

## Quality Assurance Manager

*Lean Manufacturing | Regulatory Compliance | Process Control*

Experienced Quality Assurance Specialist with proven track record of managing quality oversight and ensuring operational compliance with cGMP, policies, standards, and regulatory requirements. Expertise in GMP, quality, and in-depth risk management knowledge. Skilled in interpreting problems and effectively communicating productively to management, recognizing and grouping technical and scientific attributes and driving science based decision, and identifying opportunities for improvements and providing recommendations. Collaborate with all members in achieving and exceeding objectives.

### Areas of Expertise

*Quality Assurance & Control • Requirements & Data Analysis • Risk Management • Compliance • GMP Strategic Planning & Execution • Change Management • Project Management • Relationship Building Innovation Solutions & Improvements • Teamwork & Leadership • Training & Development • Communication*

## PROFESSIONAL EXPERIENCE & SELECTED ACHIEVEMENTS

**ABC PHARMACEUTICAL CORP.**, Morris Plains, NJ

2015 – Present

*ABC provides healthcare solutions that improve and extend people's lives using science-based innovation to address some of society's most challenging healthcare issues.*

**Quality Assurance Specialist**, 2017 – Present

Administer evaluations of investigational reports, root cause analysis, preventive actions, CAP effectiveness and trends to ensure all aspects of operational business comply with all legal and regulatory requirements. Review and approve commercial CAR-T product documentation for batch disposition. Compose, assess, and approve Standard Operating Procedures (SOPs), quality risk assessments and specifications; serve as member of QA Team.

- **Enhanced oversight of review and disposition of batches** through development of weekly quality assurance batch status update emails for quality and manufacturing groups; established communication process.
- **Served as key contributor of Sterility Assurance Team; composed new APV procedure.**
- **Conduct training sessions** with new team members on operational policies and procedures.

**Cell Processing Specialist**, 2015 – 2017

Manufactured CAR-T cell therapy CTL-019; conducted formulation and verification of all media lots. Reduced processing time by implementing novel solution; drove data mining. Provided assistance on Deviation investigations and inspections; maintained "audit ready" module.

- **Decreased documentation and clarified directives to operators** through streamlining of Aseptic Process Validation instructions.
- **Closed final formulation steps of CAR-T process and reduced materials 80%** by developing new process.
- **Delivered training sessions** with QA Specialists and Managers on good manufacturing practices (GMPs), good documentation practices (GDP), unique media processes, CAR-T process, and reviewing batch records.

**ABC CORP., CELLULAR THERAPEUTICS DIVISION, Warren, NJ**

2012 – 2015

*ABC Corp. is a global pharmaceutical company engaged primarily in discovery, development, and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through gene and protein regulation.*

***Manufacturing Operations, Senior Associate, 2013 – 2015***

***Manufacturing Operations, Associate, 2012 – 2013***

Produced multiple cell-based therapies; collaborated with Bluebird Bio and served as Lead Operator for anti-BCMA CAR-T cell therapy bb2121. Executed process development study (LN2 storage and effects of transient warming on cell health); maintained material inventories.

- **Essential team member on Process Development Team**; served as Lead Manufacturer Associate, researched and determined effects of transient warming on cell health.
- **Recognized with *Living Our Values Award*** for performance excellence (2013 and 2014).

**ABC UNIVERSITY, CELL & DNA REPOSITORY, Piscataway, NJ**

2010 – 2012

*ABC University is the largest institution for higher education in the state of New Jersey.*

***Senior Laboratory Technician***

Provided assistance with immortalization of human lymphocyte cell lines and cryopreservation of cell lines for long-term storage; produced small-scale lymphocyte cultures for DNA/RNA extraction. Supplied technical support with application of scientific research methods; executed multistage purifications and tests.

**ABC LABORATORIES, Dayton, NJ**

2010 – 2010

*ABC Laboratories provides a full range of environmental analytical services to industrial, engineering/consulting, and government clients throughout the United States.*

***Laboratory Technician***

Extracted organic compounds of interest from matrix into proper solvent; conducted analysis of GC or GC/MS. Performed advanced extraction procedures including microwave, sonication, and separatory funnel; documented methods into SOPs.

**EDUCATION & CREDENTIALS****Bachelor of Science in Biological Sciences (Minor: Chemistry)**

Rowan University, Glassboro, NJ

**Training**

IQ/OQ/PQ, Celgene Corp.

**Technical Proficiencies**

Manufacturing related IT systems: MES • SAP • LIMS  
Oracle • Salesforce • Dragon • Intralinks • Microsoft Office (Word, Excel, PowerPoint)

**Awards**

*Living Our Values Award* (two-time recipient), Celgene Corp.