Timothy D. Wood

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Microbiology and Cell Therapy Professional

Experienced professional with more than 35 years in Microbiology and Quality in cGMP / cGTP industry for cell and gene therapies, tissue-based regenerative medicines, biopharmaceuticals, radiopharmaceuticals, and medical devices. Specific emphasis on implementation of a variety of contamination control measures including setting up EM and personnel monitoring programs with risk-based approaches (e.g. FMEA, HACCP), rapid sterility methods, validation of microbiological and rapid methods, PCR Mycoplasma, microbial identification, aseptic processing and training, media fills, disinfection and sanitization, water and utility monitoring programs, radiation sterilization validation, bacterial endotoxin testing, among other control measures.

Areas of Expertise

- Cell, Gene, Tissue-based Therapies
- Rapid Microbiological Methods (RMM)
- Design of Risk-Based EM / Water Monitoring
- cGMPs Parts 58, 210, 211, 600s, 800s, 1271
- USP / Ph. Eur. / ICH Guidance and Regulations
- ISO 14644, 13408, 18362
- Method Validation / Protocols and Report Writing
- Aseptic Processing / Media Fills
- Disinfection, Sanitization, and Sterilization
- LAL / Bacterial Endotoxins
- Pharmaceutical Compounding
- Develop Basic Micro & Aseptic Training Materials
- Bioburden, Sterility, and Mycoplasma
- Design of Microbiology Deviation Investigations
- Microbial Identification Methods
- Subject Matter Expert in Regulatory Inspections
- Cleanroom Qualification (EMPQs)
- Quality Systems and Risk Management

PROFESSIONAL EXPERIENCE

CELL THERAPY MICROBIOLOGY CONSULTING, LLC – **Lynden, WA**
President and Principal Consultant, 7/2013 – Present
Independent consulting services primarily designed for the unique microbiology and contamination control challenges in the cell and gene therapy sector and biopharmaceuticals such as immunotherapies or similar regenerative medicines. Other services include aseptic processing and microbiological control of short shelf-life drugs, such as radiopharmaceuticals and sterile compounding.

- Biologics Consulting Group, Inc., Alexandria, VA: (2023-present). Worked as an Affiliate with Biologics Consulting Group for PolarityTE, Salt Lake City, UT. Writing microbiology SOPs, wrote EM site risk assessment, routine EM sampling program, and EM sampling methods including, viable and non-viable sampling, gowning qualification, personnel monitoring for skin tissue-based manufacturing.
- Celularity, Inc., Florham Park, NJ: (2022-2023). Disinfectant efficacy study review and gap analysis of executed coupon study and recommendations. Justification of alert / actions levels, EM program risk assessment for sample site justification and monitoring frequency, and justification for the reduction of routine and in-process EM samples.
- Theragent, Inc., Arcadia, CA: (2022-2023). Consulting on microbiological technical and scientific procedures and processes related to cell/gene therapy microbial control in cGMP Manufacturing setting. Including production and testing of activities in the manufacturing clean rooms as well as critical reagents, product intermediates and final products used in clinical trials.

