Elexes

CASE STUDY

Sustaining Design Control and Quality System Compliance for an FDA-Cleared Active Medical Device

Engineering Change Control | DHF, DMR and DHR Maintenance
Complaint Handling | ISO 14971 Risk Management
ISO 13485 and MDSAP Audit Support



Maintaining connected design, manufacturing and post-market quality records as an established device evolves.

01 / ENGAGEMENT CONTEXT

Overview

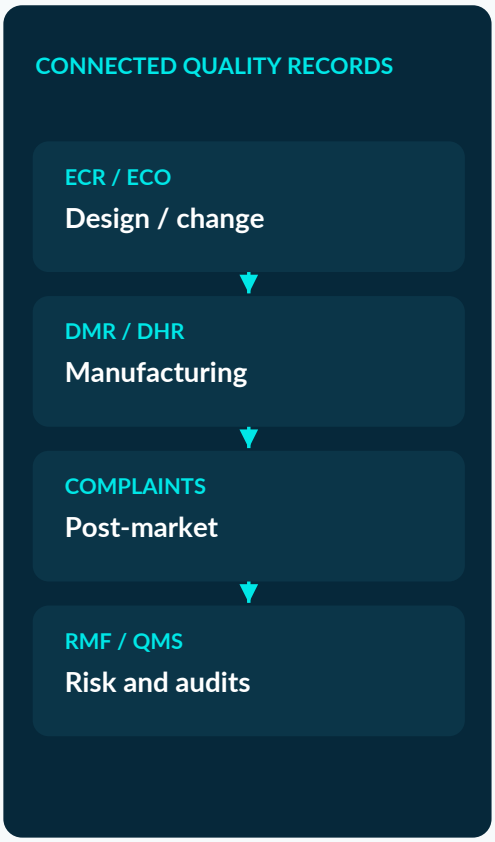
Continuing RA/QA support for an established, FDA-cleared medical device.

An established medical device manufacturer required continuing regulatory affairs and quality assurance support for an FDA-cleared active medical device incorporating electronic hardware and software for non-invasive physiological assessment.

As engineering changes were implemented and information accumulated through manufacturing, servicing and field use, the device's design and manufacturing records required continuing maintenance.

The existing Quality Management System (QMS) provided the framework. Maintaining documentation consistency required coordinated review of changes, affected technical records, customer complaints, risk management and regulatory requirements.

Elexes provides ongoing support across engineering change control, DHF and DMR maintenance, DHR review, complaint handling, post-market risk management and quality system audit activities.



ENGAGEMENT FOCUS

The work connects day-to-day engineering activity, production evidence and field experience with the controlled records needed for continued regulatory oversight.

02 / CLIENT REQUIREMENTS

The Client's Requirements

Maintaining technical and quality records while managing product changes and post-market information.

01

Engineering change control

Assess proposed changes, prepare and coordinate ECR/ECO documentation, and update affected technical and manufacturing records.

02

Design and manufacturing records

Maintain alignment among DHF, DMR, bills of materials, work instructions, production travelers and current configurations.

03

Device history records

Review production documentation for completeness, identify discrepancies and support corrections through defined quality procedures.

04

Complaint handling and FDA reporting

Review customer and service records, identify complaints, support investigations and assess reporting obligations under 21 CFR Part 803.

05

Risk management maintenance

Evaluate complaints, failure trends, investigation findings and engineering changes for relevant updates to the risk management file.

06

QMS and audit support

Support ISO 13485 and applicable MDSAP audits, management review, CAPA activities and FDA quality system documentation alignment.

03 / KEY CHALLENGES

Key Challenges

Five recurring quality-system challenges across engineering, manufacturing and post-market work.

01

Document consistency during engineering changes

Even a localized component modification can affect bills of materials, design records, work instructions, inspection requirements, packaging information or risk documentation. Relevant changes must be identified and coordinated through controlled procedures.

