prredmon@gmail.com
(703) 472-2497, (303) 642-1515

Paul R. Redmon

31480 Hilltop Rd.
Golden, CO 80403

With my experience at Sandoz and Mediatech Inc., I have gained a detailed knowledge of cGMP and cGLP standards as well as an in-depth understanding of Quality Systems and pharmaceutical manufacturing processes. I have a strong ability to problem solve, work as a contributing team member, and multitask in a fast paced environment while being committed to superior quality work and professionalism. I am very detail oriented and have excellent oral, written, interpersonal, and presentation skills.

Biology and Chemistry Skills

Proficiencies:

Clean Room Guidelines	Media Preparation	Bright Field Microscopy	Agar Plating
Aseptic Technique	Hazardous Material Handling	Environmental Monitoring	USP Sterility
USP Bioburden	USP Growth Promotion	Endotoxin Quantification	Gram Staining

Experienced:

Metal Affinity Chromatography, and Size Exclusion Chromatography
DNA / Protein quantification with UV/Vis Spectroscopy
PCR-based Site Directed Mutagenesis
Process Validation
SAP / TrackWise
DNA / Protein / RNA extraction
DNA Sequencing
Electrophoresis
Rapid Test Methods

Relevant Employment

Sandoz – Broomfield, CO

(Part of the Novartis group, Sandoz is a worldwide leader in generic pharmaceuticals. Sandoz employs approximately 24,000 people, has more than 30 manufacturing sites, and a presence in more than 140 countries. By offering a broad portfolio of high-quality affordable medicines, Sandoz contributes to the stability of healthcare systems worldwide, providing significant savings that can be used for the funding of costlier novel therapies, thus encouraging continued pharmaceutical innovation.)

Deviation Owner (Investigator / Technical Writer) – Mar 2012 to Mar 2013

Objectives:

- Authored and lead investigations that occurred in bulk, finished dosage, and packaging departments
- Partnered with QA, QC, Operations, Engineering, Maintenance, Calibration, and Supplier Quality Management to ensure appropriate and timely determination of scope, product impact, root cause, and corrective actions
- Interacted with all levels of staff to provide status updates as well as required actions for deviation report closure
- Simultaneously managed several investigations of varying complexities while meeting strict timelines and expectations
- Described complex systems and issues in reports in such a manner that an uninformed reader could understand and make decisions based on the written investigation report
- Fostered collaborative relationships focused on high quality investigations, meaningful corrective actions, and a reduction in the deviation generation rate

Investigations and Root Cause Analysis:

- Set up and ran meeting at the time of the event to accurately describe the deviation
- Provided input on immediate actions to take in response to the event
- Gathered necessary background information to provide a basis of understanding of the event
- Explained the underlying reasons why and how the issue occurred, including a discussion of investigation activities and rationale used for root cause determination
- Appropriately determined the scope of the deviation
- Performed a trend analysis to determine the prior frequency of the issue
- Determined the impact of the deviation on the items identified in the scope
- Collaborated with cross functional teams to determine appropriate corrective and preventative actions

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Mediatech Inc. - Manassas, VA

(A privately held company of about 150 employees, Mediatech develops and manufactures a broad range of high quality cell culture media and molecular biology reagents related to tissue and cell culture applications in a cGMP facility, certified to FDA Regulations 21 CFR Part 820, as well as ISO 13485:2003)

Research Associate II / Investigator / Process Development – Mar 2010 to Dec 2011

Investigations and Root Cause Analysis:

- Acted as the company's primary root cause investigator
  - Determined scope, product impact, root cause, and corrective actions for deviations
  - Documented, computed, compiled, interpreted, reviewed, compared, and presented data
  - Determined appropriate preventative actions to prevent reoccurrence of the deviation
- Presented data to and was part of the Material Review Board
- Maintained detailed and accurate records of all tests performed
- Frequently authored and distributed technical reports for investigations
- Fostered collaborative relationships among departments
- Set up and ran meetings with cross functional teams and department heads
- Authored and managed Non-Conformance Reports (NCR's) and Temporary Deviation Reports (TDR's)
- Project Manager on an extensive manufacturing process investigation to determine the root cause of frequent specification failures (sterility, endotoxin, pH, osmolarity, fill volume, appearance, and random contaminations)
  - Spearheaded a complex multi-departmental investigation. Every possible source of bioburden and endotoxin was meticulously investigated. Scheduled meetings to combine efforts. Interviewed relevant personnel. Requested special testing. Contacted vendors for data. Designed and performed many biological and chemical tests to pinpoint or rule out root causes. Organized a comprehensive inspection of gaskets, piping, and valves, replacing materials as needed and collecting samples for testing. Extensive and detailed report written which discussed the nature of the problems, method of investigation, and recommendations to relevant departments. The specification failure rate was substantially reduced as a result of the investigation.

