HEATHER NEELY, RAC, CQA ***805-886-1069 (cell)***
hlneely@gmail.com

HIGHLIGHTS OF QUALIFICATIONS

- Experience in the medical device/pharmaceutical/biotech/ industry
- Focus on Microbiology, Sterilization, Validation, Regulatory Submissions, Quality, Audits, and Project Management
- Demonstrated flexibility and adaptability to new situations throughout career and consistently applied problem solving skills
- Detail oriented, organized and dedicated professional with Knowledge of FDA, EU MDR, MDD, CFDA, ANVISA, PMDA, SOPs, USP, cGMP, GLP, GCP and ISO
- Experience leading and managing cross functional teams through influence and collaboration

PROFESSIONAL EXPERIENCE

2024-Present Independent Consulting Lakewood, CO

Principal Quality and Regulatory Consultant (09/24- Present)

- Provides regulatory consulting services for areas that include global submissions, global strategy, equipment and process validation, auditing and audit preparation, training, quality system set-up and assessment per ISO 13485, 21 CFR 820, Regulation (EU) 2017/745, MDRs, change control and labeling.

2022- 2024 MRC Global, Centennial, CO

Principal Regulatory Consultant (03/22- 09/24)

- Provides quality and regulatory consulting services for areas that include global submissions, global strategy, equipment and process validation, auditing and audit preparation, training, quality system set-up and assessment per ISO 13485, 21 CFR 820, Regulation (EU) 2017/745, MDRs, change control and labeling.

2011-2022 Kinamed Incorporated, Camarillo, CA (Medical Device <60 Employees)

Consultant-(03/22- 06/22)

Director RA/QA (08/11- 03/22)

- Manage, organize, and maintain the Quality Assurance and Regulatory Compliance requirements in accordance with applicable domestic and foreign medical device regulations
- Lead and supervise progress of assigned personnel to ensure that goals and target dates are met
- Implement European MDR in the Quality Management System and Post-Market Surveillance System
- Interact directly with FDA, ANVISA, Notified Body and customers during on-site audits, recalls, and MDR reporting
- Prepare FDA 510(k), PMDA, CFDA, ANVISA submissions for new products and product changes
- Ensure organization of Technical Files and ongoing maintenance to maintain compliance with MDD
- Review labeling, promotional material and proposed product changes against regulatory standards
- Ensures ETO, Gamma, and steam sterilization validation and routine processing cycles are maintained
- Reviews and approves subcontractor agreements
- Supplier Selection/Approval and perform external audits of critical suppliers
- Plans annual budget and reconciles the actual budget with that planned
- Designated Management's Representative, conducting and documenting periodic Management Reviews
- Implement policies and procedures as well as training to comply with 21 CFR 820 and ISO 13485
- Supervise and approve the following quality system functions- Training system, Calibration/Process Validation, Document Control (ECO), Complaint Handling, CAPA system, NCMR, and QA activities.
- Ensure occurrence of Internal Audits and Computer Software Validation
- Maintain international registration listing and FDA registrations and product listings
- Interface with Distributors for testing and international submission strategy/requirements

2010-2011 ClinForce, Assigned to Allergan, Goleta, CA (Medical Device)

Clinical Quality Manager (09/10-8/11, Temporary Assignment)

- Provide guidance to project teams to implement Clinical CAPAs on active studies
- Create study specific transition plans from existing SOPs to new Global SOPs
- Manage project timelines and due dates for the transition plans
- Teach project teams how to build quality into processes using new Global SOPs and regulations
- Write and Revise SOPs to reflect current practice and regulatory compliance

2009-2010 Medacta USA, Camarillo, CA (Medical Device- Orthopedics)

Director RA/QA/CA and Compliance Officer (02/09-09/10)

- Prepare FDA 510(k) submissions for new products and product changes
- Interface with R&D of parent company for testing and US 510(k) submission strategy/requirements

- Review labeling, promotional material and proposed product changes against regulatory standards
- Interact directly with FDA on recalls/corrections and removals as well as MDR reporting
- Maintain FDA registrations and product listings
- Maintain proficiency in regulatory requirements and monitor changes to regulatory requirements
- Designated Management's Representative, conducting and documenting periodic Management Reviews
- Implement policies and procedures as well as training to comply with 21 CFR 820 and ISO 13485
- Supervise and approve the following quality system functions- Document Control (ECO), Complaint Handling, CAPA system, Training system, NCMR, QC activities and Calibration/Process Validation
- Supplier Selection/Approval and perform external audits of critical suppliers
- Ensure occurrence of Internal Audits and Computer Software Validation
- Fill the role of Compliance Officer, establish and maintain a compliance program for Physician Consultants
- Select and manage clinical investigators/sites and CRO to meet Clinical Affairs and regulatory requirements

