# HOW TO FIELD-TEST A PQS PRODUCT.

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<th>1st edition: 08/07/2004</th>
<th>Effective date</th>
<th>Revision date</th>
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<td>(For details see revision table)</td>
<td>08/07/2004</td>
<td>06/01/2007; 27/01/2017</td>
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<th>2nd edition: 06/04/2018</th>
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<td>06/04/2018</td>
<td>(none to date) 01/04/2020</td>
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**Authorised by:**
- I. Gobina
- P. Mallins

**Reviewed by:**

Prequalification Team (PQT)
Title: How to field-test a PQS product

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Commented [GH1]: I have added a revision history note for these updates – let me know if it’s ok. I’ve changed the edit date to today too.
1. Purpose

The purpose of PQS field studies is to ensure that devices and/or technologies perform according to the specifications when used in field settings, are acceptable to end-users and have no significant negative impacts on the health system.

Field testing will generally be mandatory for products with the following characteristics:

- Based on technology(ies) not previously employed in immunization or general health programmes in the developing world;
- Require creation of a new PQS equipment category;
- Consist of a new technology not previously PQS prequalified;
- Require a substantial PQS modification, such as a need for specific tests not covered in the current verification protocols;
- Require specific user training to be operated effectively;
- Risk being rejected by health workers or patients; and/or
- Product has an R&D history of technical failures.

In addition, field testing may also be justified for products which are safety-critical or which are used in very large quantities.

Field-testing provides manufacturers with information to improve product design and it can also help end-users to choose products that are best suited to their needs. However, if test results are to be useful, there must be a completely clear understanding of the purpose to which they will be put. This requires well-developed evaluation techniques and protocols based on standardised criteria. The aim must be to obtain the maximum amount of useful information on product performance at minimum cost and with minimum disruption to the working lives of health care staff.

This SOP outlines some field-testing methods, indicates which of these is suitable for testing the various categories of immunization-related equipment and gives guidance on the development of field-test protocols. It also establishes the administrative framework within which a PQS field-test should take place. This will require the active cooperation of national EPI programme managers, as well as the assistance of technical staff in WHO/UNICEF country and regional offices.

The procedures set out in this SOP will be followed by the PQS Secretariat (Secretariat), the PQS Working Group (WG), by all product manufacturers, implementing partners and Ministries of Health (MoH) involved in field testing a PQS product.
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2. Scope

This SOP is applicable to all field-tests of products carried out under the PQS initiative.

3. Responsibility

PQS-required field studies are the responsibility of manufacturers. The PQS Secretariat (Secretariat) and/or individual members of the PQS Working Group (WG) may, in specific exceptional circumstances, fund studies.

Responsibilities and tasks will be assigned as follows.

The PQS Secretariat (Secretariat):
- Maintains a prioritised list of product types which justify field-testing and recommends appropriate field-tests for each of these types;
- Determines, if a product requires field testing as part of the prequalification process including, if required consultation with the Working Group (WG);
- Approves a protocol and/or implementing partner;
- Reviews field studies proposals and field test reports;
- Examines the proposals in liaison with the Working Group (WG) if deemed appropriate and, if satisfied of the need, directs that a model field-testing protocol be commissioned; and
- Stores field test reports in the product dossier.

The product manufacturer:
- Commissions a field test protocol;
- Identifies implementing partner;
- Funds the field test; and
- Obtains country approvals for the field study.

1 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, including the decision to award prequalified status to a product or device.

2 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.
The implementing partner(s):
- Remains independent and impartial.

The Ministry of Health (MoH):
- Approves the field test protocol; and
- Provides required access for the implementing partner.

4. Associated reference documentation
- SOP No MHP/RPQ/PQT/VAX/PQS/013: How to obtain feedback on the performance of a PQS product.
- 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/003: How to develop and publish a PQS product verification protocol.
- Product performance specification relating to the product(s) under test.
- Product verification protocol relating to the product(s) under test.

5. Procedure
Obtaining good quality information on product performance in the field is a challenge. There are two generic methods that can be used to field-test PQS products: field surveys and real-time instrumentation. In addition, there is a tailor-made field-survey based tool which has been specifically designed to evaluate the ease of use of AD syringes³.

Figure 1 indicates the strengths and weaknesses of each of these three methods.

