REGULATORY COMPLIANCE ASSOCIATES®

A Nelson Labs company

Design History Files

The Design History File (DHF) describes the design history of a finished device, including design review, verification, and validation. This is required by the FDA as part of Design Controls (21 CFR 820.30), a subsystem within the main Quality System.

At Regulatory Compliance Associates® Inc. (RCA), we know the complexity of new product development and remediating legacy DHFs within the evolving regulatory environment. Whether it's bringing a new product to market in accelerated timeframes or updating the design information necessary to validate and maintain the device throughout its lifecycle, RCA has a strong understanding of the specific requirements for US and international medical device industries to ensure regulatory compliance and drive business best practices.

RCA enlists over 500 top industry experts, blending FDA veterans and seasoned new product development, quality, and regulatory leaders. We are ready to support your project for the following:

- Quality System Regulation, 21 CFR Part 820
- The Design Control requirements of the CGMPs, 21 CFR 820.30 Design History Files (DHF) content, development, and management
- Device Master Records (DMR) and Device History Record (DHR)
- The EU's Medical Device Regulations (MDR) including Technical File / Design Dossier
- Risk management (ISO 14971) for medical devices including risk analysis, FMEA, risk evaluation, and risk controls through Corrective and Preventive Action (CAPA) plan and design control requirements
- IEC 60601-1-11 (2010) including Programmable Electrical Medical Systems (PEMS) (Clause 14)
- Total product life cycle (TPLC)

The key elements of Device Design Control which are documented in the DHF:

1. Design & Development Planning
2. Design Input
3. Design Output
4. Design Review
5. Design Verification
6. Design Validation
7. Design Transfer
8. Design Changes
9. Risk Management

The Evolving Regulatory Landscape

The DHF is a living document that reflects the product through its lifecycle and adheres to current regulations. In 2016, the latest version of ISO 13485 was released, now requiring procedures for design transfer, design changes and design and development files. The new standard is an effort to be harmonized further with US regulatory requirements, and requires device makers to identify if changes are needed in their design controls procedure for both new and legacy devices.

The requirements for a design history file (DHF) are found in 21 CFR 820.30j:

"Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part."

The RCA Process

If you need to update a legacy product design history file to meet current standards or if your product line does not conform to your quality system, RCA can help. We offer the extensive resources in DHF remediation

We start by fully understanding your situation and medical device. Through a gap analysis, we compare your design history file to identify disparities between your medical device DHF and regulatory requirements. Based on those findings, RCA works with you to develop and then implement a DHF remediation plan.

Need Help with Compliance?

Whether struggling with an upcoming inspection or dealing with regulatory compliance, Regulatory Compliance Associates Inc. stands ready to support you and your company. Armed with consultantsserious about compliance and having years in the trenches as quality and regulatory leaders, RCA can help you establish a sustainable compliance solution and remain at the forefront of the ever-evolving regulatory landscape.

Case Study: Risk Management Remediation

Client Challenge

A diagnostic equipment company received an FDA Form 483 including observations relating to product complaints. As part of their response letter, the company identified risk management as an area for further exploration.

RCA Approach

RCA was asked to remediate the 483 observations and conduct a gap analysis to identify shortcomings between the company's current systems, agency observations, and regulatory requirements. Following our comprehensive assessment, RCA developed the company:

- Implement an electronic complaint handling system
- Develop complaint handling SOPs
- Create a process to evaluate complaints for reportability
- Develop a complaint system checklist

Our assessment also uncovered gaps with the company's risk management approach, leading to our development of:

- Risk Management plans for 6 product families
- FMEA remediation for 118 assessments including hazard analysis, hazard controls, and risk-benefit determination of risk acceptability
- Updates to 118 Risk Management files in accordance with BS EN ISO 14971:2012.

Results

With RCA's remediation expertise, the company was able bring its Risk Management and CAPA plans in compliance with regulatory requirements and close the 483 letter.

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RCA helps life science companies with regulatory compliance and market access in the US and other markets worldwide.

- Quality Systems implementation and remediation
- Compliance assurance through audits, assessments and gap analysis
- US FDA and international regulatory strategy, classification and submissions
- New product development

Why Choose RCA?

- RCA is widely recognized within the life science industry and global regulatory agencies for its ability to help companies successfully resolve complex regulatory challenges
- By mining regulatory intelligence, RCA continuously evaluates FDA's current thinking and leverages thought leadership networks to advocate for our clients
- We have the know-how and proven approach to navigate warning letters, consent decrees and other situations
- We know how to partner with your executive, legal and communication teams
- We support management to assist with the growing and changing concerns
- We know a quality or compliance crisis can significantly impact your business. We help navigate the storm and manage the impact to your business

About RCA

Regulatory Compliance Associates® (RCA) provides worldwide services to the following industries for resolution of compliance and regulatory challenges:

- Pharmaceutical
- Biologic & Biotechnology
- Sterile compounding
- Medical device
- Lab Testing

We understand the complexities of running a life science business and possess areas of expertise that include every facet of R&D, operations, regulatory affairs, quality, and manufacturing. We are used to working on the front lines and thriving in the scrutiny of FDA-and globally-regulated companies.

As your partners, we can negotiate the potential minefield of regulatory compliance and private equity due diligence with insight, hindsight, and the clear advantage of our unique expertise and experience.

- Founded in 2000
- Headquartered in Wisconsin (USA)
  - Regional offices in Florida, Colorado and Europe
- Expertise backed by over 500 industry subject matter experts
- Acquired by Sotera Health in 2021

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