



## Trabue D. Bryans

CURRICULUM VITAE

President, BryKor LLC • 4132 JVL Industrial Park Drive • Marietta, Georgia 30066 • U.S.A. • (+1) 770.675.7960

### EDUCATION

University of Georgia. B.S., Microbiology: 1975  
Medical College of Georgia. M(A.S.C.P.) Certification: 1978  
Georgia State University. Selected M.B.A. course work: 1981-82

### CAREER / EXPERIENCE

1977 – 1978 Medical College of Georgia: Medical Technologist  
1978 – 1991 MacMillan Research: Chief Microbiologist, Director of Microbiology, Vice President  
1991 – 1993 NAMSA: General Manager, Coordinator of Technical Services  
1993 – 1995 Practical Consulting & Training: President  
1995 – 1997 Axios: Founder and President  
1997 – 2001 ViroMed Biosafety Laboratories (formerly Axios): Vice President and General Manager  
2001 – 2008 AppTec Laboratory Services (formerly ViroMed): Exec. Vice President and General Manager  
2008 – 2010 WuXi AppTec (formerly AppTec): Vice President and General Manager, Atlanta Division  
2010 – 2011 WuXi AppTec: Vice President of RA/QA and Service Development  
2012 – present BryKor LLC: President & Principal Consultant

### ACHIEVEMENTS

A.S.C.P. Registered Microbiologist, 1978  
M.R.I. Certification, Asbestos & Particle Identification, 1984  
Environmental Protection Division (Georgia), Water Lab Certification, 1985  
A.S.Q.C., I.S.O. Internal Auditor Certification, 1994  
A.A.T.C.C., Antimicrobial Activity Committee, 1986 - 2004  
A.S.Q.C./F.D.A. Biomedical Focus, Speaker, 1989, 1998, and 1999  
H.I.M.A., Sterilization 2000, Speaker, 1994  
A.A.M.I. Co-chair, Microbiological Methods Committee, WG8, 1992 - 2006  
I.S.O. TC 198 U.S. Delegate, Microbiological Methods, 1993 – Present  
A.A.M.I., Sterilization Standards Committee, Executive Board, 2000 - 2019  
A.A.M.I., Board of Directors, 2002 - 2008  
M.D.D.I Magazine, Editorial Advisory Board, 2003 – 2007  
M.D.A. Industrial Sterilization Course, Instructor, 1987, 2001 and 2003  
MDS Nordion Gamma Sterilization Seminar, Speaker, 2002  
A.A.T.B., Standards Committee, 2004 – 2006  
Pharma Conference, Validation Workshop instructor, New GTPs, Speaker, 2005 and 2007  
A.A.M.I. Webinar on Reprocessing Medical Devices, Instructor, 2006  
AAMI/AATB Course, Radiation Sterilization of Tissues, Instructor, 2008  
A.A.M.I., Co-chair, Assurance of Sterility WG90/WG15, 2008 - 2020  
A.A.M.I. Standards Board, 2008 - 2018  
A.A.T.B., Scientific & Technical Affairs Committee, 2009 - 2011

A.A.M.I., Co-chair, Radiation Sterilization WG2, 2010 - 2015  
 I.S.O. TC/198, U.S. Delegate, Radiation Sterilization, 2010 - 2016  
 A.A.M.I, Committee on Standards Strategy, 2010 - 2013  
 I.M.R.P. Conference, SAL & Risk Analysis, Speaker, 2011  
 FDA / AAMI Reprocessing Summit, Speaker, 2011  
 A.A.M.I, Standards Developer Award, 2012  
 I.S.O. TC/198, Convener, WG8 Microbiological Methods, 2013 – 2021  
 I.S.O. TC/198, U.S. Delegate, Assurance of Sterility, 2013 – Present  
 I.S.O. TC/198, Chairman's Advisory Group, 2013 – 2021  
 Kilmer Conferences, Presenter, 2016, 2019 & 2022  
 A.A.M.I - Spirit of AAMI Award 2022

## PUBLICATIONS – AUTHOR & CO-AUTHOR

- *Validating Radiation Sterilization*, M.D.D.I., December 1992
- *There's A Fungus Among Us*, The Validator, March 1994
- *Investigating AAMI Radiation Audit Results*, M.D.D.I., May 1994
- *Industry's Struggle with Pyronema*, M.D.D.I., October 1994
- *Using Bioburden Spikes in Radiation Dose Setting*, The Validation Consultant, January 1996
- *Industry Responds to Pyronema Domesticum: HIMA Screening Studies*, M.D.D.I., September 1997
- *Radiation Sterilization – Current Validation Methods*, Journal of Validation Technology, November 1999
- *Dose Audit Action for Product Families*, Nordion 6<sup>th</sup> GPS paper, June 2002
- *Using Recovery Tests to Assess Bioburden Procedures*, M.D.D.I., October 2002
- *Bacterial Endotoxin Testing: A Report on the Methods, Background, Data, and Regulatory History of Extraction Recovery Efficiency*, BI&T, January/February 2004
- *A Comparison of Incubation Periods for Bioburden Isolates*, BI&T, January/February 2006
- *Evaluation of the Sterility Test for Detection of Microbial Contaminants of Allografts*, Cell & Tissue Banking, March 2006
- *Sterility Assurance Levels for Terminal Sterilization of New/Emerging Healthcare Products*, CDC 5<sup>th</sup> Decennial Conference, March 2010
- *Medical Device SALs and Surgical Site Infections: A Mathematical Model*, BI&T, May/June 2012
- *The Bioburden Estimate: Not Just Math, But Microbiology*, A.A.M.I BI&T Industrial Sterilization, Sep 2013
- *Product Sterility Testing . . . To Test or Not to Test? That is the Question*, A.A.M.I BI&T Industrial Sterilization, Summer 2016
- *Radiation Dose Setting Method 2 and Modified Method 2: Use and Experience*, A.A.M.I. BI&T Horizons, Summer 2019
- *Radiation Sterilization: Dose is Dose*, AAMI Industrial Sterilization: Process Optimization and Modality Changes, Summer 2020
- *Dose Audit Failures: Truth and Consequences*, AAMI Industrial Sterilization: Process Optimization and Modality Changes, Summer 2020
- *Block's Disinfection, Sterilization and Preservation*, 6<sup>th</sup> ed., Ch 64: Bioburden Assessment and Tests for Sterility, 2020
- *Sterility Assurance Across Sectors – New Paradigms and Tools*, Frontiers in Medical Technology, Vol 3, Article 622710, August 2021
- *Sterility Assurance Levels & Aseptic Processing: An Introduction to Alternative SALs and Current Efforts to Promote Consistent Alternative SAL Language*, AAMI Array, 9 March 2023
- *Bioburden Method suitability – A Practical Solution to Screening for Inhibition*, BI&T, Aug 2023