

# SHEFALI GUPTA

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## Summary

Highly skilled Technical Program Manager with 8+ years of experience delivering NPI (New Product Introduction) and Improvement projects across Biotech/ Life Sciences industries using Agile and Scrum methodologies. Adept in team leadership, data driven decision-making, risk mitigation, process optimization, stakeholder engagement and technical project management skills

## SKILLS

<b>PM Technical Tools</b>	Jira, MS Project, Smartsheet, Asana, SQL, Confluence, Power BI, Tableau, SharePoint, SAP ERP, Oracle
<b>Project Management</b>	Scope and Budget Planning, Process Improvement, Change Management, Stakeholder Management, Risk management, Scope Creep, Resource management, Data Analysis and Interpretation, Vendor Management and Contract Negotiation
<b>Other Skills</b>	Communication and Presenter Skills, Decision-Making, Attention to Detail, Time management, Team Player, Problem Solving and Critical Thinking, Conflict Resolution and Negotiation

## WORK EXPERIENCE

### Thermo Fisher Scientific, California

06/2021- 04/2025

#### Technical Program Manager

- Spearheaded new product development hardware projects from concept to commercialization. Coordinated efforts of >25 team members globally and achieved mechanical system development, DFM, tooling and validation process.
- Championed a SaaS program using Software Development Lifecycle (SDLC) and ensured compliance with quality (ISO 13485) and regulatory (FDA; 21 CFR Part 11). Utilized Jira to facilitate daily-sprint standups
- Championed delivery of cloud-based digital health platform integrating patient monitoring and data analytics using Project Lifecycle Management (PLM) process and ensuring alignment with customer requirements
- Achieved NPI supply chain project by coordinating with ODM, JDM and CM suppliers to ensure sourcing, supplier readiness, material availability, and logistics alignment for on-time, cost-effective product launches across EVT, DVT, and PVT phases
- Collaborated with Operations, Systems, Quality and Engineering teams to define project scope, requirement documents, SOPs, budgets and resource plans
- Conducted phase-gate reviews and reported KPIs/ SLAs, ROI, financials (Capex/ Opex), risks and mitigation strategies
- Maintained Design History File (DHF) records by creating and documentation release packages such as DCOs, ECRs in SAP ERP

### Laksans Technologies, Massachusetts

10/2020- 06/2021

#### Project Management Analyst (Client - Draeger Medical)

- Created informative dashboard and project plans of Class II medical devices and led the process improvement project for packaging & labeling operations ensuring compliance with MDR regulations using Smartsheet.
- Managed project schedule by identifying critical path, constraints, contingencies and mitigations to achieve project goal

### Candela Medical, Massachusetts

07/2019- 04/2020

#### Associate Technical Program Manager

- Led a hardware NPI program of aesthetic treatment devices using Confluence to manage project planning, MRDs, SOPs, and cross-functional collaboration from initiation to launch.
- Achieved Verification & Validation (V&V), IQ/OQ/PQ effort of a new product release in compliance with MDR regulation
- Implemented effective communication plan across Marketing and Sales team, resulting in a 20% reduction in Go-to-Market (GTM) strategy timeline across medical and surgical aesthetics hardware development NPI programs

### BD (Becton Dickinson & Company), Massachusetts

03/2018 – 05/2019

#### Project Coordinator

- Played a key role in supporting the program through 510k submission and obtained regulatory clearance for IVD instruments
- Developed Gantt Charts using MS project, monitored project milestones and developed project status reports for leadership

## EDUCATION

### Northeastern University - Boston, MA

01/2016 – 12/2017

Master of Science – Project Management | GPA - 3.5

### University of Delhi - Delhi, India

07/2011 – 10/2014

Bachelor of Arts – Economics | GPA – 3.06