Title:	Product Development Engineer
Location:	Boston, MA (remote)
Main office:	Halifax, Nova Scotia (Canada)
Reports to:	Director of Engineering (Boston, MA)
Term:	Full time

About Us:

At ABK Biomedical we're transforming interventional radiology through the development of proprietary embolization technologies that enhance the treatment of hypervascular tumors and improve patient outcomes. Led by a seasoned leadership team, backed by $30M in recent Series B funding, and driven by a talented group of scientists, engineers and support personnel, we're poised to commercialize our novel radiopaque microspheres technology throughout multiple markets.

Position Summary:

We're searching for a Product Development Engineer to plan, design, implement, and test products in line with ABK Biomedical marketing plans. Reporting to the Director of Engineering, in this role you'll execute product development activities in accordance with Design Control procedures.

As an ideal candidate for this role, you're a Product Development Engineer with a solid background in medical device development. You're a technical expert with a firm grounding in project management best practices. You thrive in a fast-paced, high-performance environment, and you're an energized collaborator and problem-solver.

This is an outstanding opportunity for an intermediate engineer to join a fast-growing medical device start-up and play a key role in commercializing a ground-breaking new technology.

Key Responsibilities:

- Provide technical expertise to the design and development of new medical device product(s).
- Undertaking specific project elements s as designated in support of business activities.
- Interface with physician KOLs and Marketing to develop user needs and design inputs requirements.
- Develop new products from initial design concept to market release applying the stage gate approach to Design Controls.
- Worked on at least one medical device development project resulting in a launched product.
- Demonstrated experience of the entire product development life cycle process.
- Proficiency in ISO 13485, Quality Systems – Medical Devices – System Requirements for Regulatory Purposes and the FDA 21 CFR 820, Quality System Regulation.
- Familiarity in Risk Management as per ISO 14971.
- Experience with Class II or Class III medical devices.
- Experience with development of medical devices subject to 510(k) and/or PMA US regulatory paths.
- Provide hands-on design, generate SolidWorks drawings, fabricate prototypes, bench top testing and interface with various vendors to support subcontracted designs and their manufacturing.

- Coordinate simulated use labs to evaluate prototypes, gain product feedback, train end users and validate new designs.
- Participate in verification / validation requirements on new product introductions. Execute verification and validation protocols.
- Generate and maintain ECO's (Engineering Change Orders), protocols, and reports, in compliance with essential regulatory requirements.
- Ensure continual quality system compliance by adherence to established and evolving quality system requirements.
- Ensure all projects are completed to agreed timelines.
- Develop and maintain design history and risk files.
- Research, analyse and create intellectual property.
- This is remotely based role with frequent domestic and international travel (30-40%).

Key Qualifications:

- Bachelor's degree in an Engineering discipline is required. e.g. Mechanical, Biomedical, or equivalent.
- 3-6 years product design, development, and manufacturing experience in the medical device industry.
- Hands-on experience with manufacturing tooling, equipment, and process development.
- Experience working with operations to develop strong manufacturing process instructions and operator training to ensure smooth product transition into the manufacturing environment.
- Experience interfacing with suppliers, contract designers and manufacturers.
- Experience interfacing with medical professionals (physicians, nurses, etc.)
- Experience collaborating with cross-functional teams (Marketing, Production, Quality, Manufacturing, Regulatory) to develop and implement solutions over a wide and varied scope.
- 3D modelling and 2D drawing using SolidWorks.
- Experience with probability and statistics using Minitab or JMP is an asset.
- Possess a working knowledge of medical products lifecycle and demonstrate ability to bring products from concept to market.
- Familiarity with FDA, QSR, and ISO 13485 regulations applicable to the medical device.
- Familiarity with design/use/process Failure Mode Effects Analysis (FMEA) and root cause analysis.
- Must be able to communicate ideas and information clearly, effectively, and frequently (oral and written) within team, company, and outside consultants.
- Strong communication and interpersonal skills with the ability to work effectively in a team.
- Flexibility, persistence, resourcefulness, a drive to succeed, and an entrepreneurial spirit.
- Creative thinker; idea generator; solutions-, results- and action-oriented.
- Highly organized, with exceptional attention to detail.
- Well-suited to a small, fast-paced start-up environment.

***Compensation Overview**:*	Competitive base salary, bonus, and company equity opportunity.

ABK Biomedical is an equal opportunity employer and accommodates people with disabilities throughout the recruitment and selection process.