3D PHARM X CHANGE

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

At 3D-PharmXchange, we recognize the challenges biotech 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 their needs. We are eager to explore how our expertise can support your company in advancing your Advanced Therapy Medicinal Product (ATMP) from concept to clinic.

What does 3D-PharmXchange offer?

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 ATMP Drug Development

	CMC	Non-Clinical	Clinical	Regulatory Affairs
Scope of services	Assist with early development to clinical 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	Non-Clinical program & study design, CRO selection & monitoring, data analysis, biomarker selection	Clinical program & protocol design, medical writing, statistical support, clinical study support	Regulatory strategy & documentation, scientific advice, paediatric investigational plan, orphan drug designation

65+ projects ongoing

13 ATMP companies

15 years track record

25+ FTE (in-house)

300+ projects completed

Maidstone 48a, 5026SK, Tilburg, NL W 3d-pxc.com E info@3d-pxc.com T +31 (0)13 534 8272

Our ATMP track record

Gene therapy

Cell-based gene therapy

Cell therapy

Developing ATMP presents unique challenges. Due to their complex nature, high quality starting material is key for robust manufacturing. We offer support in finding the right partner for your viral vector manufacturing, both AAV and LV. Autologous as well as allogeneic cell products need a specialized approach towards the control and release strategy. At 3D-PharmXchange, our deep expertise in ATMP 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 they need a comprehensive program or targeted assistance, our team ensures their 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

Accelerating your ATMP development program

At 3D-PharmXchange, we provide end-to-end support for ATMP development, from late-stage discovery to late-stage clinical trials. We offer biotech companies an optimal ecosystem for advancing cell and gene therapy development. Our expertise in regulatory strategy, non-clinical and clinical development, and CMC & QA forms a robust foundation for de-risking programs, ensuring regulatory alignment, and expediting development timelines.

With a strong track record in supporting start-ups and research institutions, we help navigate development complexities, increasing success rates and attracting pharma and investor interest for the next phase.

What we bring as a partner

- Early-Stage Strategic Guidance
- Due Diligence & Feasibility Assessment
- Development Strategies & Planning
- Regulatory Strategy
- CMC & Manufacturing
- Non-clinical Development

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