Kenneth H. Muhvich, Ph.D.
Principal Consultant
Micro-Reliance, LLC

Over 35 years experience as a Microbiologist, including over five years working for the FDA's Office of Generic Drugs as a reviewer. Recognized as an FDA expert in Advanced Aseptic Processing of sterile drug products and has authored numerous guidelines and publications. Ken's microbiology expertise also includes research and clinical activities. He has provided regulatory compliance consulting to more than 70 pharmaceutical companies since leaving the FDA.

SELECTED EXPERIENCE

1 **Micro-Reliance LLC**
Principal Consultant - Newly formed consulting company to provide continued service to the pharmaceutical industry.
1 Sterile Process Design and Validation
2 Form FDA 483 Response Consultation
3 Sterile Product Filing Strategies
4 Product Release for Companies Under Consent Decree
5 Writing and Review of Sterility Assurance Validation Packages
6 Conducts/reviews sterile product failure investigations [contamination events]

2 The Validation Group Inc.
Senior V.P. Regulatory Consultant - Has provided regulatory compliance consultation, including drug product application filing strategies, to the following companies:

Abbott [HPD, SPD, PPD & AI Divisions]
• Acculab/Accugenix • AKORN • Alkermes
• Alpha Therapeutics Corporation • Apotex Inc. • Bausch & Lomb • DRAXIS (Canada)
• Drug Abuse Sciences • Epic Therapeutics
• ESI Lederle, Inc. • Faulding (Australia)
• Hikma (Portugal) • Janssen Pharmaceutica Inc. (Puerto Rico)

- • La Jolla Pharmaceutical Company
• McGhan Medical • Medefil Inc. • Merck & Co. • NOVEX (Canada) • Pall Corporation
• Pasteur Merieux Connaught Laboratories, Inc. • Pharmacia • Roche Carolina, Inc. • Roxane Laboratories, Inc.
• SABEX (Canada) • Steris Laboratories, Inc. • Wyeth

- **Food & Drug Administration - Office of Generic Drugs**
Review Microbiologist - Responsible for performing 625 sterility assurance reviews (ANDA's, AADA's, and Supplements). Was instrumental in reducing the backlog of applications in the Office of Generic Drugs from 1,400 days to less than 120 days.

1 Responsible for conducting several pre-approval inspections for AADA & ANDA drug products (domestic and foreign). Received awards for expedited review and inspection of facilities for drug products unavailable in the U.S.

2 Resolved numerous microbiology related cGMP issues for CDER Office of Compliance, e.g., provided acceptable options for release of product lots from pharmaceutical firms.

3 Provided guidance to the pharmaceutical industry regarding CDER's concerns about the use of Blow/Fill/Seal and Isolator Technologies in the manufacture of sterile drug products.

4 Authored the "Ten Percent Rule" for scale-up of sterile injectable solutions while a member of the Office of Generic Drugs' Parenteral's Committee (Letter to Industry dated August 1993).

5 Responsible for drafting the proposed rule which will require all inhalation solutions for nebulization

to be manufactured sterile.

6 Participated in the drafting of "Guideline for the Submission of Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products". (December 3, 1993 Federal Register). Since publication of the guideline, the number of review cycles before approval for most ANDA applications has been markedly reduced.

7 Responsible for counseling representatives of numerous pharmaceutical companies regarding sterility assurance information required for application approval.

- **Department of Pathology, University of Maryland at Baltimore/ Armed Forces Institute of Pathology**
  Research microbiologist - Responsible for performing numerous experiments using animal models of infectious diseases. Analyzed microbial destruction data. Also published eleven (11) articles in refereed journals, e.g., Antimicrobial Agents and Chemotherapy.

- **Clinical Microbiological Laboratory, Sinai Hospital**
  Supervisory microbiologist- Responsible for evaluating the results of antimicrobial susceptibility testing and recommended appropriate treatment regimens to physicians for specific infections based on my interpretation of the data. Also monitored identification profiles of microorganisms isolated from patient cultures.

INDUSTRY RECOGNITION

Ken has been acknowledged as an FDA expert in Advanced Aseptic Processing of sterile drug products, as evidenced in the following publications:

- January 1997 Pharmaceutical & Medical Packaging News (page 34) "Where are Barrier Isolation Systems Today?"

- January 1997 PDA Letter 33 (1) (pages 14-15) "Comments on Container/Closure Integrity Testing".

- December 1995 ISPE Barrier Isolation Technology conference, Rockville, Maryland, "CDER Perspective on Isolator Technology".

- March 1995 PDA Letter 31 (3) (page 11) "Comments on Barrier/Isolators".

EDUCATION

Ph.D. in Experimental Pathology - University of Maryland School of Medicine.
Master of Science in Microbiology - West Virginia University
Bachelor of Science in Health Sciences - University of Delaware

ACHIEVEMENTS

Received the prestigious 1997 FDA Commendable Service Award "For sustained superior performance in maintaining review consistency, quality, and productivity, and coordination of sterility assurance issues for the Office of Generic Drugs."

Received the 1997 FDA Scientific Achievement Award from the Office of Pharmaceutical Sciences Microbiologists - Excellence in Review Science "For exceptional contributions to review science as exemplified in the review of microbiological quality of drug products and the development of regulatory positions."