

## **APPLICATION OF DESIGN CONTROL (I)**



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## **PROGRAM**

### **BIG PICTURE**

**WHY 483s AND WARNING LETTERS?**

**VERY BRIEF LOOK AT REGS/STANDARDS**

**FLOW CHART**

**PLAN THRU DESIGN OUTPUT (I)**

**DESIGN REVIEW THRU DESIGN CHANGES (II)**

**Q & A**

**TAKE HOME IDEAS**

## BIG PICTURE

- To prevent problems due to improper or inadequate design and development
- To help reduce product recalls
- To get all functions involved early
- Avoids “Throw-over-the-fence”
- Understand and manage risk
- Integral part of FDA-QSIT
- To minimize surprises
- **DO IT FOR EXCELLENCE**

## WHY SO MANY 483s & WARNING LETTERS?

- Poor understanding of requirements
- Inadequate policy, procedures and training
- DC program and development culture incongruent
- DC procedure perceived too restrictive
- Functional groups lack training
- Functional groups (typically non-R&D) not committed
- Poor planning
- Unclear intended market
- Management oversight inadequate
- Design reviews inadequate
- Improper change control applied

## DESIGN PLAN

- Begins after authorization of concept
- Establish and maintain plan for design/development
- Interfaces with groups
- Review, update and approve plan
- Define responsibility for implementation

### PLAN INCLUDES:

- Goals and objectives
- Organizational responsibilities
- Interfaces and hand-offs
- Identify major tasks and responsibilities (time, resource, constraints and output form)
- Overall schedule with milestones
- Major decision points
- Who'll conduct reviews and how often?
- Get it approved
- Revise as necessary

## COMMON PROBLEMS – DESIGN PLAN

- Procedure lacking
- Procedure not followed
- Missing plan
- Inadequate plan – doesn't address key issues such as responsibilities
- Weak in non-R&D areas (purchasing, materials, manufacturing, distribution, customer service etc.)
- Missing interfaces and hand-offs
- More than a schedule; not enough big picture
- Design review set up poorly – could create administrative nightmares

## INPUT REQUIREMENTS

- Appropriate level of detail
- Avoid solutions at this stage
- Performance requirements
- Interface requirements (external systems outside the control of designers/developers)
- Device description, packaging and labeling
- Intended use
- Patient and use environment
- Shelf life
- Marketing requirements
- Risk assessment
- Service support requirements
- RA/QA
- Manufacturing requirements
- Mechanism to address incomplete, ambiguous or conflicting requirements

## COMMON PROBLEMS – INPUT REQUIREMENTS

- Not quantifiable
- Too specific (output specifications)
- Development has already begun before input approval
- Design concept not fully described and analyzed
- Lack of involvement/commitment from functional groups such as marketing
- Concept document is not an input document
- Frequently are too prescriptive

## OUTPUT SPECIFICATIONS

- Quantifiable and verifiable
- Device/product specifications
- Material and component specifications
- Acceptance criteria
- Drawings
- Assembly instructions and SOPs
- Environmental and facility requirements
- Tooling and process equipment requirements
- Performance capability, specifications and limitations
- Packaging specifications
- Labeling (instructions, manual, labels)
- Initial risk analysis (not a part of the DMR)
- QA/Release criteria, test equipment and test methods
- Installation, maintenance and servicing procedures

## COMMON PROBLEMS – OUTPUT SPECIFICATION

- Incomplete output
- Input vs. output verification not documented
- Inadequate acceptance criteria
- Test procedures and test equipment too generic
- Tolerances are missing