

NAVEENGANESH MURALIDHARAN

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Visionary biopharmaceutical leader with **19+ years** of global expertise in **MSAT, process development, process validation, and GMP manufacturing**. Author of **28+ peer-reviewed publications** with a proven track record advancing **Biologics, Gene Therapy, and Oligonucleotides** from development to commercial launch. Known for building high-performing teams, ensuring FDA/EMA regulatory compliance, and driving first-time-right execution across complex, multi-site programs.

Core Technical Expertise

- Process Development & characterization
- Process technology transfer & process validation
- Commercial support (CPV & APQR)
- CMC strategy and lifecycle management

Leadership & Team Building

- Strategic leader with strong technical acumen and cross-functional leadership
- Building and motivating high-performing teams
- Executive stakeholder communication and alignment
- Culture of operational excellence and continuous improvement
- Mentorship and talent development

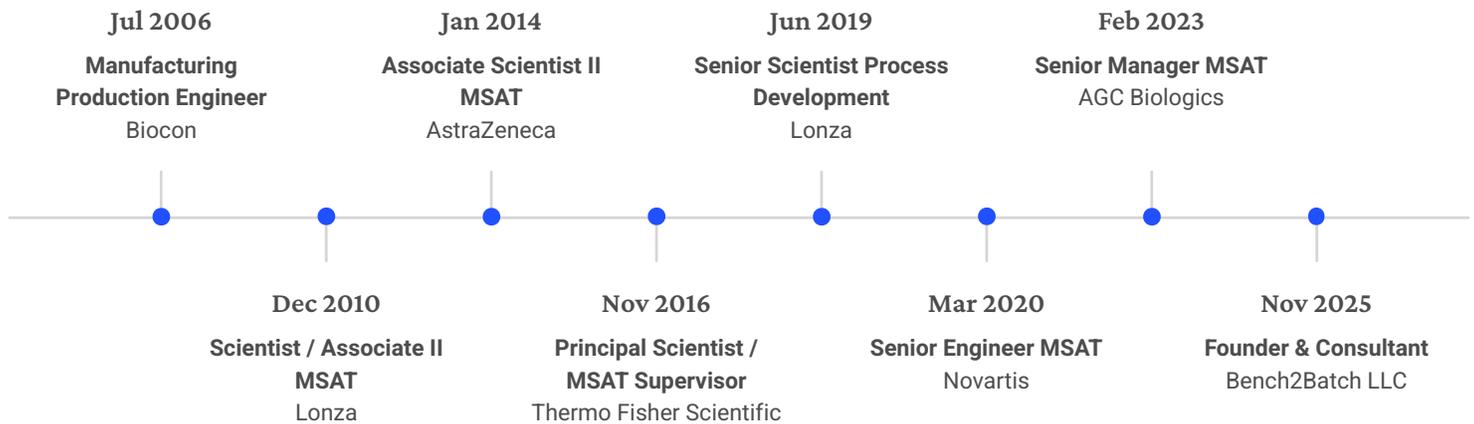
Education

- **MS in Cell and Molecular Biology**
Dec 2010 | University of New Haven, West Haven CT, USA
- **BS in Engineering – Biochemical Engineering**
Jun 2006 | SASTRA University, Tanjore, TN, INDIA

Honorary Roles

- **Strategic Artificial Intelligence Advisory Member**
Nov 2024 – Current | University of Colorado, Colorado Springs, CO
- **Member Editorial Advisory Board**
Dec 2024 – Current | Bioprocess International, New York, NY
- **Contributor and Editorial Advisor**
Mar 2025 – Current | Pharma Now, British Columbia, Canada

Career Progression



Professional Experience

Founder & Consultant – Bench2Batch LLC (CMC Lifecycle Partners) | Boulder, CO | Nov 2025 – Present

- Provide end-to-end CMC support, including phase-appropriate CMC strategy and roadmapping from IND to BLA.
- Process design and scale-up for biologics and advanced modalities, and leadership of seamless technology transfers.
- Validation and compliance (PPQ/CPV), risk management through FMEA-based control strategy development.
- Partner with startups, CMOs, and established biopharma organizations.

