## 1 Purpose

This procedure describes the process for establishing, maintaining and archiving a Design History File.

## 2 Scope

This document applies to products developed under design control as defined in SOP-6000-001 Design and Development. All personnel involved with product development are responsible for conforming to the requirements of this procedure.

This procedure complies with MBio's Quality Management System and with all relevant standards and applicable regulations as listed in the Quality Manual (QM001). Additional regulatory standards or guidance documents may be referenced within this procedure.

## 3 Additional Regulatory Standards or Guidance Documents Referenced

3.1 N/A

## 4 Procedure

4.1 Establishment

4.1.1 Upon completion of Stage 0 – Concept Exploration and Feasibility Stage, the project manager will establish the Design History File (DHF) which will be used to record all of the documentation required to demonstrate that the design was developed in accordance with the approved Project Plan and Product Requirements Document (PRD).

4.2 Maintenance and Document Control

4.2.1 Once new documents or revisions are ready for addition to the DHF, a core team member will release the documents per SOP-5000-001 Document and Records Control.

4.2.2 Quality Assurance will place the files or references into the correct electronic DHF location upon release.

4.3 Contents

4.3.1 The following records should be included in the DHF prior to product launch:

- Project Plan (PP)
- Product Requirements Document (PRD)
- Software Requirements Document (SRD)
- Risk Management Documents Risk Management Docs – Failure Modes and Effects Analysis (Design and Process), Hazard Analysis (dFMEA, pFMEA, HA)
- Risk Management Report (RMR)
- Software Documents – Software Summary (SSUM)
- Software Validation Protocols and Reports (SVP & SVR)
- Test Protocols and Reports, including those for Product V&V (TP &TR)
- Usability Documents – Application Usability Specification (AUS)

4.3.2 In addition, any documents that support or are directly referenced by the records listed above may be considered part of the DHF. These may include, but are not limited to:

- Interoffice memoranda
- Electronic mail
- Meeting minutes
- Laboratory notebooks
- Presentations
- Procedures

4.3.3 All documentation, whether electronically stored or referenced within the DHF, is the sole property of MBio Diagnostics, not the employee or contractor. Any contracts with outside parties for design and development work produced should explicitly specify that the company has the right to all design information and has the right to establish standards for the form and content of any design documentation.

## 5 Responsibility:

| Role | Responsibility |
|---|---|
| Senior Management | • Provide resources to complete and release DHF documents |
| Project Manager | • Establish the DHF once design control is initiated for a project<br>• Ensure that the contents and/or reference documents within the DHF are maintained in accordance with the company's document management procedures |
| Core Team Members | • Providing records or reference documents to the project manager for inclusion in the DHF<br>• Ensure that the documents contained within or referenced by the DHF have been generated and maintained in accordance with the relevant Standard Operating Procedures |
| Quality Assurance | • Release and maintain DHF documents |

## 6 Referenced QMS Procedures and Work Instructions (not external documents)

The following documents are cross-referenced in this SOP.

SOP-6000-001 Design and Development

SOP-5000-001 Document and Records Control

## 7 Attachments, Associated Forms, and Associated Controlled Spreadsheets

N/A

## 8 Revision History

| Revision | Effective Date | DCO Number |
| --- | --- | --- |
| 01 | 31DEC2019 | 590 |
| 00 | 16DEC2019 | 576 |