Table of Contents

1. Purpose

1.1. The purpose of this document is to outline the process at Hyfe which confirms by examination and provision of objective evidence that software and hardware specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled.

2. Scope

2.1. The scope of this document applies to Hyfe and the medical device products requiring validation.

3. References

3.1. Internal

3.1.1. Insert all internal documents that are referenced within this document, this may be procedures, work instructions, forms, templates etc.

3.2. External

3.2.1. ISO 13485, Medical Devices Quality Management Systems Requirements for Regulatory Purposes

3.2.2. 21 CFR Part 820, Quality System Regulation

3.2.3. IEC 62304:2006+A1:2015 Medical Device Software – Software Life-Cycle Processes

3.2.4. FDA Guidance, Design Control Guidance for Medical Device Manufacturers

3.2.5. FDA Guidance, Software as a Medical Device (SAMD): Clinical Evaluation

3.2.6. FDA Guidance, General Principles of Software Validation; Final Guidance for Industry and FDA Staff

3.2.7. IEC 82304-1, Health Software - General Requirements for Product Safety

4. Abbreviations/Definitions

Abbreviation/Term	**Full-Form/Definition**

QARA	Quality and Regulatory Affairs
DHF	Design History File

5. Roles & Responsibilities

5.1. Validation Team Lead / Chief Data Officer

5.1.1. Assign qualified team members to perform validation activities.

5.1.2. Review and approve all design validation related documents.

5.1.3. Ensure validation activities are independently reviewed.

5.2. Project Management

5.2.1. Ensure that a validation team member is elected for each project.

5.2.2. Ensure that design and process freeze execution is communicated to the applicable validation team member when required.

5.3. QARA

5.3.1. Ensure that all validation plans, protocols, reports and summary reports are approved and stored within Dot Compliance.

5.3.2. Support with Validation documentation related to the Design History File (DHF).

5.4. Product Management

5.4.1. Support the validation team in interpreting user needs and feature design requirements into test cases.

5.5. Independent Reviewer

5.5.1. Review validation activities independently after validation activities have taken place.

5.5.2. Have adequate knowledge of validation activities to confirm these activities are completed competently.

5.5.3. The independent reviewer may be a QARA team member.

6. Process

6.1. General

6.1.1. Team members performing validation shall be trained on this procedure and have relevant qualifications to do so.

6.1.2. The user and product requirements associated with a project shall be used as the baseline for validation activities.

6.1.3. Hyfe should perform a mixture of testing methods and techniques to support a robust validation program, these testing methods could be based on the following examples:

6.1.3.1. Development environment

6.1.3.2. Application

6.1.3.3. Size of project

6.1.3.4. Language

6.1.3.5. Risk etc.

6.1.4. Validation should be based on the software's complexity and safety risk classification.

6.1.4.1. For lower risk devices, only baseline validation activities may be conducted.

6.1.4.2. As the risk increases additional validation activities should be conducted to align with the safety risk classification.

6.1.5. Validation ensures that both the user and product requirements have been met. Ensuring regulatory compliance, patient safety & security and user satisfaction.

6.1.6. All validation activities shall have an independent review (independent of the validation but have sufficient knowledge to review the validation) for adequate reviews.

6.1.7. Clinical evaluations are planned, performed and recorded as per HYF1-015-001, Clinical Evaluation and Investigation.

6.1.8. Validation records shall be maintained and stored within Dot Compliance.

6.1.9. For process validation, refer to HYF1-025-001, Process Validation.

6.1.10. For software equipment and tools validation, refer to HYF1-026-001, Qualification and Validation.

6.2. Validation Planning

6.2.1. Validation Plan

6.2.1.1. Hyfe shall create a validation plan during this stage, this should be based on the user and product requirements and how to effectively evaluate the performance of the product.

