JOHN M. LINDSAY, SM (ACM)
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El Granada, CA 94018
(650) 430-9125

QUALIFICATIONS

- 20 years management experience (28 years total experience) for three of nation's leading pharmaceutical companies.

- Currently, President of Aseptic Solutions, Inc., a consulting firm specializing in consultation to parenteral pharmaceutical manufacturers on sterility assurance, aseptic processing and environmental control issues.

- Currently, Executive Director of the Aseptic Training Institute in Clayton, NC. The Institute specializes in aseptic processing training to the pharmaceutical and biotechnology industries.

- Formerly, Senior Consultant, KMI/PAREXEL, specializing in consultation to parenteral pharmaceutical manufacturers on sterility assurance, aseptic processing and environmental control issues.

- Previously, Senior Manager of Environmental Quality Assurance for leading Biotechnology Pharmaceutical firm, responsible for the standardization and administration of all QA activities in the area of Environmental Control.

- Also, Senior Process Engineer, coordinating all qualification/validation activities related to the expansion of a fluid-bed coating production facility for a potential half-billion dollar per year product.

- Organized and directed all validation/qualification activities for equipment and critical systems (WFI, pure steam, HVAC, compressed air, nitrogen) for the start-up of a 17,000 square foot cleanroom facility.

- Organized and directed validation of new water-for-injection system approved on initial inspection by FDA while Head Microbiological Quality Assurance for veterinary pharmaceutical firm.

- Co-author of **Cleaning and Cleaning Validation: a Biotechnology Perspective,** the first book published by the Parenteral Drug Association.

- Co-author of PDA Technical Report No. 13, "Fundamentals of a Microbiological Environmental Monitoring Program."

- Co-author of PDA Technical Report No. 35, "A Proposed Training Model for the Microbiological Function in the Pharmaceutical Industry."

- Co-author of PDA Technical Report No. 62, "Recommended Practices for Manual Aseptic Processes."

- Committee Member on PQRI Industry-FDA Joint Committee providing recommendations to the FDA on their Concept Paper on Aseptic Processing distributed publicly in August, 2002.
- Selected by National Registry of Microbiologists in 1989 as Chairman of Consumer and Industrial Microbiology Examination. Elected Chairman of the Board of the National Registry of Microbiologists in 1993 and held that leadership position until July 1999.
- Participant on a PhRMA Task Force to establish an industry standard for the environmental control of bulk manufacturing processes for the Biologics and biotechnology industries.
- Member of ISO/TC 209 Working Group 5 developing ISO 14644 "Cleanrooms and associated environments-Part 5: Operations."

EXPERIENCE

January 2008 to Present **Aseptic Training Institute, Executive Director**

- Develops and coordinates training programs for members of the pharmaceutical and biotechnology industries. Programs are primarily focused on aseptic processing, environmental control and sterility assurance.

March 2001 to Present **Aseptic Solutions, Inc., President**

- Specializes in reviewing and evaluating client's processes that relate to all aspects of sterility assurance based on a vast experience in industry operations.
- Helps client's define corrective actions where warranted and prepare for regulatory inspections or responses to regulatory actions.
- Provides "hands-on" evaluations and training in Cleanrooms including airflow studies, velocity measurements and environmental sampling rationale.

November 1998 to February 2001 **KMI/PAREXEL, Belmont, MA**
Senior Consultant

- Specializes in reviewing and evaluating client's processes that relate to all aspects of sterility assurance based on a vast experience in industry operations.
- Helps client's define corrective actions where warranted and prepare for regulatory inspections or responses to regulatory actions.

June 1992 to November 1998 **GENENTECH, Inc., So. San Francisco, CA**

Senior Manager, Environmental Quality Assurance (1995 to 1998)

Corporate responsibility for defining and documenting all environmental control systems employed to protect products and manufacturing processes. Define the overall environmental control program for Genentech. Support the environmental monitoring

program for Quality Assurance. Assure adequacy (ongoing risk assessment) of the environmental control program. Defend all environmental-related issues during FDA inspections and approve all environmental control sections in FDA submissions. Ensure that all external manufacturing operations comply with established Genentech standards.

Manager, QA Technical Support (1993 to 1995)

Responsible for reviewing and approving IQ, OQ, PQ and validation protocols and final reports. Responsible for facilitating the development and maintenance of quality policies and standards for validation and related change control systems. Review and approve all changes to GMP equipment, facilities and documentation. A technical resource to all manufacturing sites including contract manufacturers and internal support groups in order to identify and resolve validation/quality issues and maintain high quality standards and assure compliance with cGMP.

Senior QA Technologist (1992 to 1993)

Responsible for the review and approval of all validation protocols and final reports. Consult with Manufacturing, Engineering, Product Development and Quality Control to design validation master plans and individual protocols that assure that facilities, equipment and control systems function as specified and processes and procedures are in compliance with current Good Manufacturing Practices. Perform outside audits on contract manufacturers, product packagers and sterilizer firms as needed. Review and approve all SOP's, calibration documentation, batch records and change control reports as required. Perform scientific/technical evaluations of investigations of raw materials, in-process, bulk or final product problems documented in official quality problem resolution systems. Personally investigate and resolve as necessary.

