

# What is the scope of the EDQM ISO 9001 certificate?



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## Answer:

The EDQM is ISO 9001:2015 certified for the following activities:

- Evaluation of applications for Certificates of suitability to the monographs of the European Pharmacopoeia (CEP) and management of the inspection programme of manufacturing sites and associated brokers;
- Planning, implementation and coordination of post-marketing surveillance studies for medicinal products and management of related databases;
- Coordination of the elaboration and issuance of guidelines related to the Official Control Authority Batch Release (OCABR) procedure for the release of batches of human immunological medicinal products (blood and vaccines);
- Management of the elaboration, revision, correction and suppression of European Pharmacopoeia texts, their publication in printed and electronic format and their distribution;
- Conduct of laboratory studies;
- Establishment, manufacturing, storage, provision and monitoring of European Pharmacopoeia reference standards.

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