Process Development and Improvement:

- Developed methods and Standard Operating Procedures for Quality Control and Manufacturing
- Acted as a subject matter expert of Quality Control procedures and specifications
- Improved efficiency, consistency, and safety of manufacturing processes
- Authored and reviewed Material Safety Data Sheets (MSDS's)
- Managed ongoing studies of endotoxin levels for trending, total organic carbon levels for CIP cleaning validation, and product densities for trending and formulation reference

Modified, authored, or rewrote the following Standard Operating Procedures:

- **KCA Endotoxin** - rewrote entire protocol while simultaneously validating a method for higher test resolution
- **Growth Promotion** and microbial ID using the BBL Crystal ID method (SOP author)
- **Sterility** (USP 71)
- **Moisture Content** (Karl Fischer Titration)
- **Bacteriostasis and Fungistasis** (sterility testing method validation)
- **Bioburden / Microbial Limits** (USP 61 and 62)
- **ATP Detection by Luminometry** (SOP author)
- **Root Cause Analysis Worksheet** and **SOP** (author)
- **Gasket and Materials Cleaning** (SOP author)

Training:

- Voluntarily provided hands-on technical training to Production and Quality Control personnel on revised protocols, aseptic technique, new processes, and safety related guidelines
- With two colleagues, presented multiple 30 minute training sessions to all production personnel on proper aseptic technique, basic microbiology, and general information on how to increase efficiency and reduce non-conformances

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Quality Control Technician I / II, Microbiologist - Dec 2007 to Mar 2010

- Adhered to strict safety practices and company policies
- Responsible for knowing and following more than 80 SOP's
- Trained and supervised new hires on microbiological and chemical tests
- Revised more than 15 quality control SOP's to comply with USP and EP guidelines
- Reviewed batch records, CofA's, test results, and other technical and controlled documents
- Demonstrated high mechanical aptitude installing, calibrating, maintaining, and repairing Quality Control equipment (balances, pH meters, osmometers, microplate readers, titroprocessors, spectrophotometers, and computer software)
- Inspected and maintained laboratory inventory on a daily basis, ordering and organizing supplies as needed
- Working under limited supervision, organized and managed a dynamic work-flow of tests and tasks in a fast paced environment where unanticipated challenges were common
- Performed analytical testing of incoming materials, in-process materials, and finished goods to ensure compliance to established acceptance criteria

Training:

- Attended a continuing education course on cleanroom regulations and monitoring held by Hach Ultra, Sep 2008
- Attended a week long training course on KCA LAL endotoxin testing held by Charles River Laboratories, Aug 2008

Relevant Education

B.S., Biology, minor in Chemistry

Radford University, Radford, VA – May 2007

Relevant Courses:

- Genetics, Cell Biology, General Ecology, Evolution, College Chemistry II, Organic Chemistry I/II, General Biology II, Statistics, Microbiology, Molecular Biology, Biochemistry I/II, Bioinformatics
- One year of biochemistry undergraduate research with Dr. Timothy Johann on 5,10-methenyltetrahydrofolate synthetase (MTHFS)

  Research Summary:

  MTHFS is an enzyme involved in folate metabolism and its substrate is important as a rescue agent for cancer patients treated with the toxic drug methotrexate. Methotrexate, a competitive inhibitor of enzymes that use folates, is used to treat breast, head, and neck cancer, acute leukemias, and Burkitt's lymphoma.

  Our goal was to better understand what amino acids are important to this enzyme's shape and catalytic function. MTHFS was altered through site directed mutagenesis and *E. coli* cells were transformed with a plasmid containing the mutant MTHFS gene and then grown in media containing the antibiotics kanamycin and spectinomycin to prevent the growth of non-transformed bacteria. Once the mutation was verified with a sequencing gel, the *E. coli* were induced to produce MTHFS, which was then purified by metal affinity chromatography and size exclusion chromatography.

  Differences between the properties of the altered and wild type forms of MTHFS yielded information about the role of the changed amino acid in the structure and function of this enzyme. A better understanding of MTHFS could lead to improvements in cancer treatment with the drug methotrexate.