work, they will discharge their functions exclusively as advisers to WHO.

³ 'Exceptional circumstances' may include (but are not limited to), product applications in new product categories that include unique verification methods, or exceptionally large product applications that require significantly greater than average time to review and assess, irrespective of the application outcome.



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5.4 Single-use injection devices

(Secretariat)

All applications relating to single-use injection devices will be processed strictly in accordance with the procedure described in document WHO/BCT/03.09:

Procedure for assessing the acceptability, in principle, of single-use injection devices for procurement by United Nations agencies. As with other PQS products, copies of all correspondence with applicant manufacturers will be kept in the Prequalification Register.

5.5 Obtain applications

(Secretariat)

The Secretariat is responsible for obtaining prequalification applications. There are two ways in which this can be done:

1. An unsolicited application may be received directly from a manufacturer; or
2. The Secretariat may approach a potentially suitable manufacturer, [in writing](#) or by email, and formally invite him to apply for prequalification.

Standard letter A will be used as the basis for this approach (Annex 2).

5.6 Product dossier

(Manufacturer)

All manufacturers who seek prequalification will submit a product dossier to the Secretariat. This must contain all the required information and samples (where required) that are listed in the relevant PQS performance specification under the heading *product dossier*⁴. The Secretariat will screen the dossier for completeness before it is evaluated. If the dossier is incomplete, the manufacturer will be contacted in writing and will be given a single opportunity to provide the missing information or material. If, after a reasonable period has elapsed, the manufacturer fails to supply the missing information or sample, the dossier will be rejected.

⁴ See SOP No MHP/RPQ/PQT/VAX/PQS/001: *How to develop and publish a PQS product performance specification*. Annex 1, item 8.



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5.7 Evaluation

(Secretariat)

Product verification will be carried out in accordance with the route relevant to the product: either *type-examination*, *type-testing* or *full quality assurance*. In the case of type-testing, the manufacturer will nominate the independent testing laboratory which is to undertake the work. In the other two cases, the Secretariat will either carry out an in-house evaluation, outsource the work to an external evaluator, or form a group from the PQS Working Group. *Standard letter D* will be used for this purpose (Annex 5). If it is evident from the information set out in the dossier that the product will not be satisfactory, then there is no purpose in moving on to the testing stage. In such situations, use the rejection option set out in the standard letter. This option should only be used in cases where there is no doubt that the product will fail to comply.

5.8 Evaluation results

(Secretariat)

The Secretariat will monitor the evaluation process and will receive the evaluation results. If the results are *unsatisfactory*, the manufacturer will be notified in writing of the outcome of the evaluation and will be informed that the product is not suitable in its current form using. *Standard letter E* will be used as the basis for this (Annex 6). A copy will also be sent to UNICEF Supply Division. If the results are *satisfactory*, the Secretariat will approve prequalification of the product or device.

5.9 Approval process

(Secretariat)

The Secretariat (alone) takes the final decision to approve prequalification of a product or device, or not.

5.10 Publication

(Secretariat)

If the Secretariat *approves* prequalification, the manufacturer will be notified in writing of the outcome of the evaluation; they will be informed that the product has been granted PQS prequalification status and that it will be listed on the PQS database/catalogue. Copies of this notification will be sent to UNICEF Supply



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Division, filed in the Prequalification Register and filed in the Product Performance Register⁵. *Standard letter F* will be used for this purpose (Annex 7).

A new PQS website entry will then be created for the product, overwritten with the words:

NEW PRODUCT AS AT <DD.MM.YY>

The overwriting will remain on the website for a minimum period of six months, after which it will be deleted. Notification of the addition will also be posted on the TechNet-21 forum.

6. Distribution

(Secretariat)

This SOP is to be distributed to the following individuals and groups:

- PQS Secretariat,
- PQS WG,
- WHO Expanded Programme on Immunization (EPI),
- UNICEF Supply Division and UNICEF Programme Division,
- Each Technical Specialist commissioned to work on any aspect of the product prequalification process,
- All relevant manufacturers,
- PQS and TechNet-21 websites.

⁵ See SOP No MHP/RPQ/PQT/VAX/PQS/011: *How to remove a prequalified product from the PQS database* Clause 5.1.



