

POINTS TO CONSIDER WHEN INCLUDING HBELs IN CLEANING VALIDATION (WHO TRS 1033 - Annex 2)

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Overview

The linked document, **WHO Technical Report Series No. 1033, Annex 2: Points to consider when including Health Based Exposure Levels (HBELs) in cleaning validation**, provides guidelines for manufacturers to review and implement technical and organizational measures, suitability of cleaning procedures and appropriateness of existing cleaning validation studies.

Some of the main principles of good manufacturing practices (GMP) include the prevention of mix-ups and the prevention of contamination and cross-contamination. Multi-product facilities in particular, have a potential risk of cross-contamination. It is therefore important that manufacturers identify all risks relating to contamination and cross-contamination and identify and implement the appropriate controls to mitigate these risk.

Link to Document

[TRS 1033 - ANNEX 2: POINTS TO CONSIDER WHEN INCLUDING HEALTH-BASED EXPOSURE LIMITS \(HBELs\) IN CLEANING VALIDATION](#)