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Curriculum Vitae

PRESIDENT ROBERT R. REICH

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Summary of Qualifications

Robert Reich is a microbiologist with over 35 years experience in the healthcare industry in the areas of Management, Validation, Quality and Regulatory Affairs. Extensive experience in both pharmaceuticals and medical devices. Pharmaceutical experience in aseptic processing, anti-neoplastic products, terminal sterilization of ampoules and vials, establishment environmental monitoring programs for both sterile and non-sterile dosage forms, OOS/CAPA investigations, cGMP and technical training, equipment and process validations including isolators, ovens depyrogenation tunnels, washers, etc. Medical device experience in contract sterilization, contract laboratory services, packaging, biological indicators, medical device manufacturing, environmental control and microbiologically related quality control, R&D, OOS/OOL investigations, regulatory submissions, and coordination regulatory inspections. He has been co-chair of HIMA technical committees on packaging validation and sterilization monograph review, as well as a member of task groups drafting guidelines on biological and chemical indicators, bioburden quantitation and microbiological methods for the assessment of packaging integrity. He has served a co-chair of ANSI/AAMI Industrial EO committee as well as a member of ISO/ANSI/AAMI technical standards committee on Biological Indicators, product EO residuals, alternative chemical sterilants, packaging, microbiological methods and aseptic filling. He has served as a member of the PDA task force drafting guidelines on the validation of dry sterilization and depyrogenation processes.

Professional Experience

PRESIDENT, *LexaMed, Ltd.*

- Responsible for overall corporate management and profitability of company including the consulting group, marketing and sales for consulting and laboratory services as well as proprietary products.
- Provide and coordinate consulting services in areas of microbiology, aseptic processing, sterilization (moist heat, EO, VHP, radiation, dry heat), QA audits (QSR, API, Aseptic operations, GLP), CAPA management and resolution, OOS investigations, environmental monitoring programs, domestic and international compliance (TGA, MHRA, FDA, Health Canada, etc), CCI and maintenance of sterility, biological indicators, etc.

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PRESIDENT AND CHIEF SCIENCE AND TECHNOLOGY OFFICER, *Pharmaceutical Systems, Inc.*

- Responsible for overall corporate management including marketing and sales for consulting and laboratory.
- Served as consultant on issues dealing with aseptic processing, EO, steam and radiation sterilization, development and use of biological indicators, packaging, pharmaceuticals and medical devices, sterilization validation, including isolator and barrier systems, equipment and process validation, regulatory submissions, gap analysis and compliance auditing, compounding pharmacy operations, environmental monitoring and basic microbiology.
- Numerous projects with major pharmaceutical and medical device companies in over 15 years of consulting, selected examples include:
 - Multiple National Pharmaceutical Company with focus on sterile oncological products
 - Development of environmental monitoring program for aseptic manufacturing facility, including anti-neoplastic products. Development of container closure integrity (CCI) and disinfectant efficacy programs. Author annual reports for WFI and viable environmental monitoring.
 - Coordinate Commissioning and validation effort for vial and ampoule facility expansion, including critical utilities, manufacturing equipment and filling suite qualification.
 - Medical Device Manufacturer of aseptically produced pre-filled syringes.
 - Coordinate and validate aseptic filling (manual) of syringes. Development in-process QC and release specifications.
 - Medical Device Manufacturer of orthopedic support products.
 - Validation of manufacturing isolator. Validation of EO and Radiation terminal sterilization processes. Coordinate/conduct finish product release testing. Develop endotoxin and sterility test methodologies. Compliance audits.
 - Global Pharmaceutical Company.
 - Review of environmental monitoring programs, generation of microbiological training modules, sterility test isolator validation, validation of automatic microbial ID systems, review aseptic filling operation and microbiological method review.
 - Assessment audits of facilities world-wide for compliance with US FDA and international regulatory requirements.
 - Pharmaceutical Manufacturer of Solid Dosage forms.
 - Non-sterile pharmaceutical manufacturer. Establish environmental monitoring program for multiple production sites, review of microbiological methods and raw material sampling. OOS/complaint investigations. Training basic microbiology and contamination control.

