ZipQuality

Consensia

Managed Compliance Service for Medical Device Development

When product teams find themselves caught between the increasing demands of medical device regulations and business pressures to quickly deliver innovative technology, they turn to ZipQuality for compliance at speed.

The ZipQuality service manages all of your design controls and DHF documentation so product teams can focus more time on designing and testing new products and less time editing documents.

Efficient risk management with clear traceability

Predictable, systematic V&V testing, even for complex, software-intensive products ("paperless V&V")

Precise BOM management and design transfer to manufacturing

Roles it benefits:

VP Engineering

- Frees engineers to spend more time on design and test
- Keeps distributed teams in sync by providing an online collaboration hub
- Supports rapid design iterations

VP RA/QA

- On time regulatory submissions with no documentation surprises and delays
- DHF documentation stays up-to- date and audit ready
- Visibility into documentation throughout development

Benefits	Features
Up and running in days	Pre-configured system (processes and tools); no need to alter your quality system
Stay up-to-date and audit-ready	Integrated system easily handles rapid design iterations for product documentation
Minimize distractions during development	Experienced consultants guide your team at every step
Grows with your company and your products	Fully-featured, scalable software tools built on the proven, powerful ENOVIA platform
Pay for results, not for tools	Flat monthly fee

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How ZipQuality Works

Our consultants work closely with your product development team to manage design controls and efficiently and rigorously compile DHF documentation. We set up a secure, hosted environment and our quality experts import and organize your existing product documentation into the ZipQuality database. We then manage completion of the DHF documentation and all design changes throughout development.

Benefits

- Clear visibility and control of product data and documentation at all times
- Efficient, streamlined processes for rapid design iterations
- Single source of truth for distributed teams

ZipQuality services for medical device development:

- Management of Design Controls and DHF documentation:
  - Product development plan/ software development plan
  - Risk management plan / report
  - Risk analysis (System Hazard Analysis, Design FMEA, Use FMEA, Process FMEA)
  - Product requirements, hardware requirements, software requirements
  - Product design documents (mechanical , electrical, software, UI/ID)
  - Design V&V testing (test plans, protocols, reports, trace matrix)
  - Change controls
  - Design reviews
  - Design transfer to manufacturing
  - Labeling and packaging documents
- DHF/BOM/DMR management
- Ongoing training and support

ZipQuality supports efficient and rigorous compliance with FDA QSR (21 CFR 820), IEC 62304, ISO 14971, IEC 62366, EN 60601-1, and related standards for medical device development.

The ZipQuality system is based on a structured documentation framework that supports rigorous systems engineering, efficient risk management, and clear traceability.

It is designed for medical device companies, so it provides a full audit trail and support for compliance with FDA 21 CFR Part 11 regulations.

Discover a better way to manage your DHF documentation—stay fully compliant without slowing down your product development.

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