U.S. FOOD & DRUG ADMINISTRATION

Physician (Obstetrician-Gynecologist)

The Center for Devices and Radiological Health (CDRH), a major regulatory component of the Food and Drug Administration (FDA) and the Department of Health and Human Services, is inviting applications for a Physician (Obstetrician-Gynecologist) in the Division of Reproductive, Gynecology and Urology Devices (DHT3B), Office of Health Technology 3 (OHT3). The division is specifically responsible for the Total Product Life Cycle (TPLC) review of reproductive, gastro-renal, urological and general hospital devices and the CDRH Human Factors program.

Position Summary

As an Obstetrician-Gynecologist (OB-GYN), you will be working on projects involving the full range of medical devices and their accessories used in obstetrical and gynecological practice and procedures (e.g., contraceptives, assisted reproduction devices, obstetrical tools, gynecological surgical tools, surgical mesh for pelvic organ prolapse repair, endometrial ablation devices, fibroid treatment devices, etc.). Review areas include general OB-GYN, gynecological surgery, and OB-GYN subspecialties such as reproductive endocrinology and urogynecology, as well as robotic surgery and diagnostics relevant to OB-GYN practice. You will review proposed clinical trial protocols to ensure that trials are capable of collecting valid scientific evidence while sufficiently protecting patient safety, analyzing the results of clinical trials to determine whether they support the safety and effectiveness of a given product, development of scientifically sound clinical review policy for OB-GYN devices, evaluation of post market device safety issues/recalls and outreach to device manufacturers and physician groups on clinical topics.

Duties / Responsibilities

The Physician (OB-GYN) also performs the following duties:

- Review total product life-cycle actions (premarket, compliance, and post-market surveillance) related to obstetrical and gynecological devices. Actions may include 510(k), PMA, De Novo, IDE, pre-submission, submission issue request, 513(g), MDRs, recall and complaint submissions.
- Develop, modify, and evaluate guidelines concerning clinical data required in obstetrics and gynecology medical device actions to be submitted to the Agency. In this capacity, the incumbent participates as a member of a team of experts to develop agency- or center-wide guidelines applicable to the regulation of relevant obstetrical and gynecological medical devices.
- Present reviews, conclusions, opinions, and recommendations to outside stakeholders on submissions and review issues. These discussions will include key issues pertaining to the safety and effectiveness of the obstetrical and gynecological medical device(s), outlines of deficiencies, and recommendations for approval or non-approval of the device or the submission.
- Enhance professional career development by collaborating with engineers, clinicians, and scientists to better understand medical device problems. Keep abreast of current events and findings and changes in medical device law and regulations through review of scientific and legislative literature, personal contact with relevant authorities, and by attending scientific meetings.

Professional Experience/Key Requirements

To qualify for this position, you must demonstrate in your resume the necessary experience for this position, which is equivalent to the following:

- Expertise in the general aspects of obstetrics and gynecology clinical practice; a focus in gynecological surgery and robotic surgery is highly desired.

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- Ability to collaborate with a multi-disciplinary staff responsible for scientific, public health and/or regulatory activities associated with medical devices.
- Ability to interpret and assess scientific data and technical reports to determine the safety and effectiveness of medical products.
- Ability to represent the organization on committees and at professional meetings, conducting outreach to relevant stakeholder populations, and leading strategic achievement of organizational goals.

Salary
Salary is equivalent to GP-0602-14, plus physician market pay (Title 38), and is commensurate with education/experience. U.S. Public Health Service Commissioned Corps Officers may also apply.

Basic Qualifications
Physician, (GP-0602): A Doctor of Medicine or equivalent degree from a foreign medical school must provide education and medical knowledge equivalent to accredited schools in the United States. Evidence of equivalency to accredited schools in the United States is demonstrated by permanent certification by the Educational Commission for Foreign Medical Graduates, a fifth pathway certificate for Americans who completed premedical education in the United States and graduate education in a foreign country, or successful completion of the U.S. Medical Licensing Examination.

Licensure
Applicant must possess a current, active, full, and unrestricted license or registration as a Physician from a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States. It is highly desired that the prospective candidate has eligible Board Certification.

Additional Conditions of Employment
- United States Citizenship is required.
- This position requires occasional travel.
- One-year probationary period may be required.
- Background and/or security investigation required.
- All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption.
- This position is subject to strict prohibited financial interest regulations which could restrict the type of financial interest (stock holdings) for the employee, the spouse, and minor children of the employee. For additional information on the prohibited financial interests, please visit the FDA Ethics and Integrity Office website at https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

Application Period
Monday May 2, 2022 – Monday May 31, 2022

How to Apply
We invite you to apply today by completing the following steps:
1. Submit your electronic resume or curriculum vitae to CDRH Recruitment at CDRHRecruitment@fda.hhs.gov. Reference Job Code: **2020-OHT3-DHT3B-010**
2. Create/Log-in to your USAJOBS account and review the official job opportunity announcement located on USAJobs.gov at https://go.usa.gov/xtsuQ. Applications **MUST** be received by applying to the official job opportunity announcement located in the link above.

Required documentation should include: a copy of your current, active, unrestricted medical license and a copy of your Doctor of Medicine transcripts (official/unofficial) or ECFMG. Your transcripts must show completion/conferred date. Additional supporting documentation may include a bibliography, summary of research accomplishments, and names/contact information of three references.

Visit CDRH Jobs to see for additional opportunities.

The Department of Health and Human Services is an equal opportunity employer with a smoke free environment.

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