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- Generic Pharmaceutical Manufacturer.
 - Draft 483 responses, review microbiological methods, develop microbiological and environmental monitoring training modules. OOS investigations. Laboratory equipment validations.
- Global Medical Device Manufacturer of cardiac products.
 - International compliance audits against US FDA and International regulatory standards.
 - Review and modify terminal EO and Radiation processes, design environmental monitoring programs, assist with design of new clean room facilities, general microbiological consulting. Assist with 483 responses and CAPA investigations and resolution.
- Global Medical Device and Pharmaceutical Company.
 - BI manufacturing improvement processes. R&D on BI and sterilization monitoring products. Multiple facility compliance audits. Training basic microbiology and contamination control.
 - Assist in validation of isolator manufacturing facility for the production of transdermal patched product. Help establish environmental monitoring program and programs to validate controlled manufacturing areas.
- Pharmaceutical Manufacturer of sterile ophthalmic products.
 - Compliance audits. Enhancement of BI program, validation of terminal steam sterilization processes, development and validation of stopper washing and siliconization processes, and enhancement of laboratory testing programs. Training.
- Medical Device Manufacturer of dialysis products.
 - Investigate endotoxin product problem, identify root cause, and develop cleaning and sanitization method for product and water distribution systems. Validation of terminal EO and saturated steam processes.
 - Interfaced with FDA, served as expert witness in multiple lawsuits.
- Parenteral Pharmaceutical Manufacturer.
 - Develop and validate terminal steam process for vial and ampoule lines. Development microbiological and aseptic processing training modules. Validation container depyrogenation process. Enhance laboratory testing methods.
- Medical Device Manufacturer of sterilizers and sterilization monitoring products.
 - Improve BI manufacturing and testing systems. Validation of BI production equipment. Author 483 responses. Compliance audits/gap assessments.

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VICE PRESIDENT MICROBIOLOGY, *Ethox Corp.*

- Profit and loss, as well as technical responsibilities for ethylene oxide contract sterilization and related testing operations at both Ethox facilities.
- Increased sales in areas of responsibility fifty fold from 1982 to 1991.
- Profitable operation.
- Responsible for environmental monitoring and microbiological QC for two manufacturing facilities.
- Coordinated corporate laboratory operation for customer base of over 100 clients.
- Responsible for regulatory compliance of laboratory and sterilization for 2 facilities. Direct interface with FDA, international and client auditors.

SUPERVISOR OF MICROBIOLOGICAL RESEARCH, *Castle Company*

- Development and production of biological indicators.
- Research on spore production, mechanisms of EO damage to bacterial spores, recovery of EO injured bacteria, correlation of humidity and EO sterilization, storage stability of biological indicators, new decontamination and sterilization processes.
- Research on basics of steam and ethylene oxide gas sterilization

SUPERVISOR OF BIOLOGICAL QUALITY CONTROL LABORATORIES, *Pfizer, Inc.*

- Responsible for laboratories conducting Antibiotic potency, pyrogen assay (rabbit and LAL), sterility testing, particulate matter enumeration and identification, microbiology lab, environmental monitoring, and applied research and development.
- Aseptic manufacturing operation.

Professional Associations

To further develop his awareness of technical developments within the pharmaceutical industry, Robert Reich participates in the following professional associations:

- ◆ American Society for Microbiology
- ◆ PDA / Parenteral Drug Association
- ◆ ISO-International Standards Organization
- ◆ Society for Industrial Microbiology
- ◆ Association for the Advancement of Medical Instrumentation
- ◆ American Society for Testing and Materials.
- ◆ Editorial review board MD&DI magazine

Education

- ◆ Doctorate program, Microbiology, Indiana State University
- ◆ M.S., Microbiology, University of Wisconsin
- ◆ B.S., Microbiology, Rutgers University

