

CURRICULUM VITAE

Otute Akiti

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EXECUTIVE SUMMARY

- Accomplished pharmaceutical CMC and Technical Operations executive with board level experience and a proven track record of small molecule drug development from inception to regulatory approval and commercialization.
 - Adept at overseeing complex projects from conception to execution, optimizing processes, and ensuring seamless cross-functional collaboration.
 - Proven track record of implementing innovative solutions, enhancing efficiency, and achieving cost savings.
 - Globally recognized for expertise and deep understanding of small molecule Process Development and Manufacturing, Quality, Regulatory, Supply Chain Operations, and Strategic Sourcing.
 - Experienced leading regulatory filings, IND, NDA, MAA. Subject matter expert, experienced with FDA audits including PAI audits.
 - Established leader with a highly professional attitude, high reliability, and high regard for fellow personnel, and committed to empowering, developing and retaining talent.
 - Demonstrated success in leadership roles within high-growth companies.
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WORK EXPERIENCE

NEUMORA THERAPEUTICS

Vice President, Technical Operations

2020 – 2024

- Expansion of role to cover more assets through the acquisition of BlackThorn by Neumora including the recruiting of talent for the expanded team.
 - Served on Executive team to help shape company strategy.
 - Led CMC team to support the successful completion of NMRA-140 Phase 2 studies and the initiation of the Phase 3 program, including completion of registration stability.
 - Established and agile and flexible supply chain network to support Neumora development programs.
 - Led CMC technical team to transition multiple pre-clinical assets to the IND stage and support subsequent clinical studies from Phase 1 to Phase 2..
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BLACKTHORN THERAPEUTICS

Vice President, Technical Operations

2019 – 2020

HEAD OF CMC

2018 – 2019

Summary BlackThorn Experience

Led activities related to small molecule drug substance and solid oral drug product process development, including process optimization, cGMP manufacture of Drug Substance (DS) and Drug Product (DP), Analytical Development and Quality Control, regulatory filings (multiple INDs), strategic sourcing and supply chain management, in support of new and ongoing BlackThorn neuroscience small molecule clinical programs.

Responsible for BlackThorn CMC strategy, project plans, budgets, schedules, and timelines to ensure successful project completion.

RELYPSA INC, A VIFOR PHARMA COMPANY

Executive Director, Manufacturing and Process Development

2015 – 2018

Senior Director, Manufacturing and Process Development

2012 - 2015

Summary of Relypsa Experience

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- Guided a large multi-disciplinary team through the Veltassa development program and commercialization, including process validation, strategic sourcing, regulatory filing and approval (NDA,MAA) in the US and EU, Canada, Australia, Israel and Switzerland.
 - Veltassa is a novel polymeric drug developed for the treatment of hyperkalemia.
 - Developed world wide supply chain to enable the sourcing of key materials worldwide at multi metric ton scale.
 - Led activities to develop and implement a continuous manufacturing process to enhance manufacturing efficiency and lower cost of goods, including engineering and facility design, environmental issues, contract negotiations, as well as interactions with the FDA Emerging Technology (ETT) team.
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EXELIXIS INC

- **Director, Process Engineering** **2010 - 2012**
 - **Associate Director, Process Engineering** **2009 - 2010**
 - **Senior Scientist I, Chemical Development** **2007-2009**
 - **Summary of Exelixis Experience**
 - Guided a multi-disciplinary team (Process Development, Analytical Development, Quality Control, Sourcing and Supply Chain) through from the initial lab development stages to successful process validation, NDA approval, and commercialization for the cabozantinib (Cometriq) small molecule oncology franchise.
 - Established the Process Engineering function at Exelixis, recruited talent and led/provided support for several small molecule development compounds in the Exelixis oncology pipeline.
 - Led the team through evaluation and outsourcing activities for multiple Exelixis oncology compounds including Cabozantinib.
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BRISTOL-MYERS SQUIBB COMPANY

- **Senior Research Investigator I, Process Research and Development** **2004 - 2007**
- **Research Investigator II, Process Research and Development** **2000 - 2004**
- **Summary of Bristol-Myers Squibb Experience**
- Held positions of increasing responsibility in the small molecule process development department. Served as the project leader for two candidates in the BMS p38 program where I led interdisciplinary teams through initial Phase I development activities, scale-up and manufacturing, through to a successful IND filing and subsequent Phase II process development. Additionally, held lead roles for several candidates in the BMS PPAR program for the treatment of diabetes, the BMS HMG-CoA program for cholesterol lowering, as well as the BMS CRF-1 antagonist program.
- Senior process engineer for the Onglyza (Saxagliptin) and contributed to the development of Sprycel (Dasatinib) for leukemia.

EDUCATION

New Jersey Institute of Technology, Ph.D. in Chemical Engineering

Northeastern University, M.S. in Chemical Engineering

University of California at Berkeley, B.S. in Chemical Engineering

PROFESSIONAL AFFILIATIONS

- **International Society of Pharmaceutical Engineers (ISPE)**
 - **American Institute of Chemical Engineers (AIChE)**
 - Active in Pharmaceutical Division Planning Activities
 - Served Program Chair for Pharmaceutical Division
 - Regularly chair several sessions at annual meetings
 - **North American Mixing Forum (NAMF)**
 - President Emeritus
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PATENTS

Chenkou Wei and Otute Akiti: Crystallization system using homogenization, International Publication Number: WO 03/095059 A1, International Publication Date: 20 November, 2003.

Chenkou Wei, Margaret M. Peel, Otute Akiti: Crystallization system utilizing atomization, International Publication Number: WO 03/092852 A1, International Publication Date; 13 November, 2003.

SELECTED PUBLICATIONS AND PAPERS

- Piero Armenante and Otute Akiti, [*Sterilization Processes in the Pharmaceutical Industry*](#), Chapter in *Chemical Engineering in the Pharmaceutical Industry: Drug Product Design, Development, and Modeling, 2nd Edition*, Wiley 2019
- Otute Akiti and Piero Armenante, [*Mixing and Processes Validation in the Pharmaceutical Industry*](#), Chapter in *Advances in Industrial Mixing: A Companion to the Handbook of Industrial Mixing*, Wiley 2015.
- Lindsay A. Hobson, Otute Akiti, et al, "[Development of a Scaleable Process for the Synthesis of a Next-Generation Statin](#)", *Organic Process Research and Development*, (2010), pp 441-458
- Otute Akiti, Agnes Yeboah, Ge Bai and Piero Armenante, "Hydrodynamic Effects of Mixing and Competitive Reactions in Laboratory Reaction Vessels", *Chemical Engineering Science*, 60(2005), pp 2341-2354.
- Otute Akiti and Piero M. Armenante, "Experimentally validated micro-mixing based for fed-batch stirred reactors", *AIChE Journal*, 50(3) , pp 566 – 577
- Akiti et al, "Multiphasic or 'Pulsatile' Controlled Release System for the Delivery of Vaccines", in *Human Biomaterials Applications*, Humana Press Inc., 1996.

PRESENTATIONS

- Authored or co-authored several presentations at the Annual Meeting of the American Institute of Chemical Engineers since 1999.
- Full list available upon request.

LANGUAGES

- English – Fluent
- French – Speak fluently and read/write with high proficiency
- German – Speak, read, and write with basic competence.

REFERENCES – AVAILABLE UPON REQUEST