



## OUR WRITING CAPABILITIES



### TECHNICAL WRITING

#### CMC / quality writing for regulatory submissions

- ▶ Global market applications (e.g. MAA / BLA / NDA)
- ▶ Lifecycle activities (CMC variations, changes, annual reports, MA renewals)
- ▶ Clinical trial applications (e.g. IMPD / IND)
- ▶ Briefing documents for regulatory authority meetings / scientific advice
- ▶ Chemical & biological pharmaceuticals, e.g. biotechnology-derived molecules (e.g. mABs, fusion proteins, biosimilars), ATMPs, ADCs, herbals



### REGULATORY WRITING

#### Regulatory / non-/clinical writing for regulatory submissions (early new drug developments & LCM)

- ▶ Toxicological impurity evaluations
- ▶ Orphan applications (EU / US)
- ▶ Pediatric development plans (EU PIP / USA PSP)
- ▶ Briefing documents for regulatory authority meetings / scientific advice
- ▶ Clinical trial applications (e.g. IMPD / IND)
- ▶ Investigator's brochures
- ▶ Non-clinical and clinical overviews & summaries (Modules 2.4-2.7 for e.g. MAA / BLA / NDA)
- ▶ Integrated summaries of safety and effectiveness (ISE / ISS)
- ▶ Environmental risk assessments (EU / USA)
- ▶ Labeling/CCDS preparation



### MEDICAL WRITING

#### Documents related to the conduct of clinical studies

- ▶ Clinical study concepts & outlines
- ▶ Clinical study synopses
- ▶ Clinical study protocols
- ▶ Clinical study reports
- ▶ Amendments to study protocols and study reports



### SCIENTIFIC WRITING

#### Non-/clinical writing for non-regulatory purposes

- ▶ Scientific publications
- ▶ Promotional material
- ▶ Product brochures
- ▶ Product monographs

DISCOVERY /  
NON-CLINICAL

CLINICAL  
DEVELOPMENT

APPROVAL /  
AUTHORIZATION

PRODUCT  
MAINTENANCE

InnoPHLEX

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# 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.

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## CONTACT US



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WORLDWIDE

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**YEARS**  
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**9/10**  
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OF OUR PROJECTS  
ARE GLOBAL