Candice Bautista, PharmD

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Senior Regulatory & Quality Leader | AI/ML MedTech | De Novo, 510(k), IVDR
Proven track record of leading global regulatory strategy and execution for AI/ML-based SaMD products. Led successful De Novo authorizations, Breakthrough Device Designations, and EU IVDR/MDSAP submissions. Experienced in scaling RA/QA functions, leading cross-functional teams, and engaging directly with FDA, Notified Bodies, and investors. Passionate about digital health, and bringing novel products to market safely and efficiently.

JOB EXPERIENCE

Valar Labs, Inc. Apr 2026 – Present
Head of Regulatory Affairs - AI/ML-based Software as a Medical Device (SaMD)

- Leading regulatory strategy for AI-powered software as a medical device, building the regulatory function, and partnering with executive leadership to bring innovative technologies to patients.

Rellia Health Mar 2026 – Present
Regulatory Strategy Advisor

- Providing strategic regulatory guidance for emerging healthcare technologies.

Artera, Inc. Jan 2024 – Apr 2026
Regulatory Affairs Manager - AI/ML-based Software as a Medical Device (SaMD)

- Led regulatory strategy and authored successful FDA De Novo submission for novel AI-enabled SaMD (ArteraAI Prostate)
- Secured FDA Breakthrough Device Designation (BDD); authored request and aligned strategy with long-term regulatory and clinical roadmap
- Led multiple FDA pre-submission meetings; partnered cross-functionally to define regulatory path, clarify data requirements, and mitigate review risk
- Contributed to global regulatory strategy, including EU IVDR technical file submission, TGA, Health Canada, and UKCA regulatory pathways
- Managed and mentored Quality team member; supported integration of RA and QA functions across global QMS activities
- Supported QMS readiness and compliance efforts, including MDSAP scope expansion, surveillance audits, and EU IVDR Stage 2 audit preparation

Cleerly, Inc. June 2021 – Jan 2024
Regulatory Affairs Program Manager – AI/ML-based Software as a Medical Device (SaMD)

- Received 510(k) clearance for Cleerly Ischemia
- Led cross-functional teams to develop and execute global regulatory strategies for AI-ML-based SaMD product launches and lifecycle management
- Authored and submitted a De Novo classification request, two 510(k)s, and a Breakthrough Device Designation Request across novel AI/ML-enabled digital health products
- Led FDA pre-submission meetings to align on data requirements and de-risk novel SaMD regulatory pathways; authored and submitted related briefing packages
- Supported successful ISO 13485 and MDSAP audits; contributed to audit readiness, documentation, and CAPA follow-up strategy

Medtronic (SI-Boulder / Surgical Robotics) Sep 2017 – June 2021
Senior Regulatory Affairs Specialist – Various Electrosurgical and Ultrasonic Devices / Robotic-Assisted Surgery (RAS) System

- Served as regulatory lead for EU MDR technical file submissions and managed cross-functional teams to submit five EU MDR technical files for the surgical robotic system for approval in first regulated market
- Submitted and obtained 510(k) clearance for FDA class II medical device; process included submitting one pre-submission (SIR)

EDUCATION

MCPHS University, Worcester, MA **(***Doctor of Pharmacy)*
Brandeis University, Waltham, MA (*Bachelor of Science, Neuroscience*)