Elexes

CASE STUDY

Retrospective Design History File Remediation and ISO 13485 QMS Integration for a Powered Medical Device

Historical Design Evidence | ISO 14971 Risk Management
Design Traceability | Manufacturing Documentation



Preserving authentic historical evidence while building a controlled, traceable design history within an established QMS.

01 / DEVICE AND CONTEXT

Overview

A software-controlled device, established development evidence and an existing quality system.



THE PRODUCT

Battery-powered, software-controlled optical medical device

Used to support clinical assessment.

THE ENGAGEMENT

An established medical device manufacturer required support to retrospectively remediate its Design History File (DHF) and incorporate historical design and development evidence into its existing ISO 13485 Quality Management System (QMS).

The original design and development activities had been conducted by an external development partner under that organization's quality system. Consequently, engineering, verification, risk management and manufacturing records were maintained outside the manufacturer's own controlled QMS structure.

Although substantial historical evidence existed, differences in document structures, development phases and applicable standards created a need for systematic review and remediation.

Elexes developed the Design and Development Remediation Plan and supported historical record assessment, risk management updates, verification evidence review, manufacturing documentation integration and QMS procedure revisions.

The engagement preserved original evidence while establishing a coherent design documentation framework within the manufacturer's existing QMS.

02 / PROJECT OBJECTIVES

The Client's Requirements

Five connected requirements, addressed without repeating the original device development.

The manufacturer needed to bring historical design evidence under its established QMS and demonstrate alignment with applicable design-control and risk-management requirements.

01

Retrospective DHF remediation

Review historical design inputs, outputs, design reviews, technical specifications, verification records and engineering changes. Identify gaps and incorporate the evidence into controlled records.

02

ISO 14971 risk management

Review the existing risk management approach against updated requirements and remediate the risk management plan, report and relevant supporting evidence.

03

Verification and design traceability

Strengthen relationships between design inputs, verification and validation records, including software-related evidence.

04

Manufacturing documentation and design transfer

Review available contract-manufacturer records, device history information, drawings and BOMs, and complete relevant device master record and design-transfer checklists.

05

ISO 13485 QMS integration

Update affected procedures and forms, establish controlled documentation arrangements and organize phased reviews to support integration of remediated evidence.

Objective: A controlled, traceable design history within the manufacturer's existing QMS.

03 / KEY CHALLENGES

A Complex Historical Evidence Base

Original engineering evidence had to be preserved while meeting current documentation controls.



01 **Historical records under a different QMS**

The external partner used procedures, templates and design-review phases different from the manufacturer. Original technical records had to be incorporated without altering the historical evidence or its provenance.

02 **Evolving standards and documentation expectations**

Risk documentation was assessed against ISO 14971:2019. Design-control, software lifecycle, usability, labeling and performance evidence required review against applicable standards and acceptance criteria.

03 **Incomplete design-to-test evidence relationships**

Design inputs, verification evidence, validation activities and relevant software records were not consistently linked or organized under the current framework.

04 **Manufacturing evidence held across sources**

Contract-manufacturer DHRs, test data sheets, engineering drawings and BOMs had to be coordinated with design-transfer and device master documentation.

05 **Integration into an established ISO 13485 QMS**

The manufacturer needed revisions to applicable procedures, records and phased design reviews, rather than a standalone replacement document system.

04 / SCOPE OF SUPPORT

Elexes' Involvement

A coordinated documentation remediation engagement with six distinct evidence workstreams.

Elexes authored the remediation plan and coordinated the review and refinement of historical records against the manufacturer's quality processes and applicable requirements.

01

Remediation planning and record assessment

Prepared the Design and Development Remediation Plan, including scope, responsibilities, design-review phases and timeline; recorded document-level gaps and actions.

02

Retrospective documentation control

Incorporated historical records using retrospective QMS cover documentation. Original evidence remained intact, while additional records or revisions addressed identified gaps.

03

Risk management remediation

Evaluated the historical risk plan against ISO 14971:2019 and remediated the risk management plan and report.

04

Verification and traceability support

Redlined safety and performance reports against revised standards and acceptance criteria; supported manufacturer engineers with traceability matrices, including software.

05

Manufacturing evidence and design transfer

Reviewed and incorporated DHRs, test data sheets, drawings and BOMs; completed applicable DMR and design-transfer checklists.

