

Under what circumstances are EDQM inspections performed?



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Answer:

The EDQM can decide to inspect a company, be it the CEP holder or the manufacturing site(s), at any time before or after granting the CEP.

Applicants agree to be inspected and comply with EU GMP (ICH Q7 or other when justified) as part of the CEP application.

An applicant/CEP holder can request to be inspected by the EDQM by providing proper justification. The request will be considered according to the priority criteria defined in the EDQM's inspection programme, requests from companies having the lowest priority.

Before requesting an inspection, companies are asked to ensure that the site is fully compliant to EU GMP for all the steps of the process described in the dossier. Should the outcome of the inspection be negative, or if the company refuses the inspection without appropriate justification after having received the notification letter, CEP(s) related to the CEP holder and/or manufacturing site(s) will be suspended.

For more details on corresponding fees, please consult the [Inspections webpage](#).