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Curriculum Vitae

SENIOR CONSULTANT, MICROBIOLOGY/QUALITY SYSTEMS

PHILIP M. SCHNEIDER

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Summary of Qualifications

Philip Schneider is a Microbiologist with over 40 years of professional experience in the health care industry including 31 years with 3M Health Care. He has work experience in the areas of medical device manufacturing, product development, quality assurance, regulatory affairs and customer support in both health care facility and industrial applications. His most recent responsibilities for 3M included technical support for biological and chemical monitors used in sterilization processes, ethylene oxide sterilization systems and investigation of new low temperature sterilization technologies. He has extensive experience in the international marketplace and has conducted seminars and presented at National Health Care Conferences on various topics related to medical device sterilization, infection control practices and standards throughout the world.

He is presently Co-Chair of both the ANSI/AAMI Biological Indicator and the Ethylene Oxide Hospital Practices Working Groups. In addition to his leadership roles in these areas, his has also been involved in numerous other working groups during his 17 years in the ANSI/AAMI organization. Additionally he is the Convener of the ISO/TC 198 Biological Indicator Working Group 4. In these standards organization roles he has directed activity for development of all of the currently published ANSI/AAMI and ISO standards for the manufacture and use of biological indicators.

Professional Experience

SENIOR CONSULTANT, MICROBIOLOGY/QUALITY SYSTEMS, *LexaMed, Ltd.*

- Responsible for medical device and pharmaceutical client interactions relative to sterilization, disinfection, aseptic practice, regulatory agency interface, quality system management, auditing, training and problem solving.

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SENIOR SPECIALIST STERILIZATION ASSURANCE, 3M Health Care

- Prior to September 2008, responsible for international technical support of 3M Sterilization Assurance products. Activities in this role included coordination of 3M subsidiary product support, technical training of subsidiary personnel, dissemination of supporting product documentation, participation in the development of marketing initiatives and seminar/conference presentations.
- Primary representative for 3M Health Care to both the ANSI/AAMI and ISO Sterilization Standards Organizations.
- Interaction with various country regulatory agencies in Europe, Asia and Latin America.
- Major role in development of 3M Sterilization Assurance Business in China.
- Primary role in developing 3M industrial sterilization monitoring business.
- Investigation of novel low temperature sterilization technologies.
- Participation in development of 3M Rapid Readout Biological Indicator products.

QUALITY ASSURANCE MANAGER, 3M Health Care

- Responsible for all quality systems relative to 3M Asepsis/Infection Control Business.
- Development of product standards and SOP's.
- Interface with manufacturing plant quality control function.
- Quality problem resolution.
- Product recall coordination.

MICROBIOLOGICAL SERVICES SUPERVISOR, 3M Health Care

- Established service group within 3M Medical and Surgical Divisions to provide microbiological consultation and laboratory services to the Product Development, Product Support, Clinical, Manufacturing and Quality Assurance functions within these 3M Divisions.
- Validation of sterilization processes for all Medical and Surgical Division sterile products.
- Coordination of contract sterilization for selected 3M sterile products.

PLANT MICROBIOLOGIST, 3M Health Care

- Responsible for sterilization assurance and microbiological quality of all Medical and Surgical Division products produced at the Divisions' primary manufacturing site.
- Established new plant microbiology laboratory.
- Validation of gamma radiation sterilizer at manufacturing site and implementation of dosimetric release system for all irradiated products.
- Surgical Division representative on HIMA committees for biological indicators and medical device packaging.

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RESEARCH MICROBIOLOGIST, *Economics Laboratory, Inc.*

- Development of new antimicrobial agents.
- EPA testing and documentation of disinfectants and sanitizers.
- Development of hospital cleaning/disinfection and environmental monitoring programs.
- Support of Food Industry cleaning/sanitation initiatives.

Professional Associations

To further develop his awareness of technical developments within the medical device and pharmaceutical industry, Philip Schneider participates in the following professional associations:

- ◆ International Organization for Standardization (ISO).
- ◆ Association for the Advancement of Medical Instrumentation (AAMI.)

Education

- ◆ M.A., Food Technology and Microbiology, University of Minnesota, St. Paul, MN.
- ◆ B.S., Biology, St. John's University, Collegeville, MN.

Publications

1. Schneider, P.M., 1978, *Microbial Harboring Characteristics of Dishmachine-Filmed Glassware*, Journal of Food Protection, Vol. 41, No. 10, October, pp. 800-805.
2. Schneider, P.M., 1980, *Microbiological Evaluation of Package and Packaging Material Integrity*, Medical Device and Diagnostic Industry, Vol. 2, No. 5, May, pp. 29-37.
3. Carpenter, D., M. Coleman, T. Hansen, D. Hass, W. Leshniowsky, J. Mello, C. Philips, R. Reich and P. Schneider, 1981, *Methods of Bioburden Evaluation*, Developments in Industrial Microbiology, Society for Industrial Microbiology, Arlington, VA, Vol. 22, pp. 323-328.
4. Schneider, P.M., 1982, *Microbiological Evaluation of Sterile Medical Packaging*, Proceedings of Disposable Sterile Packaging Seminar, Technical Association of the Pulp and Paper Industry, Hilton Head, NC, pp. 13-20.

