Clinical Engineering Manager / Staff Clinical Product Development Engineer

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About the Company

Vitara Biomedical is a medical technology company reinventing the standard of care for extremely premature newborns. Backed by leading venture capital firms, Vitara's neonatal artificial womb, known as EXTEND, was created by doctors at Children's Hospital of Philadelphia to closely mimic natural fetal physiology for babies delivered as early as 22 weeks. Similar to a mother's womb, EXTEND's fluid-filled environment aims to protect fragile lungs and other vital organs during the first 28 days of life, allowing them to mature so that newborns may transition to an incubator with a greater hope of surviving and thriving. At this stage of life, organs grow exponentially—and Vitara is working to make every day count.

We work in a fast-paced, collaborative environment where creativity, rigor, and mission guide every decision. At Vitara, you'll be a part of a team that cares deeply about the science, the impact, and one another. As Vitara grows, you'll shape how we operate and leave your mark on a first-of-its-kind technology.

Position Summary

We are seeking a highly motivated and experienced Clinical Engineering Manager / Staff Clinical Engineer to join our team in developing innovative medical devices for neonatal and extremely premature patients. This role sits at the intersection of clinical practice, product development, and translational research — serving as a vital bridge between bedside clinicians, Key Opinion Leaders (KOLs), preclinical researchers, and our R&D engineering organization.

The ideal candidate brings knowledge of neonatal and perinatal care environments, a deep passion for improving patient outcomes, and the ability to translate complex clinical insights into actionable product and procedural requirements. Experience with complex medical devices and multi-product clinical systems, as well as a track record of delivering meaningful contributions to medical device programs are key attributes for success in this role.

We offer the opportunity to directly impact outcomes for extremely premature neonates through meaningful innovation and a collaborative, mission-driven culture.

Key Responsibilities

Procedure Development & Clinical Problem Solving

- Partner with neonatologists, nurses, respiratory therapists, and KOLs to develop, refine, and validate clinical techniques and protocols for use in neonatal and extremely premature patient populations.
- Author and maintain clinical procedure documentation, including clinical and preclinical protocols, test reports, analyses, etc., and contribute to Instructions for Use (IFU), training guides, and best practice materials aligned with current evidence and clinician workflow.
- Lead clinical working groups and advisory boards to capture expert input on technique development and clinical application of new device concepts.
- Collaborate with Clinical Education and Clinical Affairs teams to translate procedures into scalable training programs for users.
- Present clinical insights, study findings, and procedural recommendations to internal and external stakeholders, including senior leadership and clinical advisory boards.
- Contribute to regulatory submissions by providing clinical rationale and supporting documentation as needed.

Ethnography & Clinical User Research

- Conduct field-based ethnographic research at NICUs, labor and delivery units, birthing hospitals, and other neonatal care settings to deeply understand clinician workflows, environmental constraints, and unmet user and patient needs.
- Lead or support contextual inquiry, observational research, and stakeholder interviews to inform both early-stage concept development and iterative design refinement.
- Synthesize qualitative and quantitative user research into clear insights and recommendations for R&D, preclinical research, and clinical teams.
- Maintain and grow relationships with clinical sites and research partners to support ongoing access for user research activities.

R&D & Product Development Collaboration

- Serve as the clinical voice within cross-functional R&D product development teams, contributing to design inputs, user needs, and clinical use cases.
- Translate observations from clinical environments into actionable design requirements, ensuring next-generation products meet real-world patient and clinician needs.

- Support design reviews, prototype evaluations, and feasibility assessments by providing clinical context, testing, and technical expertise.
- Lead pre-clinical design validation activities through planning, protocol development, execution, and reporting.

Human Factors & Usability Engineering

- Assist in development and maintenance of user profile, use environment, task analysis, use-related risk analysis, and use scenarios that reflect neonatal care environments and clinician workflows.
- Support the planning and execution of human factors studies including simulated-use testing sessions, formative usability evaluations, and summative validations in compliance with IEC 62366 and IEC 60601-1-6.
- Collaborate with regulatory and human factors teams to ensure HFE documentation meets submission requirements.

Preclinical & Animal Study Support

- Collaborate with preclinical research teams to design and support animal studies that evaluate device performance, safety, and clinical technique feasibility.
- Provide clinical perspective on study design, relevant anatomical models, procedural endpoints, and translational significance of findings.
- Participate in in-vivo study sessions as a clinical technical resource; support data review and interpretation in collaboration with veterinary and research staff.
- Help bridge preclinical findings to clinical development plans and regulatory strategies.

Professional Qualifications

Required

- Bachelor's degree in Biomedical Engineering, Clinical Engineering, or a related life sciences or engineering discipline.
- 4+ years of experience in clinical engineering, medical device R&D, or a related field.
- Track record of success working directly with clinicians.
- Strong critical thinking, judgment, and problem-solving skills.
- Excellent organizational skills and attention to detail, with the ability to manage multiple projects simultaneously.
- Demonstrated experience with complex medical devices and clinical procedures that require the coordinated use of multiple products together as an integrated system.
- Demonstrated experience in product development processes (design controls, V&V, design reviews) within a regulated medical device environment (FDA / ISO 13485).

- Strong technical writing skills; experience authoring clinical protocols, IFUs, or regulatory documents.
- Must be able to gain and maintain access to hospitals and clinical facilities, including satisfying all requirements of vendor credentialing services (e.g., Reptrax, Vendormate, or equivalent), which may include background checks, immunization records, and annual training compliance.
- Ability and willingness to travel to clinical sites, research facilities, training sites, etc. as needed.

Preferred

- Master's degree in Biomedical Engineering, Clinical Engineering, or a related life sciences or engineering discipline.
- 6+ years of experience in clinical engineering, medical device R&D, or a related field.
- Direct experience working in or closely with neonatal intensive care (NICU) or perinatal clinical environments, either in industry or a clinical role.
- Familiarity with Human Factors Engineering principles and usability study methodology.
- Experience managing, mentoring, or leading engineers in a product development environment.
- Experience supporting or conducting preclinical animal studies in a medical device context.
- Prior experience conducting ethnographic or contextual inquiry research in clinical settings. Familiarity with neonatal respiratory, cardiovascular, or monitoring device categories.
- Knowledge of FDA IDE or PMA regulatory pathways and associated clinical evidence requirements.
- Experience in biotech or medical device industry, and/or within an agile or entrepreneurial environment, preferred.