

LOUISE J. CALABRETTA, PMP

Lower Gwynedd, PA 19002 | (215) 421-0948 | lcalabretta@me.com

PROFESSIONAL SUMMARY

DIRECTOR, COMMERCIAL SUPPLY CHAIN and PROJECT MANAGEMENT with extensive experience in managing end-to-end supply chain operations and external supply manufacturing within the pharmaceutical and life sciences industry. Demonstrated expertise in leading cross-functional teams, driving process improvements, and ensuring compliance with regulatory standards. Proven track record in commercial drug launch, packaging site selection, and ERP implementation. Adept at developing strong relationships with internal and external stakeholders.

AREAS OF EXPERTISE

End-to-End Supply Chain Management • External Supply • Commercial Packaging and Labeling • Sales & Operations Planning (S&OP) • GMP Manufacturing and Distribution • Regulatory and Quality Compliance • Team Leadership and Development • Strategic Planning and Execution • Vendor Management and Contract Negotiation • Cold Chain Shipping and Distribution • Inventory and Capacity Planning • Risk Mitigation and Continuous Improvement

TECHNICAL SKILLS

MS Project | Office Timeline Pro | MS Word | MS Excel | MS PowerPoint | MS Visio | MS Outlook | SAP | SharePoint | OnePager | APICS | cGMP | PMP

PROFESSIONAL EXPERIENCE

CARISMA THERAPEUTICS (Philadelphia, PA) 2020 - 2024

Director, Project Management - Research & Development (Apr 2022 – Apr 2024)

- Managed Carisma's collaboration with Moderna, leading to nomination of the first in vivo CAR-M candidate for IND.
- Achieved a 500% increase in abstract submissions and presentations for scientific conferences by developing a process that was participation-focused.
- Improved the communication and quality of discovery research by developing a monthly full-day discovery leadership and peer review of scientific programs, promoting collaboration and idea-sharing.

Director, Project Management – External Manufacturing (Feb 2020 – Mar 2022)

- Enabled the development of RCA-free adenoviral vector material for clinical patients by leading CDMO and internal project teams, while driving on-time manufacturing and release of GMP material.
- Achieved on-time manufacturing of GMP batch despite critical resource shortage by proposing a unique sourcing solution, while maintaining chain-of-custody documentation.

ENDEAVOR CONSULTING GROUP

2018 – 2019

Senior Project Manager - Johnson & Johnson Consumer Products (Skillman, NJ)

- Rationalized chemical suppliers and reduced material costs by leading a global cross-functional team in the identification and integration of comparable materials, while ensuring supply continuity.

THE FLEXPRO GROUP

2016 – 2017

Senior Project Manager - Janssen Biotech, Inc. (Malvern, PA)

- Managed the qualification of materials within the research material science organization, ensuring compliance with pharmacovigilance guidelines.

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WINDTREE THERAPEUTICS (Warrington, PA)

2014 – 2016

Director, Project Management

- Led CMO and cross-functional supply team in the manufacturing and release of medical devices for clinical trials.
- Implemented cost-saving measures and shelf-life extensions through stability data analysis.
- Developed ancillary supply kits, minimizing clinical supply costs and maximizing efficiencies.

THE FLEXPRO GROUP

2011 – 2014

Senior Project Manager - Windtree Therapeutics (Jan 2013 – Jan 2014)

- Managed the commercialization of a Class I Medical Device, ensuring FDA compliance and efficient supply chain operations.

Senior Supply Chain Manager - Watson Pharmaceuticals (Jan 2012 – Dec 2012)

- Identified and implemented resource utilization improvements and inventory investment strategies.
- Developed modeling tools to evaluate new business opportunities, streamlining the decision-making process.

Senior Supply Chain Manager - OptiNose US, Inc. (Sept 2011 – Aug 2012)

- Streamlined manufacturing and inventory procurement decisions to optimize resource utilization.

JOHNSON & JOHNSON SALES & LOGISTICS COMPANY (Fort Washington, PA) 2004 – 2009

Sales Operations Project Manager

- Led new product launches and promotional programs, including the ZYRTEC OTC Switch, achieving significant sales growth.
- Developed and launched new business-member test SKUs for Sam's Club, delivering \$5 million in incremental sales and 200% chain-wide distribution expansion.
- Implemented the first Sales and Operations Planning (S&OP) process for the Club OTC consumer business.

McNEIL CONSUMER HEALTHCARE (Fort Washington, PA)

1991 – 2004

(Various Roles)

- Held positions including Demand Manager, Planning Process Project Manager, National and Tactical Planner, Production Supervisor, and Manufacturing Project Leader, contribution to product development and operational efficiency.

EDUCATION & CERTIFICATIONS

HARVARD MEDICAL SCHOOL

Certificate of Achievement in Immunology, June 2022 – August 2022

PROJECT MANAGEMENT PROFESSIONAL

Certification, October 2017

DREXEL UNIVERSITY, Philadelphia, PA

Bachelor of Science in Commerce and Engineering, Operations Management

Graduated *Summa Cum Laude*