Brandon Clapp

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PROFESSIONAL SUMMARY

Cybersecurity enthusiast and seasoned Quality Assurance professional in the medical device industry with certifications including CompTIA Security+ and ISC(2) SSCP. Proven track record in ensuring regulatory compliance, managing remote teams, and crafting effective CAPA strategies. Expert in cGMP, CFRs, and ISO Standards, dedicated to contributing cybersecurity expertise to the medical device sector.

CERTIFICATIONS

- CompTIA Security+ (Sec+)
- CompTIA Network+ (Net+)
- CompTIA CySA+
- CompTIA Project+
- CompTIA Pentest+
- ISC(2) System Security Certified Practitioner (SSCP)
- ITIL Foundation in IT Service Management

TECHNICAL PROFICIENCIES

Python | Visual Basic | Data Analytics | Automation | Scripting | Network Administration | Firewall Management | Routing and Switching | Windows Administration | MacOS Administration | Linux Administration | Microsoft Power Apps

PROFESSIONAL EXPERIENCE

Manager of Quality Engineering and CAPA Dec 2021 – Nov 2023

miraDry | Remote, Colorado

- Established and supervised the CAPA program and CAPA Review Board (CRB), implementing a risk-based CAPA process compliant with CFR 820.100 and ISO 13485.
- Remediated the Quality Management System (QMS) to align with ISO/CFR regulations, with a focus on updating outdated standards and emphasizing Risk Management per ISO 14971.
- Led cross-functional teams to identify root causes, ensuring comprehensive investigation write-ups and reducing the total number of open investigations, leading to critical QMS updates.
- Reviewed and endorsed design changes and New Product Development (NPD) projects, ensuring adherence to change management processes and patient safety protocols.
- Conducted thorough internal and external supplier audits, tracking and escalating issues through the CAPA and Supplier Management processes. Provided quarterly data insights to management.
- Held ASQ – CBA (Certified Biomedical Auditor 2014-2019) certification/training, offering expertise in auditing techniques.
- Provided strategic insight into documentation and organized validation documentation to support EUMDR submission, ensuring compliance with current standards and guidance.

Regulatory Affairs Specialist Jun 2021 – Dec 2021

Philips-IGTD | Colorado Springs, Colorado

- Crafted and submitted regulatory strategies for device modifications, ensuring strict compliance with FDA and EUMDR regulations.
- Reviewed changes within the established change management process to guarantee no adverse impact on current products or associated processes.
- Conducted thorough assessments of both Product and Non-Product changes, steering the determination of requisite regulatory actions.
- Provided essential support during the transition from MDD to EUMDR approval for devices currently sanctioned under MDD.
- Assisted in evaluating product documentation, fostering close collaboration with cross-functional partners within IGTD.
- Offered cross-functional assistance to an international team in meeting registration requests, ensuring the smooth maintenance of global market access.

CAPA Manager Oct 2017 – Jun 2021

Philips-IGTD | Colorado Springs, Colorado

- Orchestrated the complete lifecycle of the CAPA program at Philips-IGTD, steering initiatives from inception to final approval and closure.
- Served as the Business Process Expert (BPE) for CAPA processes within Philips-IGTD, overhauling CAPA process Standard Operating Procedures (SOPs) to align with federal requirements and industry best practices that lead to a successful FDA Warning Letter Remediation.
- Led the cross-site CAPA Review Board, overseeing the assessment of CAPA requests, analysis of metrics, and allocation of resources.
- Provided crucial support and training to cross-functional teams in documenting the CAPA process and conducting effective root cause analyses.
- Specialized in technical writing, ensuring reviews of investigations result in CAPA documentation with a coherent narrative substantiated by objective evidence.
- Spearheaded quarterly training sessions on the CAPA process and investigation writeup strategy for new lead investigators, refining work instructions and training materials based on feedback.
- Managed a team of direct and indirect reports facilitating CAPA investigations and escalating issues to the CAPA Review Board.
- Generated and delivered regular reports on CAPA metrics, fulfilling Monthly, Quarterly, and other ad-hoc requests for management.

EDUCATION

Bachelor of Science in Cybersecurity, and Information Assurance February 2024
Western Governors University **| Salt Lake City, UT**

Bachelor of Science in Biology, with minor in Chemistry
University of Nevada Las Vegas **| Las Vegas, NV**