

JACOB NICHTER

Technical Operations Leader | Product Integrity & Chemical Management

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Professional Profile

Highly analytical Chemical Engineer with over 10 years of experience specializing in translating complex regulatory frameworks (cGMP/Process Safety) into actionable operational programs. Expert in chemical management, product risk mitigation, and driving continuous compliance standards (Lean Six Sigma Black Belt). Seeking to leverage proven success in high-volume, regulated environments to safeguard product integrity and brand reputation for Disney Parks, Experiences and Products.

Core Competencies

Regulatory Compliance & Risk

- Global Chemical Regulations (PFAS, Prop 65, REACH)
- cGMP/Quality Management Systems
- Product Stewardship & Safety Auditing
- Data Integrity & Regulatory Reporting

Process Excellence & Data Analysis

- Lean Six Sigma (LSS) Methodologies & DMAIC
- Chemical Data Interpretation & Synthesis (Tableau, SQL)
- Root Cause Analysis (RCA) & FMEA
- Operational Efficiency (OEE, Cycle Time)

Program & Stakeholder Management

- Global Program Implementation
- Cross-Functional Influence & Training
- Guidance Document Development
- Project Management (PMP Frameworks)

Key Experience

AMGEN | Thousand Oaks, CA

Pilot Plant Manager (Operations Leader) | 2022–2023

- **Regulatory Translation & Training:** Authored and delivered targeted training and guidance documents that translated complex **cGMP requirements** and **Product Safety standards** into streamlined procedures for manufacturing teams, ensuring high right-first-time rates.
- **Audit Program Execution:** Designed and executed internal audit plans to identify systemic risks in materials management and tracked corrective actions (**CAPA**) to mitigate potential brand exposure due to non-compliance.
- Utilized a hands-on approach to mentor technical staff, ensuring alignment with operational excellence goals and rigorous adherence to production standards.

Process Engineer (Improvement Specialist) | 2020–2022

- **Process Risk Mitigation:** Spearheaded standardized **Root Cause Analysis (RCA)** frameworks (5-Why, Fishbone) to eliminate recurring defects and reduce process deviations by **32% year-over-year**.
- **Data Synthesis & Reporting:** Developed downtime analysis models and leveraged analytical skills (**SQL/Tableau**) to collect and synthesize large datasets, directly contributing to state-level compliance reporting (e.g., Chemicals of High Concern requirements).
- Managed change control and project documentation for process upgrades, ensuring all improvements were sustainable and compliant.

Senior Associate Engineer | 2018–2020

- **Global Program Implementation:** Led major reliability and efficiency initiatives utilizing **Lean Six Sigma (LSS) Black Belt methodologies** to redesign maintenance intervals, resulting in an **18% increase in equipment uptime** and sustained operational excellence.
- Investigated process failures using Six Sigma tools and led corrective action teams to resolve chronic production issues.
- Partnered with front-line teams to pilot new maintenance and operating procedures before full-scale rollout.

Associate Engineer | 2015–2018

- **Systems & Data Integrity:** Supported validation and qualification of new equipment and managed operational readiness for **MES/Automation systems**, ensuring data integrity and validation aligned with strict regulatory standards.
- Conducted post-maintenance system verification, validating HMI responsiveness and sensor calibration to ensure successful startup of manufacturing lines.

Technical Systems & Expertise

Continuous Improvement: Lean Six Sigma Black Belt, DMAIC, Root Cause Analysis (RCA), FMEA, Process Mapping, Change Management.

Data Analytics & Tools: Tableau, Python, SQL, Minitab, Advanced Excel, Manufacturing KPIs, OEE Analysis.

Regulatory Systems: cGMP manufacturing, MES (Manufacturing Execution Systems), SAP (ERP), Quality Management Systems, Validation (IQ/OQ/PQ).

Education & Certifications

Education: Bachelor of Science in Chemical Engineering | The University of Notre Dame

Active Certifications:

- **Chemical Hazards and Process Safety Specialization** (UC Davis)
- **Lean Six Sigma Black Belt** (Kennesaw State University)
- **Project Management Professional Certificate** (Google)
- **Advanced Data Analytics Professional Certificate** (Google)
- **Digital Manufacturing & Design** (University at Buffalo)
- **Leadership Training:** Extensive coursework in Leading Technical Teams, Coaching Skills for Managers, and Strategic Leadership (UC Boulder, UIUC).