

BATCH RECORD COORDINATOR / DOCUMENT CONTROL

Summary

Throughout my work experience, I have focused on the quality aspects of business. I am an organized and responsible individual with good communication skills and experience in the regulatory industry.

Accomplishments

- GMP (21 CFR 111) Trainer of Production staff.
- Designed and implemented systems relating to trending measures relating to production statistics.
- Designed and implemented compressed air testing for production facilities.
- Specimen Processing Trainer Member of the Idea Team at McKay-Dee Hospital Microsoft Office All Internet Research 60 wpm typing speed.

Experience

Company Name City , State Batch Record Coordinator / Document Control 02/2015 to Current

- I am responsible for document control involving all aspect of the production batch record and master manufacturing record.
- Produce a Batch Record for each order received.
- Creates the Master Manufacturing Record for any new products.
- This includes all specifications which are defined by the customer and regulatory agencies, i.e.
- FDA - GMP (21 CFR 111) and TGA (Therapeutic Goods Administration is the regulatory body for therapeutic goods in Australia.) Makes any modifications necessary to existing Batch Records and ensure that changes are properly approved and documented.
- This includes any formulation changes, deviations and change controls to the Master Manufacturing Record.
- Maintains other documents and files that relate to the production of Batch Records (Master Formula, Master Manufacturing Record, Finished Product Testing Specifications), and ensure that any changes are properly documented (change controls).
- Review any printed material included as part of a finished product to ensure that all claims made on the label are consisted with the formula.
- Excellent communication skills and ability to interact with all levels within the company.
- Self-starter and comfortable working in a team environment or on individual projects.
- Effectively communicates with all areas of the company to maintain accurate records.

Company Name City , State Quality Assurance Specialist 09/2013 to 02/2015

- I am responsible for systems involving Quality Assurance at Albion facilities.
- I oversee and improve the facility's current quality manufacturing functions.
- Designed, implemented and update quality trending measures for all of Albion's facilities.
- Trending measures include tracking of material yields as well as costs.
- Measures are published company wide and I formalize a summary of all data that is presented to the Executive staff.
- Designed and implemented a testing program for testing particles, oil, water and microbial levels in the compressed air system according to ISO 8573.
- Currently in a Metrology training program.
- Upon completion, I will design and implement a program for the inspection, calibration and tracking for all instruments and tools relating to production according to ISO 17025.
- Formal NSF / GMP training and have trained employees to the GMP and ISO 9001:2008 standards.
- Member of the Material Review Board.
- The Board reviews and determines the direction of product disposition and of project planning.
- Direct the inspection of products to ensure adherence to established standards of quality.
- Prepare, review and organize quality assurance data and documentation.
- Write, revise, review and approve standard operating procedures and facility work instructions.
- Inspect and audit facility daily.
- Formal reviews are published and reviewed with the Production staff.
- Write, revise and review master manufacturing records (MMR) and quality control documents to include all batch records pertaining to the production of each lot of material.
- Review all batch records for the adherence to the Quality HACCP Plan.
- Provided direct involvement with the design and implementation of new procedures relating to in-house projects to further develop and improve manufacturing systems and processes according to GMP (21 CFR 111) and ISO standards.
- Excellent communication skills and ability to interact with all levels within the company.
- Self-starter and comfortable working in a team environment or on individual projects.
- Supervisor: Kory Longhurst (801-725-7348) Okay to contact this Supervisor: Yes.

Company Name City , State Specimen Processor 06/2010 to 09/2013

- Facilitates laboratory organization and patient care by ordering, preparing and directing testing to appropriate lab / testing.
- Trained and mentored new employees.
- Responsible for accurately receiving, ordering, processing, labeling and auditing specimens according to established procedure.
- Recognize factors that may affect testing outcomes, I take appropriate action to solve problems, and consistently documents solutions according to established protocols.

