JACOB E. MICHAELS

Chicago, IL 12345 • 123-456-7890
clientname@gmail.com • LinkedIn: URL

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.