

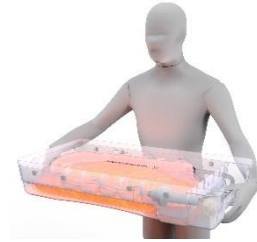
NEW APPROACH FOR QUALIFYING LIQUID HANDLING IN SINGLE-USE BAGS

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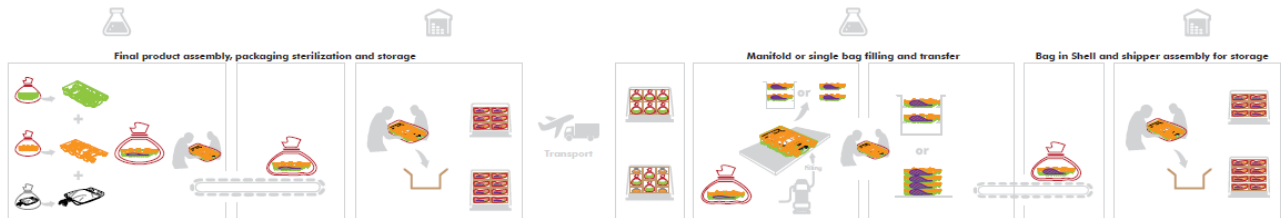
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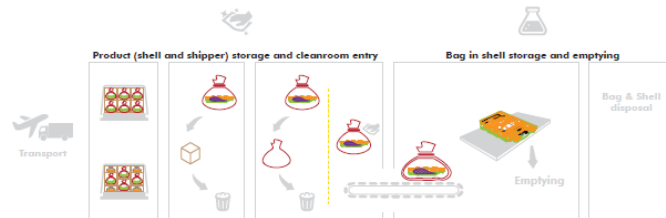
The technical and economic benefits of Single-use in bio-manufacturing are well known and the industry is broadening their adoption. The increasing manual handling of bags in the biotech process involves highly trained operators and specific guidelines in order to secure the process, especially for bulk drug substances or even for drug products handling.



The lecture will focus on a new approach of the liquid handling process life cycle analysis that led to the development of specific shells for Flexsafe® 2D bags. This scientific approach supported by bioprocess engineers, packaging engineers and material experts provides a secured way for developing and qualifying the robustness of these liquid handling systems.



Based on real life and worse case conditions experienced over the whole life cycle of the product, this approach allows to provide a comprehensive testing program with different ASTM norms and a clear rationale about the protocol tests choices and the expected safety margin.



This process qualification approach allows to secure liquid handling and demonstrates the bag integrity for the best protection of the drug substances, finally saving cost for end-user process validation.