Validation Toolkit

Operational and Performance Qualification

To facilitate testing and acceptance, medAspis offers a Validation Toolkit. It contains templates to verify and document the Operational and Performance Qualification (OPQ). This is used to verify that the medAspis FMD service operates correctly and contains all standard functionalities and options specified in the functional and design specification. In addition, this document is to verify that all user requirements specifications are correctly implemented in terms of functionality.

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General

Purpose and scope

This Operational and Performance Qualification (OPQ) contains the test scripts to verify and document that the medAspis FMD Service is correctly operating and contains all the functionalities and options as stated in the Functional and Design Specification. Also, this document is to verify if all functionality is correctly implemented.

Test procedure

For each step, the actual result (Pass/ Fail) must be completed with a Pass, only if actual result exactly matches relevant expected result, described in the "Acceptance Criteria" relevant column; otherwise "FAIL" box must be documented.

For each action whose result box is "FAIL", this needs to be logged as a deviation in the deviation log.

Provide screenshots where required and attach to the protocol. All attachments must be recorded in the attachment log.

Any correction to the written information must be crossed off with a single line, signed and dated by the person performing the correction. All entries must be recorded legibly applying good documentation practices. Any findings and comments are summarized as appropriate in the dedicated sections of the test scripts. Deviations from the protocol are recorded according to the deviation management. All the unwritten parts of the forms should be barred, signed, and dated by a team member.

When all the actions reported in the Test Script have been performed, Testing Team members must define the test result (Passed/Failed) in the dedicated section (Actual Result) of the Test Script, checking the corresponding box, "PASS" or "FAIL".

The evaluation is based on the passed/failed tests, the original objectives and related acceptance criteria. The Review Team identifies the risks that may be associated with non-conformances or failures that were encountered.

Following general acceptance criteria must be met to consider each Testing phase successfully completed:

- All required verifications have been performed and all corresponding attachments are completed.
- All deviations have been adequately resolved and approved.

Deviations

In the case of negative result for a test action, an entry is made in the Deviation Log. The Quality Manager will file the Deviation, with a brief description and the definition of proposed Corrective Actions aimed to solve the occurred deviation. Deviations should be coded. The classification of the deviation is as follows:

Impact	**Description**
Critical	A deviation which affects critical functionality or critical data. Such deviation inhibits the execution of the testing and requires immediate definition, root cause, implementation and testing of corrective actions.
Major	Not critical deviation which affects major functionality or major data. Such deviation does not inhibit the execution of the testing and it requires the definition of suitable corrective action plan with a high priority timeline and follow up actions to be defined within validation Report
Minor	A deviation which cannot be classified as either critical or major. It affects minor functionality or non-critical data and may only be a formal issue. Such deviation does not inhibit the execution of the testing and it requires the definition of suitable corrective action plan with a low priority timeline defined within validation Report.

Acceptance Criteria

The following general criteria apply to the acceptance of the testing:

- All tests have been executed and all corresponding test scripts and/or data collection sheets have been filled out, reviewed for accuracy, and approved.
- All deviations (if any) have been identified, documented, and resolved.
- All individual test acceptance criteria are met, or deviations have been researched, resolved (including retesting, if necessary), and documented.
- The executed scripts have been reviewed and approved by Test Reviewers and QA.

Prerequisites

The following items need to be in place when executing this test protocol:

- The tester needs to have a common knowledge of the medAspis Lean FMD system
- A FMD Speed Scanner device is connected to the medAspis Lean FMD system
- The system is connected to a NMVS and certified. Scans are responded by the NMVS
- Test medicine packs with 2D matrix codes are available (at least 5)

- Access to the Acceptance environment is in place
- The Acceptance environment is an empty test account in the actual production system

Please be informed that during this verification, the medicine packs may become unusable for further use. Status changes are made which can no longer be reversed. The medicine packs are then no longer usable for dispense. This is pointed out at the appropriate places.

During this verification, FMD operations are performed that cause alert messages. These messages may be forwarded to the NMVO and the competent authorities. An explanation may be requested for these messages. Use this document to explain the issues.

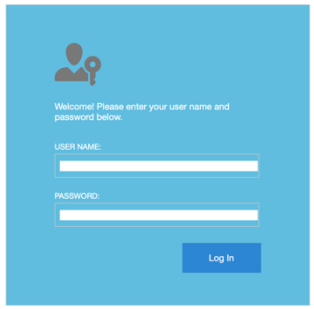
International Translations

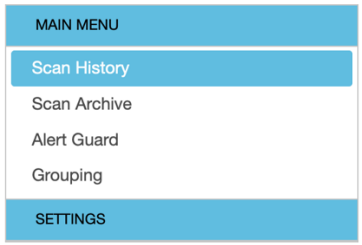
All texts translated for international versions (German, French, Dutch, Spanish, Polish and Romanian) are marked in a light blue. The translations are found in the attachment 'Language Translation Table'. For all screenshots international versions are available, too.

Operational Qualification FMD Service

1. The General Setup of the Control Panel

In this section the general access to the system is described. The medAspis Lean FMD system is web based. You can access the system by typing https://panel.medaspis.org in your browser.

Step	Action	Expected result	Actual Result
1.01	Log in to the system through https://panel.medaspis.org through Google Chrome. Make sure rights are allocated to the tester as being a wholesaler.	The login screen appears: 	☐ Pass ☐ Fail
1.02	Log out and enter the URL in each of the following browsers: - Safari - Google Chrome - Firefox	Also with Safari, Google Chrome, and Firefox the login screen appears, and the system can be accessed.	☐ Pass ☐ Fail

Step	Action	Expected result	Actual Result
1.03	Log in and enter the Control Panel. The menu is visible.	The following menu is available on the left side:  Depending on version ordered, the 'Grouping' or the 'Alert Guard' may not appear.	☐ Pass ☐ Fail
1.04	Click on each item of the menu.	Clicking on every menu item (except Scan History) shows a different screen.	☐ Pass ☐ Fail
1.05	Click on the three lines next to the medAspis logo in the top row of the browser content. 	The menu appears and disappears to reserve more space for the content.	☐ Pass ☐ Fail