- Crispr Therapeutics, Inc., Framingham, MA: (2021-2022). Development of EM and utility monitoring programs customized for Crispr facility. Specifically, EM risk assessment, utility monitoring program (e.g., CO_2, CCA, and other compressed gas), sample site selection and justification, SOPs for routine and in-process EM, personnel monitoring, alert/action investigation and response, LIMS trending and reporting, and gowning qualification procedures. Review of facility cleaning plans, disinfectant agents, frequency, and scope based on area classification and develop disinfectant efficacy project plan.
- Iovance Biotherapeutics, Inc. Philadelphia, PA: (2019-2021). Authoring and review of microbiological programs, procedures, and associated testing including EM and clean room certifications, microbiological SOPs, and disinfectant qualification strategies. Aseptic gowning risk assessment for reusable garments, technical review of PCR mycoplasma results from CMOs and mycoplasma OOS unexpected PCR results.
- Tessa Therapeutics, Singapore: (2020). Prepared EM strategy and HACCP based risk assessment report to establish qualification EM sampling plans for the Tessa cell processing facility and QC laboratory for all Grades A, B, C, D.
- NK Max America, Santa Ana, CA: (2019-2020). Evaluated manufacturing facility microbiological contamination controls and in-process sterility and final product safety release testing. Developed EM risk assessment sampling plan, SOPs, cleaning / sanitization program including agents, materials, application, and efficacy qualification.
- Rubius Therapeutics, Inc., Cambridge, MA: (2019). Reviewed validation reports and IND sections for product sterility and consulting related to the BacT/Alert® method qualification and suitability. Authored sections in regulatory submissions to justify sole use of the BacT / Alert® 3D system for drug product sterility testing to replace USP <71>.
- Discgenics, Inc. Salt Lake City, UT: (2018-2019). Review proposed cell therapy facility layout with estimates for QC Micro lab design, space allocation, and benchmarking with best industry practices and cGMPs. Generating risk assessment emphasizing aseptic processing, contamination controls, and EM for all Grades A – D. Specifically, product, materials, samples, and personnel flows; pressure differentials; appropriate Grades (at-rest, operational); BSC locations; risk-based EM sites for in-process and final fill/finish Grades A and B.
- Sigilon Therapeutics, Cambridge, MA: (2019). Review of pre-clinical cell therapy EM data and results per relevant industry guidance to assess for gaps. Provided recommendations on EM trend report format, data presentation, statistical analysis where applicable, and reporting structures, (e.g. charts, graphs, tables).
- Fate Therapeutics, San Diego, CA: (2018-2019). Provided training modules for manufacturing staff, covering aseptic techniques, working in BSCs and aseptic processing principles including, gowning, cleanroom behavior, and basic microbiology. Review new cell therapy manufacturing cleanrooms and report covering usage of these areas including, personnel, material, sample and waste flows; classifications; equipment and BSC locations; gowning; EM and PM; cleaning and sanitization agents, frequencies, flows, and sanitizing / disinfecting materials for entry into clean rooms and BSCs; appropriate segregation for multi-product and multi-donor concurrent operations; required start-up and qualification activities.
- WuXi AppTec, Inc. Philadelphia, PA: (2019). Review proposed architectural diagrams of cell therapy microbiology laboratory space and sterility testing area to ensure the design is fit for intended purpose.
- Gradalis, Inc. Carrollton, TX: (2018-2020). Provide risk-based approach for a new EM site plan program for a solid tumor cell processing facility. Developed an EM master plan that was executed for the design and performance of facility EMPQ. Developed pre-determined responses to EM excursions or environmental control failures. Developed a BacT/Alert® test method validation protocol as alternate test to USP <71> to accomplish reduced time from 14-days to potentially 7-days or less.
- Juno Therapeutics (Bristol Myers Squibb Co.), Inc. Seattle, WA: (2017-2018) Provided the design and development of documentation for rapid sterility method validation (Milliflex-Rapid, BacT/Alert®). Providing EM and microbiology expertise in support of BLA filing and readiness for pre-approval inspection. Consultation on validation of rapid Mycoplasma testing by PCR.

