

Ivaylo Valirov

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Objective

Experienced Process/Manufacturing Engineer with a strong background in development, manufacturing, data analysis and project management. Seeking to leverage my technical skills and leadership experience to drive optimization and efficiency in a new role.

Expertise

- **Operations:** Scheduling, resource allocation, production planning, supply chain and logistics, inventory management, cross functional coordination, training, ERP
- **Project Management:** Scope, planning, coordinating, risk management, communication, quality, change order, monitoring, documentation, team management, closure, evaluation
- **Documentation:** Technical writing, SOPs, Batch Records, User/Design Requirements, PFDs, P&IDs, Development and Test Protocols/Reports, Tech Transfer
- **GMP:** Deviations & Investigations, CAPAs, Change Controls, IOPQ, Validation, FMEA
- **Lean & Continuous Improvement:** Waste reduction, value stream mapping, 5S, kaizen, Kanban, standardization, practical problem solving, Ishikawa, 5 Whys, visual management
- **Six Sigma:** Gauge R&R, visualization, statistical process control, defect reduction, Pareto
- **Equipment & Reliability:** CMMS, maintenance, calibrations, asset management, system owner, spare parts management, vendor management, downtime reduction
- **Process Development:** experimental design, process optimization, scale-up
- **Troubleshooting:** Hands on diagnostics and repair of mechanical and electrical systems

Experience

Sr. Process Engineer / GOOD Meat (Eat Just), Alameda, CA

JUN 2022 – PRESENT

- Engineering lead for FAT and SAT execution of new stainless steel and single use cell culture equipment for pilot scale production of cultivated meat products
- Led process scaling and optimization studies: kLa, P/V, tip speed, parameter screening
- Project manager and technical lead for the implementation of a plant wide Ignition SCADA and historian to unify control and data collected from Siemens and Allen Bradley PLCs
- Generated new SOPs and batch records for media prep, bioreactor and harvest operations
- Defined scaled up parameters for cell culture process from flask to 3,500 L bioreactor
- Created and implemented Excel data visualization tool to track process performance, leading to a 95% reduction in time spend generating routine graphs
- Trained operations team on new equipment operation and maintenance
- Designed CIP strategy for all onsite equipment and performed cleaning validation
- Achieved 100% batch success rate for the 2023 in a new animal cell culture facility
- Implemented non-capital-intensive process and equipment modifications to reduce operational cost by over 50%

Manufacturing Process Engineer / Codexis, Redwood City, CA

JUN 2019 – MAY 2022

- Doubled manufacturing capacity for *E. coli* based protein 15 L bioreactor production line by implementing critical equipment repairs and qualifying new bioreactors
- Project manager and technical lead for a \$3 million equipment upgrade project to replace obsolete equipment including bioreactors, centrifuges, and lyophilizers
- Served as SME for fermentation, filtration, centrifugation, homogenization and lyophilization unit operations and processes

- Tech transfer of bacterial fermentation processes from development into Pilot Plant 15 L bioreactors and scale up to 650 L stainless steel bioreactors
- Implemented 21CFR Part 11 compliant CMMS system to track asset, calibration and maintenance records
- Managed reliability program to achieve 100% on-time calibration and maintenance

Manufacturing Engineer / AstraZeneca, Redwood City, CA

AUG 2016 – JUN 2019

- Implemented a new API production line, achieving a 93% reduction in campaign deviations through the implementation of new state of the art equipment, automation, leveled scheduling, hands-on training, and clear procedural controls
- Implemented and validated a new process to increase weekly production output by 60% using the existing equipment and without increasing headcount
- Increased batch success rate from 88% to 97% YoY by increasing equipment reliability, documentation simplification and robust training
- Led manufacturing continuous process validation initiative based on FDA guidelines
- Reduced facility product changeover from 3 weeks to 1 week through parallel scheduling and elimination of non-value-added steps
- Reduced manual batch record entry by 50% through the implementation of batch automation reporting and documentation improvements
- Served as SME for homogenization, spray drying, and jet milling unit operations

Process Engineer / Bayer, Berkeley, CA

JUL 2013 – JUL 2016

- Planned and executed analytical process equipment upgrade CAPEX projects up to \$1 million in value within 5% of budget
- Led a sitewide reliability improvement project to replace over 100 obsolete instruments
- Performed statistical analysis to establish process ranges for commercial products
- Evaluated new sampling and measurement technologies for biopharmaceutical processes
- Trained over 300 production operators and maintenance technicians on proper operation of cell counters, pH, DO, metabolite analyzers

Skills

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| • PMI Project Management | • Hands on troubleshooting & repair |
| • Statistical Process Control | • Root Cause Analysis |
| • Technical Writing | • Computer: MS Office, FactoryTalk, |
| • Data Analysis and Process Optimization | Python, JMP, SQL, Power BI, Ignition |
| | SCADA, SAP, Trackwise |
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Process Equipment

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| • Bioreactors | • Spray Dryers |
| • Homogenizers | • Lyophilizers |
| • Bucket and Disc Stack Centrifuges | • Washers and Autoclaves |
| • Tangential Flow Filtration | • CIP skids |
| • Sterile Filtration | • Clean Utilities: WFI, PW, CDA, Steam, |
| • BSCs, Isolators, Chemical Hoods | Chilled Water, Process Gasses (O ₂ , CO ₂ , N ₂) |
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Education

B.S. Bioengineering & Materials Engineering

IIE Lean Six Sigma Green Belt

Google Data Analytics Certificate

UC Berkeley, May 2013

2015

Dec 2023