

APPLICATION OF DESIGN CONTROL (II)



**Orange Empire Section 0701
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PROGRAM

PREVIOUS PRESENTATION (8/14)

REVISIT FLOW CHART

VERIFICATION AND VALIDATION

DESIGN REVIEW

PROCESS DEVELOPMENT & SCALE UP

DESIGN TRANSFER

DESIGN AND PROCESS CHANGES

Q & A

TAKE HOME IDEAS

VERIFICATION AND VALIDATION

- Verification: Output meets input requirements
- Validation: Device conforms to user needs and intended use
- Protocols, reports in DHF
- Get all functions involved early
- Test methods and protocols sign-off
- *in vitro* test model
- Simulated use
- Clinical testing may be required for Validation
- Risk analysis missing/inadequate, not tied to any thing
- **DO IT FOR EXCELLENCE**

DESIGN REVIEW

- Planned and conducted at appropriate stages
- Set up for success by balancing competing priorities
- DC review procedure and development culture incongruent
- Functional groups (typically non-R&D) not involved/committed
- Poor planning
- Too much information to be reviewed
- Managing design review
- Documentation in DHF

PROCESS DEVELOPMENT & SCALE UP

- Significant for major projects
- Starts with process development plan
- Verification and validation to produce similar results
- *in vitro* test model
- Process validation may be included
- Verification and validation documents in DHF
- Ready for design transfer

DESIGN TRANSFER

- Design is translated into production specifications
- DMR must be complete
- Engineering drawings, material specifications, device specifications etc.
- Production procedures, work orders, systems, materials including packaging and labels etc.
- QA/QC specifications, procedures, acceptance criteria, test apparatus etc.
- Review results of initial/test production runs
- All functions including customer service ready?
- Hold preliminary design reviews before the “final” review
- Final design review before market release
- **SUCCESS! IT ALL COMES DOWN TO THIS STEP.**

DESIGN (AND PROCESS) CHANGES

- V, V and review before implementing changes
- Production change control applies
- Usual problem: changes are not appropriately reviewed (key players are on other projects)
- V and V is sometimes lacking
- Summary of change into DHF
- V and V, if any, into DHF