Senior Manager, MSAT (Technology Transfer & Process Validation) – AGC Biologics | Boulder, CO | Feb 2023 – Nov 2025

- Directed and led department activities including people management, strategic planning, and KPI delivery.
- Developed and improved department efficiency by setting up structure and updating procedures.
- Designed and led risk assessments compliant with company validation program and industry best practices.
- Improved alignment of Technology Transfer activities globally across AGC sites.
- Led cross-site initiatives ensuring seamless cross-organizational interactions.

Senior Engineer, MSAT (Manufacturing Science & Technology) – Novartis Gene Therapies | Greater Chicago Area | Mar 2020 – Feb 2023

- Managed site Continued Process Verification (CPV) program / Stage 3 process validation.
- Performed Statistical Process Control (SPC) trending of process parameters and attributes.
- Authored quarterly CPV reports and SOPs governing Stage 3 process validation.
- Authored process descriptions, tech transfer protocols, and reviewed Master Batch Records.
- Managed complex deviation investigations, impact assessments, CAPA, and risk assessments.

Senior Scientist, Process Development, Gene Therapy – Lonza | Houston, TX | Jun 2019 – Mar 2020

- Led team of scientists and developed robust upstream rAAV process with plasmid ratio optimization.
- Scaled up process to 50L STR and led scale-down model qualification at 1.5L STR.
- Managed process characterization using FMEA and DOE methodologies.
- Collaborated with cross-functional teams on SOPs and tech transfer protocols.

Professional Experience (Continued)

Principal Scientist PD / MSAT Supervisor (Sr Engineer) – Thermo Fisher Scientific | Greater St. Louis | Nov 2016 – Jun 2019

- Designed and developed mammalian cell culture processes at bench scale for recombinant proteins.
- Led process transfer of developed upstream processes to global manufacturing network.
- Led Process Limit characterization studies using Quality by Design tools (FMEA, DOE).
- Managed small team of engineers supporting process transfer from bench scale to manufacturing.
- Responsible for tech transfer package including Facility Fit Assessment, BOM, PFDs, and process descriptions.
- Provided on-floor support, analyzed data, investigated and troubleshot manufacturing issues.

Associate Scientist II, MSAT – AstraZeneca | Washington D.C. Metro Area | Jan 2014 – Nov 2016

- Led process transfer from development to cGMP pilot scale facility.
- Wrote process transfer documents, reviewed batch records, and provided on-floor support.
- Designed satellite runs to investigate and troubleshoot manufacturing issues.
- Executed filter sizing experiments for harvest process.
- Initiated and evaluated process improvements and new technologies.

Scientist / Associate II, MSAT – Lonza Biologics | Portsmouth, NH | Dec 2010 – Jan 2014

- Led process scale-up, process transfer to manufacturing, and process optimization.
- Coordinated cross-functional teams to investigate and resolve manufacturing issues.
- Trained manufacturing on new processes and implemented process changes.
- Prepared technology transfer documents including process descriptions and consistency reports.

Scientist I, Bioprocess Development – Boehringer Ingelheim Vetmedica | Fort Dodge, IA | Jun 2010 – Dec 2010

- Wrote and executed scientific protocols for vaccine production optimization.
- Executed media preparation, inoculum expansion, and bench scale bioreactor operations.
- Performed sample analysis, data compilation and analysis.

Manufacturing Production Engineer – Biocon | India | Jul 2006 – Jul 2008

- Supported mAb upstream manufacturing functions including cell expansion and bioreactor operations.
- Performed clarification using depth filters per batch records.
- Created batch records.

