

DANIELLE M. BOURN- M.S., M.B.A.

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EXPERIENCE

MAY 2021 – PRESENT

BIOPHARMACEUTICAL DEVELOPMENT OPERATIONS MANAGER,

CMC LABORATORY MANAGER, MOLECULAR TEMPLATES, INC.- AUSTIN, TX

- Provided department-specific Project Management for 30 employees by maintaining timelines, agendas, meeting minutes, action items and collaborative websites for all asset-specific project teams.
- Managed analytical laboratory buildout from facility design phase through inauguration to meet company objectives for timing and budget.
- Oversaw quarterly department budget for alignment with expenditure projections.
- Generated cost-benefit analyses for asset-specific programs and capital expenditures.
- Refined and implemented department-wide inventory management of laboratory equipment, reagents, and consumables.
- Implemented department-wide calibration and preventative maintenance management program to track all activities, service contracts, and cost summaries.
- Managed sample submission and testing process for internal and external resources.

FEBRUARY 2020 – MAY 2021

QUALITY ASSURANCE SPECIALIST, MOLECULAR TEMPLATES, INC.- AUSTIN, TX

- Conducted quality review and approval of batch records, standard operating procedures, specifications, deviations, laboratory investigations, corrective/preventive actions, and change controls for drug substance and drug product assets.
- Conducted quality review and approval for qualifications and validations of equipment, methods, and processes for cGMP and regulatory compliance.
- Served as QA liaison on asset-specific project teams with internal and external partners.
- Generated Annual Product Quality Reports for clinical assets.
- Performed internal system and process quality audits of other stakeholder groups.
- Implemented key process improvements to batch record issuance and review processes to improve the efficiency of the department by significantly decreasing turnaround times.

MARCH 2018 – FEBRUARY 2020

QUALITY COMPLIANCE INVESTIGATOR, ICU MEDICAL- AUSTIN, TX

- Conducted investigational analysis and wrote technical exception documents in response to manufacturing process excursions, nonconforming events, and procedural exceptions.
- Performed root cause analyses to determine the underlying cause of deviations.
- Developed, implemented, managed, and tracked CAPA plans to ensure cGMP and regulatory compliance.
- Managed multiple projects to ensure on time completion within quality system timeframes.
- Working knowledge of quality software applications such as Oracle Agile and Trackwise.

MARCH 2017 – MARCH 2018

DATA VERIFICATION SPECIALIST, ICU MEDICAL- AUSTIN, TX

- Conducted independent, scientific technical data review of chemical quality laboratory activities to ensure cGMP compliance.
- Provided quality assurance approval for pre- and post-sterile product testing, investigations/investigational testing, training, and area-related projects.
- Maintained quality laboratory computer systems to warrant cGMP compliance of electronic data capture.

JANUARY 2008 – NOVEMBER 2011

SENIOR ASSOCIATE SCIENTIST, PFIZER, INC.- GROTON, CT

- Performed oral solid dose technology transfer from development through to commercial scale under aggressive timelines while complying with cGMP, EU, ISO, and FDA regulation standards.
- Managed 50 employees as controlled substance tracking program lead for the product development department.
- Recognized with an Individual Performance Award for demonstrating exceptional performance and leadership skills.

JUNE 2007 – JANUARY 2008

PROCESS DEVELOPMENT SCIENTIST I, JOHNSON & JOHNSON- RAYNHAM, MA

OCTOBER 2006 – MAY 2007

RESEARCH ASSOCIATE I, BAXTER HEALTHCARE CORP.- NORWOOD, MA

MAY 2006 – SEPTEMBER 2006

OUTSIDE TECHNICAL SALES/PROJECT MANAGER, MOLECULAR EPIDEMIOLOGY, INC.- LAKE FOREST PARK, WA

MAY 2004 – NOVEMBER 2005

RESEARCH ASSOCIATE I, BAXTER HEALTHCARE CORP.- NORWOOD, MA

OCTOBER 2002 – MAY 2004

QUALITY CONTROL CHEMIST, WATSON LABORATORIES, INC.- COPIAGUE, NY

EDUCATION

AUGUST 2013

M.B.A., UNIVERSITY OF RHODE ISLAND

JANUARY 2008

M.S.- PHARMACEUTICAL BIOTECHNOLOGY, NORTHEASTERN UNIVERSITY

MAY 2001

B.S.- MICROBIOLOGY, UNIVERSITY OF MASSACHUSETTS- AMHERST