



Rick Gillis, Ph.D.

Senior Consultant, Regulatory Affairs

EXPERIENCE:

- Scientific Advisor, Board of Directors, M-Vac Systems Inc.
- Production Manager, SGM Biotech, Inc.
- Graduate Research Assistant, University of Rochester
- Lead Industrial Engineer, 777 Boeing Commercial Airplane Group, Inc.
- Validation Specialist, JR Gillis Associates

AREAS OF EXPERTISE:

Including, but not limited to

Products:

- Dental hand pieces
- Reprocessed medical equipment
- Contact lenses
- Catheters
- Electrocautery devices
- Self-contained biological indicators

Disciplines:

- FDA 510(k) preparation and submission
- FDA Quality System Regulations – 21 CFR Part 820
- ISO 13485-Medical Devices – QMS
- ISO 13485 auditing
- ISO 11138-Sterilization of Health Care Products-Biological Indicators
- GMP auditing
- Medical Device Process validation
- Sterilization cycle and process development: steam, ethylene oxide, dry heat, HPV
- Steam-in-Place
- WFI and RO/DI systems
- Biological Indicators

EDUCATION:

- Ph.D. Microbiology, University of Rochester, Rochester, NY, USA
- M.Sc. Microbiology, Montana State University, Bozeman, MT, USA
- B.Sc. Biology, Montana State University, Bozeman, MT, USA

PROFESSIONAL AFFILIATIONS:

- Member, American Society for Quality (ASQ)
- Member, Association for the Advancement of Medical Instrumentation (AAMI)

- Member, Parenteral Drug Association (PDA)



- Member, Society for Quality Assurance (SQA)

TRAINING AND CERTIFICATIONS:

- ASQ Certified Biomedical Auditor
- ASQ ISO 13485 Lead Auditor
- AAMI QSR training

PUBLICATIONS AND PRESENTATIONS:

- Gillis RJ, White KG, Choi KH, Wagner VE, Schweizer HP, Iglewski BH. Molecular basis of azithromycin-resistant *Pseudomonas aeruginosa* biofilms. *Antimicrob Agents Chemother*. Sept 2005; 49(9):3858-67.
- Gillis RJ, Iglewski BH. Azithromycin retards *Pseudomonas aeruginosa* biofilm formation. *J Clinical Microbiol*. Dec 2004; 42(12):5842-5.
- Wagner VE, Gillis RJ, Iglewski BH. Transcriptome analysis of quorum-sensing regulation and virulence factor expression in *Pseudomonas aeruginosa*. *Vaccine* Dec 2004;22 suppl 1:S15-20.
- DeKievit TR, Parkins MD, Gillis RJ, Srikumar R, Ceri H, Poole K, Iglewski BH, Storey DG. Multidrug efflux pumps: expression patterns and contribution to antibiotic resistance in *Pseudomonas aeruginosa* biofilms. *Antimicrob Agents Chemother*. June 2001; 45(6):1761-70.
- DeKievit TR, Gillis R, Marx S, Brown C, Iglewski BH. Quorum-sensing genes in *Pseudomonas aeruginosa* biofilms: their role and expression patterns. *Appl. Environ. Microbiol*. Apr 2001;67(4):1865-73.
- Geesey GG, Gillis RJ, Zhang HJ, Bremer PJ. Influence of surface features on microbial colonization and susceptibility to corrosion of stainless steels used in the food processing industry. *Proc AIWC* Feb 1996;43(3):1053-67.
- Gillis, RJ, Gillis JR. Microbials: A comparative study of bacterial attachment to high-purity water system surfaces. *Ultrapure Water*. Sept 1996;13(6):27-36.
- Geesey GG, Gillis RJ, Avci R, Daly D, Hamilton M, Shope P, Harkin G. Influence of surface features on bacterial colonization and subsequent substratum chemical changes of 316L stainless steel. *Corrosion Sci*. Jan 1996; 38(1):73-95.
- Hamilton MA, Johnson KR, Camper AK, Stoodley P, Harkin GJ, Gillis RJ, Shope PA. Analysis of bacterial spatial patterns at the initial stage of biofilm formation. *Biometrics*. 1995; 37(4):393-408.