Ruggedness of Visible Residue Limits for Cleaning Validation

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Visual inspection of equipment has always been an important element of the cleaning validation program. Establishing visible residue limits is extremely valuable in setting a baseline for cleanliness, highlighting viewing conditions, and defining a methodology for performing routine checks on cleaning validation procedures. Understanding the results of testing, and reproducibility of test results under varying conditions allows for consistency across teams and lessens risk of error in cleaning validation activities. We do a deep dive on this topic with Richard Forsyth during this episode.

Resources for this episode:

1. Richard J. Forsyth; Ruggedness of Visible Residue Limits for Cleaning Validation, April 2, 2016, Pharmaceutical Technology
2. FDA Cleaning Validation Guideline from CFR 211.67
3. Questions and Answers on Current Good Manufacturing Practices—Equipment
4. EMA Cleaning Validation Guideline on setting HBELs
5. QnA on the implementation of the above guideline
6. WHO good manufacturing practices for active pharmaceutical ingredients
7. Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation
8. PIC/s Aide-Memoire: Inspection of Health Based Exposure Limit (HBEL) Assessment and use in Quality Risk Management
9. Health Canada Cleaning Validation Guideline