3D PHARMXCHANGE

BIOLOGICS DEVELOPMENT: FROM CLINICAL CANDIDATE SELECTION TO TAILORED DRUG DEVELOPMENT SUPPORT

At 3D-PharmXchange, we recognize the challenges biotech and pharmaceutical companies face in developing safe and effective (bio-)pharmaceutical compounds. With comprehensive in-house expertise and a vast industry network, we deliver strategic support tailored to your needs.

Why choose 3D-PharmXchange?

Full development support

Strategic & operational

Accelerate development & improve efficiency

Knowledge transfer

Direct access to highly experienced consultants

Experts in a wide range of therapeutics & indications

Flexible deployment

Cost & time effective

To meet the timeline, budget & quality requirements

Vast industrial network

Effective negotiations with CROs & CDMOs

Due diligence, valuation, and venture capture

Our Expertise in Biologic Drug Development

	CMC	Non-Clinical	Clinical	Regulatory Affairs
Scope of services	Assist with early development to commercial manufacturing	Translational, (GLP-) toxicology, ADME, dose selection	Clinical science and operations, medical writing and project management	Preparation and submission of IND/CTA & registration file (NDA/BLA/MAA)
Expert guidance	Process development, CDMO selection & management, GMP, Quality (QA/QP) QMS, CMC RA	CRO selection & monitoring, data analysis, biomarker selection & development, combination therapies	Clinical CRO selection, documentation, statistical support, Clinical study support incl. platform clinical trials	Regulatory strategy, Scientific advice, Paediatric investigational plan, orphan drug designation

65+ projects ongoing

16 biologics companies

15 years track record

25+ FTE (in-house)

300+ projects completed

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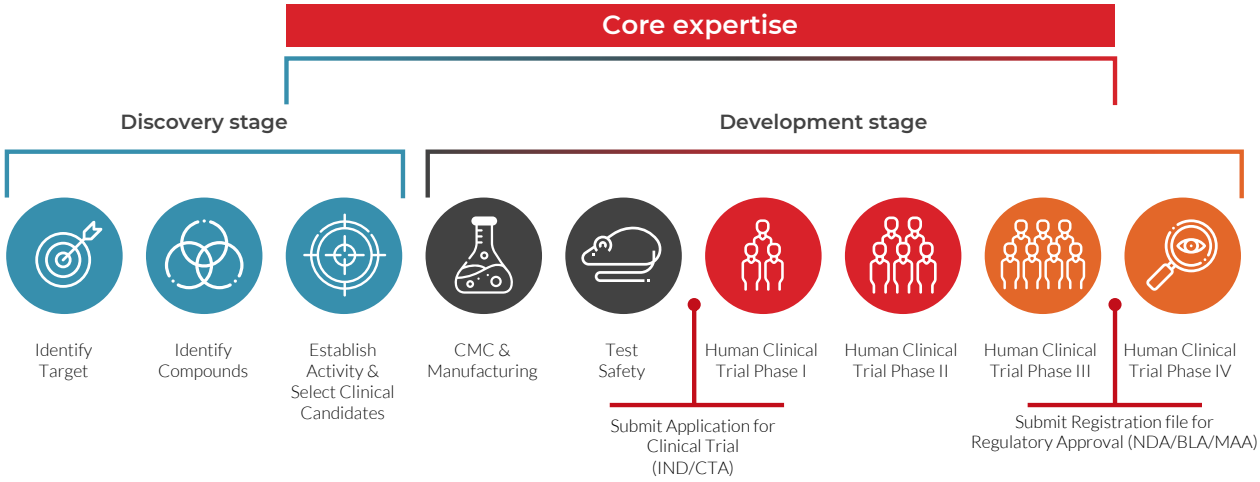
Your clinical roadmap to success



We provide end-to-end support for biologic drug development, from late-stage discovery to marketing authorization applications. Our expertise includes comprehensive process development (cell line, USP and DSP, analytics, and formulation), CDMO selection and management, clinical supplies, pre-clinical (GLP) toxicology and pharmacology, as well as regulatory affairs (RA) and quality assurance (QA) support for a range of biologic products. We take a multidisciplinary approach to de-risk projects and accelerate development, ensuring efficient and streamlined process.

Our biologics track record

Antibodies & bispecifics

Antibody-drug conjugates

Protein drugs & biosimilars

Vaccines

Developing biologics presents unique challenges, from their large molecule structural complexities to stringent regulatory demands and robust manufacturing. At 3D-PharmXchange, our deep expertise in biologic drug development enables us to overcome these hurdles, ensuring the delivery of safe, effective, and high-quality therapies to patients.

From gap analysis to multidisciplinary support

3D-PharmXchange helps biotech companies grow from concept to launch with tailored support. Whether you need a comprehensive program or targeted assistance, our team ensures your project's success.

Review of data
Outline pre-clinical strategy
Review / recommend CROs

Gap Analysis

Non-clinical
CMC & Quality
Clinical
Regulatory Affairs
Project Management

Discipline-specific support

Gap analysis
Non-clinical safety & ADME
CRO management
DS/DP & formulation development
CDMO management
FiH clinical protocol outline
Target product profile
Regulatory Strategy
Project leadership

Integrated Development

Ready to accelerate your biologic drug development?
Reach out to 3D-PharmXchange to discuss your needs.

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