Services

Cannon Quality Group excels at Quality System Implementation & Maintenance Support in Medtech, Pharmaceutical, In Vitro Diagnostics (IVD), and Software-as-a-Medical Device (SaMD) Industries.

Our services support engineering and R&D teams through the entire product lifecycle from initial design to post-market compliance.

CANNON QUALITY GROUP LLC

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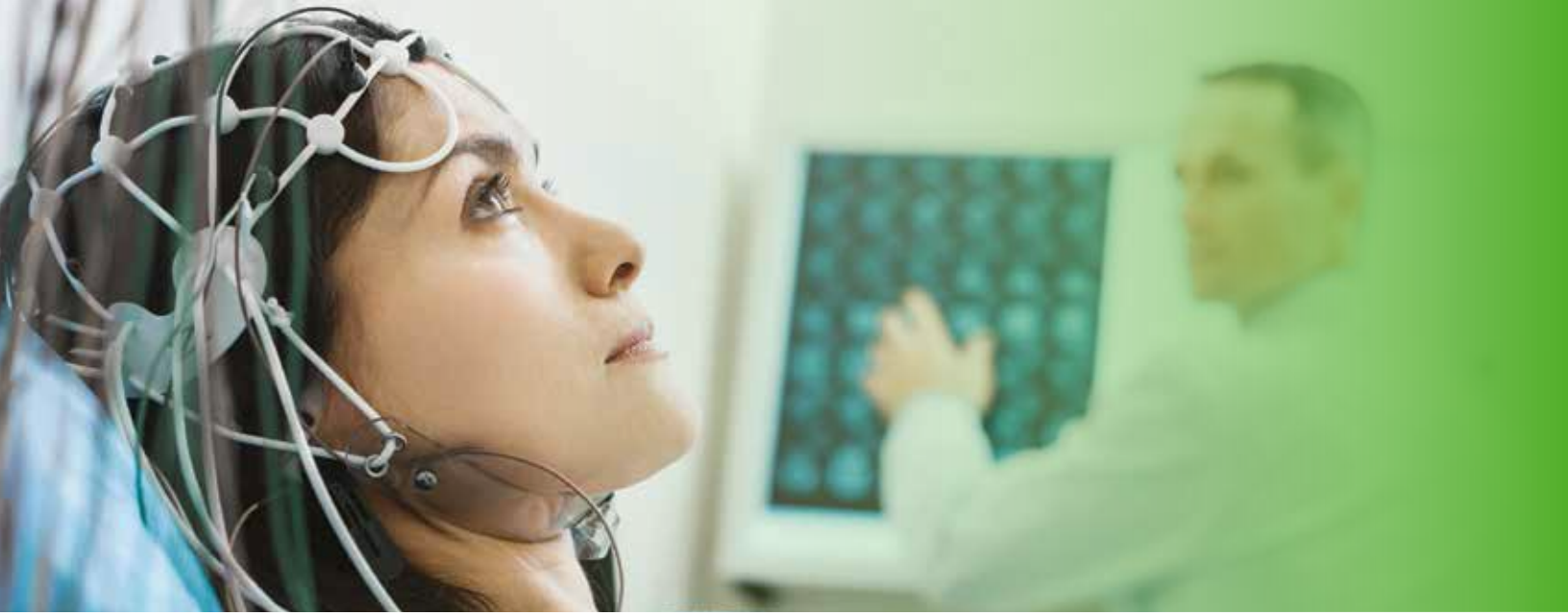

Product Launch Path

Design Control

Design Planning

Product Development Protocol (PDP)/Software Development Lifecycle (SDLC)

Design Verification & Validation (V&V)

Risk Management

Risk Analysis, Failure Mode & Effects Analysis (FMEA), Hazard Analysis

Software Validation

Off-the-Shelf (OTS)

Non-Product Software (NPSW)

Other (as appropriate):

Equipment Validation

Installation Qualification (IQ)/Operational Qualification (OQ), Performance Qualification (PQ), Move Plans, Inspection Development, Cleaning Validation, Packaging & Pouching Validation

Process Validation

Installation Qualification (IQ)/Operational Qualification (OQ), Performance Qualification (PQ), Move Plans, Inspection Development, Cleaning Validation, Packaging & Pouching Validation

Post-Market Surveillance

Plan, Report, Maintain

Inspection & Testing

First Article, Component, Sub-Assembly, In-Process, Final Inspection, Lot Release, Batch Record Review & Release, Test Method Development, Gauge Repeatabilities & Reproducibilities (R&Rs)

Quality System

Document Controls
Logs, Filing Structure, Training, External Standards Maintenance & Review, Doc Control Checking, Document Creation, Change Order Processing, Annual Document Review

Supplier Controls
Initiate, Evaluate, Track & Trend, Audit

Purchasing Controls

Acceptance Activities

Corrective Action and Preventive Action (CAPA)
Initiate, Evaluate, Root Cause Analysis, Track & Trend, Audit

Non-Conforming Material Report (NCMR)
Initiate, Evaluate, Track & Trend, Assess Effectiveness

Management Review
Plan, Organize, Present, Follow Up & Close Out Action Items

Complaint Handling
Initiate, Evaluate, Root Cause Analysis, Track & Trend, Assess Effectiveness

Returned Materials Processing
Initiate, Evaluate, Track & Trend, Assess Effectiveness

Decontamination - Disinfection

Labeling & Packaging Controls
Sterilization (EtO, Gamma, E-beam) Validation, Ongoing Maintenance, Quarterly Dose Audit (QDA)

External Audits
Support and Prep for CAL FDB, FDA, ISO 13485, ISO 15378, ISO 22716, ISO 17025, , TAPA, C-TPAT, MDSAP, UKCA, MDD, MDR & 9001 Notified Body & Customer Audits, 21 CFR parts 210 & 211, 21 CFR part 58, OECD, FSMA, ISO 14155, ISO 22716, European Union Eudralex Volume 4, EXCiPACT, EFfCI, IATA, shared auditors

Internal Audits
Manage and Perform Audits to all relevant company procedures and regulations

Perform GAP Assessments to new and/or updated regulations

Supplier Audits
Manage and Perform Supplier Audits

Servicing Controls

Statistical Techniques

Clinical Study

- Clinical Study
- CE Mark - Technical
- 510(k) Submission

Contact us today to learn more about our services:

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Additional Services Specialities

- eQMS Validation
- Facilities Validation
- Training (all subjects listed in services, including regulations/standards)
- ERP Implementation
- Cleanroom Validation

Staffing Augmentation

- Quality Leadership
- Sr. Quality Engineer
- Document Control (Internal/Supplier)
- Sr. Quality Management
- Quality Engineer

Quality System Regulations/Standards

- 21 CFR Part 820
- IEC 62304
- Medical Device Regulation (MDR)
- 21 CFR Part 11
- IEC 60601
- Medical Device Single Audit Program (MDSAP)
- ISO 9001
- ISO 27001
- SOX
- ISO 13485
- Cybersecurity
- ISO 14971
- HIPAA