ROBERT A. JERUSSI, Ph.D.

EMPLOYMENT HISTORY

Latest Employment

Pharmaceutical Consultant, November 1995 - Present

Actively providing consulting services for both pioneer and generic firms in five areas: various aspects of chemistry and manufacturing controls, reviewing FDA pre-submissions, auditing new drug substance facilities, representing firms at FDA and at public hearings, and training in regulations, guidelines and other topics. Acquired insights into the frustrations and problems experienced by firms during the regulatory process.

From 1997-2000 served as a consultant to the National Pharmaceutical Alliance's (a generic trade organization) Technical Committee.

Food and Drug Administration (FDA) Experience

I. Last Position: Associate Director for Chemistry, Center for Drug Evaluation and Research (CDER) Jan. 1992-Oct. 1995

Duties included management of the Environment Assessment staff of CDER, the Compendial Operations Branch of CDER which interacts with the United States Pharmacopeia and CDER's Quality Control function for the manufacturing and control segments of drug applications submitted to FDA. Served as chairman of CDER's Expert Peer Review Group for promotions.

Performed Quality Control (QC) of generic drug first and second time approvals, ad hoc audits of chemistry reviews, and QC audits assigned by management Responsible for setting up the first ever QC system in the drug review process at FDA with the position being transferred from the Office of Generic Drugs (OGD) to CDER. This position was at least partially responsible for the OGD being moved from the "high risk' list under the Federal Managers Financial Integrity Act, the only unit in FDA's history to have been placed on this list. Selected to participate in the International Conference on Harmonization (ICH) process for FDA both in Europe and the U. S. Also, contributed and participated in three American Association of Pharmaceutical Scientists (AAPS) workshops on Scale-Up. Used as a resource person and consultant to the OGD.

2. Previous Positions in Generic Drugs

a. Associate Director for Chemistry, Office of Generic Drugs (OGD)

Same QC function as under #1, but assigned to OGD Oct.. 1991 - Jan. 1992.

b. Acting Director, the Divisions of Chemistry I and II, OGD Oct. 1990- Sept. 1991.

   Directed approximately 40 supervisory and reviewing chemists in the review of generic drug applications. Developed OGD guides concerning the review process and worked to establish evenness, consistency and fairness in the review process. Established OGD stability and manufacturing committees to focus on generic problems in these areas.

c. Deputy Director for Chemistry, Division of Generic Drugs May 1989 - Sept. 1990

   Sent to Generic Drugs after the scandal to evaluate the chemistry and manufacturing controls review process and allowed to put in place a scientifically sound review process patterned after the new drug review process but with controls for fairness and evenness. Also, responsible for recruiting qualified chemists to assist in the review of ANDA's - approximately 36 hired in 36 months.

3. Previous positions in the New Drug Application Review Process.

a. Deputy Director, Division of Oncology and Radiopharmaceutical Drug Products June 1980 - May 1989.

   Responsible for supervising the supervisory Consumer Safety Officer, Pharmacologist and Chemist in the division. Reorganized the clerk typist/secretarial personnel to provide secretaries to clinical group leaders and a ladder from clerk typist to director's secretary within the division. Organized monthly meetings with units that provided consult reviews to the division . i.e. statistics and bio-pharmaceutics in order to set priorities and monitor the pace of the work. Signed all manufacturing and control supplemental letters. Took a leadership role in recruiting all scientific disciplines and releasing ineffective employees.

b. Supervisory Chemist, Division of Surgical/Dental Drug Products July 1973- June 1980.

   Supervised the eight division chemists in the review of surgical and dental drugs. Led the divisions efforts in a massive drug compatibility program in large volume parenteral products packaged in plastic. Responsible for the first drugs ever approved (sutures) with parametric sterility release. Supervised the chemistry review of respiratory metered dose inhaler drugs and the first dry powder inhaler drug (spinhaler).

c. Reviewing Chemist, Divisions of Metabolism and Endocrine Drug Products and Anti-infective Drug Products, Feb. 1970- July 1973.

Reviewed the chemistry and manufacturing sections of IND's and NDA's for metabolic and anti-infective drug products. Part of the team that approved Bactrim/Septra and was responsible at one time for all the chemistry IND reviews for 25-hydroxy cholecalciferol, a Vitamin D metabolite, for vitamin D resistant rickets.

