PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

REGULATORY COMPLIANCE

ASSESS YOUR RISK PROFILE AND STRENGTHEN YOUR REGULATORY COMPLIANCE

PharmaLex Ireland is an award winning EU and US Quality, Technical and Compliance consultancy to the life sciences industry. Our team of expert consultants, comprising a number of former EU and US FDA Regulatory Inspectors, works at a strategic and tactical level with our clients, providing solutions, holistic advice and guidance across the entire product life cycle. With a global network of over 90 GxP consultants, we have the bandwidth and expert capability to support the diverse demands facing our clients. In addition to providing unrivaled industry and regulatory insights, we work with your teams to implement recommendations and solutions with the goal of establishing sustainable compliance in your operations.

A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

- **Development**
  Bring products to commercial launch faster by streamlining product development and introduction processes.
- **Technology Transfer**
  Robust Technology Transfer with expert knowledge and personnel across all stages of the transfer process
- **Regulatory Approval**
  End-to-end regulatory support from consultants with extensive experience in all routes of EU and US licensing approval.
- **Manufacture**
  Expert GMP technical, quality and compliance consultancy and solutions provided by a team that includes former EU and US FDA Regulatory Inspectors.
- **Distribution**
  EU and US Good Distribution Practice compliance from a global network of expert consultants, including former EU GDP Regulatory Inspectors.
- **Post Market**
  Support in understanding and complying with the legal obligations of the Marketing Authorisation (MA) Holder.
- **Product Discontinuation**
  Meet the regulatory requirements during and after product discontinuation.

20+ years of experience in global regulatory maintenance support, CMC

***9 out of the top 10 pharma** companies are long-term clients*

500+ quality overall summary expert reports prepared

Proven track record with 6,000 successfully completed projects

9 out of 10 top pharma companies are our valued clients

Covering all formulations from generics to innovative release mechanisms

Regular interactions with all major global health agencies

Proven track record with 6,000 successfully completed projects

DISCOVERY / NON-CLINICAL

CLINICAL DEVELOPMENT

APPROVAL / AUTHORIZATION

PRODUCT MAINTENANCE

CONTACT US

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PHARMALEX

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PHARMALEX IS THE LEADING PROVIDER OF SPECIALIZED SERVICES FOR THE PHARMA, BIOTECH AND MEDICAL DEVICE INDUSTRIES

We guide you from early strategic planning activities and non-clinical requirements through clinical development, regulatory submission processes and post-approval / maintenance post-launch activities.

Our experts use **technology-enabled solutions** to support you through the entire product lifecycle. We deliver exceptional results – going above and beyond the standard to deliver tailor-made solutions worldwide.

Stay **one step ahead** of essential requirements needed by health agencies. Our knowledge accelerates your business success...

Knowledge. Accelerated.