

Joseph T. Morott, Ph.D.

Pensacola, FL

Ph: (662) 701 - 8355, Email: jmorott@gmail.com

PERSONAL SUMMARY

With a Ph.D. in Pharmaceutical Sciences and almost two decades of relevant experience as a Formulation Scientist, I possess a deep understanding of the entire drug development lifecycle, from early-stage research to NDA/ANDA filings. My expertise extends beyond the lab; as a Pharmaceutical Applications Development Scientist and a Hot-Melt Extrusion instructor, I honed my ability to translate complex scientific data into clear, actionable insights for diverse audiences, including customers and non-technical course attendees. I have a proven history of collaborative problem-solving, resolving complex issues, and successfully managing projects. This unique combination of hands-on scientific expertise and strong communication skills—honed over a decade in television broadcasting—makes me an ideal candidate for an expert witness role, where I can effectively engage with experts and non-experts alike, and continue to contribute to the successful dissemination of scientific information.

CORE COMPETENCIES

- **Strategic & Project Management:** Customer Relations, Strategic Problem Resolution, Statistical Analysis, Process Optimization, Project Leadership
- **Scientific & Clinical Expertise:** Drug Development Lifecycle, Controlled Release Systems, Controlled Substances (DEA), Drug Delivery Systems (OROS, HME), Formulation Science, Clinical Data Analysis
- **Communication & Presentation:** Scientific Presentation, KOL Engagement, Media Relations, Cross-Functional Collaboration, Technical Communication, Adult Learning/Education
- **Regulatory & Compliance:** NDA/ANDA Filings, 483/Warning Letter Remediation, DEA Compliance, GMP/GLP, Documentation Practices

WORK HISTORY

Pegasus Laboratories, Pensacola, FL - *Senior Scientist* **2023 – 2025**

- Hired to serve as a key subject matter expert, leveraging deep expertise in controlled substance handling and controlled release formulations as well as advanced presentation skills.
- Implemented DEA compliant practices for controlled substance manufacturing and inventory.
- Designed and implemented an internal professional development platform to enhance colleagues' scientific communication and presentation skills.

Catalent Pharma Solutions, St. Petersburg, FL - *Senior Scientist*, **2021 - 2023**

- Led and managed formulation strategies from bench to commercialization for both NDA and ANDA filings.
- Acted as a primary scientific liaison for customers, effectively managing expectations and ensuring project success from bench to commercialization.
- Led and orchestrated key scale-up activities, serving as the main point of contact for internal and external partners.
- Authored and presented technical reports, effectively communicating complex project outcomes to customers and securing their approval.

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Balechem Corporation, Ogden, UT - *Pharmaceutical Applications Development Scientist* 2019 - 2021

- Provided technical support and scientific consultation to customers across global markets (e.g., US, Brazil, Europe) to resolve complex formulation and processing issues.
- Successfully resolved complex formulation and processing issues both remotely and through on-site visits, building strong relationships with clients.
- Provided critical regulatory insight and guidance on pharmaceutical compliance to upper management, influencing key business decisions.

Mylan Pharmaceuticals Inc., Morgantown, WV - *Formulation Scientist* 2015 - 2019

- Served as the company's Subject Matter Expert (SME) for OROS technology, providing authoritative guidance to cross-functional teams.
- Proactively identified and resolved a potential pre-launch product failure, leading the reformulation and regulatory filing (CBE-30) to ensure a successful market launch.
- Initiated and conducted a detailed personal project to identify critical failure modes in OROS products, resulting in the implementation of new protocols that prevented future failures and material shortages.
- Contributed to 483/Warning Letter remediation and managed ANDA documentation/filings.

Hands-On Tablet Technology Course, Oxford, MS - *Hot-Melt Extrusion Instructor* 2013 - 2015

- Designed and implemented a highly interactive lab section on Hot-Melt Extrusion (HME) for industry professionals.
- Recognized by attendees and course organizers for creating one of the most engaging and effective learning experiences.
- Educated attendees on a broad range of HME applications and principles, including screw configuration, compounding, and process analytical technology (PAT).

EDUCATION

Ph.D. in Pharmaceutical Sciences (Emphasis in Pharmaceutics) 2010 – 2015

University of Mississippi School of Pharmacy in Oxford, MS.

GPA 3.8 Out of 4.0; Advisor: Michael A. Repka, D.D.S, Ph.D., Dept. Chair

Dissertation Title: "*The Influence of screw configuration and other mechanistic approaches on release and stabilization of drugs in polymeric matrices utilizing hot melt extrusion (HME) technology*"

Recipient of the Honors Convocation *Graduate Achievement Award in Pharmaceutics*

Bachelor's Degree (B.S.) in Professional Chemistry 2008 – 2010

Belmont University in Nashville, TN. 37212

TECHNICAL SKILLS & ADDITIONAL RESEARCH EXPERIENCE

- Drug Delivery Systems: Expertise in Immediate Release, Controlled/Sustained Release, Osmotic Pumps (OROS), Hot-Melt Extrusion (HME), and Tamper Resistant/Abuse Deterrent Formulations.

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- . Processing & Technologies: Proficient in Powder Blending, Pan Coating, Fluid Bed Processing, Wet & Dry Granulation, Tablet Compression, and Encapsulation. Experienced with Process Analytical Technology (PAT).
- . Regulatory & Compliance: In-Depth Knowledge of DEA Regulations for Controlled Substances and Regulatory Documentation Practices.