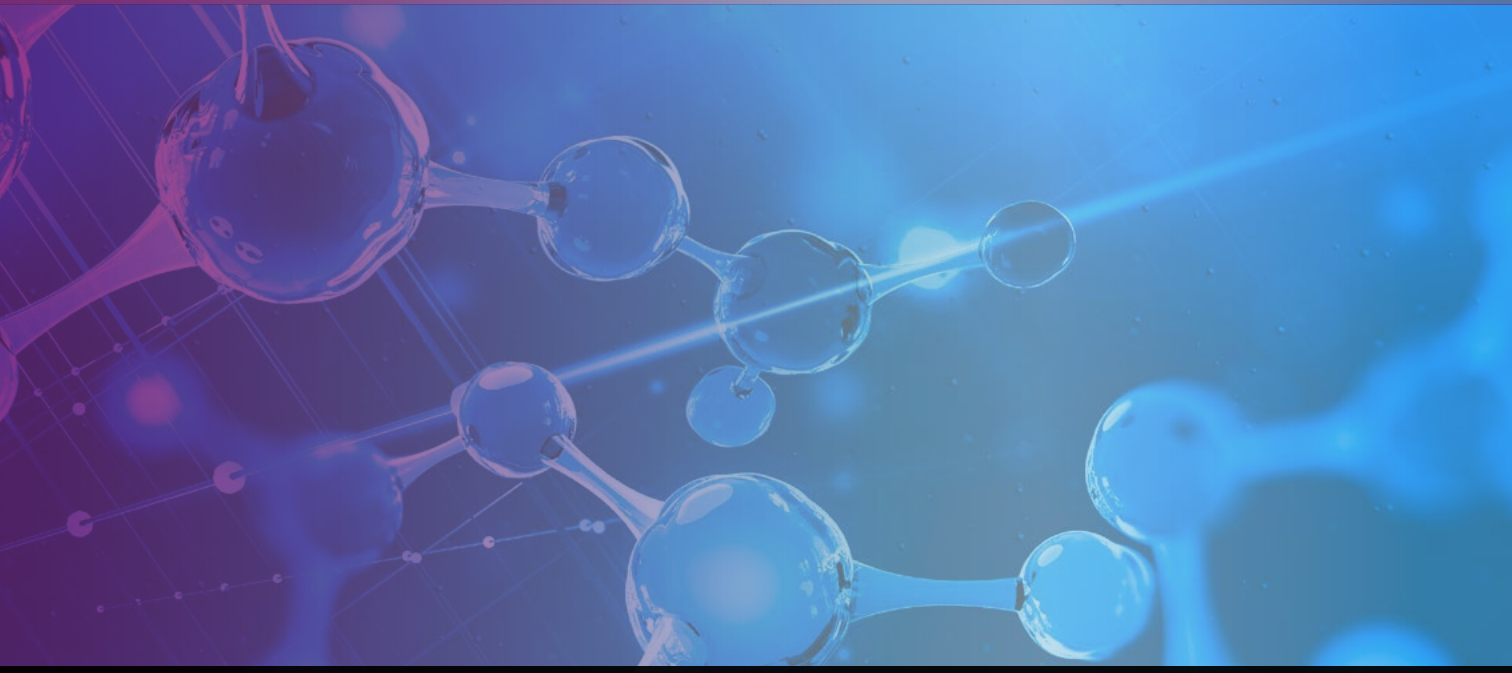
Alhena CONSULT

A small company philosophy providing consultancy services in Regulatory Affairs & Drug Development



CONSULTANCY SERVICES FOR PHARMACEUTICAL COMPANIES

www.alhena-consult.com

SERVICES

YOU ARE A START-UP, SME OR A LARGE COMPANY,

Alhena's has positioned itself as a partner for global services or services during a peak period for each step of your product lifecycle.

- REGULATORY AND DRUG DEVELOPMENT ADVICE
- OPERATIONAL SUPPORT IN REGULATORY AFFAIRS AND SCIENTIFIC WRITING
- PROJECT MANAGEMENT

DRUG DEVELOPMENT

DEVELOPMENT ROADMAP: CMC, preclinical & clinical development plan until registration encompassing regulatory pre-requisites

MARKET POSITIONING STRATEGY for the « targeted product »

PROJECT MANAGEMENT

ELABORATION OF R&D PLAN AND BUDGET

MANAGEMENT OF R&D PROJECTS from late stage research to clinical proof of concept, and then until registration

MANAGEMENT OF CMOs & CROs

SCIENTIFIC WRITING

IMPD (Investigational Medicinal Product Dossier),
IB (Investigator Brochure)

BRIEFING DOCUMENT for EU/US scientific advice

ODD DOSSIER (Orphan Drug Designation)

PIP DOSSIER (Paediatric Investigation Plan)

CTD SECTIONS including Product Information and RMP (Risk Management Plan)

EAP DOSSIER (Early Access Program) for France

EUROPEAN REGULATORY AFFAIRS

REGULATORY ROADMAP, STRATEGY & ADVICE

ADVICE, PREPARATION AND SUBMISSION
to Competent Authorities/EMA of:

- CTA (Clinical Trial Application)
- Scientific Advice for EU Regulatory Agencies
- ODD (Orphan Drug Designation)
- PIP (Pediatric Investigational Plan)
- EAP (Early Access Program) in France (ATU)
- MAA dossier (MRP, DCP, CP)

COORDINATION, review, compilation & submission of CTD dossiers for EU registration (MRP, DCP, CP)

SUPPORT FOR EXPLOITANT ACTIVITIES IN FRANCE

SERVICES

Alhena CONSULT

FROM PROJECT TO PRODUCT

DEVELOPMENT

CMC & NC studies
Pivotal clinical studies
Agencies meeting

EARLY ACCESS PROGRAM

European EAP
ATU* in France

REGISTRATION

CTD writing, coordination, submission Follow-up until approval

MARKET & MAINTENANCE

Launch activities (FR)
Variations
Update mature files

*Autorisation Temporaire d'Utilisation

10.20

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