MEDICAL DEVICE

CloudStaffing
PROFESSIONALS

SOLUTIONS FROM THE EXPERTS

Medical Device

- FDA Audits
- Equipment Validation
- Process Validation
- CSV
- TMV
- Cleaning Validation
- Document Control
- Remediation
- GMP
- Internal Audits
- Supplier Quality
- CAPA Audits
- Complaint Handling
- Toxicology
- Sterilization
- Post Market Surveillance
- Quality Assurance
- Risk Management
- Technical Writing
- Manufacturing
- R&D
- Packaging Engineering
- Design Control
- Quality Procedures
- Labeling
- Technology Transfers
- Project Managers
- Biocompatibility

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Medical Device Regulatory Submissions

- Q-Submission/Pre-Submission
- Breakthrough Device Designation
- De Novo Submission
- 513(g)
- 510(k)
- Deficiency/AI Letter
- PMA
- PMA Supplements
- PMA Annual Reports
- IDE
- IDE Amendments
- Technical Files
- Design Dossiers

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EU MDR
Regulatory Compliance

- Design Information
- Design Risk/Benefit Analysis
- Manufacturing Information
- Production Risk/Benefit Analysis
- Clinical Evaluation Report
- Device Lifetime
- Risk Management Report
- PMCF Plan and Report
- SSCP – Summary of Safety and Clinical Performance
- PSUR – Periodic Safety Update Report
- PMS Plan
- GSPR Checklist
- List of Applied Standards
- Restricted Substance Justification
- Declaration of Conformity

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