

Jacob Nichter

Biotech Manufacturing Leader | Lean Six Sigma Black Belt | Digital Transformation
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Snapshot

- 10 years at Amgen across MSAT and biopharmaceutical operations.
- Led team of five and drove readiness across QA QC MSAT Automation and Facilities.
- Expert in digital manufacturing readiness, cycle time reduction, equipment reliability, and analytics.
- Lean Six Sigma Black Belt with structured A3 problem solving.

Signature Achievements

- Reduced cycle time by optimizing CIP turnover using A3 methodology.
- Improved equipment uptime 18 percent through redesigned maintenance intervals.
- Reduced deviations 32 percent year over year using CAPA and RCA standard work.
- Created dashboards exposing KPIs, process vitals, and CAPA status enabling proactive decisions.

Experience

Pilot Plant Manager

Amgen Thousand Oaks CA 2022 to 2023

- Owned pilot plant operations and led five team members.
- Introduced visual readiness and short interval accountability reducing downtime.
- Optimized cleaning and turnover to increase asset availability and reduce cycle time.
- Built dashboard for KPIs CAPA status and readiness reviews.

Process Engineer

Amgen Thousand Oaks CA 2020 to 2022

- Improved reliability and reduced downtime 18 percent via PM redesign.
- Executed tech transfer automation updates (DeltaV MES SAP).
- Owned change controls SOP and validation documentation.
- Developed trending dashboards enabling predictive troubleshooting.

Senior Associate Engineer

Amgen Thousand Oaks CA 2018 to 2020

- Cut deviations 32 percent using CAPA health checks and standard work.
- Performed RCA (5 Why fishbone) and DOE confirmation testing.
- Built dashboards for trending and equipment health monitoring.

Associate Engineer

Amgen Thousand Oaks CA 2015 to 2018

- Executed validation troubleshooting and supported inspection readiness.
- Supported batch record review documentation and cGMP compliance.

Professional Development (Full Time Structured Focus 2024 to 2025)

Structured development across leadership MSAT operational excellence automation and analytics including A3 casework dashboards DOE exercises PM frameworks and strategy documentation.

Project & Impact Highlights

- Deviation trend A3 program standardizing countermeasures across shifts.
- Dashboard suite enabling daily tier reviews and readiness decisions.
- Downtime reduction through PM interval optimization and escalation standard work.
- DOE parameter sweeps reducing variation and protecting CQAs.

Certifications

- **Leadership Development for Engineers**
Rice University
- **Ethical Leadership**
University of Notre Dame
- **Coaching Skills for Managers**
UC Davis
- **Strategic Leadership and Management**
University of Illinois
- **Writing Skills for Engineering Leaders**
Rice University
- **Project Management Professional Certificate**
Google
- **Data Science with Real World Data in Pharma**
Genentech
- **Drug Development Product Management**
UC San Diego
- **Data Analytics Professional Certificate**
Google
- **Business Analytics**
University of Pennsylvania
- **Leading People and Teams**
University of Michigan
- **Principles of Leadership**
University of Colorado Boulder
- **Connected Leadership**
Yale University
- **Professional Success Skills**
University of Illinois
- **Lean Six Sigma Black Belt**
Kennesaw State University
- **Engineering Project Management**
Rice University
- **Chemical Hazards and Process Safety**
UC Davis
- **Python for Everybody**
University of Michigan
- **Business Foundations**
University of Pennsylvania
- **Generative AI Strategic Leader**
Vanderbilt University

Technical Stack

GMP manufacturing MSAT DeltaV MES SAP Python SQL Tableau RCA CAPA SPC DOE CPV PAT standard work A3 problem solving

Education

Bachelor of Science in Chemical Engineering
The University of Notre Dame Notre Dame IN 2015