

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

(English Translation)



**Japan
Chapter**

Authors

Keisuke Inoue, Takeda Pharmaceutical Company Limited

Yoshimi Urayama, Chiyoda Corporation

Tsutomu Kamikukita, PhD, Towa Pharmaceutical Co., Ltd.

Toshimitsu Shirai, Transtech Inc.

Osamu Shirokizawa, Life Scientia Limited

Tokuhito Sugiyama, Sumitomo Dainippon Pharma Co., Ltd.

Masao Sudoh, Ono Pharmaceutical Co., Ltd.

Hironori Tanaka, MSD K.K. Japan

Masumi Nasukawa, CM Plus Corporation

Shigeto Hirabara, Hirabara Engineering Service Ltd.

Taku Horie, Taikisha Ltd.

Hiroshi Mitsuyoshi, Shionogi & Co., Ltd.

Hiromi Mihara, Sumika Chemical Analysis Service Co.

Takayuki Miyamoto, Taikisha Ltd.

Daikichirou Murakami, Hirabara Engineering Service Ltd.

Kuniaki Yamanaka, Freund Co.

Shigehiro Tahara, CM Plus Singapore Pte. Ltd.

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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Note to Readers

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