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## Figure 1 – Field-testing techniques

<table>
<thead>
<tr>
<th>Method</th>
<th>Strengths</th>
<th>Weaknesses</th>
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<tbody>
<tr>
<td>Field-survey</td>
<td>• Can produce statistically reliable, quantitative results.</td>
<td>• Can be time consuming and expensive to administer.</td>
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<tr>
<td></td>
<td>• Able to capture multi-dimensional factors, including user behaviour.</td>
<td>• Dependent on skills and motivation of the survey team.</td>
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<tr>
<td>MSF/WHO tool for the assessment of single use injection devices</td>
<td>• Well-researched product-specific tool.</td>
<td>• Does not yet ensure with certainty ‘reproducibility over time’.</td>
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<tr>
<td></td>
<td>• Satisfactory internal consistency.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Can produce quantitative results.</td>
<td></td>
</tr>
<tr>
<td>Real-time instrumentation</td>
<td>• Relatively cheap to administer.</td>
<td>• Narrowly focused on a specific indicator.</td>
</tr>
<tr>
<td></td>
<td>• Provides accurate and complete quantitative records.</td>
<td>• Cannot directly capture user behaviour.</td>
</tr>
<tr>
<td></td>
<td>• Enables continuous monitoring to take place over extended time periods.</td>
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Figure 2 indicates which of the three techniques may be appropriate for the various categories of equipment on the PQS database. This model may not fit all future PQS categories.

**Figure 2 – Field-testing techniques for different categories of equipment**
<table>
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<tr>
<th>SOP No</th>
<th>MHP/RPQ/PQT/VAX/PQS/012</th>
<th>Date of issue 2nd edition: 06/04/2018</th>
<th>Revision date 2nd edition: (none to date) 01/04/2020</th>
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<td>Effective date 2nd edition: 06/04/2018</td>
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Figure 3 outlines the overall field-testing procedure which is described in more detail in Section 5.1 onwards.
Figure 3 – Developing a field-test protocol and implementing a field-test

- **Start**
  - Product review
  - Prepare/review model test protocol
  - Protocol approved by Secretariat

- **WG**
  - Technical Specialists
  - Peer reviewers

- **Secretariat**
  - Manufacturers
  - Other action before publication

- **Publish test report**

Commented [GH6]: Alongside redrawing this one I have deleted figure 4 entirely that was below as it duplicated many of these steps and was now its purpose was not clear. Here is figure 4; let me know if there is anything from it that you think should be included in figure 3 here, and/or if you think we still need a figure 4?
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[Diagram with flowchart steps]

- Start
- Identify products for field-testing
  - ACTIVATOR BY:
    - Secretariat
- Identify the geographical location(s) for the field test
  - ACTIVATOR BY:
    - Manufacturer, Implementing partner
- Prepare/review model field-test protocol
  - ACTIVATOR BY:
    - Manufacturer, Implementing partner, Technical specialists, Working Group
- Secretariat approval of field-test protocol
  - ACTIVATOR BY:
    - Secretariat
- Secure authorizations & ethical clearances
  - ACTIVATOR BY:
    - Manufacturer, Implementing partner, Government
- Identify regional/country office & government field test liaisons
  - ACTIVATOR BY:
    - Government, Implementing partner
- Carry out field test & report results
  - ACTIVATOR BY:
    - Working Group, Manufacturer
- Peer review test results
  - ACTIVATOR BY:
    - Working Group, Manufacturer
- Secretariat receives and approves test results report
  - ACTIVATOR BY:
    - Secretariat
- Publish test report
  - ACTIVATOR BY:
    - Secretariat
5.1 **Identify products for field-testing**  
(Secretariat)

In the course of its liaison with the *Working Group* (WG) and *Technical Specialists* (TS) on new and revised PQS performance specifications and product verification procedures, the Secretariat will decide whether field-testing of a specified product is relevant or desirable.

Based on these discussions, the Secretariat will draw up and maintain a *field-testing list*. This list will prioritise product types for which field-testing is either mandatory or desirable and will specify the appropriate generic testing method for each product type (see Figure 1).

The Secretariat will also maintain a watching brief on the product feedback reports that are posted on the PQS website, and may subsequently amend the list to take account of evidence received from the field.

