
Guidance for assessment and evaluation of changes to drug delivery systems

*Gestion des changements d'appareils dans les combinaisons de
produits pour l'administration de médicaments*

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

This document provides guidance to organizations wishing to implement a systematic approach to assess and evaluate changes to needle-based injection systems, needle-free injectors and aerosol delivery devices for medical use (see Clause 1) throughout their lifecycles. In particular, an organization can use the approach for changes to the drug delivery system from entry into pivotal or registration clinical studies through the end of commercial supply.

Due to the breadth of potential change circumstances, this document does not contain prescriptive technical requirements for assessing and evaluating drug delivery system changes but rather provides illustrative guidance for consideration.

This document does not replace or alter existing statutory and regulatory requirements for assessing drug delivery system changes.

Prior to using the process outlined in this document, the organization should have determined the objective of the change including the various opportunities/options for fulfilling the objective.

This document might also be useful for assessing and evaluating change to drug delivery systems other than needle-based injection systems, needle-free injectors and aerosol delivery devices for medical use.

The process can be applied to multiple product lifecycle stages, including design and development, production, storage and distribution, installation, servicing and final decommissioning/disposal of the drug delivery system or associated activities (e.g. up-dating of software). It can also be used by an organization's suppliers and external parties (e.g. raw materials, components, subassemblies, medical devices, sterilization services, calibration services, distribution services, maintenance services).

This document is not intended to replace or alter quality management systems, risk management, or usability engineering requirements in assessing these changes. Rather, it provides a common framework using a scientific and risk-based approach consistent with

— ISO 13485^[4],

— ISO 14971^[5], and

— IEC 62366-1^[8].

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Although this process focuses on user safety and drug delivery system performance, it also addresses lifecycle management and includes consideration of appropriate medicinal product guidance (e.g. ICH Q8, ICH Q9, ICH Q10 and ICH Q12). This will help assess the potential impact of changes on the quality, safety, and efficacy of the finished product for the target patient population.

Over the course of a finished product's lifecycle, there will be a broad array of drivers for change. These changes and their various design solutions can be motivated by, but are not limited to the following:

- a) adverse event/complaint data;
- b) voice of the customer, user feedback or market research;
- c) usability studies;
- d) changes in processes for production, production scale and supply chain logistics;
- e) changes in material or source of supply;
- f) impact of changes to the medicinal product that affect the drug delivery system.

This document provides examples of drug delivery system changes using a process flow (see [Figure 1](#)). These examples and the conclusions provided are purely illustrative and are intended to provide guidance on how to utilize this document.

It is the responsibility of organizations to provide evidence that the approach adopted is commensurate with the level of risk to ensure the quality, safety and performance of the drug delivery system. While the focus of this document is the changed drug delivery system, it is also possible that changes to the medicinal product might impact the drug delivery system (e.g. change in viscosity or volume of medicinal product resulting in changed drug delivery system performance). It is also possible that changes to the drug delivery system might impact the medicinal product (e.g. increased injection forces resulting in changed treatment). As such, one key aspect of this process is assessing the change for its potential impact on overall quality given the critical interface between the drug delivery system and the medicinal product. Organizations should evaluate potential impact to the medicinal product in accordance with relevant regulations and guidelines pertaining to medicinal products (e.g. ICH guidelines) to ensure the quality, safety and efficacy.

The core of this document is the process flow, which attempts to guide an organization through a risk-based approach based on drivers of change as mentioned above impacting the

- drug delivery system design,
- manufacturing process, and
- labelling and user interface.

The expectation is that such changes are evaluated through the risk assessment of how the change could impact system form, fit and function (including medicinal product flow paths) such that users are not negatively impacted in terms of quality, safety and performance of the drug delivery system. Given that a single change can affect more than one of the change types (e.g. a material change can also drive a process change), all change types should be assessed and evaluated.

The identification, analysis, evaluation and control of change are common regulatory requirements in the post approval phase of a product's lifecycle, but are also important in the clinical phase of development. Organizations should demonstrate that as the drug delivery system design evolves, the link between the drug delivery system and the medicinal product as tested in the clinical setting (for which market authorization is granted or is intended) is maintained.

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