

Charles "Chaz" Stephens, PMP

Medical Device Product Management

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SUMMARY

Product-minded Program Manager, PMP, with 9+ years of biotech/pharmaceutical program management experience, pivoting into medical device product management. Recently completed ELVTR's Medical Device Product Management program, building a full-lifecycle product strategy for a wearable insulin-pump delivery-confirmation device, from clinical need and market sizing through FDA regulatory pathway and go-to-market. Brings a scientific research background (Master's in Biomedical Sciences, two peer-reviewed publications, one issued patent) and cross-functional program leadership at Merck, Quest Diagnostics, and the National Cancer Institute.

FEATURED PROJECT

SubQ-Confirm - Medical Device Product Strategy

ELVTR Medical Device Product Management Program, 2026

Designed a delivery-confirmation subsystem concept for wearable insulin pumps end-to-end: clinical need and market sizing (\$5.25B TAM), product requirements and dual-modality sensor architecture, FDA 510(k) regulatory pathway, clinical evidence and risk/human-factors plan, and go-to-market economics (71% gross margin). Presented as a final executive pitch to a mock board.

Full case study: chaz-stephens.com/work/subq-confirm

PROFESSIONAL DEVELOPMENT

Medical Device Product Management | ELVTR (live cohort program) | June - August 2026

EXPERIENCE

Associate Director, Global Clinical Data Standards

Merck | January 2023 - Present, Remote

- Led the company-wide implementation of SDTM Implementation Guide v3.4 across global clinical programs.
- Direct the cross-functional governance network defining data standards and requirements for immunology and vaccine clinical programs.
- Developed and implemented standardized SOPs for data transformation processes, improving compliance and operational efficiency.
- Mentor and provide project leadership to junior staff across data standards initiatives.

Senior Project Manager

Quest Diagnostics | March 2021 - January 2023, Remote

- Oversaw cross-functional teams delivering cancer diagnostic products for Quest's Oncology Clinical Franchise, from concept through post-launch.
- Led subject matter experts through cancer diagnostics product lifecycle initiatives using Agile and Waterfall methodologies.
- Contributed to annual product roadmaps, market/competitive analysis, and resource planning with Oncology Franchise leadership.

Scientific Program Manager

National Cancer Institute (NCI) | March 2017 - March 2021, Rockville, MD

- Managed clinical trial projects for the Cancer Therapy Evaluation Program (CTEP), overseeing biomarker studies and laboratory activities across 100+ trials; received the Distinguished Achievement Award twice for this work (2018, 2020).
- Led regulatory, strategy, and compliance discussions for laboratory-developed assay validation in accordance with ICH/GCP guidelines; developed SOPs and identified process-risk mitigations across study phases.

Study Coordinator II

Smithers Avanza | June 2016 - March 2017, Gaithersburg, MD

- Supported assay transfer, validation, and sample-analysis phases; ensured regulatory compliance and quality control across project documentation.

Project Leader

Champions Oncology, Inc. | September 2015 - May 2016, Baltimore, MD

- Served as project lead for pharmaceutical clients' xenograft studies, from proposal through execution and reporting; tracked up to \$800K in study revenue.

EDUCATION

Master of Biomedical Sciences, Microbiology and Immunology

Minor in Cancer Cell Biology, Virology - Louisiana State University Health Sciences Center - Shreveport - 2015

Bachelor of Science, Biology

University of Arkansas - Fayetteville, AR - 2012

CERTIFICATIONS

Project Management Professional (PMP) | Project Management Institute (2020)

PATENTS

Stephens CA, et al. Methods to prevent and treat TGF-beta mediated activation of fibroblasts to reduce and treat cancer and fibrosis. US Patent 11,096,952.

PUBLICATIONS

Gray AL, Stephens CA, Bigelow RLH, Coleman DT, Cardelli JA. The polyphenols (-)-epigallocatechin-3-gallate and luteolin synergistically inhibit TGF-beta-induced myofibroblast phenotypes through RhoA and ERK inhibition. PLoS One. 2014;9(10):e109208. doi:10.1371/journal.pone.0109208.

Coleman DT, Gray AL, Stephens CA, Scott ML, Cardelli JA. Repurposed drug screen identifies cardiac glycosides as inhibitors of TGF-beta-induced cancer-associated fibroblast differentiation. Oncotarget. 2016;7(22):32200-32209. doi:10.18632/oncotarget.8609.
