EU retests and release analysis with QP final release

Batch release by QP

Strict guidelines for quality control and batch release (EU retest) apply to the placing on the market of pharmaceutical batches in the European Union (EU). This applies to both batches of finished medicinal products and clinical investigational medicinal products that are to be placed on the EU market from third countries[1)].

In addition to the prescribed quality control test, the Qualified Person (QP) is indispensable for the placing on the market. The QP releases the batch for the market by issuing the batch release certificate and entering it in the batch release register. The QP is personally responsible for the release to market of the batch as a whole.

Implementation of the regulations

For medicinal products for human use, mainly the Directive 2001/83 / EC of the European Parliament, the EU GMP guide, as well as national laws define the legal requirements for the EU retest and the Qualified Person. For veterinary medicinal products, the requirements are defined in EU regulation 2019/6 (amended by national laws).

Pharmaceutical manufacturers, contract manufacturers and importers benefit from Eurofins PHAST GmbH as a pharmaceutical analysis laboratory that has the necessary official manufacturing license according to §13 AMG/ §28 TAMG and Art. 88 of EU regulation 2019/6,respectively, for the release of pharmaceuticals and appropriately Qualified Persons. This makes Eurofins PHAST GmbH ideal for carrying out EU retests and batch release for your products.

[1)] Third countries that have a similarly strict quality control system as EU countries are exempted from the EU retesting obligation by Mutual Recognition Agreement (MRA). These are the states: Australia, Israel, Japan, Canada, New Zealand, Switzerland and the United States of America.

@ Contact:
DenisTheobald@eurofins.de

Why choose Eurofins PHAST?

Pharmaceutical companies, drug manufacturers and importers who do not have their own subsidiary with a Manufacturing and Import Authorisation (MIA) in a European member state need a quality control laboratory such as Eurofins I PHAST to perform the EU retest or batch release analysis for you and release your batches for the European market by in-house experts.

Due to their qualifications, the experts of Eurofins PHAST GmbH offer a unique and high-quality service:

- Import of pharmaceuticals and clinical investigational medicinal products into the EU (own import permit according to AMG)
- EU retest and batch release of finished medicinal products (tablets, capsules, TTS, Sterilia, Biologicals etc.) and clinical investigational medicinal products in the quality control laboratory of Eurofins PHAST GmbH
- Authorization for products for human as well as for veterinary use
- Preparation of the „QP-GMP Declaration“ for active ingredients required for EU approval on the basis of Annex 16 of the EU GMP guidelines
- Performance of all necessary audits of the manufacturers involved (also active ingredient manufacturers), also in the respectivethird country (except countries affected by embargoes/economic/financial sanctions)

The single point of contact for all QP services

Customers who commission Eurofins PHAST GmbH with EU retests and release analysis including QP certification have ONE competent contact person for all aspects of batch release and minimize their own workload for the batch release of their drug on its way to the European market.

Eurofins PHAST GmbH is your comprehensive service provider for all aspects of meeting the legal requirements associated with the import of medicinal products.

Contact:
Eurofins PHAST GmbH
Kardinal-Wendel-Str. 16
66424 Homburg / Saar / Germany
DenisTheobald@eurofins.de

02-2023 - V01.