Field testing will generally be mandatory for products with the following characteristics:
- Based on technology(ies) not previously employed in immunization or general health programmes in the developing world;
- Require creation of a new PQS equipment category;
- Consist of a new technology not previously PQS prequalified;
- Require a substantial PQS modification, such as a need for specific tests not covered in the current verification protocols;
- Require specific user training to be operated effectively;
- Risk being rejected by health workers or patients; and/or
- Product has an R&D history of technical failures.

In addition, field testing may also be justified for products which are safety critical or which are used in very large quantities.

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6 See SOP No MHP/RPQ/PQT/VAX/PQS/013: *How to obtain feedback on the performance of a PQS product*. 
5.2 Identify the geographical location(s) for the field test

With support from WHO PQS and possibly WHO and UNICEF regional offices, the manufacturer and implementing partner agree on a country or countries in which the field-test will be carried out.

5.2.3 Prepare model field-test protocol

Under normal circumstances the product manufacturer will fund the cost of the field-test. The manufacturer will proceed with the support of the implementing partner, and collaborating with the Ministry of Health in the selected location(s), to prepare the protocol. Specific testing sites are identified in this step of the process (details will be included in the test report).

A generic format for a protocol document is provided in the ‘Generic Guide for Field Evaluation’ (Section IV), which can be accessed at http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/catdocument.aspx?id_cat=17. Using the model field-test protocol as a basis, field staff will prepare a setting-specific field-test protocol. Changes to the model document will be confined to those aspects that have been left ‘open’ to suit test-setting conditions. NO changes will be made to the basic test design or to the method of data analysis without the agreement of the WG. A copy of this document will be annexed to the test report.

5.3.4 Peer review model field-test protocol

The Secretariat will arrange for the field-test protocol to be reviewed by technical specialist and the PQS Working Group. Once a consensus has been reached between the TS and the other reviewers, the protocol will be submitted to the
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Secretariat for formal approval. The Secretariat will decide which products most urgently need to be tested and will prioritise their review by the WG.

5.4 Organize and carry out field-test

(Government, manufacturer, implementing partner, Government).

The manufacturer and implementing partner work with the Ministry of Health to secure the relevant authorizations and ethical clearances for the field test and identify the relevant organizations to help carry out the testing.

Once the relevant country’s(ies) authorisation (including ethical clearance as appropriate) has been obtained, the regional/country office(s) will nominate and brief counterparts who will liaise with field staff during the testing programme. In addition, the regional/country office(s) will provide the Secretariat with the names(s) of the government counterpart(s). Standard letter D can be used for this (Annex 5).

In the standard situation where the test is funded in whole by industry, a copy of the test protocol, the work programme and budget should be shared with Secretariat.

5.6 Carry out field-test

(Government, Implementing partner).

In collaboration with implementing partners, Government field staff will conduct the field-test in accordance with the approved setting-specific field-test protocol. The Secretariat will liaise with product manufacturer(s), member government(s), UNICEF and/or WHO regional offices, consultant(s) and to agree funding and set up the field test.

Figure 4 outlines the process.
Figure 4—Finalise test protocol and carry out field-test

1. List with product manufacturer
2. Agree geographical setting for test
3. Prepare budget and secure manufacturer's or other funding to carry out test
4. Contract with UNICEF and/or UN/UNICEF regional office(s)
5. Obtain host government authority to conduct test including ethical clearance as appropriate
6. Nominate and brief Government/agency counterparts
7. Appointment(s) required?
   a. Yes, consult with Government/agency field staff
   b. No
8. Finalise location of field test
9. Prepare setting-specific field test protocol
10. Conduct field test
11. Report results
In the normal situation where the test is funded in whole by industry, a copy of the test protocol, the work programme and budget should be shared with Secretariat.

5.4.1 **Nominate and brief counterparts**

(Manufacturer, implementing partner)

Once the relevant country’s authorisation (including ethical clearance as appropriate) has been obtained, the Secretariat will ask the regional/country office(s) to nominate and brief the counterparts who will liaise with field staff during the testing programme. In addition, the regional/country office(s) will provide the Secretariat with the names(s) of the government counterpart(s). **Standard letter D** can be used for this (Annex 5).

