JEANNE MOLDENHAUER
Vice President
Summary of Qualifications

Jeanne Moldenhauer is a senior quality assurance/regulatory affairs professional with extensive background in the development and management of a variety of sterilization and validation processes in the healthcare industry. She has extensive practical background in both the manufacturing facilities and corporate operations. Jeanne has a proven track record of successful Device, NDA, sNDA, ANDA, and DMF submissions to FDA. This has included an extensive background in CMC development for drugs, and special expertise in sterile process validation documentation. Jeanne has been very involved in the remediation of contamination issues including: sterility test failures, media fill failures, mold contamination, and *Burkholderia cepacia.* She works extensively with methods for remediation, prevention, and monitoring of contamination. She also has extensive background in the rehabilitation of companies with negative FDA findings, restoring them to compliance. Additionally, she has substantial experience in assessing and validating laboratory and production facilities where solutions were needed for regulatory purposes. She is a Certified Quality Engineer (CQE) and Certified Quality Manager (CQM) (through the American Society for Quality). Jeanne has expertise in utilizing information technology to achieve results in quality improvement and cost savings. She has served on the Scientific Advisory Board, Program Advisory Board and Technical Book Advisory Board and was an Interest Group Leader for the Parenteral Drug Association (PDA) (1998-2016). Jeanne has also served on advisory committees for emerging technologies (rapid methods), aseptic processing and sterilization for FDA. She is a frequent speaker and trainer for a variety of topics within the device, pharmaceutical and biotechnology industries.

Jeanne was given several awards including: Distinguished Author/Editor of the Year (from PDA) several different books; Jim Agalloco Award (from PDA) for training courses, 2019 Martin Van Trieste Award (PDA) lifetime achievement award.

She served on Scientific Advisory Boards for several companies in the area of rapid microbiology.

Expert Witness for Several Cases

In the Patent Infringement case of Astrazeneca et al. vs. Breath Limited et al. IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY CAMDEN VICINAGE Consolidated Civil Action No.08-1512 (RMB/AMD) presiding Judge Bumb wrote a 166 page decision. She referred to Jeanne Moldenhauer 40 times in the decision:

Ms. Moldenhauer convincingly testified (73), persuasively explained that, (86); it also demonstrates, consistent with the testimony of Ms. Moldenhauer(90) This testimony was convincing.(93) Ms. Moldenhauer credibly testified.(95)

Other Expert Witness Cases

- International Patent Court – Steam Sterilization Issue
- Sealed Cases, four class action suits for patient damages – Sterility Failure Issues
- Patent Infringement for Microbiological Software Trending Program

Professional Experience

VICE PRESIDENT,
Excellent Pharma Consulting, Inc.
Jeanne serves as a senior quality and regulatory consultant. As part of this position she serves as the microbiology and/or regulatory consultant for several companies. She acts as a regulatory consultant for several rapid microbiology companies. Additionally, she consults on various areas of quality management and quality engineering, microbiology, rapid microbiology, sterility assurance, aseptic processing, risk assessment, compliance, and regulatory submissions. Jeanne works with compounding pharmacies and the equipment for use in these pharmacies to provide guidance on implementation of USP <797> as well as microbiology and aseptic support for regulatory submissions. She also works with regulatory submissions in the device, drug, and biologics areas.

Jeanne routinely investigates contamination events, e.g., sterility failures, media fill failures, mold contamination, *B. cepacia* contamination, and high bioburden levels. She is very involved with methods for detection, rememdiation, and prevention of contamination.

PHARMA CONSULTANT,
Vectech Pharmaceutical Consultants, Inc.,
As a Pharma Consultant, Jeanne was responsible for the creation of the Rapid Microbiology User's Group. This group hosted a monthly newsletter for the industry and annual conferences. Additionally, she was responsible for numerous projects in several different areas of expertise, e.g., sterilization, sterility assurance, environmental monitoring, aseptic processing, container closure integrity, rapid microbiological methods, regulatory submissions (NDA's, ANDA's, Sterile Process Validation Packages), compliance audits, comparability protocols, resolution of compliance issues, quality assurance, training programs, and so forth.

During this time period, she successfully developed and implemented a regulatory and validation strategy that resulted in several companies receiving FDA approval for a same day sterility test methodology. She has also been successful in submission of numerous Comparability Protocols, e.g., changes in manufacturing sites, addition of capacity, rapid microbiological methods, and so forth. Additionally, she participated in conducting due diligence activities for companies purchasing other companies, as well as for evaluation of new technologies.

