Melinda J. Rainey

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CAREER SUMMARY:

An experienced Quality Specialist with a strong background in Technical Writing, Quality Auditing and Complaint Handling. Experience in medical devices, pharmaceutical manufacturing and pre-clinical testing environment. Recognized as a Quality Assurance Top Performer and as a Cross-Functional Departmental Trainer.

EDUCATION:

Bachelor of Science in Biology (Environmental), Heidelberg University, Tiffin, Ohio

COMPUTER SKILLS:

Experience in IBM and Macintosh systems, Microsoft® Office including Power Point, Word, Office and Excel. Utilization of Data Management Software (WTDMS, EtQ, TrackWise and Enovia). Generation and publication of electronic reports using Publisher™ and kPortal™ software.

PROFESSIONAL EXPERIENCE:

Zimmer Biomet 2014 to present

- **Quality Engineer/Clinical Engineer, Post Market Surveillance**

  Evaluated Enovia or EtQ Complaint and made MDR/MDV reporting decisions for Zimmer Biomet customer complaints to the FDA and other agencies as applicable. Reviewed and submitted MDR/MDV Reports to the FDA and other agencies as applicable. Developed and managed regulatory reporting decision tools for use in reporting applicable events to the FDA and other agencies. Contacted both domestic and international customers for additional information in order to ensure compliance of the customer complaint file(s) with the FDA 21CFR and Zimmer Biomet internal procedures.

  Conducted and managed training with India counterparts (TCS) regarding contacting customers for additional reporting information and retrieval of product in order to ensure compliance of the complaint handling system with the QSR and Zimmer Biomet internal procedures.

  Reviewed complaint investigations, corrections/corrective actions (CAPA) and risk management assessments for accuracy and to ensure the customer's reported issue was appropriately addressed. Managed and tracked medical device complaint metrics for product line for reporting to upper management committee for the Zimmer Surgical Division. Completed CAPA Academy training.

Ben Venue Laboratories 2005 to 2013

- **Quality Specialist II, Quality Assurance**

  Provided guidance to Production, auditors, Specialist I and II positions to ensure compliance with all applicable regulations and acted in a managerial/supervisory capacity. Influenced and approved policies and procedures for compliance evaluation of regulated activities and acted as a resource for colleagues with less regulatory and auditing experience. Authorized to suspend manufacturing operations when situations warranted.

  Quality technical reviewer and approver of all batch-related documentation, including: compliance documents, SOPs, change forms, re-issue requests and validation protocols. Performed tasks/deviations/investigations/protocols of high complexity and visibility; assumed accountability for multiple projects and ensured completion in a timely manner.

  Trained new personnel as required and developed and implemented several new training programs across several departments. Completed Quality Training for Project Phoenix and implemented and conducted Change Management Training for Project Phoenix.

PROFESSIONAL EXPERIENCE: (cont.)

Ben Venue Laboratories 2005 to 2013 (cont.)

- **Change Control Specialist / Technical Writer, Documentation**

  Generated Change Control Request forms, processed requested changes, obtained approval for said changes and issued Master Production Records to production departments in accordance with cGMP and BVL Standard Operating Procedures.

  Reviewed Change Packages for accuracy, processed requested changes and created summary of changes to documents, compiled information to expand scope of change, verified and proofread Master Production Records, submitted requested changes and any additional changes to customers for approval.

  Recognized for extensive knowledge of Master Production Records and regarded as Subject Matter Expert for the Master Production Record and the entire manufacturing process. Provided training and support to company for electronic systems (TrackWise and Idea for Con) and the process for Change Management for all controlled documents. Completed Crucial Conversations Training, Intermediate and Advanced Adobe and Microsoft Word training. Implemented and conducted training for Change Control Specialists in Technical Writing and controlled documentation.

- **Quality Operations/Quality Assurance Auditor**

  Internal auditing of the manufacturing processes (including compounding, aseptic filling, sealing and packaging) to insure compliance to Standard Operating Procedures and current Good Manufacturing Practices. Manufacturing audits included observation of the activities being performed, assessment of the general housekeeping and review of the quality of batch documentation completed. Critical errors discovered were addressed immediately by contacting the responsible parties, facilitated corrective action and insured proper documentation. Required audit observation report for the department under review. Completed and filed internal manufacturing audit report on a timely basis.

  Initiated the process for batch exceptions generated in the “Red Tag” system and Tier I, II and III Deviations and Investigations including assembly of support documentation and advisement for disposition of final product involved in the event.

  During off shift auditing, evaluated discrepancies and situations and made quality decisions that were critical to the safety, quality, integrity and process of manufacturing a product. Trained Quality Auditors on manufacturing process and auditing procedures along with the auditing/review of Lyophilization Cycle and Recipe Review procedures.

WIL Research Laboratories, Inc. 2001 to 2005

- **Associate Study Analyst**

  Functioned as lead writer for routine study reports, including production of interim reports/data tables, in accordance with GLP and WIL Research, Inc. Standard Operating Procedures. Responsibilities included review of study records, compilation of study information, preparation of report methods and results, collation and quality control of data, preparation, verification and proofreading of report tables, running statistical analysis data, scientific interpretation of data, assisting with quality assurance audits and generation of electronic reports.

- **Biologist**

  Responsible for the performance of in-life phases of assigned general toxicology studies in accordance with Good Laboratory Practices and WIL Research Standard Operating Procedures and functioned as lead technician for complex Toxicology studies and Acute Biology studies. Skills included identifying animals via subcutaneous microchips, performance of functional observations and the collection of physical parameters such as ECGs, blood pressure, body temperature and heart and respiration rate; dosing skills included intravenous, intramuscular and oral (capsule and gavage), specimen collection skills included blood collection for canine (dog), porcine (pig) and leporine (rabbit).