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Annex 1: Provisions for evaluators of product dossiers within the scope of the evaluation procedure for PQS products

In the course of discharging your functions as an expert adviser to WHO under the attached Agreement for the Performance of Work (APW), you will gain access to certain information, which is proprietary to WHO or entities collaborating with WHO, including the manufacturers of the product(s) which need to be assessed as part of the prequalification evaluation procedure by WHO. You undertake to treat such information (hereinafter referred to as “the Information”) as confidential and proprietary to WHO or the aforesaid parties collaborating with WHO. In this connection, you agree:

- (a) not to use the Information for any other purpose than discharging your obligations under the above-mentioned APW; and
- (b) not to disclose or provide the Information to any person who is not bound by similar obligations of confidentiality and non-use as contained herein.

However, you will not be bound by any obligations of confidentiality and non-use to the extent that you are clearly able to demonstrate that any part of the Information:

- (i) was known to you prior to any disclosure by or on behalf of WHO (including by the manufacturer(s));
- (ii) was in the public domain at the time of disclosure by or on behalf of WHO (including the manufacturer(s));
- (iii) becomes part of the public domain through no fault of your own; or
- (iv) becomes available to you from a third party not in breach of any legal obligations of confidentiality.

You also undertake not to communicate your deliberations and findings and/or those of the team(s) of experts in which you will participate, as well as any resulting recommendations to, and/or decisions of, WHO to any third party, except as explicitly agreed by WHO.

You will discharge your responsibilities hereunder exclusively in your capacity as an expert adviser to WHO. In this connection, you confirm that the information disclosed by you in the Declaration of Interest is correct and that no situation of real, potential or apparent conflict of interest is known to you, including that you have no financial or other interest in, and/or other relationship with, a party, which:

- (i) may have a vested commercial interest in obtaining access to any part of the Information referred to above; and/or
- (ii) may have a vested interest in the outcome of the evaluation of the product(s), in which you will participate (such as the manufacturers of those products or of competing products).



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In connection with the above, it is noted that the manufacturer(s) of the products under assessment has (have) the right to object to your participation in the team(s) of experts which will evaluate its (their) product(s). If such objection cannot be resolved in consultation with the manufacturer(s), WHO shall be entitled to terminate this Agreement or cancel parts of the activities to be undertaken by you hereunder. In such event, any amount payable to you under the APW will be adjusted accordingly.

I hereby accept and agree with the conditions and provisions contained in this document.

Signed _____

Name (typewritten) _____

Institute _____

Place _____ Date _____

Annex 2: Standard letter A - Invitation to apply for prequalification

Dear Sirs,

Expression of interest for prequalification of a product or device under the PQS system.

WHO and UNICEF maintain a database of products and medical devices suitable for use in the worldwide Expanded Programme on Immunization (EPI). This database can be found at <web address>.

We are writing to you concerning <product description> which we believe may comply with the requirements of our performance specification <reference and web address>. If you are interested in offering this product for evaluation under the terms of the PQS system, please confirm this in writing and we will send you a prequalification information pack.

Yours faithfully,



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Annex 3: Standard letter B - Prequalification information pack

Dear Sirs,

Application for prequalification of a product under the PQS system: Prequalification information pack.

We refer to your letter dated <dd.mm.yy> in which you expressed an interest in offering <product/device description> for evaluation under the terms of the PQS system.

We now enclose a prequalification information pack. If, after reading this, you still wish your product/device to be evaluated against the enclosed product verification protocol, please supply us with a complete Product Dossier which contains all the information requested below, together with the Dossier Examination Fee of <currency><amount>.

We enclose the following:

- Performance specification <description and reference, including revision ref.>
- Product verification protocol <description and reference, including revision ref.>
- Details of the product verification process, including details of the Product Verification Fee.

Your product will be assessed against these documents. If the documents are subsequently amended to an extent which affects your prequalification status, then you will be invited to comment on the proposed changes to the performance specification and/or product verification protocol.

The Product Dossier must include the following:

- General information on the manufacturer or [approved installer](#) (including name, address and <licence, where relevant>

EITHER:

- Confirmation that you are either the legal manufacturer or a reseller licensed to act on behalf of the legal manufacturer, carrying product liability and warranty responsibilities no less onerous than those carried by the legal manufacturer.

