Brandon Clapp

Colorado Springs, CO | 719-514-3954 | brandon.clapp@ret0n.com
Portfolio: https://ret0n-journal.github.io/brandonclapp.github.io| LinkedIn: https://www.linkedin.com/in/reton-brandon-clapp

PROFESSIONAL SUMMARY

A strong foundation in Quality Assurance and Regulatory affairs and a proven track record in regulatory compliance, project management, and conducting effective CAPA investigations to improve processes resulting in increased safety and customer satisfaction. Now transitioning into cybersecurity with a unique perspective able to align compliance with business objectives. Expertise in cGMP, CFRs, and ISO Standards, as well as championing cybersecurity risk and compliance standards within regulated industries will provide immediate value to the organization. Refined ability to propose solutions that meet Quality and Regulatory requirements into processes to ensure alignment with business objectives and cost considerations to ensure regulatory expectations are met that drive business success.

I.T. CERTIFICATIONS

- CompTIA Security+ (Sec+)
- CompTIA Network+ (Net+)
- CompTIA CySA+
- CompTIA Project+
- CompTIA Pentest+
- ISC2 System Security Certified Practitioner (SSCP)
- ITIL Foundation in IT Service Management
- Pen Test with Hak5 - Training

TECHNICAL PROFICIENCIES

Python | Visual Basic | Data Analytics | Risk Management | Scripting | Network Administration | Firewall Management | Routing and Switching | Windows Administration | MacOS Administration | Linux Administration | Microsoft Power Apps | Regulatory frameworks | Nmap | Nessus | Ticket Platforms | SQL | Troubleshooting methodologies for Software and Hardware

TECHNICAL PROJECTS

- Hypervisor with virtual machines
- Unifi Network Rack – IDS/IPS, Network Administration and monitoring, VLANs, Wi-Fi monitoring
- NAS Administration (Synology) – Backups, Security Cameras
- Remote technical support for friends and family – Computer systems, troubleshooting, Web Domain and Email assistance

PROFESSIONAL EXPERIENCE

Manager of Quality Engineering and CAPA Dec 2021 – Nov 2023

miraDry | Remote, Colorado

- Crafted and submitted regulatory strategies for device modifications as well as new device designs, ensuring strict compliance with FDA and EUMDR regulations.
- Provided strategic insight into documentation and organized validation documentation to support EUMDR submission, ensuring compliance with current standards and guidance. Submission was successful for EUMDR.
- Setup process to review updated regulatory requirements, translation into working SOPs and communicate across the business.
- Established and supervised the CAPA program, CAPA Review Board (CRB), while implementing a risk-based CAPA process compliant with CFR 820.100 and ISO 13485.

- Remediated the Quality Management System (QMS) to align with Quality and Regulatory requirements, 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 resulting in successful third-party audits.
- Reviewed and endorsed design changes and New Product Development (NPD) projects, ensuring adherence to change management processes and patient safety protocols.
- Reviewed updated IFUs, Labels and promotional materials for compliance with standards and regulatory requirements.
- Provided and communicated KPI metrics for Quality Management processes responsible for to Senior Management.
- Held ASQ – CBA (Certified Biomedical Auditor 2014-2019) certification, offering expertise in auditing techniques to colleagues for internal and external auditing.
- Conducted thorough internal and external supplier audits, tracking and escalating issues through the CAPA and Supplier Management processes. Creating new supplier KPIs and escalating issues to suppliers quicker and with information to assist with their root cause investigation led to improved supplier performance and relationships.

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 Class II devices currently sanctioned under MDD.
- Managed the responses to the EUMDR submission to ensure supported responses to questions from the notified body.
- 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 a risk-based process for the CAPA program at Philips-IGTD, steering initiatives from inception to final approval and closure. Led to lower CAPA numbers for the business as well as direct focus to the problems that required resources to ensure the right problems were the focus.
- 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 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 senior management.
- Managed CAPAs to align with yearly business metrics to ensure year over year improvement of the CAPA program by reducing the total number of open CAPAs as well as ensuring greater than 90% effectiveness rate.

PET Supervisor and Sr. Quality Specialist Oct 2011 – Oct 2017

Cardinal Health | Denver CO and Las Vegas NV

- Led PET (Positron Emission Tomography) operations for the manufacture of FDG and NaF for commercial distribution.
- Trained team of technicians to standard operating procedures for compliant manufacture and testing of drug products.
- Improved the audit outcome by reduction of findings of all hosted inspections for FDA, State radiation safety inspections and internal audits.
- Investigated nonconformances and out of specification results during the manufacturing process to identify root cause and perform actions to correct.
- Performed Radiation safety, cGMP, and EH&S audits to ensure compliance with all processes.
- Planned and led continual improvement projects to reduce operating costs and increase production efficiency.
- Ensured facility and equipment maintenance as well as ensured inventory levels were adequate for business operational need.
- Reviewed and approved documentation and test results for release of FDG, NaF, and N13.
- Author and reviewer of Non-Conformance and Out of Specification reports that ensured a compliant and transparent documentation for FDA review.
- SME trainer for QA personnel on methodologies for SOPs, regulations and required standards.
- Lead the local team in setting up new high-volume PET manufacturing facility in Las Vegas compliant with all regulations.

EDUCATION

- Master of Science in Cybersecurity, and Information Assurance — June 2024
  Western Governors University | Salt Lake City, UT
- 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 — Graduated 2008
  University of Nevada Las Vegas | Las Vegas, NV