ANASTASIA G. LOLAS

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SUMMARY

- Microbial control, sterility assurance
- FDA inspection readiness
- Facility audits
- Internal audits
- Remediation of CGMP/compliance and microbiology issues
- Review of deviations, investigations, and CAPA
- CMC microbiology review of NDAs, ANDAs and biotechnology therapeutic protein BLAs
- Technical writing of regulatory submissions

EDUCATION

- *B.S. in Biology* (Food Science Option), 1997, *Magna Cum Laude*, Virginia Polytechnic Institute & State University (VPI), Blacksburg, VA
- *M.S. in Food Science* (Food Microbiology/Fermentation), 1999, University of Illinois at Urbana-Champaign

WORK EXPERIENCE

Owner/President, May 2011-present, Visionary Pharma Consulting LLC, Olney, MD

Independent consulting services to the pharmaceutical industry on a wide range of topics utilizing prior regulatory submission and inspection experience at the U.S. Food and Drug Administration (FDA).

Regulatory compliance, writing and review of the CMC section or Module 3 (CTD) of drug and biologic regulatory applications, meetings with the FDA, preparation for pre-license/pre-approval and GMP inspections of therapeutic protein drug substance and drug product manufacturers, GMP assessment, audits, qualification, validation, microbiological process controls, microbial control, sterility assurance, review of deviations, investigations, and CAPAs.

Microbiologist, September 2008 – April 2011, Biotech Manufacturing Team, Division of Manufacturing and Product Quality, Office of Compliance, CDER, FDA, Silver Spring, MD

- Wrote over 50 technical reviews of the CMC section of investigational, original and post-approval biologics license applications (BLA) regarding microbial control of therapeutic protein drug substances produced by fermentation in bacterial, yeast or mammalian cell systems and the microbiological quality and sterility assurance of the final drug product.
- Reviewed and evaluated:

- Microbial control of therapeutic drug substance processes.
- Validation of drug product aseptic processes.
- Filter-sterilization, sterilization and depyrogenation of equipment, containers and components, media fill simulations, container-closure integrity.
- Environmental monitoring protocols, test procedures and data.
- Sterility, bacterial endotoxins, container-closure integrity, microbial limits and preservative effectiveness.

- Conducted pre-approval and pre-license inspections of facilities manufacturing therapeutic protein products. Inspections were systems-based and assessed the Quality System, Facilities and Equipment System, Production System, Materials System, Laboratory Controls System, Packaging and Labeling System.
- Provided responses to meetings with industry regarding facility design and segregation of activities for biologic manufacturing facilities.

Review Microbiologist, April 2005 – September 2008, New Drug Microbiology Staff, Office of Pharmaceutical Science, CDER, FDA, Silver Spring, MD

- Wrote over 200 technical reviews of the CMC section of investigational (IND), new drug and post-approval drug applications (NDA) regarding the microbiological quality of sterile (parenteral, ophthalmic, topical, aqueous inhalants) and non-sterile (oral, inhalation, topical, otic) products.
- Reviewed and evaluated:
  - Validation of terminal sterilization (moist heat, dry heat, ethylene oxide, radiation) and aseptic processes; thermal qualification, microbial efficacy and parametric release for moist heat terminal sterilization.
  - Filter-sterilization, sterilization and depyrogenation of equipment, containers and components, media fill simulations, container-closure integrity.
  - Environmental monitoring protocols, test procedures and data.
  - Sterility, bacterial endotoxins, container-closure integrity, microbial limits and preservative effectiveness.

Science Assistant, March 2003 – September 2004, Division of Molecular and Cellular Biosciences (MCB), National Science Foundation, Arlington, VA

- Assisted in all phases of the proposal review process for federal grant funding.

Industrial Microbiologist/Hygienist, October 2000 – August 2001, Los Angeles, CA
August 2001 – September 2002, Silver Spring, MD (worked from home)
Corporate Quality Assurance, Nestlé Waters North America

- Assisted manufacturing plants in solving microbiological issues related to the manufacture of bottled water.
- Organized the 1st Corporate Training Workshop (4 days) in microbiology and hygiene to train microbiologists representing each facility.
- Updated microbiological procedures and sampling plan and wrote protocols for microbiological studies to evaluate the effectiveness of cleaning and sanitation.
- Audited manufacturing plant microbiology laboratories.

Assistant Microbiologist, December 1999 – October 2000, Nestlé Waters North America, Corporate Quality Assurance Laboratory, Los Angeles, CA

- Performed routine microbiological analyses for bottled water.
- Membrane filtration and microbial identification using Vitek Jr., Biomerieux, Inc.

