Extended Abstract Journal of Pharmacy and Pharmaceutical Research 2021
Vol.6 No.2

# Prevention of contamination in pharmaceutical industry

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**Introduction**:
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.

**Objectives**:
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.

**Results**:
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

**Conclusions**:
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 with 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.

This work is partly presented at 2nd International Congress on Nosocomial and Healthcare Associated Infections
October 15-16, 2018 | Las Vegas, USA