ZENBIOMED

Your partner for best in-class services & solutions in Quality Assurance, Compliance and Audit

We provide training, strategic consulting, staffing & project-based solutions for our customers

KEY AREAS OF EXPERTISE

Quality Management System

- QMS training and workshop
- QMS gap assessment
- Generation of QMS Manual, Policies and Procedures
- 21 CFR Part 11 compliant Document Control
- QMS compliance with ISO 13485, 21 CFR Part 820, ISO 15189, 42 CFR Part 493, GCLP (WHO & EMA guidelines)
- EU-IVDR 2017/746, EU-MDR 2017/745 transition
- e-QMS implementation and maintenance

Post Market Quality

- Complaint Handling
- Post-market Surveillance
- Vigilance and Reporting
- Periodic Safety & Performance Reports (e.g., PSUR, SSP, SSCP)
- EUDAMED compliance

Design Control & Risk Management

- Design Control implementation
- DHF remediation and maintenance
- Analytical Study design, planning & execution
- Design Transfer
- Risk Classification
- Risk Management in compliance with ISO 14971 (Hazard Analysis, FTA, FMEA, RMP, RMR)

Internal Audit & Inspection Readiness

- ISO 13485, 21 CFR Part 820
- IEC 62304
- ISO 14971, ISO 22367
- Country-specific MDSAP requirements
- EU-IVDR 2017/746, EU-MDR 2017/745
- ISO 15189
- 42 CFR Part 493 (CLIA requirements)

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KEY AREAS OF EXPERTISE

Software as a Medical Device

- Compliance with IEC 62304, TIR 45
- Align with FDA Guidance - Premarket Submissions for Device Software
- Software Safety Classification
- SDLC strategy and documentation

Usability Engineering

- Compliance with IEC 62366
- Formative & Summative Studies
- Usability Engineering File

Operations/Manufacturing Quality

- Compliance with cGMP, QSR 21 CFR 820 (US FDA)
- Generation of DMR/Medical Device File
- Quality Control Strategy & Implementation
- Compliant UDI and Product Codes
- Supplier Management: Qualification, Quality Agreements & Audits
- Management of Non-Conformances & CAPAs

Computer System Validation (CSV)

(non-medical computerized GxP systems)

Align with:

- GAMP 5
- EudraLex Vol.4, Annex 11
- EMA guideline on computerised systems in clinical trial (2023)

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