

2<sup>nd</sup> International Congress on

## NOSOCOMIAL AND HEALTHCARE ASSOCIATED INFECTIONS

&

International Conference on

## DECONTAMINATION, STERILIZATION AND INFECTION CONTROL

October 15-16, 2018 | Las Vegas, USA



### Melissa Stefko

Wells Pharmacy Network, LLC, USA

#### Prevention of contamination in pharmaceutical industry

Contamination of pharmaceutical products can cause catastrophic consequences in the pharmaceutical industry; from patient safety and patient access to drug shortages through business viability and sustainability. In the manufacturing of sterile pharmaceutical products, contamination prevention is a critical component for complying with state and federal regulations as well as protecting the safety of the public. In the wake of the meningitis outbreak of 2012, FDA and other regulatory agencies have heightened their approach and expectations on monitoring products for contamination. Although bioburden levels may be able to be controlled with suitable cleaning methods, preventing the occurrence is the best approach when assessing the risk of contamination for a facility and/or drug product. Cleanroom suites play a critical role in the creation of sterile pharmaceutical drug products. Although many methods of decontamination and sterilization have proven successful, prevention of the contamination is key to maintaining optimal microbial levels in an aseptic environment. This talk will discuss the top potential sources of contamination and how to effectively prevent them from contaminating product, the cleanroom suites and the significant impact an outbreak may have on the organization as a whole. Additionally, this talk will also evaluate the top potential sources of contamination in detail based on risk and the specific role they play in the pathway to contamination. Discussion topics include facility design, cleanroom behavior, gowning and cleaning requirements, etc.

#### Biography

Melissa Stefko is an experienced pharmaceutical and biotechnology professional with a background in Quality Assurance and Quality Control in aseptic sterile processing. Prior to joining Wells Pharmacy Network, She served as Head of Quality with a start-up 503B outsourcing pharmacy and gained a strong CGMP understanding through previous positions within pharmaceutical manufacturers. She is an active member of the American Society for Quality as a Certified Quality Auditor and is a member of Institute of Environmental Sciences and Technology, American Society for Microbiology, Parenteral Drug Association, and IACP. She holds Masters in Business Administration, Masters of Science in Biotechnology, and Regulatory Affairs Certificate.

[melissastefko@gmail.com](mailto:melissastefko@gmail.com)

Notes: