2019

Becton Dickinson/ Society of Interventional Radiology Internship Program

POSITION SUMMARY

Becton Dickinson (BD) has designed an internship program that will allow medical students the opportunity to gain valuable medical device experience. The BD/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 BD
- Review and approval of intern's presentation at SIR (to protect BD 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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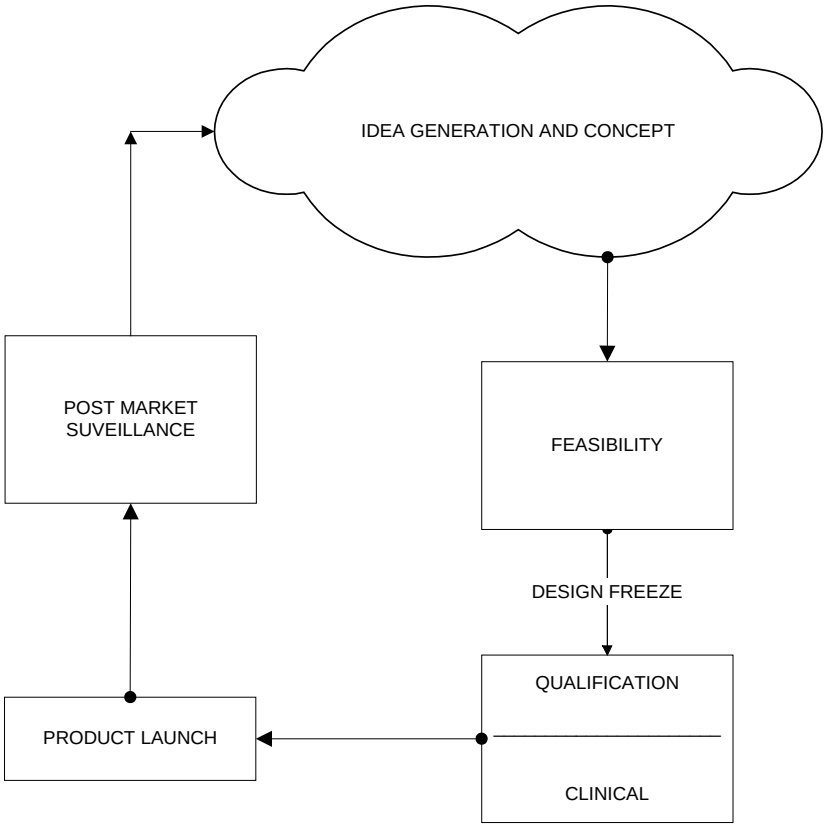
DESCRIPTION OF INTERNSHIP

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 BD measures the value of its products. The Intellectual Property (IP) Team at BD 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:

- 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
- 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)

BD (led by Quality) is responsible to evaluate user, design and process risk so that all new and existing products perform as expected and are safe and effective for the end user throughout the lifecycle of the product. At the conclusion of the module, the intern will be able to demonstrate a basic understanding of the product risk management lifecycle.

- Risk Analysis – Intended use, identification of characteristics related to safety, hazards identification, estimation of hazardous situation
- Risk Evaluation – Failure Modes and Effect Analysis
- Risk Control – Design Validation, Design Verification, Manufacturing Controls
- Residual Risk Evaluation – Overall residual risk acceptability
- Risk Monitoring - Post Market Surveillance

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.

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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 BD is responsible for facilitation 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)
- US Regulatory Submission and Clearance/Approval Process

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 BD'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 Becton Dickinson?

Core values are an organization’s essential and enduring tenets—the beliefs that guide our management practices, leadership norms and culture.

We do what is right

We are committed to the highest standards of excellence and integrity in everything that we do: on behalf of our customers, our shareholders, our communities and ourselves. We are proud to work for a healthcare company whose products and services make a difference in people’s lives. We derive our greatest sense of accomplishment from doing what is right – not what is expedient. We don’t compromise our high standards of ethics in order to achieve our objectives. We are reliable, honest and trustworthy in all our dealings. We keep our promises and if we make a mistake we make it right.

We take personal responsibility

Change is never easy, and despite our best efforts, it won’t all go smoothly. Being individually responsible means we are accountable for our decisions, even when we make a mistake, and not try to place blame or make excuses. We treat the company's reputation as our own and try to make wise use of our time and the company's resources. We expect access to the tools and information necessary to participate in any decisions that will reflect on our collective or individual reputations.

We anticipate and address the challenges of patients and customers globally

It’s not enough to just respond to customer challenges. We need to know our customers’ needs as well or better than they do, so we can be proactive. Thinking about our customers holistically, including the patients they serve, will enable us to serve them better, helping to solve their most pressing healthcare challenges.

We innovate and improve continuously

Innovation isn’t specific to R&D and new product development, nor is continuous improvement limited to our operations and manufacturing teams. We are all accountable for seeking innovative solutions to our challenges and for not settling for “good enough” but striving to improve and be better every single time. We study our progress and learn from others and ourselves how to do things more effectively and efficiently.

We respect, collaborate, challenge and care about each other

We act with respect towards each other and towards those with whom we interact. We collaborate and challenge each other, cultivating best practices throughout the organization. We demonstrate constructive candor by disagreeing openly and dealing with our differences professionally. We care about people as individuals and promote an inclusive work environment that values, appreciates and leverages diversity.

BD Values and Core Competencies

Results matter. However, HOW we achieve those results also matter. At BD, as we strive to achieve outstanding performance, we are guided by the following core behavioral competencies.

Living The BD Values

Demonstrates the core values that are the foundation for becoming a great company:

- We do what is right
- We take personal responsibility
- We anticipate and address the challenges of patients and customers globally
- We innovate and improve continuously
- We respect, collaborate, challenge and care about each other

Core Competencies

- **Action-oriented** – Is agile and timely in making things happen.
- **Continuous and Versatile Learning** – Proactively builds knowledge and skills of self and others, to increase value/contribution to the company and to ensure personal and professional growth.
- **Customer Focus** – Is flexible and nimble in keeping up with customer needs; is on the cutting edge of defining their next level of expectations, and working to exceed them.
- **Driving for Results** – Consistently strives to achieve challenging goals and objectives whether individually or through others.
- **Influencing Others** – Whether as a team leader or an individual contributor, engages others in ways that gain their willing support and cooperation in pursuing initiatives or particular courses of action.
- **Managing, Leading and Developing People** – Guides others toward shared goals, providing the development, coaching, feedback and resources to accomplish tasks.
- **Process Effectiveness** – Understands results that must be obtained and establishes efficient plans for self and/or others to achieve them; alert to opportunities to improve existing processes for accomplishing work and pursues them.
- **Promoting an Inclusive Work Environment** – Respects and values the diversity among us and leverages differences to enhance our performance and working environment.
- **Teamwork** – Puts into practice values and behaviors that contribute to group effectiveness and performance, and the achievement of team objectives.