Michael Carroll

Senior Consultant, Microbiologist

Core Competencies

- Aseptic Production
- Sterilization
- Dehydrogenation
- Process Validation
- Analytical Validation
- Biologics
- Medical Device
- Monitoring Programs
- Product Launch

Professional Summary

Mr. Carroll is an accredited Microbiologist with over 35 years of product development, quality control and GMP manufacturing experience in the pharmaceutical, biotechnology and medical device industries. He is experienced in all phases of development, PAI, regulatory approval and product launch. He provides experimental analyses and applies knowledge to resolve quality issues.

Mr. Carroll provides technical guidance reviewing analytical methodology, assuring compliance with regulatory GMP guidelines, and initiating Quality Control laboratory process improvements.

- Developing scale-up, environmental and maintenance monitoring programs,
- Created accurate low-cost LAL test: Firm was using an unreliable LAL test on a lipid-containing product. Created and validated a new LAL test with higher accuracy rate and virtually no false positives. Reduced lot turnaround times and decreased costs 60%,
- Oversaw validation and implementation of new test globally. Firm needed 'Harmonized' Compendial Microbial Limits test validated and implemented in 140+ sites,
- Managed multiple (8) successful aseptic processing facility start-ups,
- Developing and validating microbiological test methods and specifications,
- Designing, qualifying and implementing new products/processes.

Mr. Carroll earned a BS in Biology/Pre-Med from the University of California at San Diego and a Medical Technology certification from Pennsylvania Hospital. He is ASCP Certified and a member of the Parenteral Drug Association (PDA).

Education

B.S.	Biology/Pre-Med	University of California at San Diego

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Professional Experience

DS InPharmatics **2010 - Present**

Senior Consultant, Microbiologist

- Develops standards, methods and procedures for inspecting, testing and evaluating the quality of products,
- Designed and built microbiology lab from ground up, including validation support, EM program development, EM baseline, sterility and microbial limits testing. Achieved complete approval from both the EU and US (FDA-CDER).

Dendreon Corporation **2010 - 2018**

Senior Process Engineer

- Led QC and microbiology operations including laboratory control systems and QC programs,
- Manage RM qualification program, EM program, validation and tech transfer of methods, in-process and final product testing-develop standards, methods and procedures for inspecting, testing and evaluating the quality of products,
- Support Manufacturing and R&D efforts to maintain cGMP compliance, enhance and improve processes, and qualify new methods, equipment and products/processes for introduction into Manufacturing and QC.

Discovery Labs **2008 - 2009**

Sr. Manager, QC/QA

- QC/QA management of a sterile pharma manufacturing facility including environmental monitoring (EM), facility support, analytical, utility monitoring and validation, and QA function (sterile drug, aseptic production).

Schering-Plough **2007 - 2008**

Manager, Global Quality Consultant

- Oversaw qualification and implementation of Harmonized Microbial Limits test in 140+ sites.
- Participated in technology transfers, investigations, and CAPA's.

Hoffmann-La Roche **2000 - 2007**

Principal Scientist

- Managed compliance functions for six QC Microbiology labs,
- CAPA's, complaints, method/process validation, change control (analytical/process), investigations.

Additional Professional Experience

- Ortho Biotech; Sr. Manager QA
- Osteotech, Inc.; Manager, QC Microbiology & Facility Support
- The Liposome Company
- and within various Johnson & Johnson companies