Device Design History Record (v. 4.0B)
BE Design, Winter '08-'09, Dr. C. S. Tritt

A design history file (DHF) is required by the FDA's Quality System Regulation (QSR). See http://www.fda.gov/cdrh/qsr/03desgn.html#design_history_file for details regarding its required contents. The purpose of the DHF is to provide objective evidence that the design process involved systematically investigation and evaluation alternatives. This record should be maintained at a level of depth, breadth and detail such that another team of engineers with the same education and experience as the original designers could use it to reproduce the design or continue the project from its current state.

Each team should develop and maintain an abbreviated version such a file, to be called a Design History Record (DHR). The content of the DHR should be supported by and summarize the content of your logbooks. The content of the DHR should be updated as needed, in general more than least once a quarter. Every entry in the DHR must be dated. All included documents should include dates and version numbers. Superseded documents should be marked as such. The DHR should be generally be kept in 2 or more 3 ring binders with tabbed section although some faculty members may require a full or partial electronic version.

The DHR must contain the following sections, in the following order and containing the following content:

Volume 1 – Current Summary and Current Information

This volume is typically submitted to the Chief Engineer for evaluation at the end of every quarter.

Table of Contents (of Volume 1)

Each DHR volume and should include a Table of Contents listing the title, date and location (section) all DHR content. Page numbers are not required provided you used tabbed dividers between sections.

1) Project Statements

Brief statements of the goal of the project and/or description of what you are designing. You should include both short (1 or 2 sentence) and long (2 or three paragraphs) statements. The short statement should succinctly define the goals and scope of your project. The long statement is essentially an abstract and

should describe your device, market and plans in broad terms. It should also include an illustration.

2) Project Management Documents

The current (most recent) version your team's *Progress and Plans* memo.
Team Roster (list of team members, their roles (PM, APM or E) and contact information (phone numbers and e-mail addresses).
Table of Responsibilities (listing the member with primary responsibility for each significant aspect of the project).
CPM Gantt Chart and/or Schedule showing the overall project schedule.
Other management and planning documents as needed.

3) Meeting Records

Dated agendas and Minutes of team meetings.
Records of meetings with experts can also be placed in this section (possibly in the form of "Memo to File").
Design review records include lists of items that require following and the status (resolution) of each. Only records of unresolved issues and the most recent design review should be included in Volume 1. Records of previous reviews should be placed in Volume 2 – Note these should be in Section 8.
Other meeting minutes as needed.

4) Market Related Documentation

QFD related items – House of Quality or other customer needs analyses.
Competitive product information (similar and alternative).
Contact information for experts and summaries of discussions with them.
Survey IRB submissions and status information.
Other market research records (surveys, interviews, submissions, etc.).
Sources (reference citations)

5) Regulations, Standards and Intellectual Property Records

FDA class (if applicable – otherwise a clear disclaimer) and requirements.
Other relevant industry standards and/or regulations.
Sources (references to relevant industry standards and other regulatory related information).

6) Functional Specifications

Target Specifications (preferably derived in part from the QFD/HoQ method)
Test plans and IRB submissions related to test plans. Updated as needed and on an ongoing basis.

7) Technological Aspects

Retrieved

Background information related to technologies being used or likely to be used.
Copies of relevant patents with commentary.
Information commercially available component and subsystem.
Sources (reference citations)

Created

Device block diagrams (to be included around the time of junior presentations).
A sketch or sketches of your device as it is currently envisioned.
CAD drawings, schematics, etc. of device or subsystems.

8) Junior Progress and Feasibility Documents and Records (during junior year)

Progress and Feasibility Slides
Progress and Feasibility Report
Progress and Feasibility Feedback and Assessments

Design Review Documents and Records (during senior year)

Design Review Reports
Formal Minutes of Design Reviews listing date, location, attendees and issues.
Formal responses to issues raised during design reviews.

Final Documentation (at end of senior year)

Final Project Report
User and Service Manuals as appropriate and/or required by Chief Engineer

This section should only include the most recent of these items. The others should be moved to Volume 2 as they are superseded.

9) Financial Records (as appropriate)

Current budget information
Funded grant applications with a summary of how the money is being used.
Outstanding (submitted but not yet funded or rejected) grant applications.
Current funds on hand information

Volume 2 – Archives

This volume should contain obsolete versions of documents and records. Its organization should parallel that of Volume 1. It is only to be submitted for grading upon request.

Table of Contents (of Volume 2)

Each DHR volume and should include a Table of Contents listing the title, date and location (section) all DHR content. Page numbers are not required provided you used tabbed dividers between sections.

1) Previous Project Statements

Move project statements here when they are replaced by newer versions and/or you change the details of your goals.

2) Previous Project Management Documents

Progress and plans memos should be left in Volume 1 for 2 quarters (so that previous plans can be compared to current progress) and then moved to Volume 2.

3) Previous Meeting Records

Meeting records should be kept in Volume 1 for 1 year and then moved to this volume.

4) Previous Market Related Documentation

Move materials here as it becomes obsolete. Don't move currently relevant materials regardless of age. For example, IRB documentation for ongoing studies should be left in Volume 1.

5) Previous Regulations, Standards and Intellectual Property Records

Only move materials here when they become irrelevant due to changes in the focus of your project or the technical approaches you plan to employ.

6) Previous Functional Specifications

Move old versions here as you create new versions.

7) Technological Aspects

Move old versions of documents and materials related to abandoned approaches here.

8) Junior Progress and Feasibility Documents and Records (during senior year)

Progress and Feasibility Slides
Progress and Feasibility Report
Progress and Feasibility Feedback and Assessments

Design Review Documents and Records (at end of senior year)

Design Review Reports
Formal Minutes of Design Reviews listing date, location, attendees and issues.
Formal responses to issues raised during design reviews.

9) Financial Records (as appropriate)

Move records here after a year provided they are no longer of immediate relevance to your project (this includes copies of rejected grant applications along with the rejection letter or a note regarding the stated reason for rejection).

Volume Three – Supporting Documentation

This volume should contain materials you need to keep but are not necessary going to be use regularly. Be prepared to submit it for grading upon request. Only necessary, relevant and/or potential useful information should be included. In particular it should include the following, in the following sequence:

A Table of Contents (to this volume)

Specification Sheets for commercial components, devices and subsystems that may be used in the design.

Reprints of useful literature (including web) sources **with short commentaries explaining their relevance** to your project. You should not save everything you find, but you should keep notes on your searches and lists of sources found (or not found). If you need something that you didn't save, you can always refer to these lists.

You may include other documents you feel contribute to the record of what you have done and/or that you would likely refer to in the future. Keep the "someone with your skills should be able to reproduce your work" idea in mind.