

ARTHUR L. EDGE III

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SUMMARY

Strategic leader with over 13 years of broad-based experience in Healthcare, Biotechnology, and Sustainability. Team “whisper” with the know how to navigate the technical and human challenges that arise across a dynamic product development lifecycle. Accelerated complex projects through concept scouting, research, development, tech transfer, launch, and commercial operation. Motivated to close the gap between customer need, business capability, and innovation. Masters in Engineering and trained Lean Six Sigma Greenbelt.

EXPERTISE & TECHNICAL SKILLS

New Venture Due Diligence • Market Research • Intellectual Property Evaluation • Innovation Planning
Project Management • Risk Analysis • Capital Planning • Techno-Economic Analysis • Business Intelligence
Team Management • Product Development • Manufacturing • Process Improvement • Modeling
MS Teams • MS SharePoint • MS Project • Power BI • MS Office 365 • MS Visio • Asana • Minitab • JMP SAS • STATISTICA

PROFESSIONAL EXPERIENCE

AstraZeneca, Gaithersburg, MD July 2020 – Present
Global, science-led biopharmaceutical business and our innovative medicines are used by millions of patients worldwide.

Product Champion & Associate Director, Global Technical Operations, Biologics

Reporting to Senior Director, New Products and Technology, manage activities from drug development through regulatory submission, launch, commercial manufacture, and life cycle management of biopharmaceutical programs across the Respiratory & Immunology, Oncology, and COVID-19 product pipelines. Matrix leadership and responsibility for delivery across 120+ member teams.

Technical Strategy

- Global CMC Team Lead (Chemistry, Manufacturing, & Controls) for Fasenna® driving all the major activities across Operations including change implementation, process improvement implementation, and Variation management. Identified and drove yield and COGM improvement initiatives to enable ~\$10 million YoY annual cost savings for brand and maintain product supply to patients during pandemic.
- Collaborated with commercial organization to increase brand’s competitive advantage by leading CMC related regulatory filings in several international markets and life cycle management (LCM) initiatives (e.g. Autoinjector, new indications, label updates, new technologies) to achieve **\$1 billion in product revenue.**
- Established alliance joint-CMC team structure for commercial biologics, including team charter, membership, and goals. Manage partnership with Amgen to support launch of combination product, Tezepelumab for severe asthma. Manage partnership with Horizon to deliver UPLZINA® supply for rare nervous system disorder.

Pipeline Development

- Represent Operations in Global Product Team (GPT) to translate overall product strategy into key deliverables for Operations for two accelerated early Oncology assets.
- Ensure timely commercialization of product, by performing key activities such as COGM analysis, manufacturability review, site selection, aligning production scheduling based on product needs.
- Ensure Operations is ready for the pipeline product by identifying key gaps in manufacturing processes/equipment and preparing business case and implementation roadmap. Advise development led CMC teams to ensure commercial manufacturability success.

GlaxoSmithKline (GSK), Rockville, MD December 2016 – Present
Science-led global healthcare company that develops innovative Pharmaceutical, Vaccine, and Consumer Healthcare products.

Technology Manager, Biopharmaceuticals, Pharma Supply Chain

Reporting to Global Product Owner, provide technical oversight and product Life Cycle Management for immuno-inflammation therapies including risk management, change management, and knowledge management. M-ERP/ SAP Super User.

