

Abhilash Naidu Paspulati

Engineering Manager | Systems Engineering | Capital Projects | GMP
Pharmaceutical & Regulated Manufacturing

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Professional Summary

Accomplished Engineering Manager with 10 years of progressive experience delivering complex systems projects, capital programs, and technical leadership across high-assurance, regulated manufacturing environments. Proven expertise in systems engineering management, requirements development, design validation, risk management, and cross-functional team leadership. Skilled at translating strategic operational requirements into executable engineering solutions within GMP pharmaceutical, biologics, and regulated manufacturing sectors. Track record managing major technology transfer initiatives, coordinating 10+ cross-functional teams, and delivering programs at scale.

Core Competencies

Engineering Management & Technical Governance: Systems engineering & requirements management, team leadership & mentoring, major program delivery & cross-functional coordination, regulatory compliance (TGA, FDA, EU), design control & configuration management, stakeholder & vendor engagement, risk & hazard analysis, engineering change control.

Systems Integration & Technical Delivery: End-to-end systems integration, equipment specification, validation (IQ/OQ) & commissioning, FAT/SAT execution, URS & design review, design verification & traceability, manufacturing & process engineering, utility systems (HVAC, WFI, RO), technical documentation & batch records.

Safety, Quality & Regulatory Assurance: WHS & machine safety standards, regulatory compliance & audit readiness, quality assurance & CAPA processes, risk-based engineering reviews & deviation management, validation planning & lifecycle documentation, budget forecasting & ROI analysis, multi-disciplinary collaboration (QA, RA, Operations, Supply Chain).

Professional Experience

INDEPENDENT SOFTWARE ENGINEERING & AI PROJECTS

Independent Product Builder | Jan 2026 – Present

- Undertaking planned career break for structured systems engineering upskilling and AI-powered product development.
- Architected **CareerAI SubmitPro**, an end-to-end job application automation system featuring an Express.js/Node.js backend, React 19/Tailwind CSS v4 SPA, and real-time streaming SSE interfaces.
- Built a multi-source web scraping orchestrator (Seek, LinkedIn, Himalayas, etc.) utilizing **Playwright** with semantic score filtering and deduplication.
- Developed **ResumeCreatorApp** (Flutter/Dart), a cross-platform mobile and web application with dynamic PDF/LaTeX rendering and offline-first SQLite state persistence.
- Formulated autonomous multi-agent systems and real-time processing networks using **CrewAI (Crew)** frameworks and voice/audio analysis pipelines.
- **Upskilling & Rigor:** Actively pursuing dual HarvardX CS50 certifications (**CS50P - Python** and **CS50AI - Artificial Intelligence**) to apply advanced academic algorithms, graph search models, and machine learning theory directly to production codebases.

MS&T PROCESS ENGINEER (TECHNOLOGY TRANSFER LEAD)

CSL Seqirus | Jul 2022 – Dec 2025

- Led technology transfer and systems integration for vaccine (flu cell culture) and antivenom (product of national significance) platforms, including facility infrastructure and technology upgrades

- Directed and coordinated cross-functional teams across engineering, quality, operations, automation, and regulatory functions to achieve validated manufacturing readiness and scalable operational capability
- Managed requirements traceability, design control, and validation alignment with TGA/FDA/EU regulatory frameworks
- Led capital project planning, risk assessment, and design review coordination across multi-discipline engineering teams; oversaw vendor qualification, FAT/SAT execution, and equipment commissioning
- Facilitated multi-site and global stakeholder collaboration on systems integration and process scale-up

Key Achievements:

- **Capital Program Delivery:** Contributed to AUD 800M Project Banksia technology transfer initiatives, coordinating 10+ cross-functional teams from requirements through operational handover with full technical integrity
- **Engineering Leadership:** Led multi-stream technical teams; mentored junior engineers in systems thinking, design control, and quality assurance
- **Regulatory Compliance:** Delivered GMP-compliant systems under TGA/FDA/EU frameworks; maintained audit-ready documentation and supported regulatory submissions
- **Vendor Management:** Executed vendor qualification, FAT/SAT, and equipment commissioning for critical manufacturing and packaging systems
- **Process Excellence:** Standardised design control, technical documentation, and risk-based engineering reviews; implemented change control and lifecycle documentation management

PROJECT ENGINEER

Life-Space Group | Nov 2021 – Jul 2022

- Delivered 2 GMP-compliant tablet manufacturing and sachet packing production lines under aggressive timelines
- Achieved TGA license approval on first audit with zero major findings
- Led vendor coordination, commissioning, and handover of end-to-end production systems

TECHNICAL LEAD

Australian Pharmaceutical Manufacturers | Jul 2020 – Nov 2021

- Led end-to-end development and commercialisation of pharmaceutical products from formulation through pilot to commercial manufacturing
- Successfully commercialized multiple pharmaceutical products under TGA GMP compliance
- Reduced post-launch deviations through robust process design and risk-based engineering reviews

TECHNICAL SCIENTIST

Australian Pharmaceutical Manufacturers | Sep 2018 – Jul 2020

- Scientific and technical support for pharmaceutical production and process improvement
- Contributed to NPD & NPI programs from concept through routine production

LASER TECHNICIAN

Glass Expansions | Jun 2017 – Aug 2018

- Enabled laser processing of carbon materials previously considered unfeasible
- Implemented 5S and continuous improvement initiatives, significantly reducing scrap and rejection rates

MECHANICAL DRAFTSPERSON

SKF Australia Pty Ltd | Sep 2016 – Jun 2017

- Designed and drafted large bearing systems for food, oil, and mining industries
- Supported high-reliability applications in critical industrial environments
- Improved maintainability and lifecycle performance of bearing systems

DESIGN ENGINEER

Simplex CNC Systems | Feb 2016 – Aug 2016

- CNC spindle redesign for magnetic-bearing compatibility
- Electromagnetic analysis + structural/thermal FEA
- CATIA design, tolerance stack-up, manufacturability assessment

Education

- **Master of Engineering (Manufacturing Engineering)** — RMIT University, Melbourne, Australia (Feb 2015 – Dec 2016), awarded with Distinction
- **Bachelor of Technology (Mechanical Engineering)** — Jawaharlal Nehru Technological University (JNTU), Hyderabad, India (Jun 2010 – Apr 2014), First Class
- **Diploma of Project Management (BSB51415)** — Peach Institute, Melbourne, Australia (Apr 2019 – Apr 2020)
- **Diploma of Business (BSB50215)** — Peach Institute, Melbourne, Australia (2020 – 2021)
- **Certificate IV in Business (BSB40215)** — Navitas Professional Training, Australia (Sep 2018)
- **Professional Year in Engineering** — Engineering Education Australia / Engineers Australia (Dec 2018)
- **Year 12 Intermediate Certificate** — Board of Intermediate Education, Andhra Pradesh, India (Mar 2010)
- **Migration Skills Assessment (CDR)** — Engineers Australia, recognised as Professional Engineer — Mechanical Engineer (ANZSCO 233512) (Aug 2018)

Skills

Domain: GMP/cGMP Manufacturing, Technology Transfer, Process Validation (IQ/OQ/PQ), Regulatory Compliance (TGA/FDA/EMA), Risk Management, FAT/SAT, CAPA, Deviation Management, Design Control & Configuration Management

Tools: CATIA 3D, FEA, FMEA, Electromagnetic Analysis, Risk Analysis, DOE, Python, PLC Fundamentals

Management: Multi-disciplinary Team Leadership, Cross-functional Coordination, Vendor Management, Stakeholder Engagement, Technical Documentation, Audit Readiness