

Alejandro Villanueva

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Global Process Engineer IV

Diligent, goal-oriented professional with a comprehensive process engineering background, including experience working within cGMP manufacturing facilities, as well as OSHA PSM / EPA RMP regulated facilities. Demonstrated leadership abilities in managing complex engineering projects, coaching personnel, and developing process validation protocols. Adept at performing data mining and visualization to identify solutions to potential process issues. Robust technical proficiency in multiple tools and technologies, including: AFT FATHOM / ARROW, MathCAD, OSI PI, JMP, and Microsoft Office Suite.

TECHNICAL SKILLS

Front End: HTML, CSS, Responsive Design, JavaScript, jQuery, AJAX
Back End:

PROFESSIONAL SKILLS

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|-----------------------------|-------------------------------|-----------------------|
| ▪ Project Management | ▪ Process Validation | ▪ Strategic Planning |
| ▪ Process Safety Management | ▪ Data Mining & Visualization | ▪ Quality Control |
| ▪ Process Engineering | ▪ Root Cause Analysis | ▪ Process Improvement |
| ▪ Plant Operations | ▪ Process Hazard Analysis | ▪ Problem Solving |

PROFESSIONAL EXPERIENCE

AGC Biologics, Bothell, WA

Dec 2019 - Present

Global Process Engineer IV

Currently, Global Process Engineer with network wide Subject Matter Expert responsibilities for capital projects and technical consulting.

Project Management:

- Successfully delivered \$5MM facility improvement project including specification, purchase, and installation of \$1.8MM of process equipment, to add Cell and Gene Therapy manufacturing capability to the site.
- Serve as Process Engineering Subject Matter Expert for \$340MM site expansion project to triple the site’s mammalian production capacity.
- Collaborate with construction management contractor including bid review and primary contractor selection, and managing subcontractors / trades throughout demolition, construction, and qualification phases of the project.
- Subject Matter Expert for specification of new purchased equipment (such as bioreactors with associated pumps, sensors, and automation), work closely with equipment manufacturers to ensure the purchased systems will be appropriate for the intended use of the manufacturing site, including execution of Factory and Site Acceptance Testing.

Technical Expertise:

- Develop Global Engineering Standards including Clean Water System Design.
- Delivered new equipment sets to existing manufacturing suites, including leading cross-functional team to install, qualify, and release the new equipment to GMP manufacturing.
- Improved equipment control capability through control loop optimization, as technical lead and author of testing protocol, leading to better control of quality critical process parameters.

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Eli Lilly and Company, Indianapolis, IN

Mar 2013 – Nov 2019

Senior Process Engineer

Delivered exemplary technical process engineering support for multiple plants, while collaborating with a highly motivated cross-functional team.

Leadership:

- Exhibit leadership expertise to manage key projects from inception to completion, while ensuring their delivery within time and budgetary constraints.
- Adeptly execute numerous capital projects (valued at less than \$5MM) focused on enhancements in the manufacturing space through driving yield, reducing cycle time, and minimizing manufacturing costs.
- Serve as a mentor to less experienced engineers and scientists in applying data monitoring/visualization tools; maintaining compliance with global standards; and consistently utilizing good engineering practices.
- Collaborate with external partners and contractors to ensure seamless project implementation.
- Function as the Lead for Men as Allies for the Women's Initiative for Leadership.

Industry Expertise:

- Maintain a comprehensive knowledge of various unit operations encompassing reactions, chromatography, tangential flow filtration, and evaporation.
- Leverage expertise in front/back end process engineering steps, while ensuring compliance to applicable corporate global engineering standards.
- Act as a subject matter expert by establishing Process Validation (PV) protocols in support of PV campaigns for new products in multiple manufacturing plants.
- Function as a technical process engineering representative in process hazard analyses and perform lead root cause analysis for health, safety, and environmental (HSE) incident investigations.

Strategic Planning:

- Significantly slashed manufacturing costs for projects delivered, with annual savings of \$10-150K for each project.
- Realized over 95% uptime at the bottleneck step in the plant through increasing equipment reliability.
- Maintained optimal safety (ergonomic, chemical exposure) for personnel in the work environment during operations.

EDUCATION

Bachelor of Science: Chemical Engineering | Purdue University, West Lafayette, IN (*December 2012*)

CERTIFICATIONS

Full-Stack Web Development Boot Camp Certificate | University of Washington (August 2022)