02

Alignment across DHF, DMR and DHR

Part-number and other record discrepancies can undermine consistency between approved designs, manufacturing specifications and production history. Signed records require careful review, investigation and controlled correction.

03

Complaint identification within service information

Service tickets and customer communications do not all represent reportable events. Relevant information must be screened for complaints, investigated as appropriate and evaluated against applicable FDA reporting criteria.

04

Post-market findings and risk management

Complaint investigations and failure trends can reveal emerging information about hazards, risk controls or potential patient impact. Findings require evaluation with engineering, quality and regulatory stakeholders.

05

Audit readiness during continuing operations

Internal and external assessments require retrievable objective evidence, effective follow-up of findings and maintained quality records while engineering changes and service activities continue.

04 / ELEXES' ROLE

Elexes' Involvement

Continuing support across five interconnected regulatory and quality workstreams.

01

Engineering change management

Elexes reviews proposed modifications and prepares or coordinates ECR/ECO records, BOM revisions, production travelers, packaging instructions and work-instruction changes. Regulatory impact assessments are supported where relevant.

02

DHF, DMR and DHR maintenance

Design and manufacturing records are reviewed and updated to maintain consistency with current configurations. Discrepancies in signed records are identified and routed for controlled correction, with DHR review and completion supported.

03

Complaint handling and investigations

Service and customer-event records are screened to identify complaints. Elexes supports record completeness checks, investigations, applicable FDA reporting assessments and health hazard evaluations where warranted.

04

Failure trending and risk management

Failure and complaint information is assessed by component group and root-cause category. Investigation findings, trends and engineering changes inform updates to applicable risk-management documentation.

05

QMS and audit support

Elexes supports internal audits, external audit preparation, objective evidence coordination, management review, CAPA-related activities and applicable FDA quality system documentation alignment.

05 / METHODOLOGY

Elexes' Methodology: Change Control

An evidence-led process that connects change assessment, controlled documents and regulatory considerations.

ECR review — Technical rationale → **Impact check** — Affected records → **ECO package** — Controlled changes → **QMS review** — Manufacturer authority

01 Stage 1. Review engineering change requests

Review the proposed modification, technical rationale, affected components or configurations and potential effects on design, production, risk documentation or FDA requirements. Coordinate with engineering and quality personnel to identify necessary records and evaluations.

02 Stage 2. Prepare controlled change documentation

Prepare or coordinate the ECR/ECO package, including applicable BOMs, engineering drawings, production travelers, packaging instructions, work instructions and affected DHF/DMR information. Support assessment of whether further FDA regulatory action may be warranted.

03 Stage 3. Maintain design and production records

Review DHF records for discrepancies and their relationship with approved changes. Investigate mismatches, route required corrections through document control and support DHR completeness review, updates and completion under manufacturer procedures.

CONTROLLED REVIEW AND APPROVAL

Elexes prepares and evaluates the supporting evidence. Engineering, regulatory and quality decisions proceed through the manufacturer's established review and approval authorities.

05 / METHODOLOGY CONTINUED

From Service Events to QMS Review

Field information and quality records are evaluated through defined manufacturer processes.

04 Stage 4. Review customer events and assess complaints

Screen service and customer-event records against complaint criteria. Examine device information, event details and available evidence, request relevant clarification and progress identified complaints through investigation and 21 CFR Part 803 evaluation.

05 Stage 5. Investigate failures and evaluate patient risk

Review recurring complaints and failures by subassembly and root-cause category, coordinate cross-functional investigations and support health hazard evaluations when potential patient impact warrants further assessment.

06 Stage 6. Maintain the risk management file

Evaluate findings from complaints, investigations, trend analysis and engineering changes for potential implications for hazards, risk estimates and risk controls. Update the RMF where supported by the evidence.

07 Stage 7. Support QMS reviews and audits

Review procedures and objective evidence, coordinate process-owner responses, assist internal and external audit activities, and support management review, CAPA work and QMS documentation alignment.

