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Abstract

Aseptic manufacturing environment for the production of a quality product

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Abstract:

Clean rooms and other controlled environments are essential in the aseptic manufacturing environment for the production of a quality product. Monitoring microbial distribution and identifying the predominant isolates is part of any effective environmental monitoring program. Maintaining the integrity of a clean room or other controlled environment is a constant battle because of both the materials used as well as the activities that take place within the environment. Contaminated surfaces can and often do, adversely impact the quality of product manufactured. Identifying which method of application that would be most efficacious in reducing microbial numbers on surfaces is just as important as selecting the right disinfectant. To determine which method: spray or wipe, would prove more efficacious in the application of disinfectants on surfaces in the manufacturing environment, our laboratory conducted a comparison study. Using one surface (stainless steel) in order to focus the data on the application of the disinfectants and not variability of microbial attachment between different surfaces, we assessed the efficacy of application between: 5% Decon spore, Decon Quat, and 70% IPA. Our test organisms included S. aureus, P. chrysogenu, B. licheniformis, P. aeruginosa, and C. albicans. The data suggest that knowing and identifying what types of organisms typically inhabit your manufacturing environment can help with not only selecting which disinfectant works best, but also which application enhances that effectiveness.

Biography:

I am experienced in designing and delivering global microbiology strategies while ensuring harmonization, patient safety, etc., by providing support and leadership in Quality, cGxP and regulatory compliance in both sterile and non-sterile manufacturing environments. I am experienced in leading investigations for product and process deviations. I also provide technical support as an SME

in microbiology including but not limited to analytical assay design, validations and processes. I proactively identify and escalate opportunities for risk reduction and continuous improvement using quality improvement and problem -solving tools such as (Failure Modes & Effects Analysis (F.M.E.A).

Recent Publications:

1. Dr. Michelle Law; Simultaneous Measurement of Pulmonary Partial Pressure of Oxygen and Apparent Diffusion Coefficient by Hyperpolarized (3)He MRI; 2009
2. Dr. Michelle Law; Measurement of Pulmonary Partial Pressure of Oxygen and Oxygen Depletion Rate with Hyperpolarized Helium-3 MRI: A Preliminary Reproducibility Study on Pig Model; 2009
3. Dr. Michelle Law; A Robust Method for Estimating Regional Pulmonary Parameters in Presence of Noise; 2008
4. Dr. Michelle Law; Early changes of lung function and structure in an elastase model of emphysema - A hyperpolarized 3He MRI study; 2008
5. Dr. Michelle Law; Optimization of scan parameters in pulmonary partial pressure oxygen measurement by hyperpolarized3He MRI; 2008

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