

Robert Bruce Grysen

4950 Meredith Way, Boulder, CO 80303

rbgrysen@gmail.com

815.573.1929

EDUCATION

Aurora University- Aurora, Illinois

(2009-2011)

- Bachelor of Science in Biology with Chemistry Minor, Cum Laude

Eastern Illinois University- Charleston, Illinois

(2006-2009)

- Coursework toward B.S. in Biology with Chemistry Minor (Transferred to Aurora University)

PROFESSIONAL EXPERIENCE

Amgen, Inc.

(May 2012- Current)

CW Analytical Chemist II

- Analytical testing of in process, finished product, product release, stability and a variety of studies including cleaning studies and host changeover using swab samples in a cGMP environment.
- Strict adherence to good documentation practices and Title 21 CFR part 11: laboratory notebooks, controlled assay worksheets, Laboratory Information Management System (LIMS), work orders, audit trails.
- Support internal and external audits as well as inspections by a variety of regulatory bodies.
- Involved in QC projects including laboratory relocation and implementation of new laboratory instruments.
- Follow analytical methods and procedures with a low error rate in a dynamic environment.
- Support manufacturing and stability of multiple sites in a timely and precise manner.
- Perform work orders and troubleshooting for a variety of analytical instruments and laboratory equipment.
- Work Order and Job Plan creation and execution using Maximo and SuiteReq.
- Contribute to nonconformance and out of specification investigations and involved with the CAPA process.
- Participant in validations, investigations, team projects and special studies to accomplish company and departmental goals as well as meet the demands of our customers.

Medefil, Inc.

(October 2011- May 2012)

Quality Control Laboratory Technician

- Perform routine and non-routine analysis of finished product, in process, raw materials and stability samples in a cGMP environment.
- Perform daily quality inspections of bulk and raw materials for the manufacturing floor and laboratories as well as performing routine clearances of equipment, cleaning protocols, finished product and product changeover.
- Review and release product labels, barrels, syringes, caps, plungers to the manufacturing floor.
- Drafting Standard Operating Procedures, Standard Test Methods, Protocols and Forms.
- Demonstrated ability to handle multiple tasks and balance short and long term priorities.
- Performing sample preparations, dilutions, and analysis while directly following procedures, protocols and methods.
- Maintain good laboratory records: sample log, data entry, data calculation and report writing.
- Environmental monitoring of ISO 5, ISO 7, ISO 8 and controlled areas as well as stability chambers, refrigerators, freezers, and incubators.
- Ensure that the day-to-day operation of the laboratory is carried out in a timely and efficient manner.

PROFICIENT LABORATORY TECHNIQUES

- LAL Bacterial Endotoxin Kinetic Method
- LAL Bacterial Endotoxin Gel Clot Method
- Ultraviolet/Visual Spectroscopy
- Protein Concentration
- pH Analysis
- Protein Content
- Microbial Isolation and Identification
- Environmental Monitoring
- Turbidity
- Visual Inspection/Analysis
- Bioburden
- Sterility
- USP Total Organic Carbon
- USP Conductivity
- EP Osmolality
- EP Nitrates
- Aseptic Technique
- Weight and Volume Analysis
- Reconstitution and Dilutions
- Instrument Troubleshooting

Robert Bruce Grysen

4950 Meredith Way, Boulder, CO 80303

rbgrysen@gmail.com

815.573.1929

PROJECTS

Pipette Program

- Lead for the pipette program project for all site Quality Control laboratories using cGMP and Lean principles by managing, aligning, improving and smoothing process flow.
 - Synchronized the process flow of pipettes through QC laboratories, Metrology and vendor representatives.
 - Aligned each piece of equipment within Maximo as well as staggering, modifying and maintaining calibration cycles to meet cGMP requirements and laboratory needs.
 - Wrote, performed and managed work orders as necessary including installation of pilot seal implementation with laboratories and onsite/offsite vendors.
 - Applied Lean principles in order to decrease non-value added steps within calibration flow, optimize efficiency of all parties involved, redistribution to align with workplace requirements, and reduce assets where excess is present.

Laboratory Relocation

- Quality Control equipment and system contact for large scale raw materials laboratory relocation.
 - Involved in the collection of data in order to determine instrument and equipment needs including man power, vendor involvement, calibration requirements, laboratory analysis conflicts, scheduling and creating time tables for implementation and completion.
 - Participated in mapping locations and needs of instrumentation including flow of laboratory, power sources, space restraints and construction needs.
 - Wrote and performed job plans and work orders for multiple pieces of equipment and created a proposed schedule for small equipment and reagent relocation.
 - Contributed in high level planning and implementation meetings with system owners, validation engineers, IT, project management and project scheduling teams.

RELEVANT SKILLS

- Planning and organizing work through effective communication to achieve individual leadership impact and team effectiveness.
- Adaptable and versatile to meet group, site, company and customer needs.
- Thrive on exploring business needs and translating them into highly functional systems to meet business requirements for operational excellence.
- Set goals and schedules to meet and improve departmental and site metrics.
- Ability to handle and prioritize multiple job functions and projects in a dynamic work environment.
- Rigorous in completing assigned training including web based, standard operating procedures, methods, site and environmental, cGMP, FDA, part 11 and assignment vehicles.
- Strong verbal and written communication skills and experienced in effectively working within groups and on an individual basis.
- Meticulous about details while having strong analytical and problem solving skills.
- Continuously striving towards the highest level of operational excellence.
- Demonstrated proficiency with Microsoft Suite, Laboratory Information Management System (LIMS), Laboratory Method Execution System (LMES), Consumable Inventory Management System (CIMS), Mattrack, SuiteReq and Maximo.
- Reporting and investigating non conformances, out of specifications and out of trend results.