- Trained and maintained appropriate knowledge of all computer systems and test ordering practices insuring all specimens are properly entered in all computer systems.
- Effectively communicates specimen collection and handling requirements, providing service to external and internal customers.
- Performs and documents quality assurance checks and provide correction/maintenance.
- Identify opportunities for continuous process improvement and executes project conception, data collection and implementation.
- Performs sterile specimen preparation techniques.
- Follows appropriate documentation protocol and properly identify patients and correctly labels samples.
- I assist in some testing.
- I attended and completed the Specimen Processing School at IHC.
- I have many customer service duties in the area from working with the Home Health Nurses, couriers, other department Techs and taking outside calls from other Hospitals, clinics and Physician Offices.
- While a Processor at McKay-Dee, I was member of the Idea Team.
- I participated, approved and implemented process improvement ideas from all departments within the laboratory.

Company Name City , State Claims Processor 05/2001 to 07/2002

- Processed medical claims and assured proper payment in accordance with the benefit plan.
- Provided customer service for plan benefits, provider networks and available services.
- Resolved claim issues for members and providers.

Company Name City , State Rural Carrier - TRC 06/2000 to 07/2001

- Proficient in all areas of mail delivery. Numerous duties include, but not limited to: maintaining personal vehicle for use on the route, sorting and casing mail according to postal regulations.
- Maintaining the proper forms and regulations for special handling mail, bundling mail, loading vehicle, delivery and collecting of mail and parcels.
- Performing any follow up with customers and always maintaining complete and organized records of delivery.
- Maintained a very neat and organized working area.

Company Name City , State Owner 09/1999 to 07/2012

- Extensive experience in Customer Service relating to online sales and marketing.
- Developed detailed ads to accurately describe a wide range of products from health supplements, cars and home items.
- Worked one-on-one with vendors and wholesalers for the distribution of products.

Company Name City , State Chemist 06/1997 to 09/1999

- Tested environmental samples for pesticides and herbicides.
- Developed and maintained quality assurance measures in relation to the pesticide enforcement grant required for laboratories.
- Determined the type and extent of testing required to ascertain the quality of samples submitted for analyses.
- Analyzed and interpreted test results in order to assist in the administration of laws, regulations or specifications relating to the pesticide formulations or residues found.
- Made final decisions which pertain to the chemical content of individual samples.
- Prepared official reports and may be called upon to testify before the court or the Commissioner.
- Experience using Gas Chromatography and High Performance Liquid Chromatography.

Company Name City , State Customer Service Representative & Claims Processor 04/1996 to 03/1997

- Extensive training in processing, analyzing and adjudicating claims.
- Performed a complete and detailed follow-up of inquiries from providers, subscribers and departments within Mountain State.
- Extensive experience with urgent resolution of problems and research using all available resources, whether the inquiry is received by telephone, correspondence or in person.
- Experience using numerous databases and knowledge of ICD-9, CPT and HCPC coding.
- Very versatile throughout the workload and able to switch tasks immediately with accuracy and efficiency.

Company Name City , State Project Coordinator 10/1992 to 04/1995

- Maintained accurate records pertaining to productivity and budgeting.
- Generated, researched and developed effective methods for locating people for government, commercial and academic clients.
- Researched, investigated and located people using a variety of cost-effective methods to include: searches of national and regional databases, telephone interviews and library searches.
- Analyzed, wrote and produced locator reports for clients that fully describe the locations of the people and the methods used to locate them.
- Extensive experience with accessing and analyzing credit reports.

Company Name City , State Chemist II 05/1990 to 05/1992

- Direct work breakdown and scheduling of lab preparation, execution and clean up.

- Maintained specific operating procedures that insured the successful prosecution in a court of law.
- Performed numerous chemical procedures including TLC, HPLC, ELISA and other testing methods.
- Maintained records and accountability of samples, testing equipment and various stages of testing procedures.

Education

Currently Enrolled : Accounting 2018 Champlain College , City , State Currently Enrolled

Bachelor's Degree : Chemistry 08/1992 Virginia tech , City , State B.A. Chemistry

Job Related Training:

Quality Assurance Specialist - NSF / 21 GFR 111 Course completion.

Quality Assurance Specialist - AirCheck Academy, Trace Analytics Corporation - Course completion for compressed air testing in a food grade facility according to ISO 8573.

Specimen Processing School at Intermountain Health Care from June 2010 through July 2011.

Skills

Regulatory Compliance

Document Control

Quality Assurance

Auditor

GMP / ISO 9001 / NSF

Calibration

Medical Coding

Customer Service

Databases & Microsoft Office & Sharepoint

Process improvement

Product Testing

Project planning

Research