KYMOS

Batch testing
& Batch release

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LEGAL BASIS

Imported products manufactured outside of the European Economic Area (EEA), which is composed of the 28 member states of the European Union (EU) plus Iceland, Norway and Liechtenstein, have to be tested by an European laboratory GMP compliant and duly authorized, before being released into the market. The Annex 16, Volume 4, of the EU Guidelines for GMP for Medicinal Products for Human and Veterinary Use provides a guidance on the certification by the Qualified Person (QP) and on batch release.

The EU has signed mutual recognition agreements (MRAs) with third-country authorities concerning the conformity assessment of regulated products, with different degrees of coverage: Australia, Canada, Israel, Japan, New Zealand, Switzerland and United States (in transition phase). For these MRAs countries quality control retest is not always necessary, despite batch certification is.

The QP of the release laboratory is responsible to verify that the product complies with the terms of the marketing authorization and has the expected quality and is the ultimate authority to approve a batch of pharmaceutical product for being marketed or being used in clinical trials. The release laboratory is designated the Manufacturing Authorization Holder (MIA).

KYMOS SERVICES

KYMOS is offering experienced laboratories in Europe (Spain and Italy) GMP certified and FDA inspected to provide a comprehensive service of importation, batch testing and batch release. KYMOS counts with different QPs and is certified as importer and manufacturer (quality control) for human, veterinary and investigational medicinal products.

KYMOS has capabilities to release sterile and non-sterile products, small molecules and biologics. KYMOS has a lean organization with a dedicated instrumentation and quality control team that allows short lead-times at very fair prices.

KYMOS services cover:

- Qualified Person Declaration (annex 5.22) issuance
- Audit to the Manufacturing plant in compliance with EU-GMP
- Authorization of importation request to the Medicines Agency
- Quality Agreement management
- Transportation conditions review
- Importation into the EU
- Warehousing and sampling
- Analytical Method Transfer
- Batch Testing according to the Certificate of Analysis
- Out of Specification, change control and incidence management
- Batch Release in agreement with the Marketing Authorization
- Storage of retention or reference samples