Overview of changes requiring an inspection in the GMP area

Version 6, 21-11-2025

This document provides general guidance on changes, including those that do not necessarily require an update of the company authorisation. For guidance on changes to the wholesale distribution authorisation itself, please refer to this page: Application for authorisation to manufacture and import medicines and intermediates

Companies must notify the Danish Medicines Agency of changes in due time (at least 90 days before implementation) by sending an email to GMDP-krav@dkma.dk. The email must describe the relevant change in detail, outlining the activities (e.g. risk assessment, qualification, internal audit) to be performed in connection with the change. This will give the Danish Medicines Agency (DKMA) the best basis for deciding if the change requires an inspection before implementation or if the review can wait for the next routine inspection. This is determined on a case-by-case basis. If the company needs to notify several changes, they may be submitted together.

We expect companies to notify us of any major changes at the next inspection so that the inspectors can determine whether the changes require special focus during the inspection. This applies equally to changes notified to the Danish Medicines Agency and other major changes.

The examples in the list below are not exhaustive. If in doubt, please contact us at GMDP-krav@dkma.dk.

Example of change	Must GMDP-krav@dkma.dk be notified of the change?	Does the change require an inspection?
Quality system		
Significant changes to the quality system (e.g. in connection with an acquisition or merger)	Yes	Assessed by DKMA
Change of document management systems, e.g. switching to an electronic system for handling of deviations	No	No
Manufacturing premises		
New manufacturing facility	Yes	Yes
Reconstruction of manufacturing facility, including air locks, wash areas, etc.	Yes	Assessed by DKMA
Change of room classification	Yes	Assessed by DKMA
Change from dedicated to multi-purpose facility	Yes	Yes
Manufacturing equipment		
New production line (e.g. fermentation, filling, packaging)	Yes	Assessed by DKMA
New process-critical equipment (e.g. processing facility, freeze dryer, isolator)	Yes	Assessed by DKMA
New major equipment corresponding to existing equipment	No	No
Discontinuation of production line	Yes	Assessed by DKMA
Utilities		
New water plant	Yes	Assessed by DKMA
Significant changes to existing water plant	No	No
Switch to WFI water by reverse osmosis technology	Yes	Yes
New ventilation system for classified area	Yes	Assessed by DKMA
Significant changes to existing HVAC system	Yes	Assessed by DKMA
New process air system with product contact	Yes	Assessed by DKMA
Significant changes to existing process air system	No	No

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Storage facilities		
New storage building	Yes	Assessed by DKMA
Inclusion of additional rooms for storage in the existing storage building	Yes	Assessed by DKMA
Restructuring/sectioning of storage room	No	No
Planned use of temporary storage facility	Yes	Assessed by DKMA
Manufacturing		
Implementation of new manufacturing process/technology	Yes	Assessed by DKMA
New chemical API in GMP-approved facility	No	No
New sterile or biological API in GMP-approved facility	Yes	Assessed by DKMA
New medicinal product in GMP-approved multi-purpose facility with corresponding manufacturing process	No	No
Implementation of AI (artificial intelligence/machine learning)	Yes	Assessed by DKMA
Update of implemented AI (e.g. new algorithms)	No	No
Quality control		
Establishment of new laboratory for GMP analyses	Yes	Yes
Expansion of existing QC laboratory with the inclusion of new rooms	Yes	Assessed by DKMA
Establishment of new chemical, physical, microbiological or biological analysis in existing QC laboratory	No	No
New analytical equipment	No	No
Medicinal products manufactured in third country		
All changes to centrally authorised medicinal products, which are to be notified to the EMA	Yes	Assessed by EMA
Changes to decentrally authorised medicinal products, which are only to be notified to the Danish Medicines Agency	Yes	Assessed by DKMA

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Date	Version	Change
21-11-2025	6	Revision log implemented. Introduction with guidance text on the description of the change has been added. Linguistic changes and clarifications; layout changes; and the section on manufacturing has been split into premises, equipment and manufacturing. The term ”like-to-like replacement” has been removed from the equipment section. The following items, including changes not to be notified, have been added to the list: • Changes to document management system • New manufacturing facility • A distinction is made between new process-critical equipment and new major equipment • Discontinuation of production line • Significant changes to existing water plant • Significant changes to existing process air system • Inclusion of additional rooms for storage in the existing storage building • Restructuring/sectioning of storage room • Update of implemented AI (e.g. new algorithms) • Changes notified to and assessed by EMA
30.11.2021	5	Latest published version (in Danish)