OR:

- Confirmation that you are an approved installer, licensed for this purpose by the legal manufacturer(s) of each of the products that you are offering to install.
- All information listed in clause(s) <clause number(s)> of the attached performance specification.
- Indicative cost of the product per unit, <Incoterm> for <specify range numbers,



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e.g. 1-39 units>.

In addition, in order to evaluate the product/device we will require <detail the number of samples and all conditions relating to identification, packaging etc.> to be delivered free of charge to <address for delivery>. We also refer you to the general terms and conditions attached to this letter.

Yours faithfully,

TERMS AND CONDITIONS

- 1. Examination of dossier:** The Product Dossier will be screened by WHO for completeness prior to the evaluation of the dossier. The dossier can be rejected on grounds of incompleteness and returned to the manufacturer. Complete dossiers will be retained for evaluation purposes.
- 2. Dossier Examination Fee:** The Dossier Examination Fee is non-refundable and must be paid in full, in the specified currency, before the dossier can be formally examined by WHO.
- 3. Product Verification Fee:** The Product Verification Fee is non-refundable and must be paid in full, in the specified currency, before the evaluation process can commence.
- 4. Evaluation:** The WHO unit responsible for the evaluation will be independent from all UN agency procurement units. Every product, device or service will be evaluated against the relevant PQS performance specification and product verification protocol, current at the time of the evaluation. The manufacturer will receive a letter from WHO advising on the outcome of the evaluation process with regard to the specific product(s) of that particular manufacturer.
- 5. Meaning of prequalification:** The granting of prequalified status following the evaluation process indicates that the product, device or service is *technically* satisfactory for use in immunization programmes, subject to any limitations set out in the PQS website or catalogue.
 - However, the granting of prequalification status does not guarantee that an acceptable commercial arrangement can be reached between the supplier of the product, device or service and the purchaser; nor does it guarantee that the quality of the delivered product, device or service will be acceptable to the purchaser. In this context the word, 'purchaser', could cover more than one of the UN agency procurement units, including UNICEF, IAPSO, UNFPA, and WHO.
 - Furthermore, once granted, the ongoing maintenance of prequalified status is wholly dependent on the satisfactory fulfilment of a variety of post-



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prequalification procedures and requirements on the part of the product manufacturer, in addition to the absence of any serious defect reports (such as multiple product failures or repeated poor performance reports).

6. Maintaining prequalified status: Once granted, a products prequalified status will be maintained for 12-months or until the next annual review, without need for further testing as long as there and no major product changes, serious complaints or other faults and issues identified via post-market monitoring or PQS WHO quality management (QMS) investigations or any source validated by WHO. In this way, the PQS endorsement of the performance, quality and safety of all prequalified products available for procurement remains valid at all times. Re-evaluation of prequalified products may be required in any of the following cases:

- omission by the manufacturer in the initial evaluation procedure, or during the follow-up activities, is evident in relation to the requirements, including compliance with quality system standards and failure to notify complaints. If any batch or batches of supplied product(s) are documented by WHO, or one or more of the UN agencies or organizations, not to be in compliance with the agreed specifications of the product or to reveal failure(s) regarding safety, performance or quality of the device;
- the investigation or report of any product-related defects or performance complaint validated by WHO that concludes that the quality and/or safety of the product does not meet performance requirements.;
- the collection and analysis of equipment performance data from health centres and vaccine storage facilities
- planned or ad-hoc QMS inspections of manufacturing facilities reveal non-conformities with the ISO 9001 or ISO 13485 and/or the specific requirements of WHO specifications and verification protocols. Non-conformities will necessity the satisfactory implementation of corrective or preventive action plans (CAPAs) to avoid the removal of prequalified status.

In the absence of major changes, serious complaints or issues arising from PMM or QMS investigations, every prequalified product will be automatically reviewed once a year. Manufacturers will be required to communicate evidence of the annual renewal of any relevant licence and of any changes that may have an impact on the safety, performance, efficacy or quality of the product to WHO, or sooner should any change regarding manufacturing method, or manufacturing site be implemented by the manufacturer. However, the manufacturer must inform WHO of any contemplated changes to the product, changes in manufacturing process or manufacturing site.

