Revolutionizing Overkill Steam Sterilization: A Novel Approach for Flexible Loading Patterns Based on the Physical Properties of Steam and Sterilization Thermodynamics

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Abstract

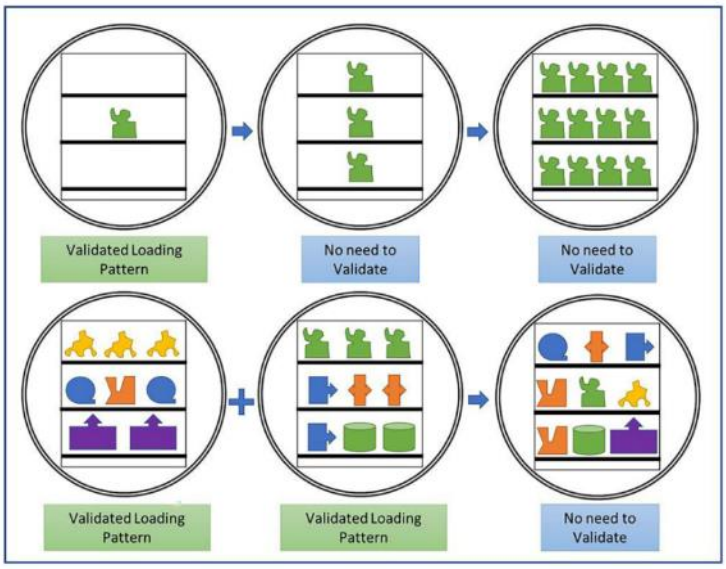
The presentation will unveil a novel approach to steam sterilization in autoclaves, introducing remarkable flexibility in their operation within sterile production. This innovative method has the potential to significantly save time and costs for sterile production facilities.

Traditionally, steam sterilization processes in autoclaves are subject to rigorous scrutiny due to their critical nature. Regulatory requirements often prescribe the use of fixed loading patterns, which have evolved over time to enhance process assurance and minimize risks.

However, overkill sterilization stands as one of the most robust processes in the pharmaceutical industry, offering the highest levels of sterility assurance. By achieving a minimum reduction of highly resilient spore populations of at least 12 logs, it attains a probability of a nonsterile unit (PNSU) as low as 10^{-6}. As these spores are more resistant than the typical microorganisms found in pharmaceutical facilities, overkill sterilization significantly lowers the PNSU values for the latter (as low as 10^{-54}!)

The fundamentals of the new approach are the physical properties of steam and the thermodynamics of steam sterilization. leveraging this with the high assurance level of the overkill cycle, the new approach allows for the creation of new loading patterns based on items that have already been validated in other loading patterns, without the need to validate the new loading pattern. The diagram provided offers a visual representation of this approach.

Furthermore, the presentation will showcase compelling data derived from the validation of six autoclaves over a three-year period, involving the sterilization of diverse loads. These empirical findings serve as practical evidence that bolsters the case for implementing the new approach.



Recent Publication

1. Ben David Arnan (2023) Flexible Loading Pattern Approach in Overkill Steam Sterilization Based on the Physical Properties of Steam and Thermodynamics of Sterilization. PDA Journal of Pharmaceutical Science and Technology, Vol 77, No. 3, 166-180.



Biography

Arnan Ben-David brings with him an impressive 35 years of expertise in the field of sterile manufacturing. His journey began as a maintenance engineer and project manager at Teva Pharmaceutical, where he gained valuable insights into the intricacies of the industry. He further honed his skills as an engineering department manager at Omrix Biopharmaceutical and later assumed the role of strategic projects director at J&J. Finally, he served as a global Subject Matter Expert (SME) for sterile manufacturing at Teva Pharmaceutical.

For the past 5 years, Arnan has been making a significant impact as an independent consultant in the field of sterile manufacturing. His consultancy work involves supporting numerous companies and providing extensive training in areas such as steam sterilization, autoclaves, and SIP (Sterilize In Place) systems. With his wealth of experience and expertise, Arnan continues to contribute to the advancement of sterile manufacturing practices across the industry..

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