

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