

INTERNATIONAL
STANDARD

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Medical devices — Application of risk management to medical devices

Dispositifs médicaux — Application de la gestion des risques aux dispositifs médicaux

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European Medicines Agency
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London, 19 April 2006

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COMMITTEE FOR MEDICAL PRODUCTS FOR HUMAN USE
(CHMP)

GUIDELINE ON THE PHARMACEUTICAL QUALITY OF INHALATION AND NASAL
PRODUCTS

DRAFT AGREED BY QUALITY WORKING PARTY	October 2005
ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION	19 January 2006
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The Committee for Medical Products for Human Use (CHMP) has adopted a guideline on the pharmaceutical quality of inhalation and nasal products. This guideline is intended to provide guidance to manufacturers on the quality requirements for these products. The guideline is available on the EMA website.

Draft - Not for Implementation
GUIDANCE FOR INDUSTRY¹
MDI and DPI

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Guidance for Industry

Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products

Chemistry, Manufacturing, and Controls
Documentation

DRAFT GUIDANCE

This document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-105), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the document number listed in the notice of availability that publishes in the Federal Register.

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