Ricky Tjandra, PhD

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Summary

Product and R&D leader with 6+ years of **medical device industry experience**, driving innovation from concept through **FDA 510(k) clearance and commercialization**. Skilled in **product strategy, requirements gathering, roadmap development, and cross-functional leadership.** Proven record of aligning customer needs, clinical insights, and regulatory requirements to deliver impactful MedTech solutions.

Experience/Education

FluidAI Medical (formerly NERv Technology)

Director of Research | 2021–Present

- Defined and executed **product strategy and roadmaps** for biosensor-based medical devices used in post-operative complication detection.
- Led cross-functional team to achieve **first FDA 510(k) clearance**, aligning product requirements with clinician feedback, regulatory expectations, and market needs.
- Partnered with surgeons, KOLs, and hospitals to translate customer insights into product features, usability improvements, and evidence-based validation.
- Expanded IP portfolio 6x over two years, securing $100K+ in non-dilutive funding.
- Built and managed a high-performing R&D team; collaborated with engineering, manufacturing, and quality to ensure product scalability and compliance.
- Reported program and product health to C-suite, clinical partners, and regulatory reviewers.

R&D Engineer | 2019–2020

- Prototyped and validated new sensor technologies for early device development and trials.

- Implemented **ISO 13485 and FDA-compliant design control processes** for first device iterations.
- Supported **preclinical and clinical studies**, gathering data to demonstrate clinical and commercial value.

University of Waterloo | PhD, Chemical Engineering (Nanotechnology) | 2015–2019

- Published 10+ peer-reviewed articles with 300+ citations.
- Developed expertise in **data analysis, experimental design, and technical communication**.

Key Skills

- **Product Management:** Product strategy & vision, PRDs/SRSs, roadmaps, customer engagement, competitive analysis
- **MedTech & Compliance:** FDA 510(k), ISO 13485:2016, 21 CFR 11/820, HIPAA
- **Leadership:** Cross-functional collaboration, KOL engagement, vendor partnerships, stakeholder alignment
- **Technical:** Medical devices, biosensors, data analysis (Python, Excel), Agile (Scrum), Jira, Confluence, Notion