Health Scientists, Scientific Project Managers, Senior Data Analysts, Data Architects, IT Program Managers, Pega Developers, SharePoint Developers, IT Business Product Managers, and Cybersecurity Specialists who will help to advance national and international partnerships and patient-focused programs, support efforts relating to the availability of medical devices and their supply chains, and manage the Center's data, informatics, and information technology (IT) initiatives.

Working as a *Health Scientist*, you may:
- Conduct vulnerability assessments, perform threat mitigation management, and establish strategic metrics and milestones centered on supply chain resiliency
- Provide sound, theoretical, evidence-based, and clinically appropriate information to ensure the sustained availability of medical devices
- Serve as an expert on the Center's cross-functional team to address challenges to promote the availability of safe and effective medical devices for consumers, patients, and healthcare providers
- Provide health science regulatory consultation and leadership, project and quality management, program development, and relationship management expertise to establish partnerships with patient organizations, healthcare professional organizations, industry, scientific and other external organizations
- Provide technology transfer and intellectual property guidance to establish collaborations that support regulatory research programs
- Represent FDA in negotiating, drafting, planning, and executing legal agreements
- Use Patient Reported Outcomes (PRO's) data to manage the Center's patient science and engagement activities
- Collaborate with scientific staff to develop policies, programs, research projects, patient documents and metrics in the field of patient science and patient engagement

We are seeking technical expertise for <u>some</u> of our *Health Scientist* positions in the following areas:
- Ability to engage, build, and sustain relationships with internal and external stakeholders
- Skill in managing public health projects of national significance
- Experience evaluating and enhancing medical device supply chains across scientific, health care, and regulatory organizations, to mitigate vulnerabilities and potential disruptions
- Expertise with technology transfer including drafting, negotiating, and executing legal collaboration agreements (e.g., Memorandums of Understanding, Research Collaboration Agreements, Material Transfer Agreements)
- Experience in licensing or patents
- Experience in strategic planning and development
- Experience with patient or professional societies or Public-Private partnerships

Working as a *Scientific Project Manager*, you will:
- Ensure the timely completion of scientific activities and attainment of scientific objectives within established project plans
- Work collaboratively within diverse, scientific teams to develop project plans, including setting time frames and milestones
- Directly manage and coordinate the work of the scientific and technical staff for the specific project to determine how much progress is being made and if any problems are surfacing
- Monitor and report the status of all activities within assigned scientific projects through interaction with project participants
- Identify activities or situations that may adversely impact project plans and recommend solutions to problem areas
- Identify and coordinate the resolution of conflicting resource needs, availability, and scheduling

To be considered for the *Scientific Project Manager* role, here are the skills and experience we're looking for:
- 3+ years of project management experience
- Experience managing scientific projects using Agile methodology

- Experience coordinating work across multiple teams
- Experience working with large databases, statistical analysis, and clinical data *is preferred*
- Formal project management certification as a Certified Scrum Master (CSM) *is preferred*

Working as a *Senior Data Analyst*, you will:
- Provide expert guidance and technical support to IT specialists regarding the requirements analysis, design, programming, testing, and implementation of existing and proposed data management systems
- Review, analyze, transform, and extract data from disparate databases used by existing CDRH systems
- Analyze the data impacts of IT initiatives and projects and how those changes may affect data across the enterprise

To be considered for the *Senior Data Analyst* role, here are the skills and experience we're looking for:
- Experience managing projects related to data collection and/or analysis
- Advanced skill in analyzing data using analytic software or tools
- Experience making strategic recommendations on data standards, data collection, and data integration
- Skill in translating the results of data analysis for diverse stakeholder groups

Working as a *Data Architect*, you will:
- Design, create, deploy, and manage the Center's data architecture
- Advise on data storage, consumption, integration, and management for different data entities and information technology systems as well as any applications using or processing CDRH data
- Assist in the design and modernization of relational and non-relational databases that fully support the Center's operational and analytical data needs

