Chrishan Fernando

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Experience

Senior Systems Engineer, Harrison.ai 2021 – 2026

Systems Strategy and Life cycle Management

- **Led Systems Engineering** and software release cycles for the Backend team. Evolved from leading the Edge product to Enterprise and most recently the Harrison Open Platform.
- **Standards Governance:** Ensured product development and release process meets applicable standards and regulations (ISO 13485, ISO 14971, IEC 62304)
- **Feasibility, Trade-off assessments:** Assessed technical feasibility of upcoming features within given time frames by evaluating options, facilitating workshops and trade-offs between teams, and escalating risk to leadership to protect release timelines.
- **Jama Connect SME:** SME for use, administration and maintenance of Jama as the requirements and V&V management tool
- **V&V oversight:** Ensured requirements are met by reviewing V&V plans, protocols and reports.
- **AI-assisted development:** Used OpenSpec + Claude Code for spec-to-code; built fluency in AI-assisted development. Reviewed specs from other developers. Developed low priority tasks myself, created POCs.
- **Mentoring:** Mentored junior systems engineers and contributed to continuous improvement of systems engineering tools, templates and review practice across the team.

Requirements and Technical Documentation

- **Owned requirements management** covering system wide functional and non functional requirements around security, performance, interface requirements.
- **Translated product visions** into Feature elaborations acceptance criteria, interface specifications, and risk controls (e.g. Comparison of Priors, Triage, Translations, 3rd Party AI Adapter)

Risk, Quality and Regulatory Compliance

- **Led patient and security risk assessments** for non medical device components as well as SaMD/AI model components, identifying hazards and ensuring risk control implementation across the SDLC, with conformance to 14971 and DCB0129
- **Audit SME for MDSAP:** Served as SME for both the front and back rooms during Medical Device Single Audit Program (MDSAP) audits specifically defending requirements in chapter 5 (Design and Development) and 6 (Production & Service Controls), leading to successful continued compliance to ISO 13485,14971 and IEC 62304
- **Production Integrity:** Conducted technical investigations and risk-impact assessments for Production Non Conformances (NCRs) and also defects during development phase, made fix/defer calls based on safety, usability, performance.
- **Sustaining & root cause analysis:** Owned design changes, impact (safety and security) and regression analyses, driving resolution of complex technical issues through structured root cause analysis; contributed to fix/defer decisions on production NCRs and CAPAs.
- **Cross-Functional Leadership**: Functioned as a cross-functional liaison between Clinical, Quality, and Regulatory teams and also other dev teams; unblocked development bottlenecks by facilitating high-level design workshops and resolving architectural trade-offs

Systems / Software Engineer, Thales Australia 2015 – 2020

- Work Package Manager: scope, schedule, budget, risk, and safety for an obsolescence remediation project for the Wedgetail flight simulator
- **Air Traffic Management (ADATS):** Contributed to the Australian Defence Air Traffic Management System programme; schematic updates and on-site validation testing at a control tower for a voice/audio (tower microphone) equipment update.
- Led engineering tooling adoption (requirements and V&V) across teams; recognised as "Champion" for requirements management, trained at Thales France HQ.

- Delivered requirements engineering across full SE life cycle; participated in competitive bids.
- Nominated for Emerging Talent; received a Business development award.
- Programmed Python scripts to analyse large volumes of Navigational data.
- Programmed updates to the Traffic Collision Avoidance System (TCAS) for the Wedgetail Flight Trainer using C.
- Experience in VMware centric virtualised environments.

Graduate Systems Engineer, Boeing Defence Australia 2014 – 2015

- Requirements management and verification on the Vigilare air defence Command and Control System, supporting integration of new capability into a deployed Royal Australian Air Force (RAAF) C2 platform
- Resolved trouble reports across Tactical Data Links (Link 11, Link 16 and AADSLINK).

Graduate Systems Engineer, ResMed 2014

- Requirements management and verification on the Astral life support ventilator
- Performed defect investigation and root cause analysis on the Astral ventilator.

Engineering Intern, Qantas Airways 2012 – 2013

- Built a C# cabin layout optimiser compliant with FAA regulations (university thesis).

Education

Bachelor of Mechatronics Engineering / Bachelor of Commerce (Finance)

University of Sydney, First Class Honours - 2009 - 2013

Merit Scholarship, Major Industrial Project Placement Scholarship

Security & Eligibility

Australian citizen. Eligible to obtain and maintain NV1. No clearance currently active. Previously held NV1 with Thales.

Skills

Systems Life cycle
Requirements Engineering, V&V Strategy, Interface Control Documents, Design Transfer, Configuration Management, System Architecture, Impact & Regression Analysis, Sustaining Engineering, Trade Studies

Regulatory and Safety
ISO 14971, IEC 62304, MDSAP (Ch 5 & 6), DCB 0129, NCR Investigation, SaMD Clinical Risk

Engineering Tooling
Jama Connect, DOORS, GitHub, Jira/Confluence

Leadership
Cross-functional Liaison, Stakeholder Management, Technical Feasibility & Trade-off Analysis

Technical
DICOM, PACS, RIS, MongoDB, Docker, K8s, AWS, Grafana, Python

AI Tooling
Claude Code, OpenSpec, GitHub Copilot, Cursor, Deep Learning Specialisation (Coursera)

References available upon request.