



2009

Mini-

Conference

Automating Compliance with FDA Quality System Regulation

- **Presenter's Biographical Summary:**

- **James H. Jones** is Principal of ODDS Company, a provider of practitioner/manager level consulting/training on System Engineering processes adapted to medical device development. (His day job is Manager of Systems Engineering at Optivus Proton Therapy, Inc.)
- Education: B.S., Business Administration and M.S., Industrial & Systems Engineering.
- He acquired skills in comprehensive, rigorous requirements management for embedded systems during work for defense corporations. His experience applying Systems Engineering to medical device new product development began with an IV infusion pumps manufacturer and now includes development of upgrades to a high throughput proton beam treatment facility.



Automating Compliance with FDA Quality System Regulation

- **The Ultimate Stakeholder for Medical Devices:**
 - US Food and Drug Administration (FDA)
- **FDA Mission for Medical Devices & Use**
 - Finished devices must be “safe and effective”.
- **The FDA Method to Ensure Compliant Products**
 - US FDA 21 CFR 820 Good Manufacturing Practices (GMP)
 - Introduction asserts is a Quality System Regulation (QSR) [that governs] “the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use.”
 - “Each manufacturer shall establish and maintain a quality system that ... meets the requirements of this part.”
- **Definitely Classical Systems Engineering Territory!**



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- **Systems Engineering sometimes is rather misunderstood:***
 - Processes not valued—a team with core technical competencies will smartly do all the right things to ‘engineer the systems’ and everyone does ‘systems engineering’.
 - Requirements Management is only overhead and just producing paper that doesn’t contribute to producing the deliverables.
 - A Systems Engineer must be expert in all the technologies in the devices, to enable single-handed designing and dealing with the vendors. ‘INCOSE is only ten years old.’ [This from a Director of R&D that wouldn’t accept relevance of NCOSE founders already having decades of applicable experience.]
- ***Disclaimer: Based on personal experience with two medical device manufacturers (one large, one small).**



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- **Systems Engineering Applied to QSR Compliance:**
 - Systems Engineering and Integrated Product/Process Team (IPPT) methods are applicable to most of the QSR. Standard Process Improvement methods are applicable as well, and will have been employed—but without an overarching systemic view customary to classical Systems Engineers. That is, the policies and procedures need examination and integration to the same extent as the product development process.
 - That is, the approaches one uses to help an organization attain increased levels of CMMI certification are applied to fulfilling the QSR requirements: Components of the desired overall process are deliverables that accompany projects to develop products for the paying customers and other stakeholders.



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- **Automating Compliance:**

- Compliance with a standard or regulation must be provable from auditable evidence. Unless product development processes require generation of that evidence during the project phases, extensive retrospective work will be required to generate it. To use Quality Assurance terminology, that rework is part of the cost of process non-conformance.
- Automating QSR compliance begins with training all employees on the overall regulation and importance of taking the little ‘extra’ time needed to produce compliance evidence (i.e., to do their job ‘right the first time’). When employees understand that their tasks performance includes generating appropriate auditable records, QSR compliance becomes relatively automatic.



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- **QSR Design Controls Compliance**

- For a product development context of familiarity to most INCOSE members, think of a Research & Development department for embedded systems medical devices.
- Provide detailed training on QSR provisions for Design Controls to employees that do or support product development efforts. Such methods are outlined in this presentation as each Design Controls provision is addressed.
- The ten QSR Design Controls subsections are: (a) General, (b) Design and development planning, (c) Design input, (d) Design output, (e) Design review, (f) Design verification, (g) Design validation, (h) Design transfer, (i) Design changes, and (j) Design history file.



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- **Design Controls 820.30 (a) General**

- “Each manufacturer of any ... class III or class II device ... shall establish and maintain procedures to control the design of the device ... to ensure that specified design requirements are met.”
- Start all projects with tailoring a Project Management Plan to the project scope and scale.
- The Quality Policies must permit tailoring and the Procedures must instruct what minimum documentation is to be provided and methods for reducing scope and scale from the anticipated worst case of a very large project..



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- **Design Controls 820.30 (b) Design and development planning**
 - The Project Management Plan (PMP) is to “describe or reference the design and development activities and define responsibility for implementation” “The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to design and development process.”
 - A PMP supports planning for conceptual worst case new/upgrade projects as well as tailoring instructions (to match tasks to scope and scale of intermediate to small projects), sets forth milestones sequencing of most project documents development and drives their auditability. A PMP shows what information to obtain, where to put it, and needed breadth and depth, assisting initial budget and schedule estimates correlation with intent of project..