7. Confidentiality undertaking: WHO will treat, and will require evaluators of product dossiers to treat all information to which they will gain access during the evaluation, or otherwise in connection with the discharge of their responsibilities in regard to the prequalification of PQS products as confidential. In addition, the evaluators of product dossiers will be required to sign a Declaration of Interest. A sample of the



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confidentiality and declaration of interest undertaking for evaluators of product dossiers can be obtained on request. If, based on this Declaration of Interest, it is felt that there is no risk of real or perceived conflict of interest and it is thus deemed appropriate for evaluators to undertake this work, they will discharge their functions exclusively as advisers to WHO.

8. The following disclaimer applies to all products that are accepted for inclusion on the PQS database.

Disclaimer: Inclusion in the PQS database does not constitute an endorsement, or warranty of fitness, of any product for a particular purpose, including in regard to its safe and appropriate use in immunization programmes. WHO does not furthermore warrant or represent that: 1) the database is complete or error free and/or that 2) the products that have been found to meet the standards recommended by WHO, will continue to do so and/or that 3) the products listed have obtained regulatory approval for use in every country of the world or that its use is otherwise in accordance with the national laws and regulations of any country, including but not limited to patent laws. In addition, WHO wishes to alert procuring UN agencies that the improper storage, handling and transportation of products may affect their quality, efficacy and safety. WHO disclaims any and all liability and responsibility for any injury, death, loss, damage or other prejudice of any kind whatsoever that may arise as a result of, or in connection with the procurement, distribution and use of products included in the list.



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Annex 4: Standard letter C - Request for missing information

Dear Sirs,

Application for prequalification of a product or device under the PQS system.
Your reference:

We refer to your letter dated <dd.mm.yy> with regard to <product/device description>, enclosing the Product Dossier requested in our letter dated <dd.mm.yy>.

We have now made a preliminary examination of the Product Dossier and find that the following material is missing:

- <list missing information, samples, etc.>

If we do not receive the missing items by <dd.mm.yy> we will have to reject your application. The Dossier will then be returned to you but we will not be able to return the Dossier Examination fee.

If you have any queries, please contact us as soon as possible.

Yours faithfully,



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Annex 5: Standard letter D - Evaluation notification

Dear Sirs,

Application for prequalification of a product or device under the PQS system.
Your reference:

We refer to your letter dated <dd.mm.yy> with regard to <product/device description>, enclosing the Product Dossier requested in our letter dated <dd.mm.yy>.

EITHER:

We have now made a full examination of the Product Dossier and confirm that we consider that the product is suitable for evaluation in accordance with the verification protocol attached to the Prequalification Information Pack. If you wish us to proceed with the evaluation please send us the Product Verification Fee in the sum of <currency><amount>. The verification will be carried out by <name of organization>.

If you have any queries, please contact us as soon as possible.

OR:

We have now made a full examination of the Product Dossier but regret to inform you that we do not consider the product/device is likely to meet the performance criteria set out in the verification protocol attached to the Prequalification Information Pack. The reasons for this are as follows:

- <list reasons>.

You are free to offer a new or modified product/device at any time in the future provided it complies fully with the requirements set out in the PQS performance specification and PQS verification protocol current at the time of re-submission.

We regret that we are unable to enter into any further correspondence on this matter.

Yours faithfully,



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Annex 6: Standard letter E - Rejection

Dear Sirs,

**Application for prequalification of a product or device under the PQS system.
Your reference:**

We refer to your application dated <dd.mm.yy> with regard to <product/device description>.

We have now received the results of the product/device evaluation and regret to inform you that we are unable to recommend the product/device for inclusion on the database of prequalified products, for the following reasons:

- <briefly list principle reasons>

We thank you for your application and enclose a copy of the evaluation report. You are free to resubmit a new or modified product/device at any time in the future provided it complies fully with the requirements set out in the PQS performance specification and PQS verification protocol current at the time of resubmission.

We regret that we are unable to enter into any further correspondence on this matter.

Yours faithfully,



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Annex 7: Standard letter F - Acceptance

Dear Sirs,

Application for prequalification of a product or device under the PQS system.

Your reference:

We refer to your application for prequalification dated <dd.mm.yy> concerning <product/device description>.

