

Matthew Miller

Cleveland, OH

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Regulatory Compliance Professional

DSCSA Compliance	Multi-State Licensing
Internal & External Audits	ISO 13485:2016
GDP, GMP, GLP, & ICH	HIPAA & PHI
Project Management	Risk Assessment

Degree:	BS, Pharmacology & Toxicology , University of Toledo
Technologies:	Compliance & Traceability Software (RFXCEL), Project Management Tools, ERPs, CRM, Oracle Fusion
Industries:	Healthcare Compliance, Medical Devices, Pharmaceuticals

WORK HISTORY

Pharmaceutical Distribution Compliance Specialist, Boxout, Hudson, OH (2020–Present)
Regulatory Compliance Manager

- Manage compliance for 4 distribution centers (FL, NV, OH, & TX).
- Sourced and implemented a Level 4 service provider for DSCSA prescription drug serialization compliance (RFXCEL).
- Provided exceptional customer service by educating an exclusive manufacturer on how to comply with DSCSA guidelines and assisted them in understanding the requirements.
- Classified 84,000 SKUs (mostly medical devices) and created a systemic restrictions process for state restrictions and medical licenses needed to purchase.
- Attained NABP Drug Distributor Accreditation for our OH and TX facilities.
- Regular audits from NABP, FDA, and Boards of Pharmacy with favorable outcomes.
- Conduct monthly Compliance Meetings with the Executive Leadership Team.
- Hands-on and interactive training for all staff for Compliance topics.

Med. Device Compliance and MDSAP Specialist, Wolf X-Ray, Deer Park, NY (2018–2020)
Plant Manager/Quality Assurance Manager

- Led an MDSAP audit as Quality Assurance Manager, promoted to Plant Manager and Management Representative following the audit (4 months after being hired).
- Supervised 83 team members, motivating them with four-day work weeks (10 hours/day), which cut overall operational costs while giving staff Fridays off.
- Purchased a \$150,000 CNC machine to replace cast iron patterns and manual cutting of lead aprons, which reduced time to cut lead 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.
- Overhauled Quality Management System (QMS) and implemented Document Management Software (QDMS)

ISO 13485 Quality Systems Specialist, Genadyne Biotech, Hicksville, NY (2016–2018)
Quality Assurance Manager

- Installed a Scroll Compressor to replace the usage of “air in a can” for cleaning sensitive PCB boards, saving \$10,000 per year on supply costs to produce negative pressure wound therapy pumps.
- Created a lab and established a process for topical antimicrobial device production, created product labeling per ISO 13485, wrote SOPs, and trained staff on production.
- Trained and managed 12 staff at two separate facilities (24 total) on compliant production, testing, and documentation per regulatory guidelines.
- Successfully attained ISO 13485 certification.

Retail Pharmacy Operations Specialist, CVS, Selden, NY (2014–2016)
Senior Pharmacy Technician

- Entered patient prescriptions, processed orders, and ensured pharmacists had adequate staffing to cover all shifts.
- Trained new staff on order entry, insurance billing, and pharmacy operations.

Supply Chain Security Officer, U.S. Army National Guard, Stratford, CT (2010–2014)
Logistics Officer

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

Preclinical Regulatory Affairs Scientist, Pfizer, Inc., Groton, CT (2005–2010)
Scientist

- Created an automated template for PK/TK study report writing, which resulted in receiving the Pfizer Achievement award.
- Managed all aspects of preclinical regulatory studies to support IND.
- Analyzed data using WinNonlin, report writing, and peer review.
- Served as Study Monitor to oversee outsourced GLP studies.
- Had to defend scientific conclusions in interviews with the FDA

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)

➤ **Additional Professional Experience**

Preclinical Regulatory Affairs Scientist, 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)

- Prepared IVs using aseptic techniques, took orders from physicians over the phone, and entered patient orders, helping to ensure patient safety.

Pharmacy Intern, Rite Aid Pharmacy, Toledo, OH (1996–1998)

- Patient counseling, order entry, taking prescriptions over the phone, and processing orders greatly assisted the pharmacist with keeping up.

Military Intelligence, U.S. Army, Various Locations (1990–1993)

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