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- **Design Controls 820.30 (c) Design input**
 - Design input is “physical and performance requirements of a device that are used as the basis for a device design.” Design input ranges from elicited customer inputs to requirements for addressing “the intended use of the device, including needs of the user and patient” to at least top level software and hardware requirements specifications that drive detailed device design.
 - Requirements Management methods are the means to produce auditable design inputs and outputs records that are evidence of compliance with QSR design controls provisions. Unambiguous and verifiable requirements become the single recipe that development teams follow for design, manufacture, and testing of a specified item.



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- **Design Controls 820.30 (d) Design output**

- Design output is “the results of a design effort at each phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labeling, and the device master record.” “Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified.” “Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified.”
- Many design inputs are outputs from the previous stages in the “total design effort.” (Basic Systems Engineering here, but with specific QSR design controls requirements fulfillment.)



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- **Design Controls 820.30 (e) Design review**
 - Design review is “a documented, comprehensive, systematic evaluation of a design to evaluate adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.”
 - Use Checklists for each design review, to consistently document output of each phase of the product development projects and to force production of much QSR compliance evidence.
 - System Requirements Review, Preliminary Design Review, Critical Design Review, Production Readiness Review, and Final Project Review are familiar examples.



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- **Design Controls 820.30 (f) Design verification**
 - Verification is “confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.” Verification is showing that the medical device was built correctly.
 - The design is verified when fulfillment of every allocated/derived requirement is confirmed by performing Hardware and Software Requirements Specification verification procedure(s) and reporting the results. (Assuming deficiencies correction and regression testing that passed, of course.) The verification procedures, results, and reports “shall be reviewed and approved by designated individuals.” .



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- **Design Controls 820.30 (g) Design validation**
 - Validation in QSR 820.3 is “establishing by objective evidence that device specifications conform with user needs and intended use(s).” Validation is confirmation that the correct medical device was built; that the device will fulfill the customer clinical and user inputs to requirements as fielded.
 - Validation method examples are deliberate use of erroneous inputs to user interfaces, accelerated life or use tests, electromagnetic compatibility testing, environmental stress screening, showing conformance to domestic and international standards, and other such means for determining system suitability for its “intended use(s)”. .



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- **Design Controls 820.30 (h) Design transfer**

- Here, emphasis is on ensuring “that the device design is correctly translated into production specifications.” Depth and breadth of each translation depends entirely on which permutation of a make or buy decision applies to the system, subsystem, or component to be produced.
- An approach for the design transfer process is to go beyond ensuring auditable compliance by including Manufacturing Engineering early in the design process (such that ease of fabrication and assembly join maintainability as a concern of the design specialists) .



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- **Design Controls 820.30 (i) Design changes**

- A manufacturer must provide “procedures for the identification, documentation, validation, or where appropriate verification, review, and approval of design changes before their implementation.”
- Released documentation that is revised due to design change must be reviewed by their identified signatories and approved.
- Requirements Management and attention to Medical Risk are maintained, as is the auditable evidence of compliance with QSR provisions for design controls. (Analysis of hazard to patients or users, rather than project technical, schedule, or cost risk.)



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- **Design Controls 820.30 (j) Design history file**
 - The Design History File is “a compilation of records which describes the design history of a finished device.” “The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.”
 - Because “this part” means the entire QSR, work requested of (and decisions made by) persons that impact development and production of a medical device through a project are pertinent for capture and retention in the DHF. .



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- **IPPT Design Controls Compliance Tools**
 - The IPPT supporting toolset providing greatest increase in effectiveness and efficiency of development project teams is integrated document templates that standardize their content and interrelationships. Even initial draft versions of the work products provide auditable Design Controls compliance support
 - Requirements management tools are database programs that import requirements from specification documents and assign a project unique identifier (PUI) to each requirement.
 - Requirements in one project document are assigned PUI to PUI linkages to requirements in other project documents to establish source driver and responder relationships (trace).



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- **Conclusions**

- Although it is easiest to begin their application at the start of a project, most described methods and templates can be applied separately [as appropriate to the project situation]. Examples lead to tentative localized acceptance and then full assimilation of the improved processes, which paves the way to quicker and more general acceptance of the next improvements.
- Experienced Systems Engineers may apply their fundamental methods to all aspects of medical devices development with confidence. The differences in Risk Management for medical devices from the classical concepts of project cost, schedule, and technical risks are easily learned. Using an IPPT approach to introducing the familiar processes recommended here can lead to automating compliance with the QSR provisions for design controls