RISK DRIVEN QUALITY CONSULTING COMPANY, LLC

Business Guidelines

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2.1 Why Choose the RdQCC?

RdQCC was found by a dedicated group of professionals, including risk management engineers, quality engineers, project managers, software engineers, and data scientists. They are passionate about seeking the best solutions to reduce product safety risks by leveraging innovative technologies such as NLP, big data, and machine learning.

The goal of RdQCC is to provide an AI-powered risk assessment application that enables users to obtain high quality risk predictions in real-time, supporting both new product development and post market surveillance. Furthermore, RdQCC aims to establish a global risk data center to support product innovation and business services.

Compared with the traditional human-driven product risk assessment, our AI-powered risk assessment application has the ability to: understand the meaning and context of well-defined data such as user needs or product requirements; explore and assess risks from various sources, including documents, reports, event statements, customer complaints, and other textual sources; analyze the surrounding text to understand the circumstances, causes, and potential consequences of each risk; provide Subject Matter Expert (SME) level service in real-time.

In contrast to the ChatGPT application, our AI-powered risk assessment application offers specialized outputs tailored to your specific hazard lists, hazardous situation lists, and harm lists, resulting in higher accuracy. Furthermore, our application and trained models are hosted on your own server, ensuring the sensitive information and visitation data within your organization.

RdQCC has been serviced for varied medical device organizations, ranging in size, culture, and budget, and has tackled various technical challenges, including projects involving total artificial heart, heart pump, pacemaker, robotic surgical, stent & graft, ventilator, medical pump, orthopedic, and disposables. RdQCC has a deep understanding of customer needs and can tailor customized solutions accordingly.

2.2 Business Scope

Develop a customized AI-powered risk assessment application for our clients. This includes:

- Establishing an AI-powered risk prediction engine tailored to meet the specific needs of our customers. This will involve creating a dedicated webpage and training models.
- Integrating the customized AI-powered application into electronic-based risk analysis worksheet, such as FMEA and Hazard analysis). This integration will enable the generation of comprehensive risk management deliverables.

- Incorporating the customized AI-powered application into project deliverable templates, allowing use to create technical files such as verification test plans and protocols efficiently.

Extract product risk information from global risk data center. It includes:

- Providing potential critical risk assessment and determining risk score in system level for new project to facilitate informed business decision.
- Proactively analyzing potential risks, failure causes, and risk mitigations to reduce project rework.
- Monitoring product risks and provide trend analysis.

Take on consulting projects. It includes:

- Conducting post-market product risk analysis (extract complaints data from FDA Maude, or other databases)
- Remediating risk documentation in response to the new version of ISO 14971:2020, EU MDR, 483 observations, or warning letters.
- Implementing risk-based CAPA escalation and deployment.
- Remediating technical documentation (e.g., verification, human factor, biocompatibility).

2.3 Examples of Consulted Medical Devices

- Total Artificial Heart, Heart Pump
- Cardiac Rhythm Management (pacemaker, ICDs, ICMs, remote care)
- Medical Robot (robotic surgical, robotic Telemedicine system)
- 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, digital solution, surgical plan)
- Neurovascular treatment/stroke treatment (coil)
- Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD)
- Catheter (microcatheter, irrigation catheter, RF catheter, delivery catheter)
- Leads (pacing lead, defibrillation lead)
- Disposable (IV set, connector, therapy pad, electrode, balloon)

2.4 Examples of Consulted Customers