From Science to Scaled Impact

A Career Journey from Through Advanced Therapies, Manufacturing, and Leadership

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Why This Story

- A journey many scientists consider, but few see clearly mapped
  - How a PhD foundation can evolve into manufacturing and product leadership
  - How decisions compound across a career
  - Growth is not always linear

Career Journey Timeline

- Increasing scope, scale, and accountability — from hands-on science to enterprise leadership

- 2003–2011 | Academic Research – Rutgers University
- 2012–2013 | Diagnostics R&D – BD Diagnostics
- 2014–2018 | Cell & Gene Therapy Development – Hitachi Chemical
- 2018–2020 | Global Tech Transfer – Celgene/Bristol Myers Squibb
- 2020–2022 | Comparability Leadership – Bristol Myers Squibb
- 2022–2023 | Product Stewardship – Bristol Myers Squibb
- 2023–2024 | Technical Product Leadership – Bristol Myers Squibb
- 2024–2025 | Enterprise MSAT Leadership – Bristol Myers Squibb
- 2025– | Independant Consultant – Stratovance Life

Parallel moves

Building the Scientific Foundation (2003–2011)

- Learning how to think before learning how to lead
  - Started as a technician, mastering fundamentals of molecular and cell biology
  - Progressed to Graduate & Research Assistant at Rutgers University
  - Designed in vivo models, published research, and secured funded projects
  - Built core skills: critical thinking, data analysis, scientific writing, presentation, and more…

First Exposure to Industry (2012–2013)

- Understanding how science can build a real product (the D of R&D)
  - Research Scientist at BD Diagnostics
  - Designed feasibility assays for early diagnostic concepts
  - Contributed to patent-generating innovations
  - Learned the importance of timelines, quality, and cross-functional collaboration

Entering Advanced Therapies (2014–2018)

- Where complexity, regulation, and impact intersect
  - Senior Scientist at Hitachi Chemical Advanced Therapeutics Solutions
  - Led process development and GMP (General Manufacturing Practice) transfers for CAR-T and cell therapies
  - Authored CMC (Chemistry Manufacturing Controls) documentation supporting INDa (Investigational New Drug application) approvals
  - Developed deep understanding of manufacturing, scale-up, and regulatory expectations

Scaling Science to Commercial Manufacturing (2018–2020)

- Moving from development success (early phase) to patient impact at scale
  - Technology Transfer Manager at Bristol Myers Squibb
  - Led global tech transfers, PPQs, and CMO onboarding
  - Supported BLA/MAA submissions for commercial approval
  - Learned how execution risk directly affects patients and supply

PPQ = Process Performance Qualification; BLA = Biological License Application; MAA = Marketing Authorization Application; CMO = Contract Manufacturing Organization;

Ensuring Change Without Disruption (2020–2022)

- Becoming a trusted voice in high-stakes decisions
  - Sr. Manager / Sr. Principal Scientist, Comparability (started with parallel move which led to a promotion)
  - Owned global comparability strategies per current Regulatory guidelines
  - Enabled major process and site changes without regulatory delay
  - Built credibility through data-driven, risk-based decision making

Owning the Product Lifecycle (2022–2023)

- Shifting from execution to accountability
  - Associate Technical Director – DP Stewardship
  - Owned commercial DP process control strategy and CPV
  - Led global launches and manufacturing harmonization
  - Balanced quality, supply, and regulatory risk across regions

DP = Drug Product; CPV = Continued process Verification

From Technical Expert to Product Leader (2023–2024)

- Aligning technical priorities with business strategy
  - Associate Technical Director – Technical Product Team Lead
  - Developed and executed technical product roadmaps
  - Drove COGS reduction, automation, and risk mitigation initiatives
  - Learned to translate technical tradeoffs into business decisions

COGS = Cost of Goods Sold

Enterprise MSAT Leadership (2024–2025)

- Leading across assets, sites, and organizations
  - Technical Director – Global MSAT
  - Led global implementation and tech transfer strategies
  - Improved process robustness across multiple sites
  - Focused on consistency, scalability, and long-term sustainability

MSAT = Manufacturing Sciences and Technology

Process Development in Cell & Gene Therapy (CGT)

Purpose

Design and optimize **robust, scalable, and GMP-ready processes** to manufacture living medicines.

Core Scope

- Cell isolation, activation, expansion & formulation
- Viral vector production & transduction
- Process parameter optimization (Critical attributes, parameters)
- Potency, purity, and viability enhancement
- Raw material, single-use system, technologies selection

Process Development in Cell & Gene Therapy (CGT)

- **Outputs**
- Defined, **transferable** manufacturing processes
- Scalable control strategies
- Data packages supporting MSAT (Manufacturing Sciences and Technology), CMC (Chemistry Manufacturing Controls), and regulatory filings

- **Bottom Line**

Process Development is the **foundation of CGT success**, determining manufacturability, cost, and long-term product viability.

Technical Operations in Pharma & Cell/Gene Therapy

Purpose
Technical Operations ensures scientific innovation is translated into **safe, scalable, and compliant medicines**, from clinical development through commercialization.

Why It Matters More in Cell & Gene Therapy

- Living systems → **high variability, low margin for error**
- Manufacturing failures directly impact **patients**
- Complex processes (cells, viral vectors, cold chain, chain of identity)
- High cost of goods; **process robustness = value creation**
- Intense and evolving **regulatory scrutiny**

Bottom Line
In CGT, Technical Operations is a **strategic risk and value driver**, not a back-office function.

Technical Operations in Pharma & Cell/Gene Therapy (CGT)

Core Responsibilities

- GMP manufacturing readiness & execution
- Process scale-up / scale-out
- Tech transfer (internal sites & CDMOs)
- Quality, compliance, and lifecycle management
- Supply continuity for clinical and commercial demand

Bottom Line

In CGT, Technical Operations is a **strategic risk and value driver**, not a back-office function.

What I Wish I Knew as a PhD Student

- Lessons that would have accelerated my growth earlier
  - Your PhD trains you to think — the application of that thinking is flexible
  - Careers are rarely linear; progression comes from skill accumulation
  - Regulated industry values judgment and clarity, not just technical depth
  - Communication and influence matter as much as experimental results

Translating Academic Skills to Industry Impact

- What carries over more than you expect
  - Hypothesis-driven thinking → Risk-based decision making
  - Publications → Regulatory submissions and data packages
  - Lab leadership → Cross-functional team leadership
  - Grant writing → Business and technical justification

Key Lessons for Students and Leaders

- What this journey reinforces
  - Careers are built through decisions, not titles
  - Depth creates credibility; breadth creates impact
  - Leadership begins long before formal authority
  - The ability to learn and adapt matters more than the first role

Closing Thought & Discussion

- From training to impact
  - Every role is preparation for the next level of responsibility
  - Scientific training enables leadership far beyond the lab
  - Impact increases when science, manufacturing, and people align