



HEALTH AUTHORITY INTERACTIONS

Health authority interactions - be it during drug development, the marketing authorization process or later during the lifecycle 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.

A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

- **Advice**
We help to decide on the strategy of approaching regulatory health authorities and which questions 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 questions 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.



40+ scientific advices incl. assistance and health authority meetings annually with FDA, EMA and national EU agencies



25+ Adaptive Pathway, PRIME, Fast Track and Breakthrough designation Therapy requests



30+ US Orphan Product and EU Orphan Medicinal Product designations



50+ US pediatric study plans / EU paediatric Investigational plans

DISCOVERY /
NON-CLINICAL

CLINICAL
DEVELOPMENT

MARKETING AUTHORIZATION
/ APPROVAL

PRODUCT
MAINTENANCE

InnoPHILEX

SourcePHILEX

DELIVERING SUCCESS WITH CONFIDENCE

PHARMALEX IS A 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.

The PharmaLex Group now has over **1000** employees, with **33** offices in **21** countries and more than **600** satisfied clients worldwide.

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

Knowledge. Accelerated.



KNOWLEDGE.
ACCELERATED.
confidence beyond compliance

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STRATEGY & CONSULTING **REGULATORY AFFAIRS** PHARMACOVIGILANCE QUALITY MEDICAL AFFAIRS

 <p>1000+ SUBJECT MATTER EXPERTS WORLDWIDE</p>	<p>25+ YEARS OF INDUSTRY EXPERIENCE</p> 	
<p> 9/10  TOP PHARMACEUTICAL COMPANIES ARE OUR SATISFIED CLIENTS</p>	<p> 40+ NATIONALITIES ON STAFF, INCLUDING FORMER FDA AND EMA EXPERTS</p>	<p>50+% OF OUR PROJECTS ARE GLOBAL</p> 