Patents & Publications

Patent Applications

2025 | Method for Optimizing Drilled Hole Sparger Design in Large-Scale Stirred Tank Bioreactors for Enhanced Cell Culture Efficiency

Muralidharan, N. — U.S. Patent Application No. 19/315,755, filed September 1, 2025.

Books Authored

2024 | Biopharmaceutical Case Studies: Engineering Challenges and Practical Solutions

Muralidharan, N. — Book Writing Pioneer. ISBN: 9798324375065

[View E-Book](#)

2025 | Biopharmaceutical Process Validation: Strategies for Risk Assessment

Muralidharan, N. — Book Writing Pioneer. ISBN: 1968260293

[View on Amazon](#)

Peer-Reviewed Published Technical Articles as 1st and Corresponding Author

1. N. Muralidharan (2026). The myth of bioreactor scale-up: A biology-first approach to achieving robust manufacturing. *BioProcess International* 24(2):240201.
2. N. Muralidharan (2026). A practical and consolidated strategy for elemental impurity-risk management in biomanufacturing. *BioProcess International* 24(1):240102.
3. N. Muralidharan (Dec 2025). Comprehensive Stability Assessment of Biotechnological Products: Degradation Mechanisms, Statistical Tools, and Regulatory Compliance, Part 2. *Bioprocess International* 23(10):27–31.
4. N. Muralidharan (Dec 2025). Rethinking Shewhart control charts for high-frequency automated data in biopharmaceutical manufacturing. *American Pharmaceutical Review*. [\[Link\]](#)
5. N. Muralidharan (Oct 2025). Comprehensive Stability Assessment of Biotechnological Products: Degradation Mechanisms, Statistical Tools, and Regulatory Compliance, Part 1. *Bioprocess International* 23(10):27–31.
6. N. Muralidharan, A. Turner, H. Michor & M. Davis (Oct 2025). From Bench to BLA: Synchronizing CMC Activities with Clinical Development for Robust and Compliant Biopharmaceutical Manufacturing. *Bioprocess International* 23(10):27–31. [\[Link\]](#)
7. N. Muralidharan, T. Younger, A. Elkin & J. Xian (May 2025). Raw Materials in Biologics Manufacturing: Comprehensive Risk Assessment and Classification. *Bioprocess International* 23(6):23–29. [\[Link\]](#)
8. N. Muralidharan (May 2025). Understanding the Variability in Bioburden Test Results in Biomanufacturing. *Pharmaceutical Technology*, 20–23. [\[Link\]](#)
9. N. Muralidharan (Apr 2025). Investigating Bioreactor Contamination, Modeling Contaminant Introduction, and Ensuring Bioburden Test Reliability. *BioPharm International* 38(3):20–27. [\[Link\]](#)
10. N. Muralidharan, L. S. Rose & M. Davis (2025). Extractables and Leachable Management: Comprehensive Risk Assessment During Process Validation for At-Scale Biopharmaceutical Manufacturing. *Bioprocess International* 23(3)E1:15–20. [\[Link\]](#)
11. N. Muralidharan, T. Younger, G. Chan, S. Ball, M. Davis & E. Bolduc (2025). Bioreactor Design – Leveraging Established Principles and Modern Insights. *Bioprocess International* 23(3)E1:4–18. [\[Link\]](#)
12. N. Muralidharan, L. S. Rose, T. Younger, A. Elkin, M. Walia, G. Chan & S. Ball (2025). Microbial-Control Hold-Time Assessments: Guidance on Matrix and Bracketing Validation Approaches. *Bioprocess International* 23(3):23–34. [\[Link\]](#)
13. N. Muralidharan, L. S. Rose, T. Younger, G. Chan, S. Ball, M. Davis, E. Bolduc & A. Elkin (2025). Buffer and solution mixing-time validation: A risk-assessment framework for analysts using matrix and bracketing approaches. *Bioprocess International* 23(1-2):23–34. [\[Link\]](#)