6.2.1.2. A plan may be created for each algorithm or feature of a product if applicable.

6.2.1.3. This plan shall include the following (if an item is not applicable justification shall be provided):

6.2.1.3.1. Identify validation scope and corresponding validation activities,

6.2.1.3.2. Identify constraints that potentially limit the feasibility of validation activities,

6.2.1.3.3. Select appropriate validation methods, input information, and associated acceptance criteria for successful validation,

6.2.1.3.4. Identify the enabling system or services such as operating environment(s), including hardware and software platforms needed to support the validation,

6.2.1.3.5. Specify the required qualification of the validation personnel; where training is required, this shall be completed before starting the validation,

6.2.1.3.6. Define the appropriate level of independence of the validation team from the design team.

6.2.1.3.7. Statistical techniques with rationale for sample size

6.2.1.3.8. The version of software used for the validation shall be detailed within the plan and report.

6.2.2. Algorithm or software system final version shall be released to the validation team from the R&D team.

6.2.3. Once the following have been completed the validation will move into the execution phase:

6.2.3.1. Validation plan established and released within the QMS,

6.2.3.2. A validation team has been set up with appropriately qualified personnel.

6.2.4. Hyfe shall utilize template HYF3-019-001, Software Design Validation Plan Template for Validation plans.

6.3. Validation

6.3.1. Execution of Validation

6.3.1.1. The validation shall be performed as per the validation plan.

6.3.1.2. Where deviations from the plan are performed, this shall be recorded within the validation report or summary validation report.

6.3.1.3. For validation associated with a project, the project manager shall have confirmed a design freeze and validation shall begin after Design Review 4 has been executed, refer to HYF2-010-001, Design Review Work Instruction.

6.3.1.4. Validation activities may also occur parallel to design as per Hyfe's agile approach to design, however the final validation shall only take place after design review 4.

6.3.1.5. Validation activities conducted shall be documented within the relevant design review meeting minutes.

6.3.2. Defects/Issues

6.3.2.1. Hyfe shall use HYF1-031-001, Software Problem Resolution to record and monitor defects/anomalies found within the validation if applicable.

6.3.2.2. Where a defect doesn't meet validation test criteria the validation should be documented in the report and reviewed during a design review to resolve the issue.

6.4. Post Validation

6.4.1. Validation Report

6.4.1.1. A validation report shall be created for each validation completed; the report shall include:

6.4.1.1.1. Date and individual performing the validation's signature,

6.4.1.1.2. The validation conditions,

6.4.1.1.3. Results of the validation activities,

6.4.1.1.4. Any anomalies identified during the validation,

6.4.1.1.5. List members of the validation team,

6.4.1.1.6. Summary of the results,

6.4.1.1.7. The conclusion that the product is validated for the intended use based on user or product requirements.

6.4.2. The validation report shall provide evidence that:

6.4.2.1. The validation results are traceable to the user or product requirements taken as an input

6.4.2.2. The product meets the user or product requirements established

6.4.2.3. The residual risk of the product remains acceptable.

6.4.3. Hyfe shall utilise HYF3-019-003, Software Design Validation Report Template for Validation reports.

6.4.4. If there is only one feature, then only one validation report may be produced. If there is more than one feature/algorithm then a Summary Validation Report.

6.4.5. Summary Validation Report

6.4.5.1. Once all validation reports have been completed for a particular product/device, a summary validation report shall be created.

6.4.5.2. This report shall summarise the conditions, results and any other information detailed within each validation report.

6.4.5.3. The summary report shall be included within the applicable design history file (DHF).

6.4.6. The summary validation report shall reference all applicable validation reports completed.

6.5. Validation of Design Changes

6.5.1. When a change is made to the product the validation status of the software needs to be reviewed and if required, re-established.

6.5.2. Whenever software is changed, an analysis should be conducted not just for verification of the individual change, but also to determine the extent and impact of that change on the entire software system or product.

6.5.3. Design Changes during design (before design transfer) shall be managed through HYF2-010-002, Design Changes Work Instruction.

6.5.4. Design Changes after design (after design transfer) shall be managed through HYF1-004-001, Change Control.

7. Revision History

Revision Number	Revision Details
1	Initial release of HYF1-019-001-1 Design Validation into Hyfe's QMS.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signatures.

Signatory Table

Action Name	User Name	Title	Signature Date
Send for Review (Written By)	Nathan Morrison	Quality Manager	11-Nov-2025 06:01
Review	Nathan Morrison	Quality Manager	11-Nov-2025 06:01
Review	Joe Brew	Chief Data Science Officer	11-Nov-2025 10:29
Send for Approval	Joe Brew	Chief Data Science Officer	11-Nov-2025 10:29
Approve	Joe Brew	Chief Data Science Officer	11-Nov-2025 11:02
Approve	Nathan Morrison	Quality Manager	11-Nov-2025 12:54
QA Approval - Skip Training	Nathan Morrison	Quality Manager	11-Nov-2025 12:55

* Dates are displayed according to the system time zone: (GMT-04:00) Atlantic Standard Time (America/Dominica)