

# Regulatory Compliance: How to accelerate your medicinal product launch in Europe

Our experts at BlueReg are covering the different pathways to accelerate your medicinal product launch in Europe.

The different subjects covered are :

## 1. Regulatory Strategy – How to prepare the regulatory launch sequence for your first medicinal product in Europe?

- EU Marketing Authorisation (MA)
- Regulatory Strategy Considerations
- How to Plan the Regulatory Activities of your Medicinal Product Launch?
- Planning of Activities for Local Market Launch is Crucial

## 2. Compliance with Regulatory Requirements

- European Definition
- Brexit Impact
- Key Requirements to Launch a Product in the EU
- Local Representatives
- National Codes
- Blue Box
- Serialisation
- Local Databases
- Local Launch Date Notification
- Promotional Materials
- Educational Materials
- Local Wholesale Distribution Authorization (WDA)
- Shared Pack and Stock Keeping Unit (SKUs)

## 3. A tailored outsourcing regulatory platform

- Outsourcing Platform to Support EU Local Market Launch

#### 4. Q&A's