

## SUMMARY

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I have been in the biotechnology sector for 9 years, working at different locations and roles. My broad background with diligent work ethic allows me to fit into adaptable situations and apply a range of skills. Participated in multiple projects and developed many end-user solutions, which empathize investigative skills and communication with groups.

## EXPERIENCE

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### Validation Engineer II

Jun 2017 – Present

*Biogen Inc. – RTP, NC*

- Responsible for Small Scale Purification, Flexible Volume Manufacturing, and Large Scale Harvest areas, overseeing changes, assessments, and routine cleaning monitoring. This includes tech transfer meetings, equipment changes, and any qualification requiring testing.
- Assisted with revising the cleanability testing process for efficiency gains, reducing overall total testing turnaround time. Currently in process of converting all current paper documentation to electronic format utilizing Kneat.
- Expert in Kneat Software to assist with other departments and sites with trouble shooting and identifying solutions.

### Production Engineer II

Oct 2016 – Jun 2017

*Biogen Inc. – RTP, NC*

- Travelled to multiple vendor locations to perform Factory Acceptance Testing (FAT) on equipment for large scale equipment (Abec MO, Abec PA, Abec IE, Allegheny Bradford, and Steris Finn-Aqua). Led testing and documentation on vessels for Seed Trains, Production Bioreactors, Buffer Hold, Product Hold. Tracked punch list items and resolve discrepancies with vendor.
- Created ShareNet to collaborate with team/contractors to manage documentation and tracking for all equipment testing across different site locations. Onboarded contractors for project to maintain the documentation and testing.
- Worked with Solothurn team to develop Wiki site, as a handbook for new hire introduction to commissioning testing.

### Validation Engineer I

Jul 2012 – Oct 2017

*Biogen Idec – Cambridge, MA*

- Site Process Owner for Kneat Solutions business software. A key member in cross-site team project to implement electronic solution for life-cycle management of validation documentation. Strategized to converting all validation governing systems to utilize Kneat software.
- Developed and scheduled protocols for quality control, engineering and manufacturing activities equipment/cleaning qualifications. Contributed to validation reports and project plans, accessing core change controls and completing action plans. Equipment areas include: water systems, facility certification, chromatography systems, centrifuges, autoclaves, soil and clean hold studies and incubators.
- Designed Microsoft SharePoint team-sites for multiple groups and departments. Created tracking pages and automated forms with notification workflows.
- Completed a seed funding project assessing the feasibility of Rapid Microbiological Methods (RMMs) to reduce environmental monitoring sampling requirements due to instrument technology via BioVigilant Air Sampler.

### Manufacturing Associate III

Aug 2008 (Mar 2009) – Jul 2012

*Biogen Idec – Cambridge, MA*

- Subject matter expert and lead operator for multiple automated chromatography and ultrafiltration processes: utilizing automation (DeltaV/Unicorn) and manual systems.
- Worked closely with engineering and validation teams on new equipment implementation: procurement, construction, commissioning and validation for chromatography and ultrafiltration systems.
- Trained and supervised operators in Denmark facility upstart. Led the completion of purification operational qualifications on product hold tanks, viral filtration and ultrafiltration systems. Helped transitioned facility from non-GMP to cGMP state.
- Developed and implemented a user-friendly electronic solution using PI ProcessBook for retrieving temperature data which saved labor time and space compared with manual recording system.

## SKILLS

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Industry Software	QUMAS MyCims, SpartaSystems TrackWise, Labware LIMS, Infor EAM, Agile PLM, Kneat Software, Emerson Process Management DeltaV, OSI PI ProcessBook, GE Unicorn, Umetrics SBOL, Atlassian Confluence
Proficient	Microsoft Applications: Access, Excel, Word, PowerPoint, SharePoint, InfoPath, and Visio.
Intermediate	Web design: HTML, CSS; Programming: JavaScript, Java, C++, VBA, PHP, Python, Perl, Bash; Operating Systems: Windows 10, Linux (Debian, Ubuntu), macOS

## EDUCATION

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### Project Management Certificate

July 2018

*Cornell University -- Online*

### B.S. in Biomedical Engineering

2003 – 2008

*Rensselaer Polytechnic Institute -- Troy, NY*