PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

# HEALTH AUTHORITY INTERACTIONS

## A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

DISCOVERY / NON-CLINICAL

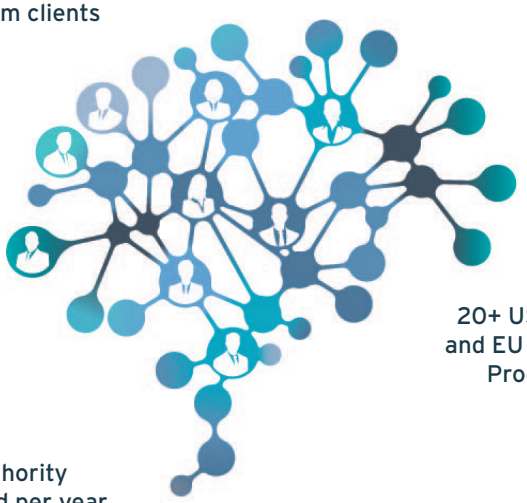
CLINICAL DEVELOPMENT

Each scientific advice from health authorities - be it during drug development, the marketing authorization process or later during the life-cycle of the drug - might ultimately affect the fate and commercial success of your investigational or already-marketed product. Meetings with health authorities are highly valuable opportunities to consolidate and optimize your development strategy with the input of the future decision makers on your marketing authorization application. Opportunities for direct interactions with regulators are still limited though nowadays all major authorities offer regulatory and scientific advice meetings to developers. To get the best out of them, they must be well prepared. We make you aware what authorities pay attention to, what kind of inquiries they make and what they expect to hear from sponsors.

## EXPERT KNOWLEDGE COMBINED WITH A GLOBAL FOOTPRINT:

9 out of the top 10 pharmaceutical companies are valued long-term clients

6+ Adaptive Pathway and PRIME eligibility applications, Breakthrough designations



20+ US Orphan Product and EU Orphan Medicinal Product designations

40+ health authority interactions led per year

35+ US pediatric study plans / EU paediatric investigation plans


## PHARMALEX CAN OFFER SUPPORT IN THE FOLLOWING AREAS:

- **Advice**
  We help to decide on the strategy of approaching regulatory health authorities and which question to ask.
- **Documentation**
  We provide support to compile a briefing package including all necessary documentation.
- **Coaching**
  We train your meeting delegates. To ask the right question and to obtain relevant answers.
- **Responses**
  We use our regulatory expertise and experience to interpret regulatory health authority requests.
- **Implementation**
  We support project teams to adequately and timely address the advice received.

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## DELIVERING SUCCESS WITH CONFIDENCE

PharmaLex is one of the largest providers for Development Consulting, Regulatory Affairs, Quality Management & Compliance and Pharmacovigilance, Epidemiology, and Risk Management worldwide. Our global teams of experts can take you through early strategic planning activities and non-clinical requirements to clinical development, through regulatory submission processes and finally guide you to market approval and product maintenance post-launch activities.

*"Since our founding in 1994, every single one of our clients is our top priority! We lead where others follow. We help clients to go beyond compliance, to capitalize on greater efficiencies, streamline complexity and to deliver true business value.*

*Ask us how we can make your job easier – over 600 customers are glad they did."*

Dr. Thomas Dobmeyer, CEO

## PHARMALEX IN NUMBERS


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