SKILLS

Microsoft Word, Excel, PowerPoint, Access
Excellent writing skills, Fluent in Greek, Good knowledge of French

PUBLICATIONS

1. A.G. Lolas. How to Prepare Your QC Microbiology Laboratory for the Next FDA Inspection. 2018. The Journal of GXP Compliance 22(4).
2. A. Lolas. The Role of Microbiology in the Design and Development of Pharmaceutical Manufacturing Processes. 2014. Pharmaceutical Bioprocessing 2(2): 125-128.
3. A.G. Lolas and I. Uydess. State of Quality and Compliance in the Biopharmaceutical Industry. 2013. BioPharm International 26(4): 16-19.
4. A.G. Lolas. Microbial Control Strategies in Bioprocessing Falling Short of Assuring Product Quality and Satisfying Regulatory Expectations. 2013. American Pharmaceutical Review 16(2): 20-31.
5. A.G. Lolas. Application of Rapid Microbiological Methods in BioProcessing and Regulatory Considerations edited by Dr. Michael Miller. January 2013. PDA & Davis Healthcare International Publishing.
6. A.G. Lolas and A.S. Rathore. Regulatory Challenges in the QbD Paradigm. 2012. BioPharma International 25(9): 44-53.
7. A. Lolas. cGMP Standards for Quality Assurance and Inspection Management. Part 2: Chapters 1-6 in Comparison of the Compliance/GMP Method (PIC/S, FDA, Japan, EU), and Inspection (Japanese title: [日本・欧州(PIC/S)・アメリカ] 各国GMP要求の徹底比較・適合方法と査察対応). 2012. Science & Technology.
8. A. Lolas. PDA/FDA Serves as Platform for Agency to Announce Initiatives, Industry to Comment. 2011. PDA Letter 47(10): 36.
9. K. Suvarna, A. Lolas, P. Hughes, and R.L. Friedman. Case Studies of Microbial Contamination in Biologic Product Manufacturing. 2011. American Pharmaceutical Review 14(1): 50-56.
10. A.G. Lolas and J.W. Metcalfe. Evaluation of the Microbial Growth Potential of Pharmaceutical Drug Products and Quality by Design. 2011. PDA Journal of Science & Technology 65(1): 63-70.
11. A.G. Lolas, B. Chi, P.F. Hughes, and K. Suvarna. CMC Microbiology Review of Biologics License Applications and Pre-License/Pre-Approval Inspections: Therapeutic Biological Proteins. 2010. American Pharmaceutical Review 13(2): 56-60.

PRESENTATIONS

- Regulatory Perspectives on Bioburden in Downstream Processing. October 2018. GE Healthcare Antibody Capture Summit, Uppsala, Sweden.
- FDA Inspection Readiness – Prepare you Lab for the Next Inspection. June 2018. IVT Microbiology Week, Philadelphia, PA.
- Challenges and Considerations Around Relaxing Environmental Controls in Biopharmaceutical Facilities. October 2014. BioProcess International Conference & Exhibition, Boston, MA, USA.
- Microbial Control Strategies in Bioprocessing Falling Short of Assuring Product Quality and Satisfying Regulatory Expectations. February 2013. PDA Europe Microbiology Conference, Berlin, Germany.
- Application of Rapid Micro Methods in BioProcessing and Regulatory Considerations. February 2012. PMF Conference on Alternate and Rapid Microbiological Methods, Las Vegas, NV.
- Regulatory Filing & Pre-License/Pre-Approval Inspections of Therapeutic Biological Proteins. February 2011. Lean for Biotechnology Symposium, Columbia, MD.
- Review and Pre-Approval/Pre-License Inspections of Therapeutic Biological Proteins. October 2009. PDA Global Microbiology Conference, Bethesda, MD.
- Biofilm and Pharmaceutical Water Systems. Videoconference. November 2008. Biofilm Conference, Research Triangle Park, NC.
- Quality by Design Approaches in Product Quality Microbiology. October 2008. PDA Global Microbiology Conference, Chicago, IL, USA.
- Regulatory Approaches for Novel Processing and Innovative Products. September 2008. International Meeting on Radiation Processing, London, UK.
- FDA Regulatory Perspective and Practical Considerations. September 2008. Drug-Device Workshop following International Meeting on Radiation Processing, London, UK.

HONORS & AWARDS

DMPQ Team Award, 2009
CDER Special Recognition Award, Spring 2008
Jonathan Baldwin Turner Fellowship, 1997-1999
M.E. Franks Scholarship, 1997
National Dairy Board Scholarship, 1996
Institute of Food Technologists Junior/Senior Scholarship, 1996

AFFILIATIONS

Parenteral Drug Association, 2010 – present
PDA Letter Editorial Committee, Jan 2011 - Dec 2012
American Society for Microbiology, 1998-2003, 2006 – present
ASTM International, 2012 - present