



14 January 2013, Strasbourg, France

EDQM ANNOUNCES THE RENEWAL OF ITS ISO 9001:2008 CERTIFICATION AND THE EXTENSION OF ITS SCOPE TO PHARMACOPOEIAL ACTIVITIES.

The EDQM is a compliant organisation for the following activities:

"Evaluation of applications (initial, revisions and renewals) for certificates of suitability to the monographs of the European Pharmacopoeia, granting of certificates, and management of the inspection programme of manufacturing sites and associated brokers.

- *Planning, implementation and coordination of post-marketing surveillance studies for medicinal products authorised by the centralised (CAP) and national (MSS studies) procedures;*
- *Management of the database related to post-marketing surveillance studies of medicinal products authorised by the mutual recognition (MRP) and decentralised (DCP) procedures and management of related interactions with users;*
- *Coordination of the elaboration and issuance of guidelines related to the OCABR procedure for the release of batches of human immunological medicinal products (blood and vaccine); according to the pharmaceutical legislation, notably directives 2001/82/EC and 2001/83/EC, as amended, and Regulation 726/2004 (EC) for the EU countries.*

Management of the elaboration, revision, correction and suppression of European Pharmacopoeia texts, their publication in printed and electronic format, as well as their distribution".

The certification was awarded by Afnor Certification (AFAQ) in December 2012. To register as ISO 9001:2008 compliant, the EDQM underwent a stringent evaluation process that included its quality management system, a full documentation review and staff training and competence management; all of which aimed at identifying any corrective actions necessary to eliminate non-conformities to the quality management standard. The process culminated in a comprehensive four-day certification audit by Afnor.

The certification of compliance with ISO 9001:2008 recognises that the policies, practices and procedures of our organisation ensure consistent quality in the services and products we provide to our customers and stakeholders. With the renewal of its certification (the certificate was first obtained in 2009) and its extension to the European Pharmacopoeia, our customers and stakeholders can be confident that the EDQM is dedicated to maintaining the highest efficiency and responsiveness in achieving our goal of total customer and stakeholder satisfaction.

We believe that our decision to maintain and extend our ISO 9001 certification is a proactive one that not only anticipates the demands of our clients and our changing environment, but also demonstrates our commitment to providing quality services to all our customers and stakeholders. They can be confident that the EDQM will continue to provide the highest quality of services and products now and into the future and that, more than ever, we are committed to seeking continuous improvements.

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Note for the Editor: Further information is available on the internet site www.edqm.eu

The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopoeia is legally-binding in European Member States. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.



¹There are now thirty-eight members of the [European Pharmacopoeia](#) Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, the former Yugoslav Republic of Macedonia, Turkey, Ukraine, United Kingdom and the European Union.* There are twenty-four observers: *the World Health Organization (WHO); 5 member states of the Council of Europe - Albania, Armenia, Georgia, Moldova and the Russian Federation; and 18 other countries in the world - Algeria, Argentina, Australia, Brazil, Canada, China, Israel, Madagascar, Malaysia, Morocco, Republic of Belarus, Republic of Guinea, Republic of Kazakhstan, Republic of Singapore, Senegal, Syria, Tunisia, United States of America.*

A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 47 member states.