

RISK DRIVEN QUALITY CONSULTING COMPANY, LLC

Business Guidelines

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1127 Thomas Ave,
San Diego, CA
92109

1244 Fremont Ave,
Los Altos, CA
94024

Tel: 515-657 2476
jxiao@rdpdm.com
www.rdqcc.us

II. Overviews

2.1 Why Choose the RdQCC?

RdQCC was found by a group of professionals from risk management engineers, quality engineers, project managers, software engineers, and data scientists who are passionate to look for the best solutions to reduce product safety risks by applying new technologies such as NLP, big data, and machine learning.

The RdPDM trademark represents the core technology developed by the RdQCC team. The software consists of two components: electronic risk analysis (e.g., FMEA, hazard analysis) and web-based risk prediction engine (e.g., data trained models). Those two components are able to be used separately or integrated as one unit dependent on user needs.

Compared with the traditional excel-based FMEA worksheet, the electronic risk analysis is able to trace risks from bottom (module level) to top (system level) and quickly evaluate product safety impacts due to design changes; compared with the traditional personal-based risk assessment, the intelligent risk prediction engine is able to provide Subject Matter Expert (SME) level service and high resolution along with growing learning data.

RdQCC has been serviced for varied medical device organizations (sizes, cultures, budget) and technical challenges (e.g., total artificial heart, pacemaker, robotic surgical, stent & graft, ventilator, medical pump, orthopedic, disposable). The RdQCC understands what customer needs are what the customized solutions should be.

2.2 Business Scopes

Build risk management automation:

- Establish a customized web-based risk prediction engine (webpage, training models)
- Develop an electronic-based risk analysis (e.g., FMEA, Hazard analysis)
- Embedded risk prediction engine with electronic risk analysis (one page operation)

Consulting projects:

- Complaint risk analysis (extract complaints data from FDA Maude, or other databases)
- Risk documentation remediation (e.g., for ISO 14971:2020, EU MDR, 483 observations, or warning letters)
- Periodic risk document reviews, or quality annual reviews
- Product development deliverables (e.g., risk, human factor, biocompatibility)

2.3 Examples of the Consulted Medical Devices

- Total Artificial Heart
- Cardiac Rhythm Management (pacemaker, ICDs, ICMs, Remote Care)
- Medical Robot (Robotic surgical, Robotic Telemedicine)
- Medical pump (infusion pump, insulin pump, pneumatic pump)
- Respiratory care (ventilator, oxygen concentrator)
- Surgical device (RF generator, 3-D mapping system)
- Stent & graft (endovascular AAA system, advanced delivery system)
- Orthopedic product (dental, kneel, hip, shoulder, elbow, foot and ankle joints)
- Medical imaging (x-ray, CT, MRI, endoscopy)
- Software as a Medical Device (SaMD)
- Catheter (microcatheter, coil, balloon)
- Leads (pacing lead, defibrillation lead)
- Disposable (IV set, connector, therapy pad, electrode, coil)

2.4 Examples of the Consulted Customers

