

Life Cycle Approach to Cleaning Validation - PODCAST Episode



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Cleaning validation is critical to the pharmaceutical industry, ensuring that risks of contamination, product carry over, and cross contamination are controlled, minimized, and monitored to maintain patient safety and product quality. Today we will discuss the lifecycle approach to cleaning validation, and the importance of creating cGMP approved cleaning programs that encompass the applications, methods and controls necessary for creation and launch of compliant cleaning programs that meet or exceed regulatory expectations. In this episode we remind listeners about the importance of formalized cleaning programs, and best practices around cleaning activities, sampling and testing.

Links:

- FDA Cleaning Validation Guideline from CFR 211.67 - <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=211.67>
- FDA CFR 211 - <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=211>
- FDA Questions & Answers on Current Good Manufacturing Practices—Equipment - <https://www.fda.gov/drugs/guidances-drugs/questions-and-answers-current-good-manufacturing-practices-equipment>
- EMA Cleaning Guidance - https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-setting-health-based-exposure-limits-use-risk-identification-manufacture-different_en.pdf
- EMA Cleaning Validation Guideline on setting HBELs - https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-setting-health-based-exposure-limits-use-risk-identification-manufacture-different_en.pdf
- QnA on the implementation of the above guideline EMA - https://www.ema.europa.eu/en/documents/other/questions-answers-implementation-risk-based-prevention-cross-contamination-production-guideline_en.pdf
- ISPE Cleaning Validation Guide - <https://ispe.org/publications/guidance-documents/guide-cleaning-validation-lifecycle-applications-methods-controls>
- WHO Cleaning Guidance - https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS20_849_Rev.1_points_to_consider_hbels_in_cleaning