

## ***Cornelia B. Rooks***

**SUMMARY:** Cornelia Rooks held various positions with FDA for twenty-five years. Her experience with FDA includes U.S. and foreign establishment inspections, official speaking engagements, and extensive management roles. Ms. Rooks has a Bachelors of Science degree in Biology from Tennessee State University and a Masters of Arts degree in Management from the College of Notre Dame. She joined Registrar Corp full-time in 2006.

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**EDUCATION:** *College of Notre Dame*, Baltimore, MD, Masters of Arts in Management, 1993, Health Care Management Emphasis; *Johns Hopkins School of Public Health and Hygiene*, Baltimore, MD, Physics and Instrumentation in Nuclear Medicine, Graduate level, 1979; *Tennessee State University*, Nashville, Tenn. B.S. Biology, 1967

**EXPERIENCE:** Jan. 2006-Present, *Senior Compliance Specialist, Drug & Medical Device Expert, Registrar Corp., Hampton, VA*. Responsibilities include medical device and drug regulatory policies to include domestic and foreign registration and listing requirements.

Jan. 1997- Sept 2005 *Division Director, GS 685 15, Division of Device User Programs and Systems Analysis, Office of Health and Industry Programs, Center for Devices and Radiological Health, U.S. Food and Drug Administration (FDA)*.

- Developed and implemented health promotion and risk reduction programs and policies to promote safe use of medical devices. These programs include risk communication, qualitative research, outreach, and human factors. Responsibilities include assuring that human factors information to include patient labeling information is available to reduce unnecessary risk in the use of medical devices.
- Provided supervision direction and oversight of a division consisting of approximately 22 professionally diverse employees engaged in professional, technical, or administrative work with wide and diverse mission responsibilities.
- Planned work operations, set priorities, established goals and objectives, determined strategic plans, developed review presentations, and provided problem resolution.
- Developed and provided training programs to support the recall and patient notification provisions of the Act, e.g. training FDA field investigators conducting audits of patients having defective devices.
- Presented division programs/policy development to Center level personnel. Establishes liaison between division and other areas of the Agency as well as constituent relations with outside organizations.
- Promoted projects/visibility to other areas within the Center, Agency and external components. Represents the Center and Agency at recruitment fairs, exhibits and conventions.

- Made presentations as an agency representative at international and national professional meetings.

1991- 1997 *Supervisory Biologist, GS-401-13, Clinical Chemistry/Toxicology/Hematology Branch, Division of Clinical Laboratory Devices (DCLD), Center for Radiological Health (CDRH), U.S. Food and Drug Administration (FDA), Rockville, MD. Temporary Detail to Division of Chemistry and Toxicology Devices (DCLD), Office of In Vitro Diagnostic Devices (OIVD), November, 2004-January, 2005, Acting Division Director. Duties same as stated below with the exception of Executive Secretary responsibilities.*

- Supervised scientific reviewers and health care professionals and support staff in the Clinical Chemistry /Toxicology / Hematology Branch/Division within the Division of Clinical Laboratory Devices/OIVD.
- Provided technical and administrative oversight of staff members in the review of in vitro diagnostic device Premarket Application (PMA), premarket notification (510K), product development protocol (PDP) and Investigational Device Exemption (IDE) submissions.
- Provided overall management of all Branch/Division activities to include performance evaluations, recruitment, hiring, disciplinary actions, procurement, contracts, and acquisition.
- Participated in sites visits of regulated industry
- Represented the Center as Executive Secretary of the Clinical Chemistry and Clinical Toxicology Advisory Panel.
- Made presentations and represented the Center at national and international professional meetings.

1987 -1991 *Biologist, GS-401-13, Clinical Chemistry/Toxicology Branch, DCLD, CDRH, FDA Rockville, MD.*

- Reviewed in vitro diagnostic medical device actions to include Premarket Application (PMAs), 510(k) notifications and Investigational Device Exemptions (IDEs).
- Developed guidelines and protocols.
- Provided scientific information and consulted with industry, academia, and other scientists.
- Made presentations at panel meetings and represented the agency at various scientific meetings.

1987 *Adverse Reaction Evaluator, GS-401-13(Detail), Office of Epidemiology and Biostatistics, Reports Evaluation Branch, Center for Drugs, FDA, Rockville, MD.*

- Provided trend analysis of unexpected adverse reaction reports for drugs and biologics.
- Medical information review and evaluation of drug experience reports to include identification and investigation of potential adverse reaction reports and presentation of reports.
- Participated in meetings leading to possible actions including labeling revisions.
- Explained and interpreted policies, programs and data concerning adverse reaction reports to physicians within CDER, industry and health professionals.

1980 -1987 *Biologist, GS-401-12, Plasma Derivatives Branch, Division of Blood and Blood Products*

*(DBBP), Office of Biologics Research and Review (OBRR), FDA Bethesda, MD.*

- Regulated blood and blood products to include review of New Drug Applications (NDA), Investigational New Drug (IND), Establishment License Application (ELA), Product License Application (PLA), and 510(k) submissions. The products included immunoglobulin. Albumin, plasma protein factor (PPF), Antihemophilic Factor (AHF), Factor IX (FIX), and Antithrombin III (ATIII).
- Conducted GMP inspections of domestic and foreign manufacturing firms of related products.
- Performed analysis of regulated products for release purposes.
- Consulted with manufacturers and represented the Office in meetings.

1971- 1980 *Medical Technologist, GS-644-9, Lipid Laboratory and Nuclear Medicine, Clinical Investigations, United States Public Health Service Hospital, Baltimore, MD.*

- Performed lipid analysis to include cholesterol, triglyceride, and HDL determination ultra centrifugal analysis for detection of lipoproteins. Classified hyperlipoproteinemias for clinical and research purposes.
- Performed various radioimmunoassay (RIA) procedures within the Nuclear Medicine Dept.
- Lectured medical technology students on various procedures in lipid and RIA methodologies.
- Coordinated hospital research operations to include administrative support. Supervised 8-10 technicians.

1970 -1971 *Instructor, Eighth grade Physical Science, Clifton Park Junior High School, Baltimore, MD.*

- Taught basic principles of physical science to eighth grade students.

1968 -1970 *Laboratory Specialist A, Medical College of Virginia (MCV) Virginia Commonwealth University (VCU), Richmond, VA.*

- Organized and managed psychopharmacology research lab.
- Performed independent chemical analysis and biobehavioral experiments.

**PUBLICATIONS:** Horowitz, M.S. et., al: Viral Safety of Solvent/Detergent Treated AHF in Patients with Hemophilia, *Lancet*, July, 1988,

Technical assistance in the preparation of the following: Luepker, R., et.al: Management of Hypercholesterolemia: Evaluation of Practical Clinical Approaches in Healthy Young Adults. Heart Disease Prevention Program, SSA. *American Journal of Cardiology*, Volume 41, Number 3, 590-596, March 1978.

Luepker, R.V., et.al: Serum Lipid levels in a Clerical Workforce. *Journal of Chronic Diseases*, 30:547-555, 1977.

Smith, L.K. et.al: Management of Type IV Hyperliporproteinemia: Evaluation of Practical Clinical Approaches. *Annals of Internal Medicine*. 84:22, 1976.