## Mark L. Lalli

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#### **Professional Experience:**

#### **Associate Director, Process Development**

Feb 2022 - Present

Be Biopharma

Cambridge, MA

- Led a team of scientists to develop and optimize manufacture of platform B cell therapy.
- Launched and led the core B cell manufacturing team.

#### **Analyst, Cell Agriculture Bioprocessing**

Nov 2021 - Present

Helikon Consulting

Cambridge, MA

• Analyzed cell agriculture manufacturing processes for market feasibility.

# Associate Director, Process Development Senior Scientist, Process Engineering

Oct 2020 - Feb 2022

May 2019 - Sept 2020

Sigilon Therapeutics

Cambridge, MA

- Led a team of scientists to streamline manufacture of core programs including scale up of adherent cells into a bioreactor platform.
- Developed protocols for cGMP manufacture of cellular drug substance and drug product.
- Supported regulatory filings and amendments for UK, EU, and USA.
- Led optimization work for cryopreservation of drug substance and drug product.
- Served as person-in-plant and tech transfer lead for SIG-001, -002, -005, and -007.
- Created xeno-free media adapted banks of drug substance precursor cell lines.

## **Senior Engineer, Conjugation Process Development**

January 2019 - May 2019

ImmunoGen

Waltham, MA

- Developed control strategies and processing methods for continuous antibody-drug conjugate (ADC) manufacture.
- Optimized countercurrent tangential flow diafiltration for ADC formulation.

## **Engineer III, Cell Therapy Bioprocessing**

January 2017 - December 2018

MilliporeSigma (Merck, KGaA, Darmstadt, Germany)

Bedford, MA

- Invented a novel, centrifugal downstream processing device for cell therapy manufacturing.
- Developed an operable cell retention filter compatible with immunotherapeutic cells.
- Modeled downstream processing steps to predict performance based on FDA and industry guidelines for final product fill/finish.
- Led technology scouting efforts to support collaborations and provided guidance to the venture capital arm of Merck, KGaA, Darmstadt, Germany.
- Reduced overall process of expanding therapeutic cells within bioreactors by an entire step by investigating parameters previously unexplored in the field.
- Scripted and automated image analyzer for the detection of defects in downstream filters.

### **Product Development Engineer**

May 2015 - December 2016

Obz Design

Boston, MA

- Developed an algorithm to calculate blood hemoglobin levels in a patient based on *in vivo* spectroscopic data acquired non-invasively.
- Prototyped novel medical device.

#### **Education:**

PhD, Chemical Engineering, 4.0 GPA

College of Engineering, Northeastern University

Dissertation: "Control of epithelial cell electrotaxis through manipulation of cell-cell interactions"

B.S.E., summa cum laude, Chemical Engineering

College of Engineering, University of Massachusetts, Lowell

Nanomaterials Engineering Track

Passed the Fundamentals of Engineering Exam

## **Research Experience:**

## Graduate Research Assistant, Cell Engineering Lab

September 2012 – August 2016

Northeastern University

Boston, MA

- Designed, built, and validated a novel electrotactic device.
- Computationally modeled electrotaxis and electrophoretic redistribution of surface receptors.
- Reduced processing time of cell tracking by 80% by creating label-free image analysis algorithms to automate the tracking of clustered epithelial cells.
- Mentored three undergraduate students in chemical engineering in preparation for research oriented cooperative education positions.

## **Undergraduate Research Assistant, Frontier Materials Lab**

June 2009 – August 2012

University of Massachusetts, Lowell

Lowell, MA

- Developed process for producing nanostructured conductive polymers and surface coatings.
- Scripted algorithms to interpret signals from an electronic nose resulting in the ability to sense and identify a variety of airborne chemicals such as the explosives, DNT and RDX.

#### **Select Honors and Awards:**

Sigilon Collaboration and Innovation Award	2019
MilliporeSigma Spot Award	2017
Northeastern University College of Engineering Excellence in Research Award	2016
MassChallenge, Gold Winner	2015
Northeastern University Chemical Engineering Outstanding Seminar Travel Grant	2015
Northeastern University Chemical Engineering Best Teaching Assistant Award	2013
AIChE Outstanding Chemical Engineering Student of the Year Award	2012
University of Massachusetts Lowell Chemical Engineering Scholarship Award	2012
University of Massachusetts Lowell Dean's Gold Medal Award	2012
Commonwealth Scholarship	2009-2012

#### **Select Publications:**

- 1. Luo, C. Y., Natividad, R. J., Lalli, M. L., Asthagiri, A. R., PLoS ONE 15 (9): e0239188.
- 2. Natividad, R. J., Lalli, M. L., Muthuswamy, S. K., Asthagiri, A. R., BioPhys J. 2018; doi.org/10.1016/j.bpj.2018.10.006.
- Schnitzler, A. C., Lalli, M., Aysola, M., Anant, J., Murrell, J. <u>Bioreactors for Stem Cell Expansion and Differentiation</u>, edited by Joaquim M.S. Cabral, Claudia Lobato da Silva, "Chapter 6: Bioprocessing of Human Stem Cells for Therapeutic Use through Single-Use Bioreactors." ISBN 9781498795906.
- 4. Lalli, M. L., Wojeski, B., Asthagiri, A. R., Cell Mol. Bioeng. 2017; 10:89.
- 5. Lalli, M. L., Asthagiri, A. R., Cell Mol. Bioeng. 2015;8: 247–257. doi:10.1007/s12195-015-0383-x.
- 6. Walsh, D. I. III, **Lalli, M. L.**, Kassas, J. M., Asthagiri, A. R., and Murthy, S. K. Anal. Chem. 2015;87(11):5505-5510.

#### Fiction:

Lalli, Mark. Storm's Center. ASIN: B07DT8W3NB. June 17, 2018.