FIELD INFORMATION

Complaint details, service observations, failure patterns and investigation evidence are assessed for potential safety or quality impact.

CONTROLLED FOLLOW-UP

Applicable outputs may include reporting assessments, RMF updates, CAPA actions or engineering change records, subject to QMS review.

The engagement is ongoing. Additional documentation and risk actions arise as relevant new information becomes available.

06 / TECHNICAL EXECUTION

Design and Manufacturing Record Control

Maintaining consistency between the design baseline, manufacturing requirements and produced-device evidence.

DHF

Design history

Development evidence, design changes and relevant investigation records.

DMR

Manufacturing definition

Specifications, BOMs, work instructions and production requirements.

DHR

Production evidence

Device or lot records showing applicable manufacturing and release activity.

ENGINEERING CHANGE CONTROL

Elexes supports the preparation and coordination of change packages, including related design, manufacturing and configuration updates. The manufacturer retains responsibility for controlled review and approval.

Documentation discrepancies

Signed design records are checked for mismatches, including part-number inconsistencies. Identified issues are investigated and routed through controlled correction processes.

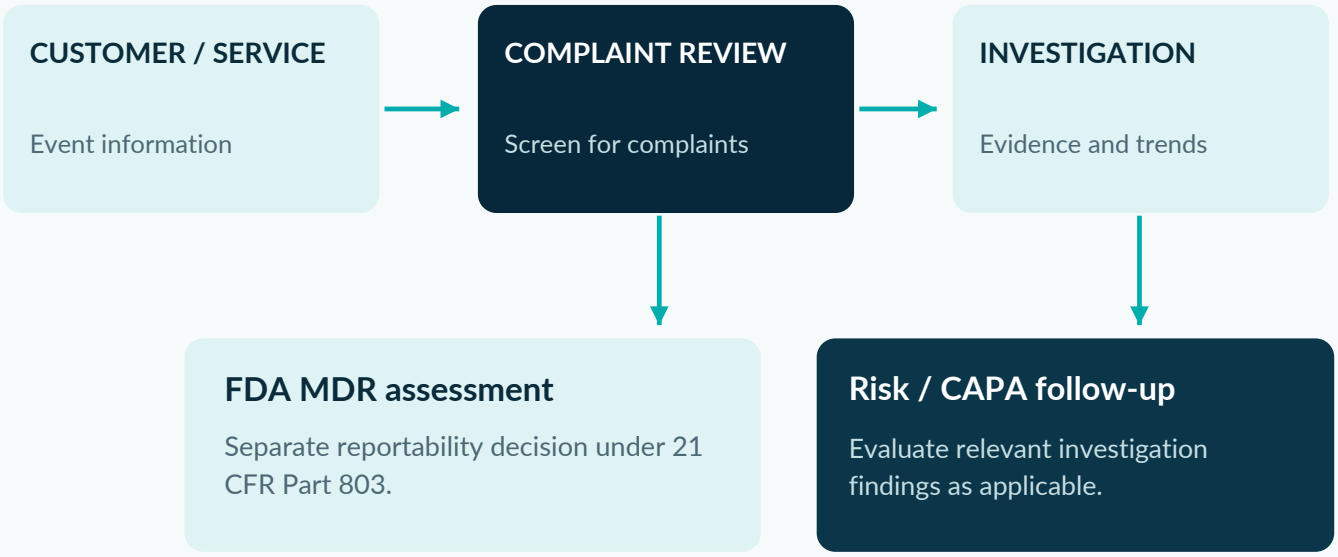
Regulatory impact

Design and component modifications are assessed against applicable FDA guidance to determine whether additional regulatory action requires consideration.

07 / POST-MARKET QUALITY

Complaints, Investigations and Risk Management

Linking service information to complaint evaluation, reporting decisions and risk management.