Experience Previous to FDA (Excluding Post Doctoral)

4. Research Chemist, General Electric R&D Center, Niskayuna, NY, Sept. 1965- Feb. 1970.

Performed research on polymers and monomers to improve company's products and understand the mechanisms of polymer degradation. Research led to 4 patents and 6 publications.

5. Assistant Professor, NYU, Bronx, NY, Sept. 1964 - Sept. 1965.

Taught organic chemistry to chemical engineering students and was responsible for all the undergraduate organic chemistry at University College of NYU - 5 labs/week (approx. 150 students).

6. Research Chemist, American Cyanamid, Stamford Conn., June 1961 - June 1962.

Performed research on potential softening agents using long chain amines generated via the Ritter reaction for eventual use in home laundering.

7. Chemist, Sperry Gyroscope Co., Lake Success, NY, 1953-1957.

Performed analyses as a chemist in the firm's Materials Laboratory on incoming chemicals, paints, plastics etc. Also, did some development work on polymeric encapsulating compounds and metal cleaning solvents.

Education

High School	Cardinal Hayes, Bronx, NY - Regents Diploma 1946
College	Canisius, Buffalo, NY - B S Chemistry 1950
Post Graduate	New York University, NY - Ph.D. Organic Chemistry 1961

Post Doctoral	Worcester Foundation for Experimental Biology June 1962- Aug. 1964. NIH sponsored program in steroid biochemistry
Miscellaneous	American Chemical Society and FDA sponsored courses in synthetic organic chemistry, stereochemistry, stability, biopharmaceutics, etc. and a variety of seminars on specific drug classes, pharmaceutical manufacturing, formulation research, clinical studies, etc.
Affiliations:	American Chemical Society: member of the Organic, Medicinal Chemistry, Chemistry and the Law and Professional Relation divisions. Past member New York Academy of Science and Society of Sigma Xi. Member, Parenteral Drug Association
Service:	U.S. Army Jan 3. 1961 - Dec 31, 1952. Honorably discharged - Corporal - served in Korea during the war.

PROFESSIONAL SOCIETY ACTIVITIES

1. One of founding members of FDA Society of Sigma Xi Club and its first Secretary (1970- 1971) and its second President (1971 - 1972).

2. Alternate Councilor for the Chemical Society of Washington to the National American Chemical Society (ca. 197 1-1973).

3. Served on several committees within the Chemical Society of Washington and was Chairman of the Tellers Committee (1972- 1975).

HONORS AND/OR AWARDS

1. Bronze Star - U. S. Army, 1952
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2. Phi Lambda Upsilon, inducted ca. 1960

3. Founders Day Award from New York University, 1962
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4. FDA Award of Merit - 1991 (FDA's highest civil service employee award).

5. FDA Commendable Service Award - 1994 and 1995 (part of group awards).

6. Several cash awards during FDA career; one for being acting Division Director, HFD-160, for two months; another for simultaneously being the Deputy Director of HFD-150

and the acting Deputy Director for Chemistry, Division of Generic Drugs for a period of 6 months in 1989.

R.A. Jerussi Research Publications

1. The Oxidative Rearrangement of 5 alpha-Cholestan-3-one, Tetrahedron 2.0, 741 (1964). H. M. Hellman and R. A. Jerussi

2. The Stereochemistry of the Kinetically Controlled Bromination of 19-methyl 5 alpha-3-keto Steroids, J. Org. Chem. 3Q, 1650 (1965). R. A. Jerussi

3. The Mechanism of the Bacterial C-1,2 Dehydrogenation of Steroids III. Kinetics and Isotope Effects, Biochemistry 4, 2113 (1965). R. A. Jerussi and H. J. Ringold

4. Selenium Dioxide Oxidation of 5 alpha-Androstane-3.17-dione. The Stereochemistry of Dehydrogenation, J. Org. Chem. 31,3199(1966). R. A. Jerussi and D. Speyer

5. Stereochemistry of Some Diphenylbicyclo (3,3,1) Ketones, J. Org. Chem. 32, 2148 (1967). H. M. Hellman, R. A. Jerussi and J. F. Lancaster

6. Aryl End-Capping of 2,6-Dimethyl- 1,4-polyethylene Oxide, J. Poly. .Sci. (A-1), 6, 3167 (1968). R. A. Jerussi and M. R. McCormick