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5. Schneider, P.M., 1985, *Powered Surgical Instruments: Microbiological Considerations in Sterilization*, AORN Journal, Vol. 41, No. 1, pp. 254-261.
6. Palmieri, C., D. Janssen and P. Schneider, 1986, *Readout Reliability and Sensitivity of a Self-Contained Steam Biological Indicator (Attest 1262)*, Proceedings of Biological Monitoring of Sterilization Workshop, EUCOMED, Kerkrade, Netherlands, pp. 225-228.
7. Schneider, P.M., 1990, *Alternative Low Temperature Sterilization in United States Healthcare Institutions*, ISSM Journal, Vol. 1, No. 11, pp. 6-13.
8. Schneider, P.M., 1990, *Alternative Low Temperature Sterilization in the Clinical Setting*, Proceedings of Polymers, Laminations & Coatings Conference, Technical Association of the Pulp and Paper Industry, Boston, MA, pp. 293-300.
9. Schneider, P.M., 1992, *Alternative sterilization technologies Come of Age; Peracetic Acid*, Medical Device & Diagnostic Industry, Vol. 14, No. 12, December, pp. 43-44.
10. Janssen, D.W., P.M. Schneider, 1993, *Overview of Ethylene Oxide Alternative Sterilization Technologies*, Zentral Sterilization, Vol 1, pp. 16-32.
11. Schneider, P.M., 1994, *Low Temperature Sterilization Alternatives in the 1990's*, TAPPI Journal, Vol. 77, No.1, pp. 115-119.
12. Schneider, P.M., 1996, *Le System de Sterilization Abtox Plazlyte*, Revue de l'APPHRO, Vol. 21, No. 3, pp.53-55.
13. Schneider, P.M., 1997, *Ethylene Oxide Sterilization: Employee Monitoring, Sterilization Technology for the Health care facility*, 2nd ed., M. Reichert ed., Aspen Publishers, Inc., Gaithersburg, MD, pp. 220-227.
14. Schneider, P.M., 1997, *Emerging Low Temperature Sterilization technologies (non-FDA Approved)*, Disinfection, Sterilization and Antisepsis in Health Care, W.A. Rutula, ed., Association for Professionals in Infection Control and Epidemiology, Inc., Washington DC, pp. 79-92.
15. Schneider, P.M., 2000, *Requirements for Parametric release of Steam Sterilized products*, Zentral Sterilization, Vol. 8, January, pp. 15-23.
16. Schneider, P.M., 2002, *Parametric release of Steam Sterilized products*, Managing Infection control, Vol. 2, No. 4, April, pp. 56-63.

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17. Schneider, P.M., 2004, *New Technologies for Disinfection and Sterilization*, Disinfection, Sterilization and Antisepsis: Principles, Practices Challenges and New Research, W.A. Rutala, ed., Association for Professionals in Infection Control and Epidemiology, Inc, Washington, DC, pp. 127-139.
18. Schneider, P.M. et al, 2004, *Performance of Various Steam Sterilization Indicators Under Optimum and Sub-Optimum Exposure Conditions*, Disinfection, Sterilization and Antisepsis: Principles, Practices Challenges and New Research, W.A. Rutala, ed., Association for Professionals in Infection Control and Epidemiology, Inc, Washington, DC, pp. 200-215.
19. Schneider, P.M. and M. Young, 2004, *Did You Know – Sterilization Process Monitoring*, Managing Infection Control, Vol. 4, No. 10, pp.66-71.
20. Reich, R.R., P.M. Schneider, C. Kinsley, 2005. *Global Sterilization: Making the Standards Standard*, Medical Device & Diagnostic Industry, Vol. 27, No. 3, March.
21. Schneider, P.M., 2007, *Technologies for Sterilization and Disinfection*, Disinfection, Sterilization and Antisepsis: Principles, Practices, Current Issues, and New Research, W.A. Rutala, ed., Association for Professionals in Infection Control and Epidemiology, Inc, Washington, DC, pp. 135-145.
22. Schneider, P.M., 2010, *New Technologies in Sterilization and Disinfection*, Disinfection, Sterilization and Antisepsis: Principles, Practices, Current Issues, New Research and New Technologies, W.A. Rutala, ed., Association for Professionals in Infection Control and Epidemiology, Inc, Washington, DC, pp. 105-120.
23. Schneider, P.M., 2010, *Routine Monitoring of the Steam Sterilization process in Healthcare Facilities*, Disinfection, Sterilization and Antisepsis: Principles, Practices, Current Issues, New Research and New Technologies, W.A. Rutala, ed., Association for Professionals in Infection Control and Epidemiology, Inc, Washington, DC, pp. 168-202.