2004-2009 GlobeImmune, Inc., Louisville, CO (Biotechnology- Recombinant Yeast Product)

Sr. QA Specialist, (01/08-02/09)

- Design, review and approve labeling, packaging, distribution of clinical trial material for double blind and open label clinical trials in India, United States and Europe
- Manage drug supply, distribution and randomized kit verification for clinical trials in Prism EDC system
- Manage drug supply and distribution using packaging/labeling contractor custom validated software
- Resolve complaints from clinical trial sites, central pharmacies and contractors
- Advise QA Specialist's, QC, and Manufacturing on product quality and safety issues and CAPA
- On-site QA representative for aseptic fills and QA representative for project teams
- Manage cross functional project team for new fill/finish site
- Lead auditor for external contractors
- Interact with the manufacturing director, QC manager, inventory control, and purchasing to ensure no interruption in supply of clinical trial materials

QA Specialist III, (09/05-01/08)

- Lead auditor for aseptic fill/finish sites, fully electronic labeling/packaging sites (US and Europe), sterile gowning site, QC testing laboratories for LAL and microbial identification
- Author CMC section of IND annual reports to the US FDA
- Enhance compliance and safety as clinical trials of multiple products progress to phase II and III
- Evaluation, auditing, and identification of an alternate aseptic fill/finish site
- Review and approval of equipment Commissioning, IQ/OQ and PQ protocols for new facility and revalidation including cleanroom validation and ISO 14644 compliance
- Review and approve calibration, equipment maintenance, and environmental monitoring excursions.

QA Specialist II, Contractor (6/04 – 09/04), Permanent (09/04-09/05)

- Implement Calibration Manager 4.1 software, build queries/ad hoc reports and assist with software validation
- Batch record review and release of master, primary, and secondary yeast banks, biologic substance and product (includes review of Safety test required by biologics)
- Coordinate and execute equipment inspection, calibration, maintenance and repair/trouble shoot
- Review and monitor placebo, biologic substance and product stability data
- Author raw material specifications for critical process raw materials and establish raw material system
- Lead internal audits of Manufacturing, Quality Control and QA deviation system
- Document change control of QA procedures, batch records, QC testing, and equipment procedures

2005-2011 RMC Pharmaceutical Solutions Inc., Longmont, CO (Pharmaceutical and Biotechnology)

Sub-Contractor (03/05-08/11)

- Review and advise on microbiology related method validation, environmental monitoring and steam sterilization validation

2000-2004 FeRx Incorporated, Aurora, CO (Pharmaceutical and Medical Device)

QA/QC Specialist II (7/03 – 5/04)

- Manage annual PQ of FeRx cleanrooms and routine environmental monitoring program plus trend analysis
- QA approval of safety related protocols; reports and validations (steam sterilization, depyrogenation, LAL, bioburden)

- QA/QC compliance review of labels, packaging, non-conforming material reports, work orders, deviations and complaints
- Lead auditor for sterilization contractors and QA/QC audit team member
- Coordinate contract lab validation of compendia microbiology methods (sterility, LAL, bioburden)
- Supervise the work of two Environmental Monitoring Analysts
- Write and revise SOPs to reflect current practice and regulatory compliance

QA/QC Specialist I (7/01 – 7/03)
- Perform HPLC and GC Assays using Chem. Station Software
- Review and QA release of raw materials and device assembly records
- Participate in audits of all contract laboratories and FeRx contract manufacturers
- Perform internal audits during GMP manufacturing and testing
- Review, document, and resolve QC analytical testing and environmental monitoring investigations

QA/QC Analyst II (2/00 – 7/01)
- Coordinate and perform QC release, in-process, stability, and analytical testing for clinical trial samples
- Record review of bulk and final product testing, raw material testing, and stability data
- Coordinate and monitor QC stability program
- Train and coordinate workload of a part-time QC Analyst
- Develop and implement the initial Environmental Monitoring program for Fitzsimons (new facility)
- Assist in document control activities and external audits

EDUCATION

University of Colorado at Boulder
Bachelor of Arts in Environmental, Population & Organismic Biology with a Minor in Biochemistry

RAC Certification 11/2008, ASQ CQA 06/11, Northeastern University Regulatory Courses

COMPUTER SKILLS

Knowledge of GDSN, GUDID, Prism- Electronic Data Capture System, Calibration Manager, TMS- Electronic Document Management System, Windows, Access, Excel, Word, Power Point, Outlook, FileMaker, Macola, Internet