STEFANIE COHEN

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EDUCATION

Tufts Human Factors Engineering in Medical Devices and Systems Est. Completion 2026
Tufts University
M.Eng. Bioengineering, B.S. Bioengineering 2016, 2014
University of Maryland, College Park

WORK EXPERIENCE

AI Product Consultant May 2026 - Present
Pelly Systems Ltd - Tufts University collaboration

Deliver an AI-driven, regulatory intelligence and recruitment support module into Pelly's football data consolidation platform, transforming complex legal/eligibility frameworks into a navigable process:

- Conduct qualitative interviews with professional football scouts to map existing workflows, identify friction points and high-value opportunities for AI intervention.
- Evaluate cross-industry best practices and academic literature regarding neurosymbolic AI integration, establishing human-centered UI/UX principles to balance user autonomy with automated decision support for both novice and expert users.
- Vibe code functional prototypes, evaluating interaction concepts that surface trustworthy, evidence-based regulatory insights with iterative user testing.

Director, Remote Patient Monitoring Program Manager (3-month placement) Jul 2025 - Oct 2025
Evinova - an AstraZeneca Health Tech Subsidiary

Oversaw the strategic alignment and execution of RPM modules for toxicity data collection, tolerability endpoint generation, and self-management as a differentiating feature of the Unified Clinical Trial Solution:

- Created cross-functional initiative to resolve customer complaints about compliance data access by organizing a multi-pronged approach to identify where data exists and existing access, improve internal support team and external user training, and get technical improvements prioritized in PI.
- Supported the development of vision and roadmaps for stomatitis, pulmonary, and digestion RPMs by engaging customer-facing and technical teams to estimate business opportunity and feasibility.
- Conducted interviews to identify points of failure in scientific team collaboration and proposed standardized processes, deliverables, and norms to improve knowledge transfer and delivery.

Director, Scientific Capability & Delivery Nov 2023 - Jun 2025
Evinova - an AstraZeneca Health Tech Subsidiary

Spearheaded product feasibility activities for new opportunities under consideration by Evinova leadership. Most notably, created a program to expand clinical trial remote monitoring capabilities into routine care:

- Pivoted an ongoing project team to scale delivery of one remote patient monitoring digital biomarker to three RPM digital biomarkers.
- Coordinated with pharma brand teams to incorporate digital solutions that meet their needs into their launch strategies and navigated compliance and safety processes.
- Delivered rapid prototypes followed by user research-informed prototypes to conduct pilot integrations into clinic workflows as proof of concept for long-term, scalable product strategies.
- Elicited technical, operational, and compliance requirements from subject matter experts to bring enterprise-level investment decisions to leadership team including legal manufacturer certification, quality risk appetite, HIPAA compliance, and architecture.

- Provided go/no-go recommendation to leadership team with rationale based on infrastructure and resource requirements and documented conclusions for posterity.

Director, Product Manager Sep 2020 - Dec 2024

AstraZeneca - Digital Health Oncology R&D

Led cross-functional team to develop Interstitial Lung Disease (ILD) predictive model and Pneumonitis Digital Therapeutic (DTx) from 0 to 1:

- Delivered a demonstrable MVP using insights from formative testing conducted with internal and external design research teams to enhance patient and HCP interfaces and experience.
- Managed RFP process with procurement teams for expert evaluation of legal manufacturer candidates and prepared subsequent master service agreement and statement of work contracts.
- Participated in pre-submission planning and FDA interaction strategy with regulatory and quality subject matter experts for 510(k) clinical decision support and pre de novo pathways.
- Developed a project management framework, increasing transparency and cross-collaboration, now used as a model for all Remote Patient Monitoring development teams.
- Authored SaMD design control documentation (FDA class II, SSC B) and drove document approvals and design checkpoints to maintain Software as a Medical Device (SaMD) quality management.
- Owned vendor relationships to foster effective collaboration and shared SaMD QMS.

Product Marketing Manager Dec 2016 - Sep 2020

Medicrea - Acquired by Medtronic

Managed the development of a posterior spinal fixation system from market research and in-depth competitor analysis through prototyping, testing, 510(k) clearance, evaluation, and launch:

- Introduced the implant system with a surgical planning and implant selection service incorporated into UNiD ASI software platform.
- Collaborated directly with surgeons to iterate designs and provide support in the operating room.
- Strategic product development road-mapping and financial forecasting for sales and production.
- Organized congress booths, surgeon office visits, in-house events, demo requests, and training.
- Developed product marketing collateral, web content, and communication for internal and external team members and users using Adobe Creative Suite.
- Provided logistical guidance for instrument and implant roll-outs and reworks.
- Launched sales and education app for internal employees and distributors.

SKILLS AND CERTIFICATIONS

Certifications

Diversity by Design Women in Leadership Completed 2024
SAFe Scaled Agile Framework Product Owner/Product Manager Certification Completed 2021
I-Corps Lean Startup & Design Thinking Completed 2014

Software and Skills

ProductBoard, Microsoft Copilot Studio, Claude, AI Rapid Prototyping, Jira, Confluence, Sharepoint pages and automations, Smartsheet, Figma, Miro, Airtable, Adobe InDesign, Adobe Photoshop, Adobe Illustrator, Product Market Fit, Go-To-Market, Storyboards, Executive Stakeholder Management, Design Thinking, Lean Startup, Human Factors Evaluation, Task Analysis, Hazards Analysis, Use-Related Risk Analysis, UAT, User Needs and User Stories, Master Service Agreements, ISO 62304, ISO 82304, IEC 62366.