Device Design History Record (v. 3.0)
BE Design, Winter '08, Dr. C. S. Tritt

A design history file (DHF) is required by the FDA's Quality System Regulation (QSR) and as documented at http://www.fda.gov/cdrh/qsr/03desgn.html#design_history_file. The purpose of the DHF is to provide objective evidence that you systematically investigated and evaluated alternatives to arrive at your final design. This record should be maintained at a level of depth, breadth and detail such that another team of engineers with your education and experience could use it to reproduce your results or continue the project from its current state.

I want each team to start developing and maintaining an abbreviated version such a file, to be called you Design History Record (DHR). Note that every entry in the DHR should be dated. I recommend you keep the following information in a 3 ring binder with tabs for each section (although a fully electronic version might be acceptable):

Volume One – Current and Summary Information

Table of Contents (to everything listed below) with Submission Records

Placed in the front of each volume and should list the title, date and location (section) of recent submissions.

Project Statement

Brief statements of the goal of the project and/or description of what you are designing. You should include *a)* a one or two sentence statement and *b)* and one or two paragraph statement. Both should begin with words like "We are designing…" and continue to describe what it is you are designing and why (or more generally the goal of your project).

Project Management Documents

The current (most recent) version of team *Progress and Plans* memo.
Table of Areas of Responsibilities.
CPM Gantt Chart and Schedule showing who is doing what.
Other management and planning documents as needed.

Meeting and Design Review Records

Agendas and Minutes of team meetings.
Formal Design Review submissions and records.

Market Related Documentation

QFD related items – House of Quality.
Competitive product information (similar and alternative).
Contact information for experts and summaries of discussions with them.
IBR submissions and status information.
Other market research records (surveys, interviews, submissions, etc.).

Regulations and Standards

FDA class (if applicable – otherwise a clear disclaimer) and requirements.
References to relevant industry standards and other regulatory related information.

Specifications

Target Specifications (preferably derived in part from the QFD/HoQ method)

Technological Aspects

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 of device or subsystems.
Background information related to technologies being used or likely to be used.
Commercially available component and subsystem information.
Particularly relevant intellectual property records (patents) - particularly relevant patents or references thereto.

Financial Records (as needed)

Current budget information
Current funds on hand information
Plans and open requests for funding; details of funding received.

Volume Two – Supporting Documentations

This volume should contain materials you want to keep but are not necessary going to be use regularly. In particular it should include:

A Table of Contents (to this volume)

Previous (not the most recent) team *Progress and Plans* memos.

Older copies and versions of other project related submissions.

Older Intellectual Property Records - particularly relevant patents or references thereto.

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.