06

QMS updates and phased reviews

Updated applicable design, risk, software, change-control, process-validation, labeling and technical-documentation procedures and forms; tracked work through design reviews.

05 / METHODOLOGY

Historical Evidence: Plan, Assess, Preserve

Six linked stages connect original records with controlled remediation, risk evidence and QMS reviews.

01 PLAN ▸ 02 ASSESS ▸ 03 PRESERVE ▸ 04 REMEDIATE ▸ 05 INTEGRATE ▸ 06 REVIEW

01

Stage 1 | Establish baseline and plan

Elexes developed the Design and Development Remediation Plan to establish scope, responsibilities, planned review phases, timing and remediation activities. The manufacturer's design-control procedure, ISO 13485:2016 and the then-applicable FDA Quality System Regulation design controls (21 CFR 820.30) informed the review.

02

Stage 2 | Inventory and assess historical records

The team reviewed product requirements, risk plans, hazard assessments, design FMEA, verification protocols and reports, device history records, drawings and engineering change notices. Each record was assessed for gaps and associated follow-up actions.

03

Stage 3 | Preserve and incorporate original evidence

Historical development records were brought under QMS controls using retrospective cover documentation. Original evidence remained unaltered, while subsequent reviews and remediation actions were distinguished from the historical development work.

Record-control principle: retain original evidence and distinguish subsequent remediation activities.

05 / METHODOLOGY CONTINUED

Risk Evidence, Manufacturing and QMS Control

Technical remediation was supported by structured review phases and applicable approval processes.

04

Stage 4 | Remediate risk and verification evidence

Elexes assessed historical risk documentation against ISO 14971:2019, remediated the risk management plan and report, and reviewed test evidence against applicable standards and acceptance criteria. Safety and performance reports were redlined where clarification or correction was required. Elexes supported manufacturer engineering teams with design-input, verification and validation traceability, including software.

05

Stage 5 | Integrate manufacturing and design-transfer records

Relevant manufacturing evidence, including device history records, test data sheets, BOMs and engineering drawings from the contract manufacturer, was reviewed and incorporated. Applicable device master record and design-transfer checklists were completed to support consistency between design and manufacturing requirements.

06

Stage 6 | Update QMS and complete phased reviews

Elexes updated applicable procedures and forms across design control, risk management, software lifecycle, engineering changes, process validation, labeling and technical documentation. Design-review phases and DHF, DMR and design-transfer checklists supported tracking of remediation progress and controlled integration.

Phased reviews linked record remediation to the manufacturer's existing design-control procedures.

06 / TECHNICAL EXECUTION

ISO 14971 Risk and Verification Evidence

Risk documentation, test-report review and traceability required connected but distinct evidence records.

ISO 14971 RISK MANAGEMENT REMEDIATION

The historical risk management plan was assessed against ISO 14971:2019. Identified gaps included risk-scoring consistency, references to applicable standards, evidence supporting risk-control effectiveness, and coverage of production and post-production information.

Elexes remediated the risk management plan and report, strengthening the documentation connecting risk activities with design evidence and the device lifecycle.

VERIFICATION, VALIDATION AND DESIGN TRACEABILITY

Existing safety and performance test reports were reviewed against applicable revised standards and documented acceptance criteria. Elexes prepared redlines where clarifications or corrections were needed, and coordinated technical comments with the contract manufacturer and testing laboratories.

Elexes also supported the manufacturer's engineers in developing traceability matrices connecting design inputs with verification and validation evidence, including relevant software records.

RELATED DESIGN AND VERIFICATION EVIDENCE

DESIGN INPUTS	RISK CONTROLS	VERIFICATION	VALIDATION
Requirements	Control measures	Test evidence	Evidence of user needs and intended-use suitability

07 / MANUFACTURING AND QUALITY

Manufacturing Records and QMS Integration

Design history evidence must align with production requirements and controlled QMS procedures.



MANUFACTURING RECORDS AND DESIGN TRANSFER

Historical manufacturing documentation was incorporated into the review and remediation activities. The record set included device history records, test data sheets, engineering drawings and bills of materials supplied by the contract manufacturer.

Elexes completed the applicable device master record and design-transfer checklists to support consistency between the documented design and manufacturing requirements.

