2017

Bard Peripheral Vascular/
Society of Interventional Radiologist
Internship Program
POSITION SUMMARY

Bard Peripheral Vascular (BPV) has designed an internship program that will allow medical students the opportunity to gain valuable medical device experience. The BPV/SIR Internship program will expose the intern to the entire process of developing a medical device from idea generation to commercialization. The intern will interface with all responsible functional groups necessary to develop a product such as Research and Development, Quality, Clinical, Regulatory and Marketing. In addition, the intern will have the added benefit of learning critical workplace skills and networking with professionals. This experience will prove invaluable for those medical students with an entrepreneurial spirit who are interested and advancing healthcare by innovation.

INTERNSHIP REQUIREMENTS

- Must be currently enrolled in Medical School
- Must be in good academic standing
- Willing to commit 40 hours per week for an 8 week period.
- Must be a U.S. citizen or be otherwise legally entitled to be employed in the U.S.
- Interns will be required to successfully pass our pre-employment screening process which include a drug screen and background check. Interns will be required to complete an orientation program during their first week.
- Strong analytical skills required
- Able to relocate to Tempe, AZ for duration of Internship
- Desire to join a team committed to helping people lead longer, healthier and more productive lives!
- Sign non-disclosure agreement
- Obligation to assign any invention conceived during the internship to Bard
- Review and approval of intern’s presentation at SIR (to protect Bard confidential information)

COSTS

- Sponsor will provide transportation (to and from Tempe, AZ and any additional off-site training travel requirements).
- Sponsor will provide housing
- Sponsor will pay intern a total of $5000.00 US gross for the duration of the program (evenly distributed payments will be paid bi-weekly over the course of program)

PROGRAM OVERSIGHT

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DESCRIPTION OF INTERNSHIP

During this internship program, the medical student will be exposed to the entire process of commercializing a medical device. As depicted in the figure below, this process will cover everything from Idea Generation/ Concept, Feasibility, Qualification, Clinical, Product Launch and Post Market Surveillance. The program will be broken down into a “User Needs Finding” project utilizing the Biodesign process and seven product development modules as described below.

“User Needs Finding” Project

During the internship program, the medical student will learn a systematic approach to needs finding, invention and implementation of new biomedical technologies based on the Biodesign process. The medical student will be given a project to investigate and determine user needs which can be translated into biomedical solutions. The project will focus on addressing the needs of Interventional Radiologist in treating their patients. The elements of the project will consist of the following objectives:
- Develop user needs statements based on problem, population and outcome
- Brainstorm and give recommendations for technologies that can be used to address user needs.
- Research and describe regulatory path of each technology recommendation
- Research and describe reimbursement strategy of each technology recommendation
- Research and describe intellectual property landscape of each technology recommendation
- Create high level business model for each technology recommendation

Legal (Module 1)

Innovation is one of the metrics through which Bard measures the value of its products. The Intellectual Property (IP) Team at Bard assists each Project Team at different points through every phase of product design. It is expected that the SIR Intern will come to understand the role and purpose of IP in product development, including:

- Review all of the features of a product so that freedom to operate is analyzed
- Review of potentially patentable subject matter for each product, as well as alternative designs, and decisions on seeking patent protection
- Decisions on branding and obtaining trademark registrations
- Review of product labeling and review of collateral materials for compliance with IP laws

Research and Development (Module 2)

At BPV, our goal is to provide a constant supply of new, innovative medical technologies that improve clinical outcomes and help to control the costs of care. Our products are responsive to the needs of healthcare practitioners and are sensitive to the issues of patient safety, comfort, and care. We originate and develop products through the innovative thinking, skills, and capabilities of our Research and Development organization and through outside resources from which we identify, acquire, and develop new medical technologies. BPV leverages its capabilities in product development, and its demonstrated ability to commercialize products in a timely fashion to attract suitable partners from the academic, practitioner and industrial communities to ensure that products and product development opportunities from other organizations will properly supplement its internal development efforts. At the conclusion of the Research
and Development module, the intern will be able to demonstrate a basic understanding of the following:

