ROBERT J. MELLO, PH.D.

12428 Preserve Way, Reisterstown, MD, 21136
410-526-2128 (Email) rjmello1@aol.com

SUMMARY:

Team player providing balanced experience in quality assurance, manufacturing, and research management. Eighteen years experience in cGMP control, manufacture and validation of parenteral drug products, bulk pharmaceutical chemicals and medical devices. Successfully converted academic research skills into product/process development expertise within an entrepreneurial setting. Transferred technology from lab bench through regulatory processes to market.

PROFESSIONAL EXPERIENCE:

RJM PHARMACEUTICAL CONSULTANTS, Reisterstown, MD 2000-Present
Owner

Experienced in CDER, CBER, and CDRH regulations to assist clients in Quality and Regulatory Affairs, Contract Manufacturing and Facility Design review.

- Assess existing client Quality Assurance Systems and cGMP programs for compliance to FDA regulatory requirements and current inspectional practices. Work with staff to establish these systems for clients new to the industry.
- Sixteen years experience in the contract manufacturing and fill/finish operations of aseptically produced parenteral products (liquid and lyophilized).
- Experienced in assessing new facility designs for potential compliance problems.

CHESAPEAKE BIOLOGICAL LABORATORIES, INC., Baltimore, MD 1994-2000
Vice President, Quality and Regulatory Affairs; Corporate Secretary

Establish and direct Corporate Quality and Regulatory policies for an aseptic processing/parenteral fill-finish GMP contract facility. Establish cGMP and ISO 9001 programs. Provide management leadership and direction for four departments: QC-Chemistry, QC-Microbiology, Quality Assurance, and Regulatory Affairs. Establish and control Departmental budgets. Provide Corporate Management liaison to regulatory agencies (FDA). Prepare CMC sections for regulatory filings (INDs, NDAs, ANDAs, PMAs and Supplements) for Contract Manufacturing clients.

LEDERLE LABORATORIES, DIVISION OF AMERICAN CYANAMID 1992-1993
Pearl River, NY
Manager, Validation Services

Provided management direction and guidance to a staff of twelve for validation activities at four sites. Established, coordinated and monitored validation programs for parenteral operations, bulk pharmaceutical chemical processes and laboratory equipment. Trained staff to effectively execute validation programs.

- Re-established Divisional validation management controls in Puerto Rico facility.
- Modified the freeze dryer media fill program to more closely represent operational conditions, thus avoiding FDA citations.
- Successfully compressed the freeze dryer validation program which permitted on-time facility restart to maintain production schedules.
- Identified and corrected inefficient cleaning validation procedures.
- Reduced lab equipment qualification time lines 30-50% by elevating the quality of supplier validation programs to Lederle Divisional standards.

CHESAPEAKE BIOLOGICAL LABORATORIES, INC., Baltimore, MD 1982 -1992

Director, Quality Assurance & Regulatory Affairs (1990 - 1992)

Established and directed parenteral facility cGMP compliance programs assuring product quality and adherence to regulatory requirements. Interfaced with FDA at District and Federal levels. Managed staff of ten QA/QC, engineering and clerical personnel.

- Reviewed and approved Master/Batch production records, labeling controls, SOPs, testing and specification standards.
- Responsible for final product release.
- Established and implemented required validation, training, audit and calibration programs.
- Maintained drug and device master files.
- Supported submissions during FDA Advisory Board hearings.
- Coordinated responses to FDA inspectional observations.

Director, Research and Development (1982 - 1990)

Evaluated new technologies/products for future development. Transferred technologies from laboratory through manufacturing and regulatory processes to market. Established new manufacturing/QC processes and modified existing ones to improve quality and/or throughput. Responsible for preclinical safety studies to obtain IDE approvals.

- Directed product and process development.
- Developed and scaled up extraction processes for medical products from biological sources.
- Maintained project sponsor support by successful demonstrations of product safety and effectiveness.
- Set specifications and test regimens for critical class 100 aseptic processing areas. Planned and implemented two facility expansions during scale-up.
- Established the microbiology lab to support aseptic operations, then expanded its role as a revenue generator by performing contract laboratory tests.
- Designed and implemented FDA acceptable validation studies supporting aseptic operations.

JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE - WILMER INSTITUTE (1979 - 1982)

Assistant Professor, Dept. of Ophthalmology

Instructor, Dept. of Ophthalmology

Responsible for funding, budgets, research operations and staffing of a basic biomedical research laboratory. Organized studies, assigned tasks, analyzed data and presented results in oral and written forums.

- Established techniques to study growth factors on cultured endothelial cells.

UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL SCHOOL, **Dallas, Texas**

Postdoctoral Fellow (1977 - 1979)

Biomedical research on lipoprotein (LDL) receptors.

- Improved cell fractionation and protein purification methods to isolate a protein associated with receptor internalization.

EDUCATION:

Postdoctoral: University of Texas Southwestern Medical School
Department of Molecular Genetics
Dallas, Texas 1977-1979

Graduate: Johns Hopkins University School of Medicine
Department of Physiological Chemistry (Biochemistry)
Baltimore, Maryland
Ph.D. Biochemistry, 1977

Undergraduate: Providence College
Providence, Rhode Island
B.S. Biology, cum laude, 1972

Continuing: cGMP for Pharmaceutical and Allied Industries; Validation of Aseptic Processes; Fundamentals and Concepts of Metrology and Calibration; cGMP Compliance and Regulatory Affairs; Computer Validation; Total Quality Management; Terminal Sterilization; OSHA Compliance; Microbial Evaluation & Monitoring of Cleanroom Environments; Advanced Barrier Technology; Validation of Microbial Retention for Sterilizing Filters; FDA-Biotech Policy Issues; Understanding FDA Guides & Guidelines; PDA/AAPS Joint Workshop on Clinical Supplies; PDA Special Scientific Forum on Environmental Monitoring and Aseptic Processing; PDA/FDA ConferenceTeam Biologics Three Year Review

AWARDS:

1983	Small Business Innovation Research Grant Award (SBIR Phase I Grant, Tendon Adhesion Studies)
1981-1983	Juvenile Diabetes Foundation Grant Award
1977-1979	NIH Postdoctoral Award

PATENT:

1989 "Stable Solution of Hyaluronate in a Balanced Salt Medium"

PROFESSIONAL ORGANIZATIONS:

Parenteral Drug Association (PDA)
- 2000-2002 Board of Directors
- Regulatory Affairs and Quality Committee (1997- current)
- Chairman, First Party Audit Committee (1998- current)
- PDA Task Force on Harmonization of Regulations (2000-)
- PDA Latex in Pharmaceuticals Study (1999)
- Annual Meeting Program Committee 1997,1998,1999
- PDA Packaging Task Force (1997)

PDA Capital Area Chapter President-elect1999,Treasurer 1997-98