

Medical Device Company QMS/eMDR

Business Challenge

The client, a medical device company, decided to implement Electronic Medical Device Reports (eMDR). Since the client was already using TrackWise for their existing complaints project, it was decided to also implement eMDR with the TrackWise tool. In order to get to that point, their complaints forms had to be upgraded to adhere to certain guidelines set forth in the eMDR standard. The TrackWise system then had to be linked to the client's EDI tool for electronic submission to the FDA.

RCM was charged with identifying the gaps from the Current Complaints and MedWatch process the client had in TrackWise.

This involved adhering to the eMDR standard as far as field types, implementing and validating those changes in the client's system. In addition, the submission and FDA acknowledgements had to be built into the existing workflow for the MedWatch records in TrackWise. This ensured that all information was captured in the system.

Requirements Approach

- Define the boundaries and constraints
- Install the eMDR tool in the development environment
- Identify gaps in the workflows, forms and fields based on a preliminary map with the eMDR tool
- Configure and validate changes in the gap assessment
- Identify and assist with steps necessary to communicate with the FDA gateway for eMDR submissions
- Utilize three (3) prototypes to streamline rollout during which validation preparation and planning will take place
- The system evolves into production upon completion of validation and approval



Value Delivered

Project Results: This project was completed on time and on budget. By implementing eMDR within the TrackWise environment, the client was able to significantly reduce the time and subsequent costs associated with submitting eMDR reports. This effort ensured that no eMDR reports were overlooked and significantly reduced underreporting by automating the reporting process through rules within the system.

More efficient use of time and resources: By hiring RCM as its services partner, the client's IT resources, scientists, business analysts and compliance specialists were able to remain focused on the myriad of tasks that the business required.

Effective knowledge transfer to client: By working in a team environment, document walkthroughs, regular status meetings and timely presentations on data and results.

Solution

The client selected RCM because of its life science compliance and validation expertise. RCM provided a favorable rate by quoting a fixed-price, deliverable-based estimate (versus ambiguous time and materials proposals). RCM's resources - with years of QMS experience - implemented eMDR accurately, on time and under budget.

The RCM Difference

As a business trying to navigate today's changing economy, RCM understands our client's need to respond to industry demands and make their organization more profitable by reducing expenses, maximizing revenues, increasing overall customer satisfaction, streamlining processes and gaining competitive differentiation. RCM's solutions have been proven to help clients achieve and exceed these goals.