Traps for the unwary on quality systems

Design controls before you manufacture

Presented by Brandwood Biomedical

Peter Austen, Senior Consultant

- Over twenty-five years of experience working in the medical device industry
- Roles ranging from engineering, project management, quality and regulatory management
- Experience working with regulators in Australia, USA, Canada and Europe
- Expertise in Quality System implementation and surveillance, product registrations, recalls and post-market reporting and investigations; Supplier and QMS auditing
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Agenda

- What are design controls?
- All elements must be addressed
- Documenting the elements
- Records
- Potential consequence of unfavourable inspections
- Q&A
What are design controls?

A process of records of activities

- User Needs
- Design Input
- Design Process
- Verification
- Design Output
- Medical Device
- Validation
- Review
Planning is essential

Have you written the Design & Development plan?

- Outlining responsibilities and authorities
- The quality planning aspects
- The resources, disciplines/dep’t interaction
- The phase gates – based on the product development procedure
- Other specifics to the project
  
  Technology  Equipment  Experts
Clearly define input requirements

Have you covered?

- Clinical or Home Environment
- User & Patient – single or multiple use
- Human Factors – reduce human error
- Risk Management (ISO 14971)
- Review of complaints, MDR’s, etc.
- Special conditions
- Regulatory requirements (ISO 13485, . . . )
Human Factors

YOUR USER REQUIREMENTS INCLUDE FOUR HUNDRED FEATURES.

DO YOU REALIZE THAT NO HUMAN WOULD BE ABLE TO USE A PRODUCT WITH THAT LEVEL OF COMPLEXITY?

GOOD POINT. I’D BETTER ADD “EASY TO USE” TO THE LIST.
Mapping of Requirements

Clearly map the device input requirements to outputs

- Develop a traceability matrix – a powerful project tool!
  Map all design inputs to design outputs to verification to validation, etc.

- Don’t have inputs where the outputs cannot be verified or validated
## Traceability Matrix

<table>
<thead>
<tr>
<th>Input Req’t</th>
<th>Description</th>
<th>H/W</th>
<th>S/W</th>
<th>Elect Design description</th>
<th>Specification Ref#</th>
<th>Verification id</th>
<th>Validation id</th>
<th>Input Req’t met?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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</table>

Basic traceability matrix
V & V

Design Verification

*Does the output meet the input requirement?*

- Do you have records of inspections and tests?
- Does it work in the lab?

Design Validation

*Does the overall output meet intended use and user needs?*

- Do you have evidence of Clinical Evaluation?
- Does it work in the real world?
Design Reviews

*Did the Design & Development Plan detail?*

*How many? (Depends on complexity and risk rating)*

- One, two, three, ... ?

*When?*

- Input requirements
- Design verification
- Design validation
- Design transfer

*Who?*

- Key project team members, Experts, independents
Design Changes

Occurs during the design phase onto manufacturing and continues through to obsolescence . . .

- Are your design changes documented?
- How well are they documented?
- Have the changes been reviewed by the same functions?
- Have you assessed impacts of the changes?
- What V & V activities did you perform to confirm the change?

And . . . don’t forget software
- Device, support, test, spreadsheets with macros, etc.
Design Transfer

Is the device ready for manufacturing?

- Are all component specifications & procedures completed?
- Are all processes validated?
- Is the equipment ready?
- Is the manufacturing facility ready?
  - Special environmental conditions, storage, access, etc
- Are critical suppliers qualified?
  - Special processes, sterilisation, disinfection, etc
Design History File

For the life of the Product!

- Do you have a compilation of records?
- Meeting minutes, design reviews, photo’s, sketches, specifications, risk management file, plans, protocols, reports, etc.
- Which shows compliance to design control elements?
# Design History File

<table>
<thead>
<tr>
<th>Inputs</th>
<th>Outputs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Requirements Document(s)</td>
<td>Product Specification (Drawings, BOM)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk Management</th>
<th>Verification Records</th>
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</thead>
<tbody>
<tr>
<td>Risk Analyses, Risk traceability matrices etc.</td>
<td>Test Data and Certificates, Raw data (Lab Books)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Validation Records</th>
<th>Project Management</th>
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</thead>
<tbody>
<tr>
<td>Clinical Evaluation Reports and Records</td>
<td>Plans, Meeting Records, Design Reviews and Approval records</td>
</tr>
</tbody>
</table>
Records

“Establish and maintain procedures for . . . “

- Design Input & Output
- Design Reviews
- Design Verification & Validation
- Design Transfer
- Design Changes

The procedures & records = the DC process
These will be audited.
Don’t Do This

- Implement procedures when the project is completed

- Try to produce the required documents after submission time

- Change a record without reapproving and justifying why

- Use liquid paper or equivalent, strike through and initial
Don’t Do This

- Rubber stamp, documents must be appropriately reviewed
- Approve your own work
- Make a change without formal review
- Create burdensome procedures that no one will adhere to
The Consequence

Design controls must be in place prior to Market release . . .

Identification, documentation, validation or where appropriate, verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i). Changes made to your initial device design, including material specification and device labeling, lacked change notices, change rationale, and evaluation as to whether the changes would affect device function or quality.

Design transfer to ensure the device design is correctly translated into production specifications, as required by 21 CFR 820.30(h). As such, your firm has also failed to ensure XXXX device can be repeatedly and reliably manufactured using the production specifications when transferred to manufacturing.
Lack of DC’s - the consequences

- You’re unable to market the device until you have addressed the issues and they are accepted. A recall may be invoked.

- They could close your doors.

- Your competitors will have access to the warning letter(s) and subsequent regulatory actions, and will let your customers know!

- Your reputation could be impacted.
Questions?

help@brandwoodbiomedical.com
Let’s talk!

- TGA Submissions
- Australian Sponsor Service
  - and others including China & New Zealand
- Regulatory Strategy
- Risk Analysis and Standards Compliance
- Quality Systems
- Clinical Trials
- Postmarket Compliance
- Reimbursement
- Regulatory Intelligence
- Training

Contact us for a free no-obligation initial consultation and quote
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Brandwood Biomedical has offices in Sydney, New Zealand and Beijing and offers specialist expertise throughout the Asia Pacific