- Tessa Therapeutics, Singapore: (2017) Worked with HH Consulting, LLC to provide due diligence assessment on behalf of Temasek Holdings. Reviewed microbiological-related aspects of Tessa Therapeutics' CMC for proposed commercial cell therapy manufacturing facility. Determined standards of quality, identified gaps in processes and protocols, with recommendations on how to address these gaps.
- Bluebird Bio, Cambridge, MA: (2017) Assisting in the development and execution of rapid sterility testing for company's cell therapy product platforms.
- Argos Therapeutics, Durham, NC: (2017) Provided microbiology support for rapid sterility test validation by contract cell therapy manufacturer. Review and comment on company's rapid safety test regulatory filing including PCR Mycoplasma and rapid sterility.
- bioMerieux Corporation, Durham, NC: (2017) Providing a paper intended for publication discussing the validation of rapid alternate sterility testing methods of cellular therapy products. Paper to address several aspects including: regulatory requirements and expectations, considerations for test sample volumes, selection of challenge organisms, laboratory resource requirements and constraints (in-house vs. contract lab), estimates for Return on Investments (ROI), considerations for 361 vs. 351 cGMP cell products, and phase of product development whether in Phase 1, 2, 3, or commercially licensed cell products.
- Atara Biotherapeutics, Westlake Village, CA: (2016–2017) Review of GMP product manufacturing processes, with an emphasis on (a) microbiological design aspects of a planned CTL manufacturing facility, including lab design and benchmarking on best industry practices for microbiology methods and GMP compliance; and (b) development and review of microbiology QC SOPs and methods including rapid sterility in-house.
- Cognate Bioservices, Memphis, TN: (2016–2017) Evaluated the Company's EM policies and practices and provided EM risk assessment reports for existing as well as newly constructed aseptic cell processing areas. Assessments included personnel monitoring practices; material transfer / bioburden reduction policies; and EM trending. Revised the Company's SOPs for EM of Aseptic Processing Areas, including the build out of the Company's Memphis facility with an emphasis on baseline routine EM in anticipation of PAI and commercial readiness. Designed EM trending spreadsheet templates for trending of routine and personnel EM. Reviewed and revised Company's cleaning and sanitization program and assisting in disinfectant efficacy qualification.
- NIH, Department of Transfusion Medicine (DTM), Bethesda, MD: (2016) Reviewed microbiology programs and developed recommendations for multi-facility EM including assessments for number & locations of EM sites, frequencies, and justify site-specific alert and action levels. Assessed cGTPs / cGMPs against regulatory and accreditation standards. Reviewed aseptic processing practices, cleaning, and gowning SOPs. Provided comprehensive SWOT report with clear and supported recommendations.
- Kite Pharma, Inc. Santa Monica, CA. (2015) Provided microbiological risk review of CAR-T manufacturing process with recommendations on closing open process steps on batch records where feasible. Performed training sessions on aseptic processing for operators. Review and provided recommendations on product microbial testing methods. Contamination control recommendations on clinical/commercial facilities.
- Progenitor Cell Therapy (PCT Caladrius), Allendale, NJ: (2015) Evaluated companies EM and Microbiology product and safety testing programs at multiple facilities. Performed gap and FMEA risk analysis, provided recommendations to harmonize systems from site to site.
- Juno Therapeutics, Inc. Seattle, WA. (2015) Worked with Microbiological Consultants, LLC (Dr. Michael Miller) providing a summary white paper of the current regulatory expectations for validation of a rapid sterility test for autologous activated T-cell products regulated as biologics under cGMPs.

LEXAMED LTD – **Toledo, OH**

Consultant Sub-contracted work under LexaMed Ltd. Work covered services related to aseptic processing and microbiology for various manufacturing firms including aseptic filling, compounding, and radiopharmaceuticals.

- QuVa Pharma, Sugar Land TX. (2016) Created an aseptic process simulation master plan document to support sterile compounding manufacturing operations at QuVa Pharma 503B facilities.
- Fresenius-Kabi, Buffalo, NY: (2016) Provided EM risk assessment and EM site selection report for new aseptic processing Isolator filling lines.
- Par Pharmaceuticals, Rochester, MI: (2014) Comprehensive evaluation of the aseptic filling environmental and personnel monitoring programs at the Rochester 171,000 sq. ft. production facility. Provided well-received written comprehensive report with clear and supported recommendations.
- Cardinal Health, Dublin OH: (2014) Reviewed and revised the aseptic process media fill program applicable to 36 U.S. Cardinal Health PET (Positron Emission Topography) manufacturing sites. Defined and revised the Operator Qualification and Manufacturing Site Qualification SOPs and Batch Records for process simulation media fills.

