CASE STUDY

Case Study Alio

By Cannon Quality Group

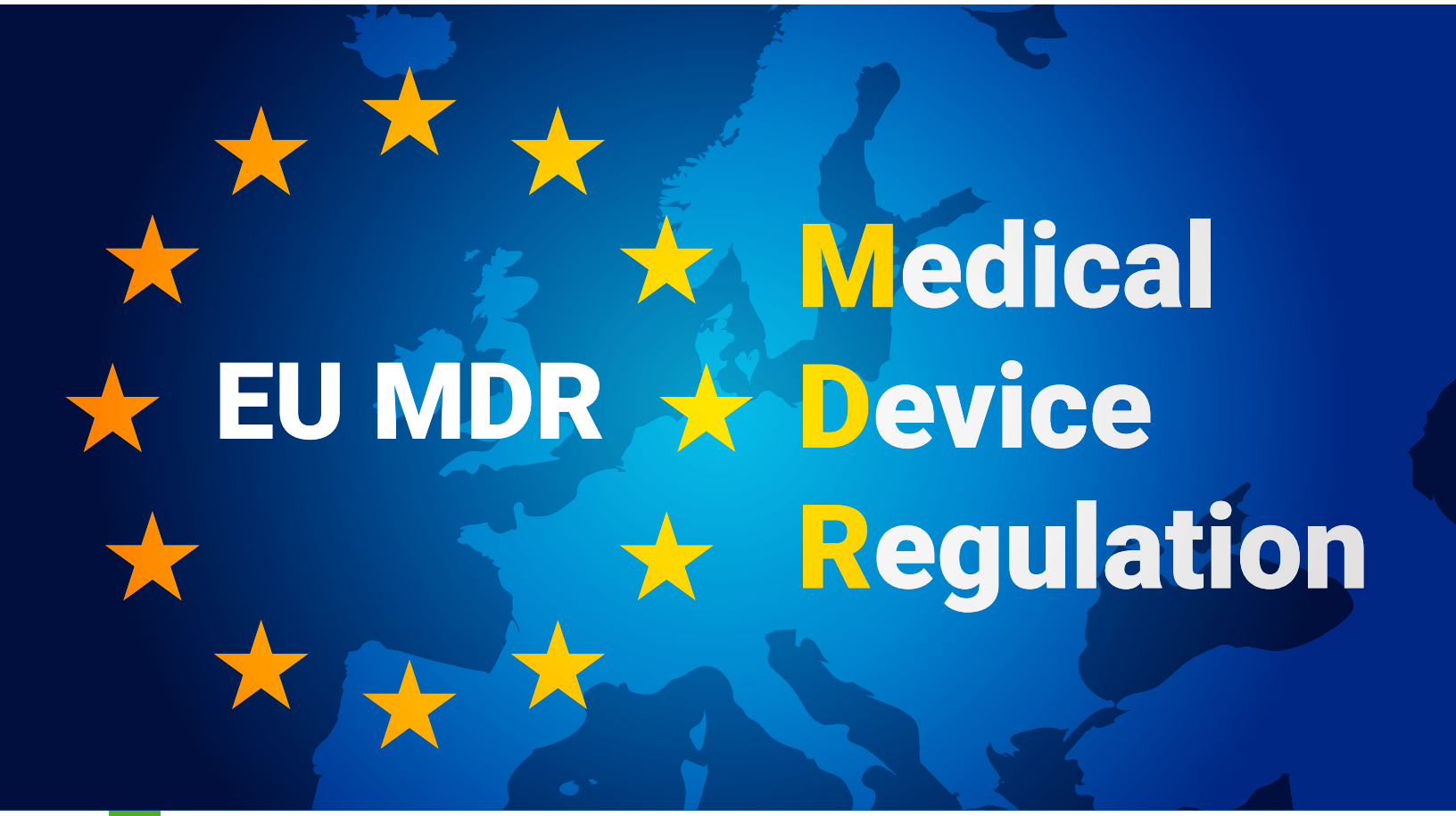
Introduction

Alio pioneered the SmartPatch, a noninvasive remote monitoring for dialysis patients. The SmartPatch is a multi-metric wearable medical device designed to monitor potassium, hematocrit, hemoglobin, auscultation, heart rate and skin temperature for hemodialysis patients, preventing the need for finger sticks.

The Challenge

As a small start-up medical device company with less than fifty employees, Alio lacked the internal resources needed to ensure EU MDR compliance and Kingdom of Saudi Arabia (KSA) Medical Device submissions, as well as update their internal QMS documentation to comply with MDR 2017/745.

Juggling multiple projects, Alio had to balance submission deadlines while meticulously reviewing internal documentation against multiple regulatory requirements.



The Solution

Cannon Quality Group was able to provide subject matter experts to keep their projects moving forward. CQG performed literature review search, compiled GSPRs, and reviewed all submission documentation. Additionally, CQG led and completed Non-Product Software Validation, detailing requirements and validating Alio's systems.

Alio Director of Quality, Roop Pandher said, "CQG kept us organized with weekly meetings and were able to work quickly and efficiently on their own. CQG was able to manage multiple projects at once and internally split off and balance their tasks."

She continued, "They have shown impressive flexibility with projects as we've switched gears multiple times throughout our partnership. Each project was assessed individually and assigned a core team that had the skills to manage it. They have been a pleasure to work with, and we recommend them to anyone considering working with them in the future."

"CQG's impressive flexibility kept multiple projects on target, assisting us with a variety of projects from non-product software validation to EU MDR implementation and support. With Cannon's help, we were able to prepare for EU MDR and Kingdom of Saudi Arabia (KSA) Medical Device submissions. CQG also performed literature review and compiled our GSPRs prior to submission. CQG proved to be an invaluable partner in keeping us organized and on track."

-Roop Pandher, Director of Quality, Alio

Cannon Quality Group Services

Do you need a robust, accurate, and scalable quality management system for your start-up?

Cannon Quality Group provides outsourced Quality Management System solutions that are efficient and compliant. Cannon's number one priority is delivering QMS solutions that make sense for the stage and goals of its clients' business. Cannon Quality Group's mission is to be the Change in Quality.

Product Launch Path

Design Control
- Design Planning

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
- Process Validation
- Post-Market Surveillance
- Inspection & Testing

Quality System

- Document Controls
- Supplier Controls
- Purchasing Controls
- Acceptance Activities
- Corrective Action and Preventive Action (CAPA)
- Non-Conforming Material Report (NCMR)
- Management Review
- Complaint Handling
- Returned Materials Processing
- Labeling & Packaging Controls
- External Audits
- Internal Audits
- Supplier Audits
- Servicing Controls
- Statistical Techniques

Medical Writing

Medical Writing Services
- Clinical Evaluation Protocol & Report
- Literature Search Data forms
- Literature Search Protocol & Report template
- Data Extraction form
- Declaration of Interest (DOI) form

Quality System Implementation (QSI) Templates
- Design & Development
- Software Development Lifecycle
- Production Controls
- Clinical

Additional Services Specialities

- eQMS Validation
- ERP Implementation
- Facilities Validation
- Cleanroom Validation
- Training

Clinical Study

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

Staffing Augmentation

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

Quality System Regulations/Standards

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

CANNON QUALITY GROUP LLC

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