

Warning Letters and Compliance

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Top 5 reasons for WLs not changed much

- Design Controls
- CAPAs
- Complaints
- Supplier Controls
- Process Validation

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Real reasons for WLs and their increase

- M(ergers)A(cquisitions)D(ivestitures)
  - Leading to Disparate Systems
- Increased Scrutiny by agencies
  - Money collected for this from companies
  - More hiring by agencies
- Changes in Regs
  - EU – unannounced Inspections
  - Requiring long term relations broken
- Experience levels variance of humans

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Excerpts from Warning letters highlight several issues in validation

"Your firm **failed to establish a validation program for the computer software** Microsoft Dynamics used for production, inventory, lot number generation, and laboratory test methods used for raw material, bulk, and finished product test release."

"Failure to validate computer software for its intended use according to an established protocol when computers or automated data processing systems are used as part of production or the quality system. Validation Master Plan developed as part of CAPA 2335, states that redacted, redacted, and redacted, are software programs that are considered critical, which requires software validation. These programs have not been validated by your firm."

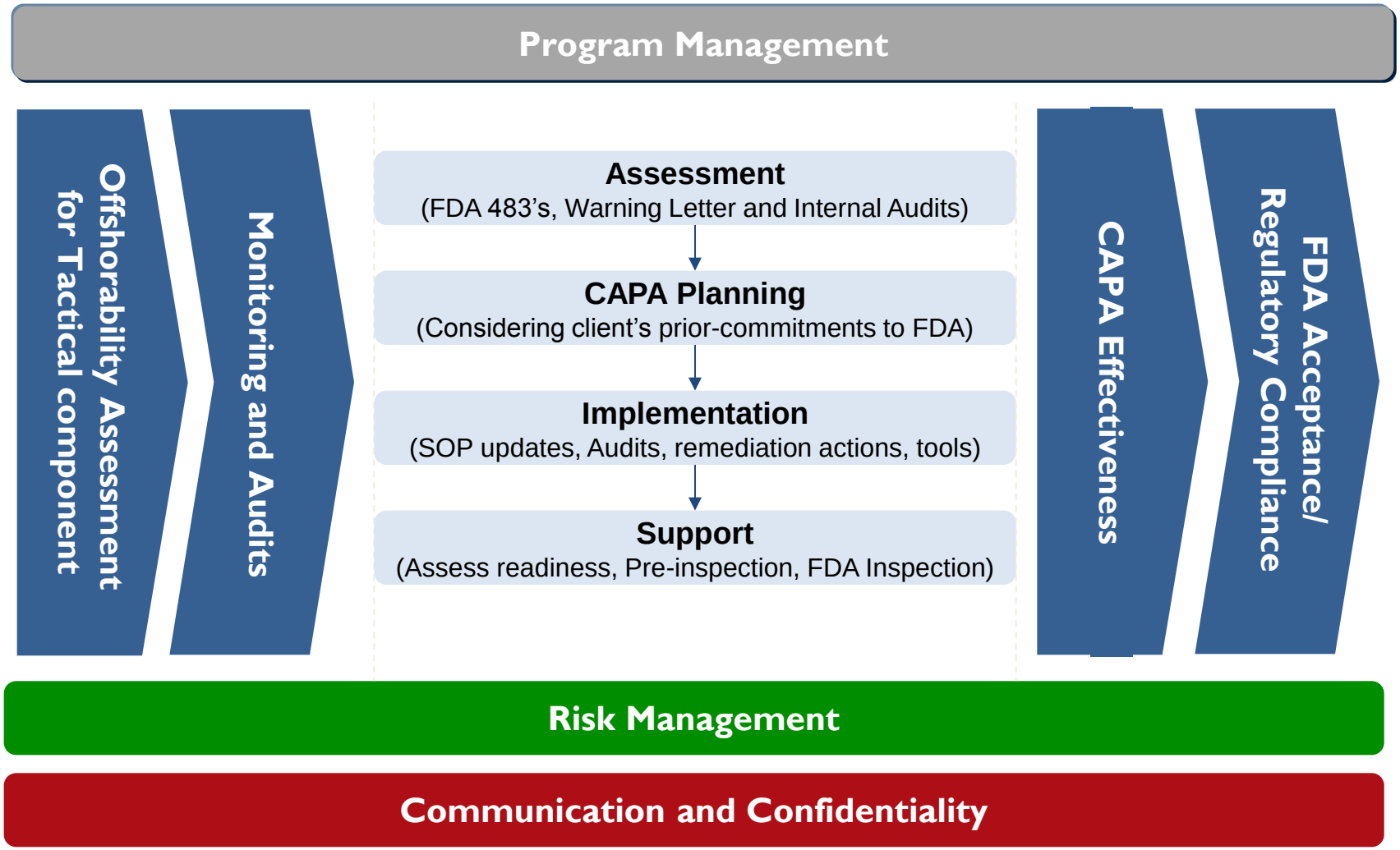
"Failure to validate computer software used as a part of production or the quality system for its intended use according to an established protocol. For example, **your firm could not provide any documentation to demonstrate that the software used** for the 6111 PCB **was validated for its intended use. "**

"Your firm **failed to exercise appropriate controls over computer or related systems to assure that only authorized personnel institute changes in master production and control records, or other records** (21 CFR 211.68(b)). Additionally, there is no audit trail in place to determine any previous deletion of raw data."

Source: FDA http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm

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FDA 483/WL Remediation Framework



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Case Studies



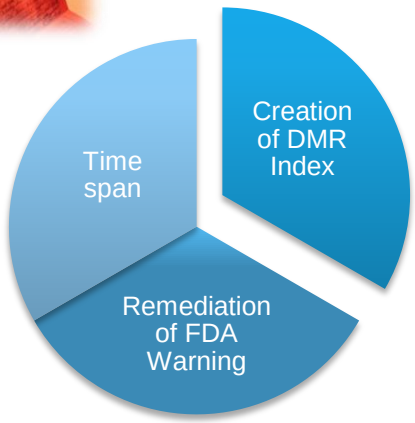
FDA WL Remediation – DMR Index

Client Situation

- ✓ Medical device manufacturer focusing on Neuromodulation involving direct stimulation of the nervous system with electrical signals and used as a treatment for unmanageable chronic pain and/or movement disorders.









Scope

- ✓ Create an Device Master Record(DMR) Index for Implantable Infusion Pump and Deep Brain Simulator

Business Challenge

- ✓ Satisfy customer by providing remediation for FDA warning letter
- ✓ Complete PILOT DMR Index for implantable Infusion Pump within very short period of time.
- ✓ Complete DMR Index for nearly 400 products

Our Approach

- ✓ Wipro defined multiple processes for creating DMR Index, spanning, design, manufacturing and purchasing (including supplier Quality) as a result of which customer could expedite creating DMR Index Work instruction.

Key Features

- ✓ Record maintenance using various tools like PLM< ERP, MES and Document Management Systems

Benefits

- ✓ Improved Quality system meeting FDA guidelines 820.181
- ✓ Creating Errorless DMR Index
- ✓ Reduced time to create DMR Index
- ✓ Reduced cost due to automation and Offshore/Onsite model
- ✓ Inspection is stress free

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Process Validation for Class III Device

Client profile

Medical device manufacturer focusing on neuromodulation involving direct stimulation of the nervous system with electrical signals and used as a treatment for unmanageable chronic pain and/or movement disorders.

Scope

Provide process validation and manufacturing engineering support as result of transferred manufacturing operations.

Situation	Our Approach	Benefits
▪ Setup duplicate Manufacturing lines at new location ▪ The renovated building has a cleanroom into which the manufacturing activities ▪ Requires help in preparing for and executing validation activities with an aggressive schedule.	▪ Develop OQ and PQ protocols based on the critical requirements per SOPs/Templates and flow diagram. ▪ Complete the Operation Qualification-OQ and Performance Qualification-PQ validation of components. ▪ Update Process Planning Matrix & Process FMEA. ▪ Define device configuration requirements for development builds. ▪ Select methods and tools for validation and prepare/review reports.	▪ Provide technical support per Project Plan. ▪ Training, test setup and knowledge acquisition for project team. ▪ Team helps assure the validation processes are well thought out, protocols are comprehensive and that the final packages are well documented. ▪ Compliance with policies and procedures and FDA requirements for validation.

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PMS experience, spanning 3 large med tech clients with proven results

Wipro Client	Project Context	Wipro Role	Volume p.a	Benefits Delivered
Class III top 10 Medical Devices Major	Supported complaints management processes for its range of implantable devices	• 500+ Product Families supported • Global support for Complaint intake, processing, and reporting • Investigation of non product recall returns	~195,000	• 100% Compliance in External Agency Audits • 100% Timely Submission of Regulatory reports • ~40% savings on operations costs • First Time Complaint Capture Accuracy (Avg) of 95%
Class II Global Drugs Devices Company	Supported post market surveillance activities for its drug delivery systems	• 4 Product Families / 3000 products supported • US support for complaint intake and processing (non AE only) and Software Investigation	~60,000	• 36% reduction in Average Handling Time (AHT) within 3 weeks of Go Live • Upfront ~15% savings on operations costs • 6 month performance on FE Accuracy Metric, ~99.7%
Class III Medical Devices Manufacturer for Pelvic Health	Deployed a technology solution and processed legal complaints for one of their product lines	• Legal Complaints for US • Support for complaint intake, processing, and reporting	~17,000	• Introduction of inhouse Auxilium Tool for case management • Exceeded all KPI's

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Questions & Next Steps

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Thank You

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