



Ivaylo Valirov

CONTACT

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SKILLS

- Repair and Maintenance
- Project Management
- Statistical Process Control
- Operational Excellence
- Lean Manufacturing
- Six Sigma
- Root Cause Analysis

UNIT OPERATIONS

- Bioreactors
- Centrifuges
- Homogenizers
- TFF Systems
- CIP
- Process Vessels
- Autoclaves and Washers
- Lyophilizers
- Spray Dryers
- Clean Utilities

COMPUTER SKILLS

- Microsoft Office Suite
- SAP
- Trackwise
- JMP
- Python and VBA scripting
- DCS and SCADA

EDUCATION

University of California, Berkeley
B.S. Bioengineering & Materials Science and Engineering

CERTIFICATION

IEE Six Sigma Green Belt
PMI Project Management

EXPERTISE & RESPONSIBILITIES

- Plant process equipment maintenance and compliance
- Project management of equipment and plant upgrades
- Generation and execution of change controls within a GMP environment
- In-depth investigation analysis using practical problem solving techniques like 5 Whys and Ishikawa diagrams to determine deviation root cause
- CAPA generation and implementation to improve equipment reliability and eliminate process quality issues
- Generation of equipment and process SOPs and batch records
- Manufacturing asset master data maintenance in CMMS and ERP
- Calibration and maintenance vendor management
- Hands on troubleshooting, repair, and maintenance of process equipment
- Engineering documentation: URS, PFD, P&ID, IOQ, PQ protocols/reports
- Statistical process control and data analysis
- Contractor management to design, install, and commission electrical, mechanical and piping system

EXPERIENCE

Codexis — *Manufacturing Process Engineer*

Jun 2019 - Present

- Increased production capacity from 34% to 100% for 15 L *E. coli* bioreactor units
- Project management and technical lead for a \$3 million plant equipment upgrade project to replace obsolete and unreliable equipment including bioreactors, centrifuges, fume hoods and lyophilizers
- Tech transfer of processes from development into Pilot Plant 15 L bioreactors and scale up to 650 L bioreactors
- Achieve 100% on time execution of preventive maintenance and calibration service through CMMS implementation

AstraZeneca (Pearl Therapeutics) — *Manufacturing Engineer*

Aug 2016 - Jun 2019

- Increased batch success rate from 88% to 97% YoY through increasing equipment reliability, documentation simplification and robust training
- Led an effort to reduce human error deviations by 93% by qualifying a new automated production line and implementing a new training program
- 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

Bayer — *Process Engineer*

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 analytical instruments
- Trained over 300 production operators and maintenance technicians on proper operation of cell counters, pH, DO, metabolite analyzers