SOFTWARECPR®

CRISIS PREVENTION AND RECOVERY, LLC

ROBERT (BOB) WEST

EXPERIENCE

- Project manager supporting development of a large digital health ecosystem / Class III medical device. Implemented risk-based Monte Carlo scheduling methods with strategic "what-if" scenarios for alternate development paths; quantified program risks and initiated mitigation activities.
- RA Project Management for licensing of MDR changes for large, international Medical Devices manufacturer in 108 countries outside of CE, involving over 90,000 products. Developed process flow for program. Planning, document acquisition, and execution of license renewals, integration of other major parallel projects, reporting to stakeholders, and co-ordination with Supply Chain for inventory planning and control.
- RA Project Management for the rebranding of 8000+ products across 75+ countries after a major acquisition. Designed, developed, and implemented a custom database relating products, countries, 3000+ licenses, and 90+ manufacturing sites to schedule all RA license submissions over a 3-year period. MDR relabeling is included in work scope.
- RA Project Management for the rebranding of 1000+ products across 50 countries after a major acquisition. Developed MS Project schedule for RA actions based on label and rebranded product availability dates. Extended RA schedule work into the supply chain, developing data for product import and distribution blackout periods for affected countries. Turned schedule work over to client staff for implementation.
- Consolidation of 3 Design Control QMSs into one. Reviewed all three systems, selected best practices and consolidated all into one set of documents, including updates for EN ISO 14971:2012 and ISO 13485:2016. Made revisions on a total of 35 SOP's, WKI's, Forms, and Templates. Extended work supporting client in developing various templates for PDP documents.
- Initiated a multi-year remediation program of 92 Technical Files covering 3000+ products to bring them into MDD conformance. Established containment for CAPA, performed, coordinated, and summarized the high-level gap analysis of Tech Files, DHF's, DMR's, risk files, CER's, biocompatibility, and sterilization/packaging to determine scope of program work. Coordinated efforts with three other major remediation programs for risk, combination products, and plant quality processes.
- Managed the QA portion of the shutdown and technical transfer of a design/manufacturing facility for a Class II (FDA) / Class III (CE) medical device. Drove six work streams to move R&D, quality, and RA functions to another US location and international locations. Work was controlled by multiple Quality Plans and included moving a local QMS system onto two existing QMSs at new locations. Scope included registering new sites, 20 new quality agreements, work on over 100 SOP's, and coordinating 6 notified body audits at 3 sites for 13485 and product certifications.
- Lead consultant of three-person team for Design Control remediation in response to FDA 483 and 3rd party audit findings.
- Managed a one year, forty-person consulting team to reduce CAPA backlog.
- Led RA support on selected product lines for a major orthopedic manufacturer, globally releasing over 400 new Class I and II instruments and cases.
- Provided final stage project management and RA support for a leading dialysis device manufacturer.