14. N. Muralidharan & L. S. Rose (2024). Process Validation: Assessing the Need for At-Scale Physicochemical Stability Studies in Biologics Manufacturing. *Bioprocess International* 22(11):E1. [\[Link\]](#)
15. N. Muralidharan, T. Younger, G. Chan, S. Ball, M. Davis & E. Bolduc (2024). Maintaining protein disulfide-bond stability during culture harvest: Exploring the effects of temperature and oxygen on reduction-reaction kinetics. *Bioprocess International* 22(11):E1. [\[Link\]](#)
16. N. Muralidharan, T. Johnson, L. Rose & M. Davis (2024). CPV Monitoring – Optimization of Control Chart Design by Reducing the False Alarm Rate and Nuisance Signal. *Science Journal of Applied Mathematics and Statistics*. [\[Link\]](#)
17. N. Muralidharan, E. Bolduc & M. Davis (2024). Strategies Used in Manufacturing Processes to Drive and Control Mammalian Cells to Undergo a Lactate Metabolic Shift. *Pharmaceutical Bioprocessing* 12(2):152–157. [\[Link\]](#)
18. N. Muralidharan, T. Younger, G. Chan & M. Davis (2024). Shear Assessment for Cell-Culture Clarification in a Disc-Stack Centrifuge. *Bioprocess International* 22(3):2–7. [\[Link\]](#)
19. N. Muralidharan, E. Bolduc & M. Davis (2024). Characterizing Oxygen Mass Transfer and Shear During Cell Culture: Calculating the Maximum Cell Density Supported by a 20,000-Liter Stirred-Tank Bioreactor. *Bioprocess International* 22(1-2):2–10. [\[Link\]](#)
20. N. Muralidharan & D. Lorson (2024). Determining Sample Size for Demonstrating Zero Failures: Ensuring the Effectiveness of Corrective and Preventive Actions. *Bioprocess International* 22(1-2). [\[Link\]](#)
21. N. Muralidharan, T. Johnson, E. Bolduc & M. Davis (2024). CO2 Control Strategy for Large-Scale Cell Culture Bioreactor Operation. *Advances in Bioscience and Bioengineering* 12(1):1–13. [\[Link\]](#)
22. N. Muralidharan, T. Johnson & M. Davis (2023). Identifying False Metabolite Measurements During Cell-Culture Monitoring: Effective Application of the Multivariate Hotelling's T2 Statistic. *Bioprocess International* 21(11-12):29–31. [\[Link\]](#)
23. N. Muralidharan, T. Wombaker, T. Johnson & E. Bolduc (2023). Validating Prefiltration Dirty-Hold Times for Upstream Media and Feed Solutions: Implications for Establishing In-Process Microbial Control. *Bioprocess International* 21(9):26–35. [\[Link\]](#)
24. N. Muralidharan (2023). Specification Limits for Biomanufacturing Processes: Comparing Tolerance-Interval and Process-Capability Methods. *Bioprocess International* 21(6):40–43. [\[Link\]](#)
25. N. Muralidharan (2023). Process Validation: Calculating the Necessary Number of Process Performance Qualification Runs. *Bioprocess International* 21(5):37–43. [\[Link\]](#)
26. N. Muralidharan (2023). Quantitative Risk Assessment of Limits for Residual Host-Cell DNA: Ensuring Patient Safety for In Vitro Gene Therapies Produced Using Human-Derived Cell Lines. *Bioprocess International* 21(4):33–37. [\[Link\]](#)
27. N. Muralidharan (2023). Shear-Proof Design Space: Scaling Stirred-Tank Bioreactors for Cell Culture Processes. *Bioprocess International* 21(1-2):36–38. [\[Link\]](#)
28. N. Muralidharan (2022). Statistical Method for Establishing Control Limits for Nonnormal Data Distribution: Focus on Continued Process Verification Monitoring. *Bioprocess International* 20(10):20–2 [\[Link\]](#)