DENDREON CORPORATION – **Seattle, WA**

QC Scientist / Sr. Scientist II, 2006 – 6 / 2013

- Responsible for the development of microbiological policies, ongoing multi-site support, and the design, implementation, and harmonization of the environmental monitoring (EM) programs and microbiological testing at all Dendreon commercial cell therapy processing facilities.
- Developed and validated Provenge® cell therapy microbiological testing methods at all commercial sites.
- Lead cross-site Microbiology Management Team and initiated micro method and EM improvements. Aided all Dendreon sites for microbiology troubleshooting, EM and sterility failure investigations.
- Development of automated microbiological and rapid endotoxin tests to reduce labor and TAT.
- Microbiology method and technology transfer to US satellite sites and EU CMO.
- Development and design of disinfectant efficacy studies and the qualification of cleaning and sanitization program for aseptic processing areas.
- Participated as SME in FDA and regulatory inspections at multiple manufacturing facilities.
- Given several presentations (e.g. ISCT, PDA, AABB symposiums) concerning development and validation of alternate sterility testing by BacT/Alert® method.

QC Microbiology Supervisor, 2003 – 2006

- Training and supervision of analysts in microbiology test methods, water and EM program, product testing, endotoxin, microbial IDs, data review and approval, setting goals and objectives, and timelines.
- Functioned for over two years as central EM program coordinator for multiple satellite CMOs. This included development of EM plans, site selections, executing / overseeing clean room PQ, and periodic trend reports. Write portions of Biological License Application (BLA) for microbiological testing and environmental controls.
- Performed successful feasibility studies resulting in obtaining FDA approval for using the BacT/Alert® alternate rapid sterility test method in lieu of biologics regulation 21 CFR 610.12.
- Radiation Sterilization Validation team member for medical devices: bioburden recovery, sterility testing, dose audits per AAMI, ISO, and VDmax guidelines.
- Member of cleaning validation team to develop procedures, swab recovery studies, and method validations.

QC and Sr. QC Associate, 12 / 1999 - 2003

- Responsible for setting up and implementing the Dendreon QC Microbiology laboratory.

- Training personnel and provided oversight of satellite environmental controls and product testing programs.
- Creating and revising SOP's, Test Methods, technical and validation protocols / reports.

ICOS CORPORATION – **Bothell, WA**
QC Associate, 05 / 1999 – 12 / 1999
- Responsible for testing of biopharmaceutical water systems and EM of purification/fermentation plant. Created and revised SOP's as needed. Work supporting cleaning validations, steam sterilizations.

DENDREON CORPORATION – **Seattle, WA**
Consultant, 04/1999 – 05/1999
- Consulted for Dendreon writing EM Policy Program, microbiological SOPs and testing methods to prepare company for initiating in-house microbiology testing program.

XCYTE THERAPIES – Seattle, WA
Microbiologist, 12 / 1998 – 03 / 1999

- Responsible for identifying and procuring laboratory test equipment, materials, and supplies for setting up the Xcyte Therapy QC Microbiology laboratory for the Seattle clinical facility.
- Provided research in order to provide cost effective, reliable, and compliant laboratory sampling and testing equipment. Responsible for creating the Xcyte microbiological laboratory methods and procedures.

CELLPRO – **Bothell, WA**
QC Microbiologist, 1993 – 12 / 1998

- Responsible for overseeing the QC microbiology function. Training of lab analysts and data review.
- Participated in successful Quality System and FDA inspections pre and post approval.
- Developed and validated microbiological tests of bioburden and sterility for sterile products and devices.
- Maintained existing EM and water monitoring programs. Developed new aseptic fill monitoring program.
- Sterility dose audits and execution of bioburden recovery and sterility testing in support of medical device radiation sterilization per AAMI and ISO Standards.
- Maintained water quality and environmental quality databases.
- Member of multiple project teams interfacing with Engineering, Manufacturing, Facilities, and QA.
- Performed microbiological testing including endotoxin, sterility, product bioburden, microorganism identification, and biological indicator testing for sterilization validations.

