Remediation of Legacy Medical Devices
What Drives Legacy Remediation?

- Proactive
  - Recertification / CE Mark
  - Audit Readiness
  - M&A / Due Diligence
- Reactive
  - Enforcement Action
Recertification Audit Example: Class IIb Medical Device
The Importance of Standards and the ERC

- Horizontal Standards
- Vertical Standards
- Applicability
- Updates
Regardless of whether a medical device is manufactured within the EU or outside the EU, it cannot be placed on the market within the European Economic Area without a CE mark demonstrating conformity to one of the three medical device Directives.
Strategies for Legacy Remediation

- Gap analysis
- Verification of legacy products
- Validation of legacy processes
- Labeling Updates
- Links to DHF review and Risk Management
- Business ROI analysis, triage, and prioritization
- Deciding how far back to go
Remediation of Legacy Designs

Part 1
Establishing Initial Design Requirements

- 21 CFR 820
- FDA’s Design Control Guidance
- 93/42/EEC (MDD) becoming Medical Device Regulation (MDR)
- ISO 13485:2016
- ISO 14971:2007
- MEDDEV
- UDI
Establishing Initial Design Requirements

- Design Inputs
  - Market Specification
  - Product Specification
  - Risk Management
  - Usability
  - Applicable Standards
Product Characterization

- Taguchi Fractional Factorial DOE
- Challenge/Limit testing
- Establishing acceptance criteria
- Tie to risk
Post-Market Inputs

- Quality Metrics
- Severity, Frequency, Detection
- New Failure Modes, Hazards, Situations, Harms
- Increased Risk Assessment
- Increased Reliability/Confidence
- Additional Testing
Remediation of Legacy Manufacturing Processes

• Part 2
Validation Standards & Regulations

- ISO 13485:2016
- GHTF/IMDRF
- 93/42/EEC Medical Device Regulation
- 21 CFR 820
Reasons for Validation

- New process
- Modified process
- Remediation
- Enforcement action
- Evolving standard/regulation
- Facility relocation / duplication
Strategies for Process Validation

- What to combine
- What NOT to combine
- Stacked challenge testing
- Test Method Validation
- Risk and sampling plans
- Conclusion Statements
Confidence and Reliability are Essential Inputs

- Confidence Level
- Typical Values
- Reliability and Risk
- Reliability and Percent Defective
Remediation of Legacy Documentation

• Part 3
Remediation of the DHF

- Product Specifications
- Standards Assessment
- Risk Management + Post Market Surveillance
- Test Method Validation
- Design Verification and Design Validation
- Biocompatibility and Sterilization
- Process Validation
- Labeling
Requirements of the Medical Device File

◊ Purpose: to contain or reference documents generated to demonstrate conformity to the requirement of the ISO 13485:2016 standard and compliance with applicable regulatory requirements.
Requirements of the Medical Device File

◊ General description of device
◊ Intended use
◊ Labelling incl. IFU
◊ Product specifications
◊ Procedures or specifications for manufacturing, packaging, storage, handling and distribution
◊ Measuring and monitoring procedures
◊ Requirements for installation and servicing
## Traceability of Inputs to Outputs

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Maintaining and Updating the Design File

- Standards Database Subscription
- Sections of a Technical File/Design Dossier
- Paper or Electronic
- Design Traceability Matrix
- Medical Device Files
Best Practices

◇ Standards assessments should be documented and stored for use across sites. This provides traceability and drives alignment.

◇ Have an independent third party review your technical file or design dossier for accuracy.

◇ Make the technical documentation a pointer document.

◇ When you touch a legacy product’s technical documentation, you must bring it fully up to standard.

◇ Ensure the ERC is up to date and that you have objective evidence to support conformity with each relevant article in the ERC.

◇ Audit the completed file for Good Documentation Practices.

◇ Your company designee must sign a new Declaration of Conformity when any info on DoC changes, a change is made to device for which NB approval is required, and upon recertification.
Legacy Watch-Outs

- Not linking TMV (method defect detection capability) to complaints and risk docs
- Not considering MDD above ISO 14971:2007 which mandates reduction of risks AFAP
- Not linking sampling plans in Incoming Inspection and V&V to risk documents and complaints
- Not considering risk separately in vulnerable populations like the elderly and children.
- Over-emphasizing frequency as opposed to systemic trends
- Records don’t support updated standards (e.g., V&V)
Iterative Updates and Improvements

- Evolving Standards (horizontal and vertical)
- Regulatory Enforcement
- Mergers/Acquisitions
- Line or Facility Transfer
- New Market Entry
- Continuous Improvement (proactive)
- Postmarket Data
- CAPA
- Audits/Gap Analyses (mfg and supplier)
- Recertification
Case Study

- Provided as Bonus Material to Attendees
Thanks!

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