SERVICES SUMMARY

Smarter Quality.
Smarter Business.

CANNON QUALITY GROUP LLC

QUALITY SYSTEM IMPLEMENTATION AND MAINTENANCE SUPPORT

Compliant with FDA, Sherman Act/CAL FDB, Medical Device Directive, ISO 13485, ISO 14971, IEC 6060 1, IEC 62366, IEC 62304

DOCUMENT CONTROL
- Logs
- Filing Structure
- Training
- External Standards Maintenance and Review
- Doc Control Checking
- Document Creation
- Change Order Processing
- Annual Document Review

SUPPLIER CONTROL
- Initiate
- Evaluate
- Track and Trend
- Audit

CAPA
- Initiate
- Evaluate
- Root Cause Analysis
- Track and Trend
- Assess Effectiveness

NON-CONFORMING MATERIAL
- Initiate
- Evaluate
- Track and Trend
- Assess Effectiveness

MANAGEMENT REVIEW
- Plan
- Organize
- Present
- Follow up and Close out Action Items

DESIGN CONTROL
- New Product Development – Quality Support
- V&V Protocol and Report Development/Support
- Software V&V
- Test Method Development/Support

RISK MANAGEMENT
- Risk Analysis
- FMEA
- Hazard Analysis
- Human Factors/Usability

POST MARKET SURVEILLANCE
- Plan
- Report
- Maintain

INSPECTION AND TEST – FIRST ARTICLE THROUGH FG RELEASE
- First Article
- Component
- Sub-Assembly
- In-Process
- Final Inspection
- Lot Release
- Batch Record Review and Release
- Test Method Development
- Gauge R&Rs

EQUIPMENT CALIBRATION & MAINTENANCE SUPPORT
- Initiate Records
- Evaluate
- Control
- OOT Investigations

AUDITS
- External: Support CAL FDB, FDA, ISO 13485
- Internal: Manage, Perform, Doc Support
- Supplier: Manage, Perform, Doc Support

PROCESS AND EQUIPMENT VALIDATION SUPPORT
- IQ/OQ/PQ
- Move Plans
- Inspection Development
- Cleaning Validation
- Packaging and Pouching Validation

COMPLAINTS
- Initiate
- Evaluate
- Root Cause Analysis
- Track and Trend
- Assess Effectiveness

RETURNED MATERIAL PROCESSING
- Initiate/Evaluate/Track and Trend/Assess Effectiveness
- Decontamination – Disinfection

STERILIZATION *(EtO, Gamma, E-beam)*
- Validation
- On-going Maintenance
- QDA

REGULATORY
- CE Mark – Technical File/Design Dossier
- 510(k) Submission
- On-going Support and Maintenance

SERVICES SUMMARY

QUALITY PROJECTS

- Electronic Quality Management System
- ERP Implementation
- Inspection Plans
- Post Audit Remediation
- Facility Transfer
- Manufacturing Transfer
- Line Extensions
- Contract Manufacturer Transfer
- Second Source Support
- Validation (IQ/OQ/PQ)
  - Process
  - Equipment
  - Software Internal
  - Computerized System/Quality System Software

STAFFING—INTERIM AND PART-TIME

- Management Rep
- VP/DIR of Quality
- Senior Quality Engineer
- Quality Engineer
- Software Quality
- Document Control
- Inspector
- Supplier Control
- Internal Auditor

CONTROLLED ENVIRONMENT ROOM (CER)

- CER/CDA Qualification/Validation Documentation
  - Fabrication and Launch
    - Requirements Definition
    - Implementation Plan/Execute
    - IQ/OQ/PQ Laminar Flow Hoods/Biosafety Cabinets
    - Establish On-going Monitoring Plan

- CER/CDA QS Procedures In Support of CER
  - Environmental Monitoring
  - Gowning
  - Cleaning

- CER/CDA On-going Services
  - Trending and Limit Setting
  - Annual Re-evaluation
  - Excursion CA Support
  - Room Expansions/Modifications/Move Equipment/Process Validations

TRAINING

- QSR/ISO/GMP
- GDP
- Complaints/MDR/Vigilance
- Process Validation
- Equipment IQ/OQ
- Complaints and Reporting

COMPLETE OUTSOURCING

- Quality Department
- Document Control
- Inspection and Test
- Supplier Control

Let's discuss your Quality System needs.

Contact Cannon Quality Group today!

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