The Study in Risk-Based Manufacturing Environmental Control for Non-Sterile Drug Products

(English Translation)

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PDA Japan Chapter, Kansai Study Group

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Abstract

This publication has been prepared to express a sound and practical view on better manufacturing environmental controls for non-sterile drug products. This topic has been discussed over several years by a special working group of the Kansai Study Group (KSG), an accredited committee of the Parenteral Drug Association (PDA) Japan Chapter. The opinions proposed or advanced in the document are presented for the purpose of furnishing beneficial and valuable guidance to any person or organization concerned with establishing appropriate manufacturing control systems for quality products.

The leading subjects discussed among the KSG are focused on preventing cross-contamination and foreign matter ingress and are categorized into five themes: HVAC systems, facilities, gowning, cleaning, and cleanliness standards. Constructive and earnest discussion has been devoted to the key processes, where considerable amounts of powders are handled safely during the operations of weighing, granulation blending, and tableting. In the expectation of good usage, many of the principles and approaches presented here can be applied or adjusted to suit a wide spectrum of other manufacturing processes for various dosage forms of non-sterile drug products.

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