Highlighted Achievements to Date

Technical Leadership

- Member of site Extended Leadership Team (ELT) with co-ownership of strategy. Accountable for technical decisions for BENLYSTA® (belimumab) autoimmune antibody product. SME for upstream operations. Member of Raw Material Board (RMB), Change Control Review Board (CCRB), and Biopharm QbD and Control Strategy Community of Practice.
- Led four engineers and matrix team of 50+ members/23 functions to achieve 40 metrics for on time manufacture and release of bulk drug substance at 20,000 L scale. Reduced deviations by 15% and achieved **93% batch success.**

- Built portfolio of artificial intelligence/machine learning and multivariate process models to optimize operations and prevent **\$15 MM/year** defects in manufacturing and quality attributes. Led projects across Informatics, Digital Data Analytics teams, and National University of Ireland-Galway with **\$200 K/year spend** to increase CPV maturity level.
- Drove technology transfer for **first product to launch in new \$139 MM retrofitted 10,000 L scale facility**. Facilitated relationships and confidentiality agreements with 10 suppliers to forecast, cost, and procure >50 materials.
- Advanced product specifications, regulatory change controls to 70+ markets, and agency Responses to Questions (RTQ). Organized regulatory inspection (PAI) readiness, risk registers, and **\$1 MM/year yield improvements**.
- Headed up talent and recruitment initiatives to **improve engagement metrics** from 74% to 77%. Launched Career Growth Network ERG. Relationship manager for National Society of Black Engineers, Johns Hopkins Institute for NanoBioTechnology, and George Mason University Bioengineering Alliance.

Emergent BioSolutions, Gaithersburg, MD May 2015 – December 2016
Specialty global biopharmaceutical company that develops medical countermeasures (MCMs) against biological health threats

Process Engineer (Senior), Process & Analytical Development, Bio-Defense Division

Reporting to Director of Engineering and Operations, managed the introduction and transfer of prophylactic and therapeutic technologies between R&D, third party clients, and Contract Manufacturing Organizations (CMO).

Highlighted Achievements

Budget Management

- Managed complex tech transfer with HHS/BARDA for rapid scale up and delivery of three monoclonal antibodies for animal model (non-clinical) testing of **Ebola therapy**. Reported earn value on **\$19.7 MM procurement contract**.
- Customized and proposed innovation model to capture ideas for new products and business processes across company division. Overhauled global procedures to improve tech transfer efficiency, providing maturity model for sites to conduct gap analysis and standardize.
- Spearheaded critical **capital projects >\$500 K**; Expanded site R&D labs, negotiated vendors, and acquired technologies to ensure operational flexibility and win external partnerships (Business, Government, University).

Project Management

- Communicated process map to define strategy and work packages for launching new drugs as part of Lean Product Development Team. Scoped R&D through Phase 3 for Chemistry, Manufacturing, and Controls (CMC).
- Advised teams on vaccine design and characterization via small scale models to de-risk **whole virion inactivated virus** platform in Vero cells for **Zika** and **modified vaccinia ankara** platform in avian cells on NIAID grant for **tuberculous**.
- Benchmarked disruptive **high throughput** cell engineering technology for **rapid response** protein production to decrease development time from **6 months to 2 months**.
- Received and demonstrated pilot process for production of **Ricin toxin** vaccine in **recombinant E. coli**; Collaborated on data review, root cause analysis, and corrective action assessments as lead engineer.

DSM (formerly Martek Biosciences), Columbia, MD December 2009 – May 2015
Global purpose-led, science-based company in Nutrition, Health and Sustainable Living

Bioprocess Engineer, Biotechnology, Research & Development

Reporting to Senior Manager, Biotechnology R&D, supported technical process and product development to convert microbial sources (yeast, microalgae, fungi) into products for Human Health, Animal Health, and Bioenergy global business units.

Highlighted Achievements

Product Innovation

- Developed omega-6 and omega-3 nutritional lipid products for **pregnant and nursing mothers, infants, and adults aged 55+** to support brain, eye, and heart development. Influenced health platform value proposition and discovered intellectual property opportunities via patent investigation, competitive intelligence scouting, and industry meetings.
- Delivered animal feed product samples that linked composition to performance and complied with regulatory authorities (ESFA, USDA) allowing for broader commercialization strategy in US, Brazil, and China.
- Acquired **\$150 K** seed funding for business assessment on Centriant Pharmaceuticals beta-lactam antibiotics process. Investigated **co-product valorization**. Ranked options by competitive edge, tech maturity, and readiness to implement.