1986 to 1992 **MARION MERRELL DOW INC., Kansas City, MO**

Senior Process Engineer (1991 to 1992)

Organized, wrote and successfully defended (to the FDA) the process validation for NDA approval of a potential half-billion dollar per year product. Develop and implement many aspects of process control throughout the manufacturing unit. Specific items include: cleaning validation, GMP and technical training documentation, equipment and process change management, drawing control, validation master plans, safety incident monitoring, equipment engineering standards, NDA reviews, trending process data.

Manager — Wound Care Production/Project Leader (1990 to 1991)

Managed all aspects of a Wound Care Manufacturing Unit and two product development projects, artificial skin and a transdermal delivery system of an antibiotic for severe burns. Directed two supervisors and twelve hourly employees in the management of the 17,000 square foot cleanroom facility. Managed a $300,000 budget for the unit.

Supervisor — Wound Care Quality Assurance (1989 to 1990)

Supervised staff in design and implementation of protocols and procedures, assuring quality production of two new wound care products within a cleanroom environment in accordance with established Good Manufacturing Practices. Included the successful start-up and validation of all critical systems and production equipment.

Microbiologist (1987 to 1989)

Performed outside vendor audits. Wrote validation protocols. Served as a consultant to microbiology technicians.

1972 to 1986 **COOPERS ANIMAL HEALTH, Kansas City, KS**
(Formerly Wellcome Animal Health)

Head Microbiological Quality Assurance (1980 to 1986)

In charge of staff of eight. Organized validation of SVP and LVP production equipment, sterility testing in vivo and in vitro potency and safety tests. Managed the validation efforts for SVP, LVP and lyophilization processes. Participated as needed in FDA inspections. Responsible for ensuring compliance with GMP's, GLP's and regulatory expectations.

Section Head — General Services (1975 to 1980)

Trained all Quality Assurance and technical personnel while directing staff of seven employees. Interfaced with Animal Services. Wrote standard operating procedures.

Microbiologist (1972 to 1975)

In charge of sterility, safety, mycoplasma and potency testing of SVP and LVP pharmaceutical and biological products.

1971 to 1972 **UPSHER LABORATORIES, Kansas City, MO**

Microbiologist
Responsible for routine clinical microbiological diagnostic investigations.

EDUCATION

Master of Arts, Microbiology, 1980 University of Kansas, Medical Center, Kansas City, KS

Bachelor of Arts, Biology, 1970 Westminster College, Fulton, MO

CERTIFICATIONS

Certified Specialist Microbiologist [(SM(ACM)] — Consumer and Industrial Microbiology, by National Registry of Microbiologists of The American College of Microbiologists

JOHN M. LINDSAY

PROFESSIONAL MEMBERSHIPS

American Society for Microbiology
Parenteral Drug Association
PDA's Task Force on Cleaning Validation in the Biotechnology Pharmaceutical Industry
PDA's Task Force on Environmental Monitoring
Certification Board of the National Registry of Microbiologists — a division of the American College of Microbiology (one of five boards of the American Society of Microbiology)
International Society of Pharmaceutical Engineers (ISPE)
Institute of Environmental Sciences and Technology (IEST)

PUBLICATIONS

- Wood, G. M., Tilzer, S. A., Gollahon, K. A. and Lindsay, J. M., 1979
- Association Between Immunoglobulin and Macrophages in Primary Methylcholanthrene-Induced Sarcomas. Cancer Res., 39:4588-4593.
- Lindsay, J. M., Manning, L. S. and Wood, G. M., November 1982 "Immunoglobulin Bound Exclusively to Fc Receptors on Macrophages in Methylcholanthrene-Induced Murine Tumors," J. Natl. Cancer Inst., 69:1163-1174.
- Parenteral Drug Association Environmental Task Force, 1990, "Fundamentals of a Microbiological Environmental Monitoring Program," J. Parent. Sci. & Tech., Supplemental, Technical Report No. 13, Vol. 44, No. S1.
- PDA Biotechnology Cleaning Validation Committee, Cleaning and Cleaning Validation: A Biotechnology Perspective, published 1996 by the Parenteral Drug Association.
- PhRMA Biological and Biotechnology Committee White Paper Task Force, 1998, "Environmental Control and Monitoring in Bulk Manufacturing Facilities for Biological Products," published in *Pharmaceutical Technology,* and *BioPharm,* May, 1998, and in press in *Pharmaceutical Technology--Asia,* and *Pharmaceutical Technology--Europe.*
- *Environmental Impact on Media Fills*, Chapter 14 in **Environmental Monitoring: A Comprehensive Handbook, Volume 2,** Jeanne Moldenhauer, editor, DHI Publishing, River Grove, IL, 2005.
- Akers, J.F. and Lindsay, J.M., *Determining Facility Mold Infection,* Pharmaceutical Technology, 37: Issue 10, pp 84-88.
- *Steriplex, a New Silver-based Disinfectant, Non-corrosive, Non-toxic, Sporicidal: Disinfectant Efficacy Evaluation,* in **Environmental Monitoring: A Comprehensive Handbook, Volume 8,** Jeanne Moldenhauer, editor, DHI Publishing, River Grove, IL, 2015. (In press)
- *A New Silver-based Disinfectant—Non-corrosive, Non-toxic, Sporicidal:Disinfectant Efficacy Evaluations,* Pharmaceutical Technology, in press.