
Equipment Hold Times - Why Their Importance is Overrated in Small-Molecule API Manufacturing

Andreas Bamberg Michael Abbass Michael Schmidt Thomas Nicola

By

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Are hold times – sometimes considered as lost parameters for cleaning validation (1) – overrated for cleaning validation in manufacturing of small-molecule APIs? This article puts hold times into the context of the typical change-over process in shared facilities for small-molecule APIs and, based on a risk assessment, describes why the risks resulting from long hold times are adequately controlled by the change-over process in these facilities. Introduction We all know that we'd better wash a cooking pot with tomato sauce residues immediately after use: every hour left dirty...

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