Program Management

- Led work pages to advance **\$10 MM joint research program** with BP to create renewable biodiesel. Communicated experimental feedback to fermentation, cell physiology, and molecular teams to screen 22 microorganisms. Identified top 3, exceeded stage gate milestones, and generated biofuel for **2012 London Olympics BMW vehicle fleet**.
- Generated financial tool to equate cash flow changes to 1% improvements in project rate of return (IRR). Facilitated techno-economic analysis and down select from seven to two product and process designs with **>50% capital savings**.
- Represented North America on steering team for global employee resource group of 1,000+ early career professionals (DSM NEXT). As Operations lead, managed organization structure and goal alignment across six geographic regions to measure impact on company. Co-planned bi-annual **strategy conference in Hyderabad, India**.

EDUCATION

Master of Engineering, Chemical and Biomolecular Engineering, Johns Hopkins University – Baltimore, MD
Bachelor of Science & Engineering, Chemical Engineering, University of Michigan – Ann Arbor, MI

Advanced Courses: Pharmacokinetics, Pharmacodynamics, Metabolic Systems Biotechnology,
Technical Project Management, Creating New Ventures in Engineering and Science-based Industries

SPECIAL ASSIGNMENTS

Bioengineering Alliance, George Mason University

September 2019 – Present

- Board of Directors leading 25-member alliance for Department of Bioengineering.
- Aligning education programs, increasing program ranking, fostering research and industry relationships, and facilitating technology translation.

National Society of Black Engineers – Healthcare Innovation SIG, Director

May 2017 – May 2021

- Organized multiple technical sessions with J&J Center for Device Innovation / J Labs, Baxter, Phillips Healthcare, University of Pittsburgh, Carnegie Mellon, and University of Michigan for 1,200+ special interest group (SIG) members. **Appointed from Treasurer to Director in May 2019**.
- Launched pilot workforce development program with National Institute for Innovation in Manufacturing of Biopharmaceuticals (NIIMBL) and White House Initiative for Historically Black Colleges and Universities (HBCU). **Honored with 2018 Technical Ambassador Award**.
- Oversaw management and reporting of finances. Facilitated national partnership with Biomedical Engineering Society (BMES) to promote joint membership and advance projects to improve health outcomes for underrepresented communities.

Montgomery County Public Schools – Engineering Advisory Board, Chair

March 2016 – Present

- Multi-year appointment. Evaluating budget, engineering curriculum, recruitment and engagement initiatives to ensure student success in Montgomery College and Montgomery County Public Schools.
- Develop data dashboards and assessed completion rate of five-course Project Lead the Way (PLTW) engineering curriculum with **4000+ student enrollment and \$200 K** annual spend. Advised Assistant Superintendent on organizational restructuring and multi-year strategic plan to equip students for college and workforce entry.

Solgreen Solutions – Management Advisory Board Member, Business Development

June 2016 – October 2017

- Reported to CEO of startup clean tech company that designs solar charging stations to meet demand for sustainable outdoor infrastructure.
- Translated business strategy into easy-to-communicate project portfolio. Overhauled business plan and developed pitch decks to support investor due diligence and acceptance to Potential Energy DC incubator, US Green Building Council and Business Council for Sustainable Energy.
- Married outputs from financial modeling, forecasting, and market research allowing Solgreen to discover new customer segments and win clients from direct competitors.

Re-Nuble – Scientific Advisory Board, Member

August 2013 – January 2017

- Bio-agriculture startup converting food waste into non-toxic hydroponic nutrients via anaerobic digestion.
- Reviewed and provided feedback regarding equipment selection, process design, and formulation approaches.
- Secured \$50,000+ annually to fund chapter initiatives including the launch of Executive Mentoring Program for young professionals; Recognized nationally as 2012 Chapter of the Year.