QMS DOCUMENTATION AND DESIGN-CONTROL INTEGRATION

The remediation extended beyond technical files. Applicable procedures and forms were updated to align historical evidence with the manufacturer's established ISO 13485 QMS. Documented phase design reviews and checklists were used to track the remediation work and support its controlled integration.

AFFECTED PROCEDURES AND FORMS

- Design control
- Risk management
- Software lifecycle
- Change control
- Process validation
- Labeling
- Technical documentation

08 / RESULTS AND IMPACT

Documented Deliverables and Outcomes

A structured record set supported by historical integrity, completed checklists and updated QMS controls.

The engagement established a systematic approach for reviewing, remediating and integrating historical design documentation into the manufacturer's existing QMS.

Design and Development Remediation Plan

Scope, responsibilities, review phases and timeline established.

Design traceability support

Manufacturer teams supported with design-input to verification and validation matrices, including software.

Historical record assessment

Records reviewed; document-level gaps and actions documented.

Manufacturing and design transfer

Relevant manufacturing records incorporated; DMR and design-transfer checklists completed.

Controlled retrospective evidence

Original records preserved with retrospective cover documentation.

QMS procedure and form updates

Applicable design, risk, software, change-control, process validation and labeling controls revised.

ISO 14971 risk documentation

Historical risk evidence assessed; risk plan and report remediated.

Phased remediation review

Work tracked through documented phase reviews; applicable DHF, DMR and transfer checklists completed.

Verification evidence review

Applicable safety and performance reports reviewed and redlined.

Labeling and technical documentation review

Labels and user manuals reviewed and redlined.

PRACTICAL IMPACT

Historical design records were incorporated into the QMS, with supporting risk, verification and manufacturing records aligned while the original development history was preserved.

09 / TRANSFERABLE EXPERIENCE

Where This Experience Can Be Leveraged

Applications for manufacturers with established products, inherited records and evolving regulatory needs.

01 Retrospective DHF remediation

Assess fragmented or historically maintained design records, document gaps, preserve original evidence and bring files under controlled design-history processes.

02 ISO 14971 risk documentation

Assess and remediate existing risk management records using design, hazard, risk-control and verification evidence, with lifecycle considerations.

03 Design traceability and verification evidence

Strengthen relationships among design inputs and outputs, risk controls, verification and validation records, including relevant software evidence.

04 Manufacturing records and design transfer

Coordinate DHRs, drawings, bills of materials, specifications and design-transfer records with the approved device documentation.

05 ISO 13485 QMS integration

Integrate device-specific records into established document-control, review and approval processes without replacing the manufacturer's entire QMS.

06 Regulatory documentation readiness

Improve organization, consistency and retrieval of technical evidence for applicable quality and regulatory assessments.

07 Engineering change and legacy records

Maintain reliable documentation when established devices undergo component changes, design updates or related regulatory impact evaluations.

08 Additional regulatory market support

Use an accurate evidence baseline to inform jurisdiction-specific documentation gap assessments and supporting regulatory records.

10 / INDUSTRY RELEVANCE

Who This Approach Is For

The same evidence-led framework supports many established device technologies and regulatory programs.

MANUFACTURER SCENARIOS

This approach is relevant to organizations seeking stronger historical technical documentation, design traceability and controlled QMS records.

- **Inherited development evidence**
  Records created by external design partners or contract manufacturers.
- **Fragmented records**
  Engineering, testing or manufacturing evidence maintained outside the current QMS.
- **Retrospective remediation needs**
  Historical DHFs requiring updates while preserving original records.
- **Risk and traceability gaps**
  ISO 14971 documentation or relationships between design and test evidence needing strengthening.
- **Regulatory or quality review**
  Existing products preparing for technical assessment or QMS review.
- **Device-specific QMS integration**
  Documentation integration without replacing an established quality system.

OTHER PRODUCTS AND MARKETS

The approach extends across medical technologies and jurisdictions where established evidence must remain accurate and controlled.

Powered and electromechanical devices
Historical design evidence, risk management, verification and manufacturing integration.

Electronic and software-controlled devices
Requirements, software records, test evidence and risk documentation alignment.

Established FDA-regulated devices
Design-control record remediation and documented assessment of changes.

EU medical device manufacturers
Technical documentation remediation and compliance evidence review.

Market expansion
Evidence gap assessments and market-specific supporting records.

Broader value | Preserve historical design evidence, resolve documentation gaps and strengthen the controlled quality foundation for future device activities.