

Raquel Dubois

Technical Batch Record Writer II - Lonza Biologics

Portsmouth, NH

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WORK EXPERIENCE

Technical Batch Record Writer III

Lonza Biologics - Portsmouth, NH - December 2010 to Present

Technical Batch Record Writer

- Function as the lead liaison and change agent for approved changes for campaign readiness.
- Revise manufacturing batch records and/or product specifications based on approved changes.
- Provide appropriate justification/reasons for process improvement changes to the manufacturing batch records.
- Collaborate with various departments to ensure changes are incorporated appropriately.
- Ensure Change Controls, CAPAs, and Deviations are applicable to document revisions.
- Responsible for the timeliness of the project schedule to ensure that each batch record is approved and effective within the Document Management System.
- Setup and run daily documentation meetings when necessary to ensure project team members are clear on timelines and expectations.
- Communicate effectively with identified internal and external reviews and approvals.
- Generate document metrics for upper management.
- Assess and identify when a process change will affect more than one contract product.

Quality Systems Specialist I

Boehringer Ingelheim, Ben Venue Laboratories - Bedford, OH - October 2009 to October 2010

Investigation Specialist

- Review and approve investigation related to Drug Substance Contract Manufacturing
- Lead liaison between Contract Customers and Quality Systems
- Review GMP documentation: Applying knowledge of GMPs with the familiarities of manufacturing to review and assess. (Investigations, CAPAs, Protocols, and Interim Reports)
- Supervised Interns/Temporary employees: Managed workload, assignments, schedules and approved timesheets.

Quality/Data Analyst

Simplified Clinical Data Systems - Milford, NH - November 2008 to February 2009

Project development and qualification:

- Responsible for assisting with and working on all phases of projects including analysis of research requirements: Design and configuration of new system projects.
- Work with programmers on data mapping, testing, training and post-implementation as support
- Develop and implement new enhancements for process improvements.

General Functions:

- Helpdesk support, Train personnel on functional area SOPs, and customers on system enhancements/improvements
- Provide daily support for document management, including scanning and library maintenance
- General office administration activities.

Quality Compliance Specialist, Wyeth Biotech

Biotech External Supply - Wilmington, MA - October 2005 to October 2008

Change Control Coordinator:

- Develop and implement External Supply Site Change Control System process improvements.
- Management of Second and Third Party Changes through Triage Meetings, processing, tracking and maintaining Change Control Documentation files
- Lead liaison between Second/Third parties and internal Quality Assurance functions.

Investigations Coordinator:

- Review and approve investigations related to Drug Substance and Drug Product manufacturing.
- Instrumental in the development of investigation tracking process for third party deviations
- Perform data analysis for Annual product review reports as it relates to investigations.
- Develop, compile, structure, and present weekly trending reports to Senior Management.
- Present metric reports to the Site Quality Council.

General Functions:

- Train personnel on functional area SOPs.
- Provide daily support for processing records/ reports in the TrackWise® system database.
- Assist with internal and FDA audits.

Quality Assurance Operations Coordinator

Wyeth Biotech - Andover, MA - September 2002 to October 2005

Provide Quality Assurance support for investigations generated during GMP activities in a Commercial Manufacturing Facility, including writing, compiling, structuring of data for Investigations Reports.

- Organize compile, structure, and present weekly reports to upper management, Create work flows: how to do reports, Monthly Metric reports.
- Collect and maintain data for Investigation group, Query's, Memo's, and Archives.
- Maintain systems for issuing extension, and Corrective Plans.
- Assist Internal and External audits: Gather requested information/data, answer applicable information, run and operate validated system.

EDUCATION

Bachelor's of Science in Business Studies

Southern New Hampshire University - Salem, NH
2014

Business Administration

Hesser College - Salem, NH
2005

ADDITIONAL INFORMATION

SPONSORSHIP MANAGER for Non-profit

The Seacoast Rugby Club: Position: Flanker

Executive Committee Member, Title: Sponsorship Manager, as a 501(3) (c) non-profit organization. I am responsible for all fundraisers and sponsorship donations. I have organized, planned and run the Annual Golf Tournament. Run and organize all community projects: Adopt a Spot, Beach Clean-ups and Market square day.

COMPUTER SKILLS

Windows Word, Excel, Access, PowerPoint, Adobe Illustrator, TrackWise®, HTML coding,
Document Compliance Manager System (DMS), Aspen Schedules.