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Publications

1. Reich, R.R., and C.L. Duncan. "Ultrastructural Changes Associated with Alteration of the Normal Germination System of *Clostridium perfringens* Type A Spores." Abst. Annual Meeting ASM. 1972. pg. 76.
2. Duncan, C.L., R.G. Labbe, and R.R. Reich, 1972. "Germination of Heat and Alkali-Altered Spores of *Clostridium perfringens* Type A by Lysoyme and an Initiation Protein." J. Bacterial. Vol. 109, Pp 550-559.
3. Reich, R.R., J.E. Whitbourne, and L.L. Morien. "Critical Evaluation of Ethylene Oxide Biological Indicator Performance Characteristics." Abst. Annual Meeting ASM 1978.
4. Whitbourne, J.E., and R.R. Reich, 1979. "Ethylene Oxide Biological Indicators: Need for Stricter Qualification Testing Control." J. Parenteral Drug Assoc. Vol. 33, Pp 132-143.
5. Labbe, R.G., R.R. Reich, and C.L. Duncan, 1978. "Alteration in Ultrastructure and Germination of *Clostridium perfringens* Type A Spores Following Extraction of Spore Coats." Canadian Journal of Microbial. Vol. 24, Pp 1526-1536.
6. Reich, R.R., J.E. Whitbourne, and A. McDaniel, 1979. "Effect of Storage Conditions on the Performance of *Bacillus stearothermophilus* Biological Indicators." J. Parenteral Drug Assoc. Vol. 33, Pp 228-234.
7. Reich, R.R. 1979. "Unilab: A New and Improved Biological Sterilization Monitoring System." Presented Annual Meeting Canadian Hospital Infection Control Association.
8. Reich, R.R. 1980. "Effect of Sublethal Ethylene Oxide Exposure on *Bacillus Subtilis* Spores and Biological Indicators." J. Parenteral Drug Assoc. Vol. 34, Pp 200-211.
9. Reich, R.R. 1980. "Storage Stability of *Bacillus subtilis* Ethylene Oxide Biological Indicators." Appl. and Environmental Microbial. Vol. 39, Pp 227-229.
10. Reich, R.R. and L.L. Morien, 1980. "Storage Stability of *Bacillus stearothermophilus* and *Bacillus subtilis* Biological Indicators." In proceedings of the Third Pharmaceutical Manufacturers Assoc. Seminar on Validation of Sterile Manufacturing Processes: Biological Indicators. Chicago, IL. Pp. 54-67.
11. Carpender, D.F., M. Coleman, T.L. Hansen, D. Hass, C. Flahive, J. Mello, C. Phillips, R.R. Reich, and P.M. Schneider, 1981. "Methods of Bioburden Evaluation, Developments in Industrial Microbiology", Vol. 22. Pp. 323-328. Society for Industrial Microbiology, Arlington, VA.
12. Reich, R.R. 1981. "*Bacillus stearothermophilus* Spore Suspensions: Effect of Storage Conditions and Time on Viability and Moist Heat Resistance." J. Parenteral Sci. and Technol. Vol. 35, Pp 74-78.

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14. Reich, R.R. and L.L. Morien, 1982. "Influence of Environmental Storage Relative Humidity on Biological Indicator Resistance, Viability, and Moisture Content." Appl. and Environmental Microbial. Vol. 43, Pp 609-614.
15. Reich, R.R. and J.E. Whitbourne, 1982. "Dosimetric Release of Steam Sterilized Products." Presented Annual Meeting ASM 1982, Atlanta, Georgia.
16. Reich, R.R. 1982. "In-Hospital EtO Sterilization." Particulate and Microbial Control, No. 1, Vol. 1, Pp 69-71.
17. Reich, R.R. and G.T. Frederick, 1982. "Microbial Barrier Properties of Sterilizable Glassine paper Used for BI Packaging." Particulate and Microbial Control. No. 2, Vol. 1, Pp 71-74.
18. Reich, R.R., 1983. "A comparison of the Microbial Barrier Properties of vented and Non-Vented Luer Guards." Particulate and Microbial Control. No. 4, Vol. 2, Pp 46-49.
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24. Reich, R.R., 1985. "A Method for Evaluating the Microbial Barrier Properties of Intact Packages." Med. Device and Diagnostic Industry. No. 3, Vol. 7, Pp 80-88.
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29. Reich, R.R. and H.D. Anderson, 1986. "Sterilization of Membrane Filters with Ultraviolet Irradiation." Pharmaceutical Manufacturing, No.1, Vol. 3, Pp 12-15.
30. Reich, R.R., 1986. Packaging Films: "A Method of Microbial Barrier Evaluation." Med. Device and Diagnostic Industry. No.2, Vol. 8, Pp 19-21.
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34. Reich, R.R., Sharpe, D.C. and H.D. Anderson, 1988. "Accelerated Aging of Packaging: Considerations, Suggestions and Use Expiration Date Verification." Med. Device and Diagnostic Industry. No. 3, Vol. 10, Pp 34-39.
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