DONNA DEGRAIDE

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Mastered the skills of time management, problem resolution, priority setting, effective communication, and meticulous organization in various administrative, laboratory, manufacturing, and management positions. My various job functions have allowed me to hone the skills of performing well under pressure, handling multiple tasks without sacrificing quality for quantity, and dealing effectively with employees at all levels within the organization. Adept at combing enthusiasm for team work as well as demonstrating individual initiative to produce results and solve problems. Other strengths include dependable, flexible, driven to succeed, attention to detail, and providing quality performance of tasks.

PROFESSIONAL SKILLS

Technical

- Demonstrated knowledge of FDA/QSR and ISO Quality System Requirements
- Proficient in cGMP compliance in the manufacture of biopharmaceutical products including cell culture, operation of bioreactors and protein purification process equipment, and aseptic technique
- Author, revise, review, and approve operational, equipment maintenance, and quality system SOPs and other types of controlled documentation including work instructions, batch records, material specifications, and quality control specifications
- Management of quality systems including document change control, CAPA, deviation/OOS reporting, and audit procedures

Administrative

- Excellent computer skills including Microsoft Office and familiar with various database software systems including SAP
- Verbally articulate with good listening skills to coordinate with all levels of an organization
- Able to recognize the need to utilize resources while maintaining confidence in abilities
- Welcome constructive criticism with vision of constant improvement in all skills
- Adept at adopting to challenges or new situations and embracing change and new ideas

EMPLOYMENT HISTORY

Saand, Inc., Webster, MA 07/2017 – 01/2018

Process Quality Technician

- Supported and built a customer-focused quality culture through data collection, processing monitoring, root cause analysis, and corrective action.
- Authored, revised, reviewed, and approved procedures, work instructions, and forms related to sales and manufacturing processes.
- Performed routine manufacturing area inspections to ensure compliance to company policies/procedures, regulatory requirements, and customer standards.
- Led regulatory audits and provided corrective actions as necessary.

Expert Staffing, Southbridge, MA 03/2017 – 05/2017

Quality Assurance Coordinator (temporary)

- Provided direction in revising controlled documents including procedures and work instructions to clearly and effectively document processes in logistics center.

Oak Transcription of NY, Inc., Sturbridge, MA 2013 – 2017

Medical Transcription Specialist

- Transcribed medical reports from dictated recordings made by medical physicians and psychologists.
- Exhibited proficiency in understanding medical terminology, anatomy and physiology, diagnostic procedures, pharmacology, and treatment assessments.

Accomplishments

- Achieved and maintained a 99.6% accuracy rate exceeding the minimum 98% accuracy rate while maintaining a 24-hour turn-around time.

Continued Experience

Harrington Memorial Hospital, Southbridge, MA 2010 – 2011
Medical Secretary/Transcriptionist

- Accessioned surgical pathology specimens.
- Submitted pathology slides and blocks to outside sources for consultation as necessary.
- Provide gross description and diagnostic impression transcription of dictated recordings within the Pathology Department on specimens submitted from various inpatient and outpatient medical physicians.

PP Manufacturing, Framingham, MA 2005 – 2009
Quality Assurance Supervisor

- Implemented and executed QA systems to support lot release, audit, and training.
- Performed manufacturing batch record and quality control specification review for the disposition of antigen, vaccine, and adjuvant products.
- Critically evaluated investigations including Out of Specification (OOS), Corrective and Preventative Action (CAPA), and complex deviations with emphasis on root cause analysis.
- Initiated and/or assisted departments with investigations related to manufactured products.
- Reviewed and approved validation protocols (IQ, OQ, and PQ) as required.
- Wrote, revised, reviewed, and approved SOPs, batch records, material specifications, and test records.
- Trended and reported QA-related information (deviations, OOS, CAPA, and Formal Investigations).
- Prepared routine updates and project status reports of Quality Assurance activities.
- Prepared for and/or conducted internal and supplier audits. Prepared audit reports and assisted in and monitored the implementation of corrective actions for close out.
- Assisted with preparation for USDA and other regulatory inspections.
- Trained and critically evaluated personnel for compliance to cGMP procedures and company procedures.

Accomplishments

- Managed and executed the document change control of over 400 controlled documents to reflect a company name change, more user-friendly and effective format, and content to reflect current procedures and materials in a 2-year period.
- Promoted from Quality Assurance Associate (Wilmark Group) to Quality Assurance Supervisor (PPM) in a 6-month period.
- Conceived, developed, and implemented a more extensive training program to ensure cGMP compliance and decrease unplanned deviations by 30%.

ViaCell, Inc., Worcester, MA 2001 – 2004
Clinical Production/Research Associate

- Established and maintained *ex vivo* hematopoietic stem cell cultures for research and/or clinical production (Phase I/II) utilizing aseptic technique in Class 100 hood.
- Prepared clinical grade media, buffers, and growth factors.
- Maintained databases and laboratory notebooks.

Accomplishments

- Recipient of Key Contributor award for contributions made in coordinating the activities of clinical production, quality control, quality assurance, and logistics during clinical trial preparation.
- Member of a team of scientists and research associates who participated in generating high quality experimental data following standard protocols for an IND submission.

EDUCATION

Community College of Rhode Island | A.A.S. | Chemical Technology

Worcester Polytechnic Institute | 4-day workshop in Management Development

Bay Path Adult Evening School | Medical Coding and Billing | Certificate