

Matthew Miller

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Regulatory Compliance • Quality Systems • Operational Excellence

Regulatory, Quality & Operations leader with 20+ years of experience across pharmaceutical research, medical device manufacturing, pharmaceutical distribution, and healthcare compliance. Known for building scalable systems that integrate regulatory compliance, quality, and operational excellence to reduce risk, improve quality, and strengthen organizational performance.

Regulatory Leadership: DSCSA • FDA • Multi-State Licensing • NABP Drug Distributor Accreditation • HIPAA

Quality & Operations: ISO 13485 • GDP/GMP/GLP/ICH • CAPA • Internal & External Audits • Risk Assessment

Technology: Power BI • Oracle Fusion • RFXCEL • SharePoint • Smartsheet Automation • Process Improvement • Microsoft 365

Education: B.S., Pharmacology & Toxicology, University of Toledo

WORK HISTORY

Enterprise Regulatory & Compliance Leadership, Boxout, Hudson, OH (2020–Present)
Regulatory Compliance Manager

- Lead enterprise regulatory compliance across four multi-state distribution centers supporting pharmaceutical and medical device operations.
- Led implementation of an enterprise Level 4 DSCSA serialization and traceability solution (RFXCEL) to support federal supply chain security requirements.
- Lead regulatory classification standardization across an 84,000-SKU healthcare catalog using AI-assisted workflows and FDA databases.
- Led successful NABP Drug Distributor Accreditation for two distribution centers.
- Successfully led regulatory inspections and audits by NABP, FDA, and multiple State Boards of Pharmacy, consistently achieving favorable outcomes.
- Chair the monthly Compliance Committee, presenting executive reporting and leading discussions on regulatory risk, audit findings, enterprise initiatives, and CAPA strategy.
- Designed enterprise compliance training and automation processes utilizing Microsoft Forms, SharePoint, Smartsheet, and Power Automate to improve training effectiveness and compliance tracking.
- Designed executive Power BI dashboards providing real-time visibility into multi-state licensing portfolios, renewal status, distribution center compliance, and key regulatory performance indicators.

Plant Operations & Quality Leadership, Wolf X-Ray, Deer Park, NY
Plant Manager/Quality Assurance Manager

(2018–2020)

- Directed plant operations through eight department managers and 83 employees while serving as Plant Manager and Management Representative, providing executive leadership for manufacturing, engineering, quality systems, production planning, and regulatory compliance as second in command to the company owners.
- Led an MDSAP audit as Quality Assurance Manager, promoted to Plant Manager and Management Representative following the audit (4 months after being hired).
- Researched and procured a \$150,000 CNC machine to replace cast iron patterns and manual cutting of lead aprons, which reduced time to cut lead patterns from 40 minutes per apron to 6 minutes.
- Created production planning within Monday.com to give better insight into order fulfillment for custom-made garments.
- Modernized the Quality Management System by implementing electronic document management and strengthening ISO 13485 quality processes across the organization.

Quality Systems & Manufacturing Leadership, Genadyne Biotech, Hicksville, NY
Quality Assurance Manager

(2016–2018)

- Improved manufacturing quality and process reliability by designing and installing a centralized purified compressed-air system for PCB cleaning, eliminating inconsistencies associated with canned air while reducing annual operating costs by approximately \$10,000.
- Designed and established a laboratory for topical antimicrobial medical device production, including facility layout, ISO 13485 labeling, SOP development, process validation, and staff training.
- Trained and managed 24 employees across two facilities in compliant production, testing, and documentation practices aligned with regulatory requirements.
- Successfully attained ISO 13485 certification.

Retail Pharmacy Operations, CVS, Selden, NY
Senior Pharmacy Technician

(2014–2016)

- Supported high-volume retail pharmacy operations, managing prescription intake and order entry, insurance adjudication, patient information, and dispensing workflows in coordination with pharmacists.
- Coordinated pharmacy technician staffing and workflow coverage to maintain efficient prescription processing and support safe pharmacy operations.
- Trained new pharmacy staff on prescription order entry, insurance billing, pharmacy systems, and operational procedures.

Military Logistics Leadership, U.S. Army National Guard, Stratford, CT
Logistics Officer

(2010–2014)

- Supply Officer responsible for equipping a unit to always be deployable.
- Procured all new supplies and gear prior to deployment in 2013.
- Assisted with Hurricane Irene relief to the Stratford area, clearing roads to make them passable and dropping supplies by helicopter to those in need.

Preclinical Drug Development, Pfizer, Inc., Groton, CT
Scientist

(2005–2010)

- Created an automated template for PK/TK study report writing, which resulted in receiving the Pfizer Achievement award.
- Directed preclinical regulatory studies supporting Investigational New Drug (IND) submissions, coordinating study execution, data analysis, scientific reporting, and outsourced GLP activities.
- Served as Study Monitor to oversee outsourced GLP studies.
- Presented and defended scientific conclusions supporting regulatory submissions during FDA interactions.

ADDITIONAL EXPERIENCE

➤ **Volunteering**

Board Member, Toledo Alumni Association, Cleveland, OH

(2023–Present)

- Plan events to keep our Cleveland Chapter graduates connected and engaged, like Cleveland Guardians baseball games, with meet and greet pre-game parties.
- Raise money and grade applicants for annual scholarship grants.

➤ **Certifications**

Notary Public Commission, Ohio Secretary of State

(2024)

Remote Online Notary Authorization, Ohio Secretary of State

(2024)

➤ **Awards**

Pfizer Achievement Award, Pfizer, Inc.

(2008)

➤ **Earlier Professional Experience**

Pharmaceutical Research, P&G, Mason, OH

(2001–2005)

- Planned and conducted preclinical GLP studies in all animal models, formulations, dosing, sample collection, PK data analysis, and report writing.
- Screened compounds to identify candidates with the most favorable pharmacokinetic profiles.

Toxicology Regulatory Affairs Scientist, WIL Research, Ashland, OH

(2000–2001)

- Study development for GLP inhalation toxicology studies in various animal models.

Pharmacy Intern, St. Luke's Hospital, Maumee, OH

(1998–2000)

- Supported hospital pharmacy operations through sterile IV preparation using aseptic technique and laminar flow hoods, controlled substance handling, physician order intake, and medication order entry to support safe patient care.

Military Intelligence, U.S. Army, Various Locations

(1990–1993)

- Participated in multiple real-world missions, including overseas tours.