5.4.2 **Finalise test locations**

(Manufacturer, implementing partner):

The appointed field staff will liaise with government and agency counterparts and, where relevant, with manufacturer(s) to finalise the test locations. Details will be included in the test report.

5.4.3 **Prepare setting-specific field-test protocol**

(Field staff, WG, manufacturer)

Using the model field-test protocol as a basis, field staff will prepare a setting-specific field-test protocol. Changes to the model document will be confined to those aspects that have been left “open” to suit test-setting conditions. **No changes** will be made to the basic test design or to the method of data analysis without the agreement of the WG. A copy of this document will be annexed to the test report.

5.4.4 **Conduct the field-test**

(Field staff)

Field staff will conduct the field-test in accordance with the setting-specific field-test protocol.
5.4.5 Report results

In collaboration with implementing partners, Government field staff will prepare a test report and submit it to the Secretariat for peer-review within two weeks of leaving the field. The layout of the report will be as specified in the model field-test protocol.

5.5.8 Peer review

The test report will be sent to the WG and the product manufacturer(s) for peer review, before it is submitted to the Secretariat for the final approval process. A minimum of two reviewers will be members of the WG. All review comments will be documented.

5.6.9 Approval

PQS is responsible for the review of a device or product that has been submitted for prequalification and the Secretariat (alone) is responsible for its approval.

(Note: there may be cases where a field-test report raises important policy-related issues. In such circumstances, the Secretariat may require further corroborative testing or may instruct other action before the test report can be published. On the other hand, if only minor changes are required, the Secretariat will arrange for these to be made.)

5.7.10 Publication

Test reports will be published electronically in .pdf format on the PQS website. A copy of the final report will also be sent to the product manufacturer(s).
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.
Annex 1: Terms and definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Device</td>
<td>A medical device such as a syringe or temperature monitor for example.</td>
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<tr>
<td>Evaluator</td>
<td>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.</td>
</tr>
<tr>
<td>In writing</td>
<td>Communication by letter, fax or email. A hard copy will be kept on file.</td>
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<tr>
<td>Legal manufacturer</td>
<td>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 party.</td>
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<tr>
<td></td>
<td>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.</td>
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<tr>
<td>Manufacturer</td>
<td>In the context of this SOP, the word manufacturer includes both legal manufacturers and resellers.</td>
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<tr>
<td>Product</td>
<td>In this document, where the word ‘product’ is used on its own, it includes device.</td>
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<tr>
<td>Reseller</td>
<td>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.</td>
</tr>
<tr>
<td>Verification protocol</td>
<td>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: How to develop and publish a PQS product verification protocol.</td>
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7 Definition derived from Article 1 2.(f) of the EU Medical Device Directives.
Title: How to field-test a PQS product

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

SOP Number: MHP/RPQ/PQT/VAX/PQS/012

Date of issue 1st edition: 08/07/2004
Date of issue 2nd edition: 06/04/2018

Revisions

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<td>06/01/2007</td>
<td>• ATT team was changed to QSS team due to the reorganization in the IVB Department.</td>
<td>Drafted by O. Afsar Approved by U. Kartoğlu</td>
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<tr>
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<td>• The code VML was changed to PQS in the SOP No.s for easy reference.</td>
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<td>• The person responsible for giving no-objection clearance for the specifications was identified as the QSS Coordinator.</td>
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<tr>
<td>27/01/2017</td>
<td>• Footnotes defining the PQS Working Group and the PQS Secretariat added in Clause 3.</td>
<td>Drafted by P. Mallins Approved by I. Gobina</td>
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<td>• 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).</td>
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<td>• ‘Responsibilities’ clause revised to separate out specific responsibilities of key actors and to remove process elements.</td>
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<td>• Clause 6 ‘Distribution’ edited to include complete group of stakeholders.</td>
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<td>• ‘Terms &amp; definitions’ moved to annex, revised, definitions updated in line with WG reviews of PQS glossary Feb 2018.</td>
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<td>• Sub-clause 5.4 ‘Organize and carry out a field-test’ simplified: notably the field-</td>
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- Test preparation phases. Field-test is responsibility of manufacturer. Replaced with references to ‘Generic Guide to Field-testing’ where relevant.

- MHP/RPQ/PQT/VAX is renamed MVP/EMP/PQT 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))

- Edits to the field test process steps to reflect current practice and stakeholder responsibilities.