COMPLAINT HANDLING AND FDA REPORTING

Elexes screens service and customer-event records for potential complaints, reviews record completeness and supports investigations. Identified complaints are evaluated separately for applicable FDA reporting requirements under 21 CFR Part 803, with health hazard assessment support where warranted.

POST-MARKET RISK MANAGEMENT

Failure and complaint information is reviewed for recurring patterns, including relevant subassemblies and root-cause categories. Findings from investigations, trends and engineering changes inform updates to the manufacturer's risk management documentation where appropriate.

ISO 14971:2019 provides the framework for considering production and post-production information within ongoing device risk management.

08 / QMS AND ONGOING OUTPUTS

QMS Support and Documented Outputs

A continuing engagement across controlled documentation, investigations, risk and audit activities.

- **Change packages**
  ECR/ECO records and applicable engineering or manufacturing updates.
- **DHF and DMR maintenance**
  Review and updating of design history and manufacturing specifications.
- **Device history records**
  DHR review, updates and completion through defined procedures.
- **Discrepancy resolution**
  Investigation and controlled correction of record mismatches.
- **Regulatory assessments**
  Evaluation of design/component changes for potential FDA submission implications.
- **Complaint handling**
  Customer-event review, investigation support and reporting assessment.
- **Failure trending**
  Recurring issue analysis and cross-functional investigations.
- **Risk management**
  RMF updates based on relevant field and engineering information.
- **QMS and audit activities**
  Internal/external audit, CAPA, management review and documentation alignment.

QMS SUPPORT

1. **ISO 13485**
   Internal audit
2. **MDSAP**
   Applicable tasks
3. **CAPA**
   Review and follow-up
4. **Management**
   Review inputs
5. **QSR-to-QMSR**
   Terminology alignment

Ongoing scope

Activities continue as device and QMS needs evolve.

09 / TRANSFERABLE EXPERTISE

Where This Experience Can Be Leveraged

Eight service applications supported by the ongoing regulatory and quality work.

01 Engineering change management

Controlled ECR/ECO documentation, affected-record updates and regulatory impact assessment.

02 DHF, DMR and DHR maintenance

Consistency between design history, manufacturing requirements and production records.

03 Component and configuration control

Updates to BOMs, part-number references, drawings and related work instructions.

04 Regulatory change assessment

Structured review of modifications against applicable FDA expectations.

05 Complaint handling and investigations

Identification, investigation support and applicable FDA reporting considerations.

06 Post-market risk management

Evaluation of field experience, trends and design changes within the RMF.

07 ISO 13485 and MDSAP audit support

Objective evidence, internal audit work and coordination of external assessment activities.

08 Continuing RA/QA support

Ongoing technical documentation, quality records, investigations and QMS activities.

10 / BROADER APPLICABILITY

Who This Approach Is For

Manufacturers maintaining authorized devices and operating QMS processes across the commercial lifecycle.

WHO THIS APPROACH IS FOR

- Manufacturers of FDA-cleared or otherwise authorized devices undergoing design changes.
- Organizations maintaining extensive engineering, manufacturing and production records.
- Teams handling complaints, service investigations and risk management updates.
- Manufacturers preparing for ISO 13485, MDSAP or applicable FDA quality assessments.
- Organizations seeking specialist RA/QA support across ongoing quality functions.

OTHER PRODUCTS AND MARKETS

- Active and electronic devices: Engineering and manufacturing changes involving electronic hardware and software.
- Monitoring and assessment technologies: Complaint investigations, design-record control and post-market risk evaluation.
- Electromechanical and rehabilitation devices: Component modifications, service information and regulatory change assessment.
- Established FDA-regulated devices: Controlled changes, regulatory impact reviews and QMS maintenance.
- Multimarket manufacturers: ISO 13485, MDSAP and documentation supporting additional regulatory markets.

THE BROADER APPLICATION

Sustained design and quality control depends on keeping engineering changes, manufacturing evidence, field feedback and risk documentation connected as the product and regulatory expectations evolve.