VICE PRESIDENT, REGULATORY AFFAIRS AND TECHNICAL SERVICES,
Jordan Pharmaceuticals, Inc.
As Vice President of Regulatory Affairs and Technical Services at Jordan Pharmaceuticals, Inc., Jeanne developed and implemented a technical services department, which included validation, calibration, a microbiology department and QC Microbiology. She successfully staffed all departments, and implemented policies and procedures that were subsequently approved by the FDA. Jeanne was instrumental in resolving regulatory issues, which had been acquired by Jordan Pharmaceuticals in the purchase of the company from its former owners, with the FDA District and Washington offices. Additionally, Jeanne developed and implemented Jordan's regulatory affairs and compliance departments, and created ANDA and NDA templates to be used for regulatory submissions. Finally, Jeanne developed and implemented a Regulatory Affairs department, which she staffed and trained.

CONSULTANT, *Bracco*

As a consultant, Jeanne served as an expert witness in an international patent suit on sterilization

development and validation, which Bracco went on to win.

SENIOR MANAGER, REGULATORY AFFAIRS/STERILITY ASSURANCE and MANAGER, STERILITY ASSURANCE, *Fujisawa USA, Inc*.
At Fujisawa, USA, Inc., Jeanne established the quality systems for documentation for the company's manufacturing plants, which included corporate specifications, requirements for documentation of equipment, normal operation, release criteria, validation, and handling of aberrant conditions. She was a member of the team responsible for analyzing, identifying and correcting a nationwide recall of over 500 batches of product due to "short-fill". The error was corrected quickly, which allowed for production to resume with minimum downtime, and the regulatory compliance issue with the FDA was resolved.

Jeanne managed the submission of numerous NDA and ANDA products that were successfully approved by FDA. She also was responsible for the on-going maintenance of these submissions. She was also responsible for the development, submission and maintenance of numerous Drug Master Files.
Jeanne developed and standardized regulatory documents to support sterile process validation for drug product applications to the FDA. In addition, she assessed the validation statistics of domestic and foreign facilities for process validation and regulatory liability risk. She trained audit teams, identified deficiencies, and determined necessary requirements within established timelines. While at Fujisawa, Jeanne developed a validation strategy to meet FDA requirements for the software used for the microprocessor control of sterilizers. She designed and conducted training for the software manufacturer's employees on validation procedures and applicable regulatory requirements. Finally, Jeanne conducted an intense review of regulatory requirements and sterilization cycles, and devised a plan to standardize sterilization cycles. This standardization reduced sterilizer down time, resulting in a $13 million cost reduction per year.

SENIOR RESEARCH ASSOCIATE , *Baxter Healthcare*
As a Senior Research Associate for Baxter Healthcare, Jeanne developed an action plan to disprove the FDA determination that a method used for thermal death time testing of a drug was not appropriate. She managed the investigation and prepared the final report for Baxter senior management and the FDA. The drug was subsequently approved, and the FDA praised the quality, accuracy and approach used in the report. Jeanne also developed a lab design for Baxter and coordinated the building, stocking, validation and implementation of the laboratory. She participated on multiple project teams which developed better strategies for how and when testing should be performed. Additionally, Jeanne developed and validated microbiological methods for more than 50 different "difficult to validate" drugs, resulting in FDA approval on all.

Education
- Bachelor of Arts in Biology, University of Missouri
- Master of Science in Biology, Loyola University

Technical Seminars & Courses
Jeanne has participated in numerous seminars and courses that contribute to her continuing education in pharmaceutical manufacturing processes and technology and safety. These courses include, but are not limited to:
- Phil Crosby Defect Free Quality
- CpK Analysis
- Train the Trainer-GMPs
- Statistical Packages for Regulatory

Submissions
- Six Sigma Quality
- Quality Improvement
- Kaizen Quality
- Chemistry Manufacturing and Controls Section Development
- Submission of ANDAs
- Sterile Process Validation Documentation to be Submitted in Product
- Applications
- Pharmaceutical Microbiology
- Sterilization Microbiology and Engineering
- D-value and z-value analysis
- Sexual Harassment Training
- Ethics and Integrity Training
- GMPs
- Advanced GMPs
- Statistical Analysis and Design of Studies
- Aseptic Processing
- Environmental Monitoring
- Parametric Release
- Sterilization and Aseptic Filling Regulations
- PAC SAS Training
- PDA meetings (At least two/year) for the last 20 years
- Computer Validation Auditing of Suppliers
- Preparation for the CQE Exam
- Preparation for the CQM Exam
- Environmental Control for Aseptic Processing
- Sterility Testing – USP
- Microbiology Data Media Fills
- Current uses of Microbiological Testing during
- Stability Studies

Professional Associations

To further develop her awareness of technological developments within the pharmaceutical industry, Jeanne Moldenhauer participates in the following professional associations:

- Member of the PDA / Parenteral Drug Society – Microbiology/Environmental Monitoring Interest Group Leader, Scientific Advisory Board (2000-2015), Program Advisory Board (periodically), Technical Book Advisory Board, Instructor at the Training and Research Institute (periodically), Participant in Many Task Forces
- Regulatory Affairs Professionals Society (RAPS)
- Rapid Microbiology Users Group (RMUG), founder and Editor in Chief from 2002 to 2007
- Institute of Validation Technology
- American Society for Quality (ASQ) – Certified Quality Engineer, Certified Quality Manager

Courses Presented

Jeanne has presented numerous seminars and lectures during her career in the pharmaceutical and healthcare industry. These courses and lectures include, but are not limited to:

- Sterilization Microbiology - Basic Microbiology - Aseptic Filling Course Instructor - Environmental Control - Sterilization of Commodities - Moist and Dry Heat Sterilization Validation - LAL Basics and Oven Depyrogenation - Product Contamination Testing - Feasibility of Using Scan RDI for Biological Indicator Enumeration - Contributing Factors to Biological Indicator	- B. coagulans resistance in various Parenteral solutions - Software Validation Requirements - Handling Aberrant Sterilization Cycles - Training of Operators - Sterile Product Development - Determining Whether a Product can be Steam Sterilized - The Myth of Harmonization for Steam Sterilization - The Validation Master Plan

Variability - Steam Sterilization Cycle Development - Container Closure Integrity Testing - Validation of Rapid Microbiology Methods - CpK Analysis - Sterilizer Validation - Environmental Monitoring for Aseptic Filling - Development of Quality Systems - Quality Engineering Course - Quality Manager Training - Microbiology Laboratory Training - Microbiology for Non- Microbiologists - Pharmaceutical Microbiology -Comparability Protocols	- Writing SOP's - Writing Validation Plans - Preparing for FDA Inspections - Systems Based Inspections - Quality By Design - Risk Based Manufacturing - Auditing Facilities - Sterile Process Validation Documentation - Submissions - Requirements for CMC development - Product Development Requirements - Training for FDA Drug School - Sterile Fill Comparability - PAT Submission-Rapid Microbiology - Conducting Audits - Microbial Data Deviations -Rapid Sterility Testing, overview, validation and implementation

Publications

1990 - 1999

- Effect of 24 hour Room Temperature Hold Time on Heat Resistance of *B. coagulans* Spores Suspended in 10% Calcium Gluconate, **PDA Journal of Science and Technology**, Vol. 48, p.50
- Effect of Rubber Composition, Preservative, Pre-treatment and Rinse Water Temperature on Moist Heat Resistance of *B.stearothermophilis* ATCC 12980, **PDA Journal of Science and Technology**, Vol. 49 (1), Jan-Feb 95, p.29
- Heat Resistance of *B.coagulans* Spores Suspended in Various Parenteral Solutions, **PDA Journal of Science and Technology**, Vol. 49 (5), Sep-Oct 95, p.235
- Microbiological Barrier Assessment of Tyvek Stopper Packaging for Rubber Closures, **PDA Journal of Science and Technology**, Vol. 50 (6), Nov-Dec 96, p.391
- Antimicrobial Resistance of Three Species of Bacillus to Thirty Various Antimicrobial Agents, **PDA Journal of Science and Technology**: p.324
- Determining Whether a Product is Steam Sterilizable, **PDA Journal of Science and Technology**, Vol. 52 (1), Jan-Feb 98, p.28
- Resolving Differences in Biological Indicator Performance Characteristics, **PDA Journal of Science and Technology**, Vol. 53 (4), July-Aug 99, p.137
- Development of an Oil-based Dye Immersion Test for Container Closure Integrity Evaluation (Haloperidol), **PDA Journal of Science and Technology**, June 1998
- Comparison of Incubation Temperatures, **PDA Journal of Science and Technology**, August 1998

2000-2005

- Parametric Release, Much Ado About Nothing, with Russ Madsen, **PDA Journal of Science and Technology**, May 2000
- Steam Sterilization and the Myth of Harmonization. **Cleanrooms** Magazine, May 2000
- Committee Member, PDA Technical Report 33, Evaluation, Validation and Implementation of

New Microbiological Test Methods, **PDA Journal of Science and Technology**, Vol.55(3) Supplement, May-June 2000