We have now received the results of the product/device evaluation and are pleased to inform you that <product/device description> has been recommended for inclusion on the database of prequalified products, devices and related services.

We enclose a copy of the evaluation report for your information. You will note that there are certain matters about which the evaluator(s) had concerns. These are as follows:

- <list any items that need to be drawn to the manufacturer's attention>

We hope that you will be able to deal with these matters by the time the product/device is re-evaluated in one year's time.

Finally, we draw your attention again to the terms and conditions set out in the prequalification information pack sent to you on <dd.mm.yy> which apply to all products, devices and services listed in the PQS database. Note particularly the requirement set out in the performance specification that you inform us of any future changes to the product or device specification or changes to the manufacturing site, and that you notify us of any product recalls, component defects and other events that may affect the product or device.

Yours faithfully,



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Annex 8: Terms and definition

Approved installer	A person or organization approved by the legal manufacturer or reseller as a competent installer of the system components and who has been appointed by the Employer to carry out the installation of the System.
Correspondence	Includes mail, fax and email.
Device	A medical device such as a syringe or temperature monitor for example.
Evaluator	An individual or organization (including a testing laboratory) responsible for evaluating the suitability of the components and services described in this specification for inclusion in the register of PQS prequalified products.
In writing	Communication by letter, fax or email. (A hard copy will be kept on file.)
Legal manufacturer	<p>The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party⁶.</p> <p>A legal manufacturer may commonly contract another company to manufacture products or devices sold under the legal manufacturer's name. A manufacturer that is contracted in this way is typically known as an Original Equipment Manufacturer, or OEM.</p>
Manufacturer	In the context of this SOP, the word manufacturer includes both legal manufacturers and resellers.
Product	In this document, where the word 'product' is used on its own, it includes device.
Reseller	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.

⁶ Definition derived from Article 1 2.(f) of the EU Medical Device Directives.



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Verification protocol	Describes in detail how the performance of a product or device will be tested or otherwise evaluated as part of the PQS product prequalification procedure. See SOP No. MHP/RPQ/PQT/VAX/PQS/004: <i>How to develop and publish a PQS product verification protocol.</i>
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Revision history

(form number MHP/RPQ/PQT/VAX/PQS/GEN/F002)

SOP Number:	MHP/RPQ/PQT/VAX/PQS/009	
Date of issue 1 st edition:	08/07/2004	
Date of issue 2 nd edition:	06/04/2018	
Revisions		
Date	Change and reason	Authorised by (Signature and Name)
06/01/2007	<ul style="list-style-type: none">• ATT team was changed to QSS team due to the reorganization in the IVB Department.• The code VML was changed to PQS in the SOP No.s for easy reference.• The person responsible for giving no-objection clearance for the specifications was identified as the QSS Coordinator.	Drafted by O. Afsar Approved by U. Kartoğlu
27/01/2017	<ul style="list-style-type: none">• Hyperlink to each PQS category added in the ‘Purpose’ clause.• Footnotes defining the PQS Working Group and the PQS Secretariat added in Clause 3.• PQS system structure simplified, removing FMWG, Steering Group. IVB/QSS is also renamed EMP/PQT. Revisions to this SOP reflect these changes (text and figures).• ‘Responsibilities’ clause revised to separate out specific responsibilities of key actors and to remove process	Drafted by P. Mallins Approved by I. Gobina



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	<p>elements.</p> <ul style="list-style-type: none"> • Footnote defining ‘Exceptional circumstances’ added in sub-clause 5.2. • Clause 6 ‘Distribution’ edited to include complete group of stakeholders. • ‘Terms & definitions’ moved to annex, revised, definitions updated in line with WG reviews of PQS glossary Feb 2018. • Removal of sub-clause 5.6 ‘Pre-qualification information pack’ 	
01/04/2020	<ul style="list-style-type: none"> • MVP/EMP/PQT is renamed MHP/RPQ/PQT/VAX throughout to reflect structural changes: (Vaccines & Immunization Devices Assessment Team (VAX), Prequalification Unit (PQT), Regulation and Prequalification Department (RPQ), Access to Medicines and Health Products Division (MHP) 	<p>Drafted by P. Mallins Approved by I. Gobina</p>