
Cleaning Validation Proposed Standard



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By

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The following proposed standard is intended to reflect desirable contemporary practices, is not binding in any way, and can be modified to suit a firm's specific needs. This proposed standard incorporates imperative verbs (e.g., shall, will, must) to provide users with unambiguous quality assurance auditing tools, and is prefaced by a Preamble that provides rationale for several of the more complex concepts. This document is also directed toward users located at a given plant site that may or may not be a part of a larger corporation. Terms that are bold and asterisked (*) the first time they are used are defined in Section IV - Glossary.

Contents of the Proposed Cleaning Validation Standard

In order to be consistent with the prototype standard (Validation Standard VS-1) the Proposed Cleaning Validation Standard VS-3 will be divided into the following five sections:

- I. Policy statements - Proposed standards that indicate what is required
- II. Procedural Statements - Proposed standards that describe how to meet requirements
- III. Acronyms - Meaning of each acronym/abbreviation used in the document
- IV. Glossary - Definition of key terms, which are highlighted and asterisked (*) when first used in the proposed validation standard
- V. Regulatory Excerpts - Regulatory language (United States, Australia, Canada, World Health Organization [WHO], Japan, and European Union) related to each Standard

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