ABBOTT RESEARCH INC. (ABBOTT LABORATORIES) – Bothell, WA
R & D Technician / QC Technician, 1987 – 1993
- Responsible for development and testing of in-vivo continuous blood gas medical devices. Developed new sensor designs and manufacturing techniques.
- Responsible for training technicians in manufacturing process and functional testing
- Performed QC testing for device bioburden, toxicity, and LAL gel-clot assay.

PROFESSIONAL PROFILE

Education Bachelors Degree, Biology, Pacific Lutheran University – Tacoma, WA 1984

Affiliations Parenteral Drug Association (PDA)
International Society of Cellular Therapy (ISCT)

American Association of Blood Banks (AABB)
Pharmaceutical Microbiology Forum (PMF)

SPEAKING ENGAGEMENTS AND PRESENTATIONS

Invited Speaker: BioXchange Meeting. Philadelphia, PA. 2019.
Invited Speaker: BioXchange Meeting. Salt Lake City, UT. 2018.
Poster Presentations: International Society for Cell Therapy (ISCT) Annual Meeting. Montreal, NV 2018
Invited Speaker: AABB Annual Meeting. San Diego, CA. 2017.
Invited Speaker: AABB Annual Meeting. Anaheim, CA. 2015.
Poster Presentations: International Society for Cell Therapy (ISCT) Annual Meeting. Las Vegas, NV 2015
Invited Speaker: IVT Microbiology Week-Institute of Validation Technology. San Diego, CA. 2013.
Invited Speaker: Seventh Annual Somatic Cell Therapy Symposium-ISCT. Bethesda, MD. 2007.
Invited Speaker: Rapid Methods in Pharmaceutical and BioPharm Manufacturing-Barnett Int'l. Brussels. 2005.
Invited Speaker: 4th Annual Somatic Cell Therapy Symposium. Houston, TX. 2004.
Invited Speaker: International Society for Cell Therapy (ISCT) 9th Annual Meeting, Phoenix, AZ. 2003.
Invited Speaker: AABB Symposium and 27th Congress of the ISBT. Vancouver BC. 2002.

Continuing Education and Conferences

PDA Annual Meetings, Cell Therapy Workshop, Anaheim, 2017, San Diego 2019
AABB Annual Meetings, ISCT Annual and North America Regional Meetings
Open Conference on Compendial Change-Pharmaceutical Microbiology Forum (PMF), 2009
Pharmaceutical Water System Design and Operation-Center for Professional Advancement, 2008
Environmental Monitoring and Controls-Institute of Validation Technology, 2004
Validation Requirements for Rapid Microbiology-RMUG (Rapid Micro Users Group), 2002
Rapid Methods: Strategies for Automation, Detection, & Validation of Microbiology Test Methods-Barnett 2002
Cleaning Validation Seminar – Ionics Instruments. Taught by Destin LeBlanc 2002
Modern Pharmaceutical Microbiology-Advancing the Science, PDA Conference 2001
Critical Environments Seminar, by Anne Marie Dixon, Clean room Mgmt Assoc. 1999
Use of Disinfectants in Parenteral Facilities – James Wilson, PDA 1996
Radiation Sterilization/Terminal Sterilization of Injectables, PDA 1995
Advanced Environmental Monitoring – James Akers, PDA 1994

SCIENTIFIC PUBLICATIONS

Wood, Timothy D. "*Regulatory Perspective*: *Sterility sampling of cell and gene therapy products*". Cell & Gene Therapy Insights 2019; 5(9), 1247–1257.

Wood, Timothy D. *"Validation of the BacT/Alert® Microbial Detection System as an Alternate Rapid Sterility Test for Dendreon Active Cellular Immunotherapy Products"*. Encyclopedia of Rapid Microbiological Methods, Miller ed. PDA. 2013.

White Paper: Environmental Monitoring Considerations for Cellular Therapy Products, 2013.

White Paper: Validation and implementation of Alternate Sterility Tests for HCT/Ps, 2014.

AWARD

U.S. Patent # 4,651,476 "Compact Receptacle with Automatic Feed for Dissipating a High-Velocity Fluid Jet"