

John R. Gillis, Ph.D.

Dr. John R. Gillis is president and founder of SGM Biotech, Inc., Bozeman, MT. SGM manufactures biological indicators for monitoring most types of sterilization processes. He has developed biological indicators for monitoring many of the sterilization processes in use today. These include steam, dry heat, ethylene oxide, hydrogen peroxide, and radiation sterilization systems. These products are used worldwide by both healthcare and industrial manufacturers of sterile products.

Dr. Gillis, in his 45 years of experience, has become an internationally recognized expert in the application of bacterial spores to monitor sterilization processes.

Dr. Gillis studied the mechanism of bacterial sporulation in his graduate research. He was in charge of Spacecraft Sterilization projects for General Electric's Space Technology Center under contract with the U.S. National Aeronautics and Space Administration. Dr. Gillis was responsible for developing sterilization processes for both manned and unmanned spacecraft and microbiological controls associated with interplanetary missions and planetary quarantine. Dr. Gillis participated in the formulation of the concept of sterility assurance levels that evolved from the NASA sterilization program.

Dr. Gillis was a pioneer in the development of validation programs for industrial sterilization processes as Director of Process and Product Development at American Sterilizer Company (AMSCO) and was responsible for developing and manufacturing commercial biological indicators and their manufacturing processes.

In 1978, Dr. Gillis founded Skyland Scientific Services to assist manufacturers of sterile products to develop and validate their sterilization processes; in 1986 he co-founded Quality Sterilization Services, an ethylene oxide contract sterilizing facility; and in 1987 a co-founder of Biotest Laboratories, a contract laboratory performing sterility testing, bioburden analysis, pyrogen testing and ethylene oxide residual testing for manufacturers of sterile products.

Dr. Gillis is the inventor of several sterilization and biological indicator patents. He was a member of the USP XX's Expert Advisory Committee on Microbiology; served on the FDA Bureau of Medical Devices GMP advisory committee on Sterilization and Validation; was invited by the Canadian Standards Association to participate in establishing sterilization standards; and has actively worked with the Association for the Advancement of Medical Instrumentation and the Health Industries Manufacturing Association. He was a member of the AAMI committee that wrote the first BIER vessel standard for evaluating biological indicators. He has also taught courses for the Parenteral Drug Association and the International Society for Pharmaceutical Engineers in the areas of Validation and Microbiology. He is currently a U.S. delegate to the ISO committee for biological indicator standards.

Dr. Gillis holds – B.S. in Biology from Bucknell University, 1962
M.S. in Microbiology from Syracuse University, 1965
Ph.D. in Medical Microbiology from the University of Montana, 1972