AMRUTA MHASHILKAR

PHARMACEUTICAL DEVELOPMENT LEADER

Driving late-phase development to launch through integrated CMC and manufacturing.

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CORE COMPETENCIES

Late-Phase Development

Launch Readiness

CMC Strategy & Regulatory

PPQ, CPV & Validation

Tech Transfer & Scale-Up

Manufacturing Science & Technology (MS&T)

Inspection Readiness

Portfolio Leadership

Cross-Functional Leadership

Risk Management

People Leadership

EDUCATION

MBA – 2019

Florida Southern College

PhD – 2015

University of South Florida

MPH – 2012

University of South Florida

MD – 2008

Grant Medical College, INDIA

SUMMARY

Senior Pharmaceutical leader with a proven record of steering complex late-stage development through launch, delivering 9 Rx products to market with compliant, inspection-ready precision. Currently lead a $45M+ portfolio across 80+ programs, integrating CMC, regulatory, and manufacturing strategy for global commercial readiness. Known for decisive leadership, scalable tech transfer, and cross-functional execution that drives right-first time launches and lifecycle performance. My leadership style is equal parts precision and foresight, grounded in data, aligned with global regulatory expectations, and fiercely committed to quality, speed, and patient impact.

KEY PROFESSIONAL EXPERIENCE

ASSOCIATE DIRECTOR **2024 – PRESENT**

FORMULATION AND PROCESS DEVELOPMENT

Catalent Pharma Solutions

- Lead 35+ scientists and operations staff across 80+ clinical, late-phase and commercial programs, driving formulation and process development from Phase I through launch.
- Manage a $45M+ multi-client portfolio with 95% on-time delivery and 99% right-first-time execution, accelerating launch timelines and reducing rework.
- Delivered 8+ commercial launches across Rx, VMS, and animal health, ensuring PPQ success, validated processes, and global supply readiness.
- Spearhead CMC strategy and regulatory execution for IND, NDA, ANDA, and ANADA programs, serving as SME during health authority interactions.
- Align cross-functional launch execution across Manufacturing, MS&T, Quality, and Regulatory to ensure inspection readiness and supply continuity.
- Instituted best-practice templates and process standards for PPQ and scale-up activities, enhancing process robustness and reducing variability across commercial programs.
- Led commercialization strategy for lipid-based formulations, enhancing scalability and lifecycle performance through platform innovation.
- Prioritize technical risk mitigation and capital investment to ensure site readiness and alignment with global commercial forecasts.
- Fostered a high-performance culture with accountability, collaboration, and technical excellence across development teams.

SENIOR MANAGER **2023 – 2024**

Product Development, Catalent Pharma Solutions

- Led late-phase formulation and process development for Phase II/ III programs preparing for PPQ and commercial launch readiness.
- Oversaw end-to-end tech transfer and scale-up execution, ensuring on-time PPQ preparation and strengthened governance with cross-site technical teams.
- Delivered 95% on-time project execution across late-stage programs, while mitigating technical risk through structured development and risk management planning.
- Developed integrated launch timelines and resource plans, improving coordination across departments and accelerating readiness milestones.
- Supported regulatory documentation and responses for IND, NDA, ANDA, and ANADA submissions, contributing to robust CMC packages and inspection preparation.
- Strengthened cross-functional governance and program accountability, serving as technical operations lead during late-phase to launch transitions.

AMRUTA MHASHILKAR

PHARMACEUTICAL DEVELOPMENT LEADER

SELECTED WEBINAR & CONFERENCES

- 2025 Speaker AAPS
- 2025 LinkedIn Webinar "Fast, Flexible, Bioavailable: Lipid-Based Softgels for BCS I–IV"
- 2024 AAPS Annual Conference
- Delivered multiple posters and talks during PhD and postdoctoral research

PUBLICATIONS

- Phenotypic and molecular analysis of the effect of 20-hydroxyecdysone on the human parasite Brugia malayi

(International Journal of Parasitology)

- Identification of Ecdysone Hormone Receptor Agonists as a Therapeutic Approach for Treating Filarial Infections

(PLOS Neglected Tropical Diseases)

- The genome of Onchocerca volvulus, agent of river blindness

(Nature Microbiology)

- Stage-specific transcriptome and proteome analyses of the filarial parasite Onchocerca volvulus and its Wolbachia endosymbiont

(mBio ASM)

- Development of a toolkit for piggyBac mediated stable integrative transfection of the human filarial parasite Brugia malayi

(PLOS Neglected Tropical Diseases)

MANAGER/ GROUP LEAD **2022 – 2023**

Product Development, Catalent Pharma Solutions

- Managed and developed a team of 8 scientists, building technical strength and execution discipline to support late-phase development and commercial launch.
- Delivered 3 Rx commercial launches and led the introduction of the OptiGel® DR platform, enabling its first VMS commercial product.
- Established late-phase readiness practices to align cross-functional teams and reduce tech transfer cycle times.
- Built technical succession pipelines and growth plans, strengthening group capability and sustaining delivery across a growing late-stage portfolio.
- Served as program lead for high-priority launches, coordinating timelines, technical execution, and risk mitigation to ensure compliance with late-phase execution standards.

LEAD SCIENTIST **2020 – 2022**

Product Development, Catalent Pharma Solutions

- Led a team of 4 scientists supporting technology transfer, scale-up, and ANADA programs for animal health products.
- Served as technical lead for GMP execution, including batch oversight, troubleshooting, and coordination with Manufacturing and Quality.
- Applied QBD and DOE approaches to reduce variability, mitigate technical risk, and improve process robustness ahead of late-phase execution.
- Led client-facing technical discussions and regulatory interactions, contributing to CMC strategy and submission readiness.
- Built technical depth within the group through mentoring, training, and hands-on leadership.

SENIOR SCIENTIST **2018 – 2020**

Product Development, Catalent Pharma Solutions

- Led technology transfer and scale-up of multiple Rx products into manufacturing, enabling successful commercial execution.
- Authored process risk assessments, transfer protocols, and control strategies to ensure robust and reproducible processes.
- Supported process qualification and tech transfer workflows and validation activities in partnership with Manufacturing and Quality.
- Investigated and resolved batch inconsistencies through structured root cause analysis and CAPA.

SCIENTIST **2016 – 2018**

Product Development, Catalent Pharma Solutions

- Supported technology transfer and scale-up through preparation of process documentation, execution of transfer studies, and manufacturing readiness activities.
- Performed process characterization, stability, and analytical testing (XRPD, HPLC, DSC, TGA, dissolution, microscopy) to support process understanding.
- Supported batch execution, documentation, and deviation investigations in collaboration with Manufacturing and Quality.
- Contributed to FDA correspondence and preparation of technical content for regulatory submissions.