

Job Title	PRODUCT DEVELOPMENT ENGR
Requisition Number(system-generated)	10-1561
City Where Position Is Located	Bedford
State(2 char. only)	MA
Generic Job Description	<p>This individual is responsible for assisting in the development and testing of medical products within Covidien's Bedford office. This position requires knowledge and experience in the field of medical device design and development and some understanding of delivery device design, implantable medical devices, hydrogel chemistry, and manufacturing processes. Manufacturing process development and medical device materials experience is a plus. Candidate will work under general supervision, following established procedures under limited guidance, and will contribute as a technical team member who may lead technical aspects of low complexity projects. Good communication skills are needed to understand and manage product needs as conveyed from internal and external sources. Principal Duties and Responsibilities include the following:</p> <ul style="list-style-type: none"> • Establish, execute, and report on product development deliverables within Covidien's design control system, including verification and validation activities. • Conduct product testing and develop models and prototypes. • Prepares reports, presentations and spreadsheets of an analytical and interpretative nature to solve lower to medium complexity problems. • Provides primary technical contributions and or may lead sub projects. • Provide regular updates to various Covidien audiences. • Work closely and manage external companies involved in product development activities for Covidien. • Collaborates with peers to manage the development of appropriate testing to verify product meets internal and external customer requirements. • May provide training and guidance to less experienced team members. This individual may supervise engineering support/technicians or interns.
Requirements	<p>Qualification Requirements: Education: A BS degree in Mechanical Engineering, Chemical Engineering, Biomedical Engineering, or an equivalent technical degree is required. Experience: Clarify if prior experience must be in a specific area of expertise or at a particular position level. Development Engineer II: A BS degree with 2 – 5 years experience in device development required, including experience in the medical device industry.</p> <ul style="list-style-type: none"> • Basic understanding of medical device industry and competitor products. • Basic understanding of clinical and regulatory pathways, IP and internal processes. • Basic understanding of clinical uses of product. • An aptitude to learn or a preexisting understanding of product development and documentation. • Ability to take concepts through validation and into commercialization • Understanding of regulatory standards (FDA, ISO) as they pertain to developmental projects and Design History Files. • Some knowledge of medical device delivery systems, including single use designs. • A general familiarity with the hydrogel chemistry, the physics of flow and atomization and manufacturing processes are required. • This individual will need to work well with others, including outsourcing manufacturing. • Good communication skills, both oral and written are required. No strenuous activities are envisioned for this position. Occasional work and assembly in a clean room and/or dry room environment.