- Design of Experiments (DOE)
- *In-vitro* testing
- *In-vivo* testing (Design and conduct of animal research)
- Project management
- Fatigue testing
- Finite Element Analysis (FEA)
- Biocompatibility testing
- Protocol and Report writing
- Installation Qualification (IQ), Operational Qualification (OQ), Process Qualification (PQ)

**Quality Engineering (Module 3)**

As a Medical Device company, Bard is regulated by various Domestic and International Regulatory bodies including the Food and Drug Administration (FDA) and the International Standards Organization (ISO) (European equivalent to the FDA). These regulatory standards provide minimum requirements for the New Product Development (NPD) process. Here at Bard the NPD process starts with identifying unmet customer needs and convert the design inputs collected related to the unmet need, the use environment and intended use into a marketable medical device that meets the unmet need. At the conclusion of the module, the intern will be able to demonstrate a basic understanding of the following NPD processes:

- Collection of Design Inputs
- Conversion of Design Inputs into Product Specifications
- Design Development Planning
- Understand the NPD Risk Management process
- Understand the typical Verification and Validation methods
- Generation of Design Outputs
- Design Review requirements
- Product approval and launch activities

**Clinical (Module 4)**

Adherence to the principles of good clinical practices (GCPs), including adequate human subject protection (HSP) is universally recognized as a critical requirement to the conduct of research involving human subjects. Many countries have adopted GCP principles as laws and/or regulations. The Food and Drug Administration's (FDA's) regulations for the conduct of clinical trials, which have been in effect since the 1970s, address both GCP and HSP. At the conclusion of the Clinical Affairs module, the intern will be able to demonstrate a
basic understanding of the following components of clinical trials sponsored by industry:

- The foundations of Good Clinical Practices (GCPs), medical device regulations, and the related principles which guide clinical trial conduct.
- The role of the clinical affairs team in the product development process.
- Development of clinical trial strategies and study design.
- The foundations of clinical operations including GCP monitoring, data validation, data analysis, reporting, publication, clinical trial registration, and project management.
- The roles of pre and post market research, surveillance, and reimbursement.
- Industry sponsored vs. Investigator Sponsored research studies.
- Common pitfalls often experienced during sponsored clinical trials.

In addition, if scheduling allows, the student will be able to visit a clinical site and shadow a clinical coordinator for a day.

Regulatory (Module 5)

The Regulatory Affairs group at Bard Peripheral Vascular (a division of CR Bard) is responsible for facilitating the device development for Class I, II, and III medical devices that are regulated by the US FDA. As a result of the Internship experience, the participating individual will obtain a bird’s eye view of the regulatory process from beginning to end, leading to clearance/approval of a medical device. Following completion of Module 5, the intern will have a working understanding of:

- The device development process including identification of FDA test requirements.
- Negotiation experiences with FDA to identify requirements to support a human clinical study (IDE Study).

Marketing (Module 6)

The Marketing module will focus on both the strategic and tactical implementation of the marketing program(s). In the marketing module the intern will start with the idea of upstream marketing and gathering user inputs for idea generation and follow the idea to R&D. The intern will also learn how to launch a product and post market activities that take place in conjunction with our sales organization. This will also tie in the sales component and give them an appreciation of the sales process. At the conclusion of the Marketing module, the intern will be able to demonstrate a basic understanding of the following marketing elements:
- Upstream Marketing (activities to include market research for idea generation as well as design input specifications)
- Become articulate in SPIN and focus efforts on needs assessments
- Downstream Marketing (Pre and post launch advertisement design. Post launch market research as well as physician surveys)
- Product Launch (Intern will have mock product launch to match efforts in upstream marketing and R&D activities. This launch will pull together all modules to culminate the overall experience)

