

Norman Noble, Inc.

Microprecision Medtech Manufacturing



Manufacturing Processes and Validation for Next Generation Implants



FDA Validation Requirements

- 21 CFR part 820
- Sec. 820.75 Process Validation
 - “Where the results of a process cannot be **fully verified** by subsequent inspection and test, the process shall be validated.”
- Sec. 820.250 Statistical Techniques
 - “Where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and **verifying** the acceptability of process capability and **product characteristics**.”

ISO Validation Requirements

- ISO 13485:2003(E) section 7.5.2
 - “The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement.”
- Interpretation guidance assistance
 - Global Harmonization Task Force
 - SG3/N99-10 – Process Validation Guidance



Why is validation important?

- It's the law!
- It makes good business sense to:
 - Understand and control our processes.
 - Insure that our equipment operates correctly.
 - Insure all employees perform their tasks consistently.
 - Significantly reduce manufacturing and inspection costs for long run production.
- It makes good business sense!

Preliminary Work

- Systems and equipment qualified for installation and operation
 - The expected process parameters must be within the equipment operational limits
- Highly recommend an early and thorough review of all process requirements
 - Components
 - Assemblies
 - Packaging and labeling

Preliminary Work (continued)

- Data Analysis and Statistical Techniques expectations
 - Attribute vs. Variable Data
 - Sample sizes based on Risk Analysis
 - Acceptance criteria
- Protocol deviations, re-validations, etc.
 - Deviation procedures
 - Prospective, concurrent and retrospective validations

Preliminary Work (continued)

- Quality documentation
 - Quality Plan
 - pFMEA
 - Requires dFMEA where applicable
 - Calibration of relevant gages
 - Gage R&R
 - Test Method Validation
- Process Documentation
 - Job traveller/router
 - Process flow diagram
 - Design of Experiments
 - Historical process knowledge
 - Material traceability
 - Raw material
 - Components
 - Sub-assemblies, devices

Confidentiality vs. Disclosure

■ Proprietary processes

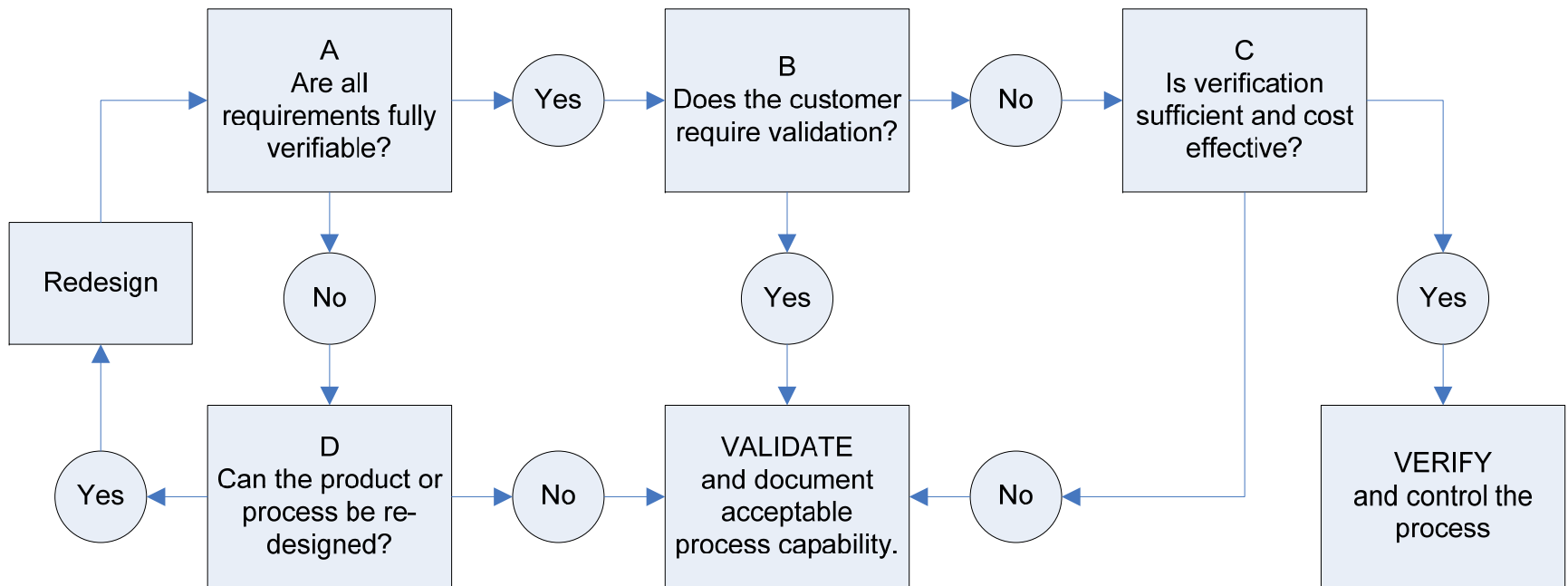
- Those processes where the contract manufacturer has developed a significant edge over all others
 - If the process was developed for and with the customer, full disclosure is most likely required
 - Otherwise, these processes may only require the disclosure of the completion of process qualification

■ Universal processes

- Those processes that were developed per an existing industry standard
 - Passivation, thermal treatments, etc.

Decision Time

Validation Decision Tree during Contract Review





Customer-Vendor Responsibilities

- Master Plan and Timeline (Validation Strategy)
 - Typically co-authored and dually approved
- Protocols and Reports
 - Typically dually approved
- Execution and Inspection
 - Typically the responsibility of the Contract Manufacturer
- Data review & interpretation
 - Typically dual responsibility
- Device Master Record
 - Typically the responsibility of the Contract Manufacturer

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