To be considered for the *Data Architect* role, here are the skills and experience we're looking for:
- Knowledge of data architecture practices and techniques to support data science activities (e.g., applied knowledge of computer science, mathematical and statistical theories, techniques, and methods to perform data architecture work)
- Knowledge of computer programming and tools used in data management to include those used to conduct observational analyses
- Experience analyzing, planning, and executing work in data architecture and/or engineering

Working as an *IT Program Manager*, you will:
- Lead programs and projects using emerging/best agile practices and advances in technology with responsibility for gathering information, identifying, and analyzing issues and making recommendations through development of detailed plans
- Develop detailed plans, tasks, milestone dates, and schedules to ensure proper sequencing of milestones and tracking of processes and costs throughout the lifecycle of the Center's IT programs and/or projects
- Manage resources that provide CDRH and its IT partners with delivery and project support services to help the Center implement, operate, and optimize current and future technology systems, processes, and procedures
- Participate in program planning sessions, report on the status and progress of work accomplished to date, and monitor work in progress
- Perform business and systems analyses to identify business opportunities for adopting and implementing emerging technology

To be considered for the *IT Program Manager* role, here are the skills and experience we're looking for:
- 5+ years of experience in IT project or program management
- Demonstrated experience in leading large-scale, complex projects and programs
- Strong understanding of Agile methodology
- Excellent interpersonal and communication skills, with the ability to interact effectively with individuals at all levels of an organization

- PMP or other project management certification *is preferred*
- Certification and/or knowledge of SAFe *is preferred*

Working as a *Pega Developer*, you will:
- Design, code, test, and debug Pega Business Process Management (BPM) applications, within planned sprint timelines, which are built for rapid change and meet functional and non-functional requirements
- Ensure the development of robust, scalable technical Pega solutions with reusable components/common elements
- Perform solution architecture within the Pega RULES Process Commander (PRPC) environment
- Serve as a Pega advisor, mentor, and specialist to management and staff

To be considered for the *Pega Developer* role, here are the skills and experience we're looking for:
- Advanced knowledge of Pega Class Hierarchy, experience with Java-based applications, and high-level project management skills
- Ability and experience with designing scalable applications to improve process management

Working as a *SharePoint Developer*, you will:
- Serve as a recognized technical authority on administering, configuring, and customizing the Center's Microsoft SharePoint cloud-and web-based collaborative platform
- Analyze the validation of IT needs and requirements, including data, access needs, and security, to design and develop appropriate systems designs, access methods, and information security controls
- Perform SharePoint administration activities, such as site provisioning, permissions management, site collection configuration, and other system administration tasks

To be considered for the *SharePoint Developer* role, here are the skills and experience we're looking for:
- 5+ years of experience developing and supporting enterprise-level SharePoint applications
- Strong problem-solving and communication skills

Working as an *IT Business Product Manager*, you will:
- Provide technical expertise on business solution matters related to product plans, business value and results, including related technologies and concepts, to both internal and business customers
- Consult with business owners to determine business needs and requirements for products
- Be responsible for the successful execution of assigned Operations and Maintenance (O and M) activities of participating production systems and products

To be considered for the *IT Business Product Manager* role, here are the skills and experience we're looking for:
- Expertise in software engineering
- Experience in IT product management
- Experience in managing an IT product throughout its lifecycle
- Ability to problem-solve and prioritize
- Ability to work effectively with diverse, cross-functional teams

Working as a *Cybersecurity Specialist*, you will:
- Serve as a subject matter expert in cybersecurity
- Provide information, analysis, and consultation to support complex scientific and regulatory issues related to cybersecurity of medical devices

To be considered for the *Cybersecurity Specialist* role, here are the skills and experience we're looking for:
- Experience in the application of cybersecurity for operational technology

- Degree in engineering or computer science or 2+ years working on cybersecurity for operational technology
- Master's degree in computer science or computer engineering, 2+ years working in operational technology, and experience with medical devices *is preferred*