**Post Market Surveillance (Module 7)**

Monitoring the performance and safety of medical devices after their release for distribution is mandated by the FDA. Post-market surveillance of Bard’s products is conducted by the Field Assurance team. The SIR Intern will gain a thorough understanding of all phases of the complaint handling and regulatory reporting process, including:

- Identification and documentation of domestic and international complaints
- Assessment of complaints for reportability per FDA adverse event reporting guidelines under the Medical Device Reporting (MDR) regulation, as well as international reporting responsibilities
- Investigation of the event, including evaluation of the returned device, medical images and records, and the development of a root cause
- Corrective and preventive action (CAPA) based on the results of the event investigation
- Appropriate closure of the complaint file, ensuring compliance with FDA regulatory requirements.
Why Bard?

COMPANY BACKGROUND

Since 1907, Bard has been developing innovative medical technologies that are cornerstones of modern health care. Charles Russell Bard, an importer of French silks, founded the company that bears his name after a bout of urinary discomfort prompted him to try Gomenol, a medication refined from eucalyptus trees and manufactured in France. Impressed with the results, he obtained exclusive U.S. distribution rights to the product, and soon expanded his offerings to include a number of urological products. Today, C.R. Bard, Inc. is a leading multinational developer, manufacturer and marketer of innovative, life-enhancing medical technologies in the fields of vascular, urology, oncology and surgical specialty products, employing approximately 9,400 people in over 20 countries around the world. Bard’s innovations include the first Foley catheter, the first heart pacing catheter, the first arterial prosthesis and the first angioplasty catheter.

MISSION STATEMENT

To advance the delivery of Healthcare by profitably developing, manufacturing and marketing value-driven products which meet the quality, integrity, service, and innovation expectations of our customers while providing opportunities for our employees. As a result, we will optimize shareholder value and be a respected worldwide health care company.

BPV MISSION STATEMENT

To improve the quality of patients’ lives around the world by being a leading provider of innovative medical devices for peripheral vascular patency and dialysis access and maintenance. We will focus our efforts on providing exceptional service and support to surgeons and interventionalists. Our vascular customers will think of BPV as the peripheral vascular experts.

VALUES

As an organization we have developed a set of Core Values that represent our reality and our aspirations. These four values, Quality, Integrity, Service and Innovation, prepare us for the challenges ahead and guide our everyday activities and align us to our mission. They are central to how we behave and want to be viewed by our fellow co-workers, customers, shareholders and communities.
GUIDING PRINCIPALS

Passion for Our Work
We focus on improving the lives of the patients who require our products and services. We are proud of our long history of achieving this goal, believe our work makes a difference, and are relentless in our efforts to provide the highest quality products and services. Be Indispensable to Our Customers
We believe in anticipating and exceeding customer expectations, and in eliminating any barriers to meeting our customers’ needs. We place high value on being the company of choice for providers and other clinicians wanting to transform their inventive concepts into valued products and services.

Foster Creative Thinking
We value fresh, resourceful, and creative ideas that enable us to achieve our mission, set standards, and win in the market place. By fostering an open and flexible environment, we encourage inventive concepts and solutions from our employees and from inventors and physicians, who have ideas for new medical devices or services to treat their patients.

Highest Ethical Behavior
We believe that fundamental honesty and ethical behavior are at the core of who we are and what we do. We demonstrate our respect for each other, our shareholders, customers and communities by honoring our commitments and being reliable and trustworthy.

Demonstrate Ownership and Pride
We take pride in our work, act with conviction, and feel accountable to each other, our company, customers and shareholders. As an integral part of Bard, we involve each other appropriately and openly communicate so we can all add value to and share in Bard's success.

Leadership by Example
We are committed to the importance of leadership and initiative. We believe in supporting employees with the courage and knowledge to establish new standards and the skill to motivate others to positive action. We expect leaders to communicate effectively, to remove obstacles, and to provide the tools we all need to achieve excellence.

Play to Win
We believe a collective competitive spirit, guided by our values, is key to market leadership. We play to win and, therefore, set challenging and aggressive goals that provide focus and value results over activity.