Christine Hong

Christine.Hong@adventhealth.com
QualityMatters@pharmacystars.com

Professional Summary

Certified ASQ Pharmaceutical GMP Professional (CPGP) and seasoned Pharmaceutical Microbiologist with a proven track record as Quality Assurance Manager at AdventHealth. Leads Environmental Monitoring program and providing consultation for sterile compounding quality investigations and cleanroom design. Extensive background in quality assurance and microbiology leadership within the pharmaceutical industry, spanning large-scale drug manufacturing, medical devices, and 503B outsourcing. Recognized for expertise in compliance, auditing, aseptic processing, quality systems, training and development, as well as proficiency in microbiological and stability test methods and investigations. Dynamic and accomplished Editor-In-Chief and Contributing Editor with a strong background in leading editorial initiatives for "Sterile Compounding Quality Matters."

Education

University of Central Florida - Bachelor of Science, May 2010

- Major: Health Sciences
- Scholarship: Florida Bright Futures

University of Central Florida - Bachelor of Science, July 2013

- Major: Biomedical Sciences (Microbiology and Molecular Biology)
- Minor: Health Services Administration

Experience

Pharmacy Stars Sterile Compounding Expert Panel (SCXP) ***July 2022-Present***
Editor-In-Chief, Lead Panelist (QC Microbiology)

- Appointed as the Editor-In-Chief and Lead Panelist (QC Microbiology) for a distinguished expert panel featuring nationally recognized professionals in cleanroom design/certification, industrial hygiene, engineering, infection prevention, pharmaceutical microbiology, and pharmacy technology.
- Instrumental in establishing journal policies and providing oversight for all editorial and peer-review processes governing panel publications, presentations, webinars, and other official engagements.

Pharmacy Stars Sterile Compounding Quality Matters ***January 2021-Present***
Editor-In-Chief and Contributing Editor

- Established inaugural publication policies and overseeing all editorial and peer-review processes for panel publications, presentations, webinars, and official engagements.
- Demonstrated a keen understanding of sterile compounding issues, contributing valuable insights to elevate the publication's content and relevance within the industry.
- Performed as a proven leader and collaborator, dedicated to advancing knowledge and best practices in sterile compounding.

AdventHealth Pharmacy Microbiological Quality Services ***March 2020 – Present***
Quality Assurance Manager/Lead Pharmaceutical Microbiologist

- Pioneered and executed a cost-saving strategy resulting in $1.7 million savings by optimizing and standardizing a dynamic Environmental Monitoring Program for 30 pharmacy locations.
- Directed and elevated a high-impact Quality Assurance Program, ensuring regulatory compliance and championing best practices in the industry.
- Demonstrated mastery as a Microbiology expert, serving as a frontline liaison during regulatory inspections, leading Environmental Monitoring Teams, and swiftly resolving excursions in Compounding Cleanroom Areas.

AdventHealth Central Florida Division
System Quality Assurance Manager ***January 2019-2020***

- Pioneered and chaired the organization's inaugural Compounding Compliance Committee, known as the "Designated Persons Panel."
- Developed system-wide risk assessment and root cause analysis tools, forms, and SOPs, establishing a comprehensive framework for investigating non-conformances and out-of-trend recoveries in products and environmental monitoring.
- Crafted audit tools and conducted the initial gap analysis for the division's compliance with the 2019 USP <797> and <800> updates.
- Spearheaded the division's initiative to standardize cleanroom cleaning protocols, including an approved supply list and agent formulary, along with the implementation of a system-wide sterile compounding training program.
- Successfully led the implementation of a system-wide electronic quality management software, playing a key role in building out quality templates for critical process controls.

AdventHealth Central Fill Pharmacy
Quality Assurance Manager ***November 2016-2019***

- Developed and oversaw a near GMP level compounding quality program for centralized compounding operations serving 9 hospitals across central Florida.
- Created the first inhouse comprehensive environmental monitoring program modeling GMP requirements for an AdventHealth location.
- Improved the master formulation record and document and label control processes for the facility.
- Successful began the expansion of the independent quality unit's microbiological services beyond Central Fill Pharmacy becoming a system resource.
- Consulted as lead pharmaceutical microbiologist for the division's pharmacy department.

