



Rutland, VT  
Product Development Engineer

**Education Requirement:** BS in Engineering

**Training Skill Requirement:** SolidWorks, Microsoft Office, MS Teams, some programming, design control processes, standards and policies

**Experience Requirement:** experience with controlled documents, project management methods, design and development practices

**Reports to:** Executive Vice President, Product Development and Engineering

**Responsibilities:**

- Execute and maintain Healthy Design's product development pipeline
- Execute product development projects in compliance with FDA 21 CFR 820.30 guidance for design controls
- Execute detailed design of new products and associated drawing packages
- Own risk management practices as applied to product development and design
- Carry out continuous improvements, product lifecycle change management, and engineering investigations and responses to complaints and CAPAs
- Execute R&D and rapid prototyping (3D printing, laser cutting, and fabrication), concept development, and early phase project planning
- Collaborate with Manufacturing to develop manufacturing and assembly processes and work instructions
- Collaborate with Clinical Development to define user needs and usability requirements
- Develop and execute verification, validation, and in-line testing plans and processes
- Oversee engineering interns and academic sponsorships (SEED, Capstone, etc.)

**Authorities:**

- Supervisor for engineering interns, contractors
- Owner (with EVP) of product development portfolio and priority setting
- Development (with EVP) of and execution against engineering budget
- Ownership of Design History File (DHF)