7. The Copper Promoted Oxidation of Tri-n-butylamine. The Carbon-by-Carbon Degradation of an n-Butyl Group, Chem. Comm. No. 12, 639 (1969). R. A. Jerussi and M. R. McCormick

8. The Oxidation of Enamines. Ketonization at the beta-Position to Give alpha-Aminoketones. J. Org. Chem. 34, 3648 (1969). R. A. Jerussi

9. Thermal Rearrangement of ortho-Methyl Diaryl Ethers. J. Org. Chem. 35, 57(1970). A. Factor, H. Finkbeiner, R. A .Jerussi and D. W. White

10. The Oxidation of Phenols with iso-Amyl Nitrite. A Simple Preparation of Diphenoquinones. J. Org. Chem. 35, 2104 (1970). R. A. Jerussi

11. Thermal and Photochemical Oxidation of 2,6-Dimethylphenyl Phenyl Ether. A Model for Poly 2,6-Dimethyl-1,4-Phenylene Oxide, J. Polymer Sci. (A-1) 9, 2009 (1971). R. A. Jerussi

12. Selective Catalysts for the Trimerization of Conjugated Acetylenes, Tetrahedron Letters No. 1, 61 (1972). A. J. Chalk and R. A. Jerussi

13. The Oxidative Rearrangement of Ketones to Carhoxylic Acids, Annals N.Y. Acad. Sci.. 192, 44 (1972). H. M. Hellman, R. A. Jerussi and A. Rosegay

14. Imidazole Catalysis in Carbamate and Polyurethane Formation. J. Applied Poly. Chem., 2853 (1972) R. A. Jerussi and C. M. Orlando

Review Article

Selective Oxidations with Selenium Dioxide. Chapter by R. A. Jerussi in “Selective Organic Transformations”, P. S. Thyagarajan. Ed.. Interscience. Oct. 1970

TALKS by RA. JERUSSI SINCE RETIRING from FDA, OCTOBER, 1995

1. "Symposium on FDA Registration Requirements for Generic Drugs" (only speaker) at the XXVIII National Conference on Pharmaceutical Sciences sponsored by the Association Farmaceutica Mexicana. Merida, Mexico, October 24, 1995.

2. "A Partnership between FDA and the Pharmaceutical Industry; the Next level for FDA and the Generic Drug Industry?" at the Generic Products Industry Assoc. Meeting in Boca Raton, Florida, March 19. 1996

3. "Foundation of World Class Pharmaceutical Industry: Preparing and Submitting Abbreviated New Drug Applications and Drug Master Files to FDA" at the Third International Conference of the American Chinese Pharmaceutical Association, Monterey Park, California, August 9. 1996.

4. "An Outside Look-In at OGD by a Former Insider" at the Office of Generic Drugs (OGD), FDA. Rockville, MD. July 10, 1997.

5. "Regulatory Update", at the Fall Meeting of the National Pharmaceutical Alliance (NPA), Las Vegas, Nevada, September 26, 1997.

6. "ICH Q3A/Q3B - Impurities in New Drug Substances and Drug Products. Potential impact on Industry", at the 1997 Fall Technical Workshop of NAPM, GPIA, NPA & FDA. Bethesda, MD, October 9, 1997.

7. "PAC-SAS: Post Approval Changes-Sterile Aqueous Solutions" at SUPAC' 97 Cherry Hill, NJ, December 9, 1997.

8. "The New FDA Guidance on Stability Testing - How Will This Be Applied to NCEs, Generics, Line Extensions, Etc" at the fourth International Conference on Stability Testing. London, England, February 23-24, 1998.

9. "Blends and Impurities" at RAPS meeting on Generic Drugs: Regulations, Submissions. Future Issues - A Look at the Opportunities and Challenges, Newark, N .J. April, 1998.

10. "PAC-SAS: Post Approval Changes - Sterile Aqueous Solutions" at SUPAC' 98, Philadelphia, PA. May 14. 1998.

11. "Should the ICH Stability Requirements for New Molecular Entities Apply to Generics?" at STABILITY TESTING. Achieving Global Acceptance, Harmonization & ICH/FDA Compliance for International Registration of Pharmaceuticals, Princeton, N. J. September 15, 1998,

12. “BAC PAC I & II; Industry Perspective“ at the Generic Industry Associations/FDA Fall Technical Workshop. Bethesda. MD, November 2-3, 1998.