Nephron Pharmaceuticals Corporation .
Quality Assurance Manager of Operations **(Orlando, Fl)** ***March 2016 - October 2016***
Senior Manager, QC Microbiology **(West Columbia, SC)**

- Championed FDA compliance, focusing on investigations and product quality, ensuring regulatory adherence.
- Oversaw quality assurance shifts, maintaining stringent production quality standards and serving as final approval for product batch records and controlled documents.
- Oversaw regulatory operations including communication with the FDA for Field Alert Reports

QC Microbiology Supervisor/Acting Lab Manager **(Orlando, Fl)** ***January 2015 - March 2016***

- Collaborating seamlessly with R&D and Regulatory Affairs for successful new product submissions.
- Efficiently managed daily operations of the Microbiology Department, ensuring high-performance standards.
- Spearheaded training and development initiatives, including an On-The-Job Training Program, to enhance team skills.
- Optimized lab efficiency by revising procedures, test methods, and validations, leading to improved workflow.
- Successfully conducted Non-Conformance and Lab Excursion investigations, collaborating seamlessly with QA and driving CAPA and EPs development.

QC Microbiology Analyst I/II (Orlando, Fl) ***July 2013 – January 2015***

- Executed microbiology tests following USP methods and procedures, ensuring compliance with cGMP guidelines.
- Demonstrated exceptional aseptic techniques in an FDA-regulated facility, ensuring high-quality standards.
- Provided rigorous Quality Control through the analysis of raw materials, in-process samples, and finished products.
- Conducted diverse testing, including bioburden, stability, and pathogen screening, with a focus on environmental monitoring and identification.

Publications

Journal Articles

- Amanda Danielle Wollitz, PharmD, Christine Hong, BSc, Fernando Blanco, PharmD, MBA, Compounding sterile products during a personal protective equipment shortage, American Journal of Health-System Pharmacy, 2021;, zxab112, https://doi.org/10.1093/ajhp/zxab112

Magazine Articles

- Hong, C., Maynard, M., & Duncanson, B. (2023). Environmental Monitoring Drives Cleanroom Design. *Pharmacy Purchasing and Products, Vol. 20* (Issue No. 7 July 2023), Cover Story.
- Hong, C., Maynard, M., & Duncanson, B. (2023). Cleanroom Design for Contamination Control. *Pharmacy Purchasing and Products, Vol. 20* (Issue No. 11 November 2023), Cover Story.
- Hong, C., Maynard, M., & Duncanson, B. (2024). Optimizing Airflow in Cleanroom Design. *Pharmacy Purchasing and Products, Vol. 21* (Issue No. 1 January 2024), Cover Story.

Selected Works in Progress

- Hong, C., Maynard, M., & Duncanson, B. (2024). HVAC Considerations Cleanroom Design. *Pharmacy Purchasing and Products, Vol. 21* (Issue No. 4 April 2024), Cover Story.
- Hong, C., & Duncanson, B. (2024). Making the Most of the Cleanroom Suite You Have. *Pharmacy Purchasing and Products, Vol. 21* (Issue No. 7 July 2024).

Selected Conference and Invited Presentations

- "What's the Problem? Corrective Action Plans that get to the Root of the Cause", Sterile Compounding Recertification Course at APhA2024, Orlando, Florida, March, 21, 2024.
- "The ABCs of BUDs: Understanding Beyond-Use Dating in the Revised USP Chapter 797", Environmental Monitoring (EM) Requirements: Moving to an In-House EM Program, Symposium at ASHP Summer Meetings & Exhibition, Baltimore, Maryland, June, 12, 2023.
- "Creating Your Own Comprehensive EM Program", Webinar CE, Online/Virtual, April 21, 2022
- "Developing a System-Wide Compounding Quality Program", Premier Breakthroughs 21, Nashville, Tennessee, June, 15, 2021.

Certifications

- ASQ Certified GMP (Good Manufacturing Practices) Professional (CPGP)

Memberships in Associations and Institutional Affiliations

- American Society for Quality (ASQ)
- American Society of Hospital Pharmacists (ASHP)
- Controlled Environment Testing Association (CETA)
- Institute of Environmental Sciences and Technology (IEST)
- Parenteral Drug Association (PDA)