- Performance Qualification of a Stopper Washer, with Robert Rajczak, **Journal of Validation Technology**,2001
- Contributed a chapter, Environmental Monitoring, for **Microbiology in Pharmaceutical Manufacturing**, edited by Richard Prince and published by Davis Horwood Publishers/PDA, June 2001
- Implementing an Automated System for Environmental Monitoring, **Cleanrooms** Magazine, August 2001
- Chaired Committee to Issue PDA Technical Report 13 (Revised) Fundamentals of an Environmental Monitoring Program, **PDA Journal of Science and Technology**, Vol.55 (5) Supplement, Sep-Oct. 2001
- Development of a Heat Sensitive Oxygen Sensitive Sterilization Cycle, A Case Study, **Journal of Parenteral Development 2003**
- *Steam Sterilization: A Practitioner's Guide*, published by Davis Horwood Publishers/PDA, April 2003
- Implementation of an Automated System for Environmental Monitoring, **BD Catapult**, May 2003 Vol.4(1)
- *Laboratory Validation: A Practitioner's Guide*. Editor. Davis Horwood Publishers/PDA. 2003
- Contributed a chapter, Biological Indicator (BI) Performance Standards and Control, for **Microbial Contamination Control in the Pharmaceutical Industry** by Luis Jimenez. Marcel Dekker, Inc. 2004
- Sutton, S.V.W. and Moldenhauer J. (2004). Towards an Improved Sterility Test. *PDA J of Science and*
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- Industry Concerns – Can Rapid Micro Become a Reality? *Rapid Microbiology Newsletter*, Vol.1 (1), May 2002, p. 2-3.
- Companies that Aren't Converting to Rapid Methods Won't Be in Business in 10 Years – The OPS Meeting, *Rapid Microbiology Newsletter*, Vol.1 (2), June 2002, p. 1-2.
- Issues with Validation and Hindrances to Purchase of a Rapid Microbiology System, *Rapid Microbiology Newsletter*, Vol.1 (3), July 2002, p. 1-2.
- Selecting a Rapid Microbiology System for Biological Indicator Testing, *Rapid Microbiology Newsletter*, Vol.1 (4), August 2002, p. 1-4.
- An Introduction to Polymerase Chain Reaction (PCR), *Rapid Microbiology Newsletter*, Vol.1 (5), September 2002, p. 1-4.
- Nucleic Acid Amplification, *Rapid Microbiology Newsletter*, Vol.1 (6), October 2002, p. 1-2.
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- Europe's Microbiology Conference of the Year, *Rapid Microbiology Newsletter*, Vol.1 (8), December 2002, p. 1-3.
- Industry Perceptions Regarding Rapid Microbiology Cripple the Industry, *Rapid Microbiology Newsletter,* Vol.1 (11), March 2003, p. 1-7.
- FDA is Paving the Way to Regulatory Approval and Implementation of Rapid Methods, *Rapid Microbiology Newsletter*, Vol.2 (1), April/May 2003, p. 1-3.
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- Applications of Raman Spectroscopy to the Microbiology Laboratory – Rapid Identification of Microorganisms, *Rapid Microbiology Newsletter*, Vol.2 (2), June 2003, p. 1-4.
- Use of Impedance Methods in Pharmaceutical Methods, *Rapid Microbiology Newsletter*, Vol.2 (3), July/August 2003, p. 1-3.
- Use of Photoluminescence Methods for Detection of Bacterial Endospores, *Rapid Microbiology Newsletter*, Vol.2 (4), September 2003, p. 1-4.
- Use of Imaging Processing Techniques for the Counting of Microbial Colonies, *Rapid Microbiology Newsletter*, Vol.2 (5), October 2003, p. 1-3.
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- Labor Saving Devices and Rapid Microbiology, *Rapid Microbiology Newsletter*, Vol.2 (6), November 2003, p. 1-2.
- Better Living (in the Microbiology Lab) Through Chemistry! *Rapid Microbiology Newsletter*, Vol.2 (7), December 2003, p. 1-2.
- Use of Impedance Methods – Microbial Limits/Detecting Pathogens, *Rapid Microbiology Newsletter*, Vol.2 (8), January 2004, p. 2-4.
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- The New Gram Stain and Other Staining Methods Using Molecular Probes, *Rapid Microbiology Newsletter*, Vol.2 (10), March 2004, p. 1-2.
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- Using a Known Level of Contamination When Validating Rapid Microbiology Systems, *Rapid Microbiology Newsletter*, Vol.3 (4), August 2004, p. 1-2.
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- FDA Approves an Automated Sterility Test Procedure, *Rapid Microbiology Newsletter*, Vol.3 (5), September/October 2004, p. 1-2.
- Comparability Protocols Part II, *Rapid Microbiology Newsletter*, Vol.3 (5), September/October 2004, p. 4-6.
- Comparability Protocols Part III, *Rapid Microbiology Newsletter*, Vol.3 (6), November/December 2004, p. 1-3.

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- Contributed three chapters, PDA TR #33, Comparability Protocols, and Validation of Rapid Methods to *Encyclopedia of Rapid Microbiological Methods* Volume I, by Michael Miller, Ph.D.
- PDA Technical Report No. 33: Evaluation, Validation and Implementation of New Microbiological Testing Methods.
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Industry Awards

PDA, Distinguished Author Awards for five different books

PDA, James Agalloco Award for Teaching at the PDA-Training and Research Institute (2008)

Patented (4 282326) a serum replacement for use in cell culture applications.

PDA, Service Award (2014)