NorthX Plasmid Solutions

NorthX Biologics is providing expert plasmid DNA

solutions for all phases ranging from early pre-clinical through to commercial manufacture. We offer a range of plasmid qualities with the right level of control for every purpose, ensuring efficient expedition of your program with full regulatory compliance. We are providing pDNA as critical staring material for viral vector gene therapies and mRNA applications but also complete drug product manufacturing including aseptic fill/finish for pDNA vaccines and other modalities. By applying our flexible proprietary platform process we can deliver high quality plasmids with compressed timelines facilitating speed to market. We are using aligned processes ensuring scalability from small to large scale with full in-house analytical support. In our modern Innovation labs, we are providing full development services to meet you specific needs for optimization and process adaptions. By applying a structured R&D model we help to mitigate later manufacturing risks.

Plasmid platform with open entry depending on client preference

Screening

Performance Verification

3 Manufacturing

In-house QC testing

5 QP Certification and Releas

Plasmid manufacturing

Cell bank manufacture
RCB, MCB

Upstream
Downstream
Fill/Finish

Quality control





Research Grade

- · For discovery and pre-clinical development
- · Single use or reusable equipment
- · Cost effective and fast turnaround
- · Flexible analytical panel

High Quality Grade 5–6 Weeks

- Critical starting material for CGT applications
- In vitro or in vivo applications including toxicology studies
- Segregated laboratories
- · Analytics aligned with GMF
- · Fully single use process
- Traceable non animal origin raw materials
- \cdot TSE/BSE certification
- · CoA

GMP Grade 8–12 Weeks

- Drug substance applications; pDNA vaccines, direct GTs, late stage critical starting material
- · Fully single use process
- Traceable non animal origin raw materials
- Phase appropriate validation if analytical methods
- \cdot TSE/BSE certification
- · CoA
- · QP release and certification







NorthX Biologics provides process development and manufacturing services with expertise in plasmids, proteins and other advanced biologics. We sit in the heart of Sweden, and our team has been manufacturing biologics to GMP since 1988. In 2021 we were recognized as a national innovation but for advanced the rapeutics and vaccines.

We take pride in adapting new technologies and different innovative platforms to our GMP processes. This enables development, upscaling and finally GMP manufacturing of innovative clinical material and supports our collaboration partners to help patients. We work closely with our staff and clients to provide solutions for biologics and ATMP's.

Learn more at nxbio.com