

VGXITM

Delivering Life's PotentialTM

WWW.VGXII.COM



CGMP CONTRACT MANUFACTURING

Flexibility, Trust, Quality, Value & Experience





VGXI, Inc. is a leading manufacturer of DNA plasmids. We deliver flexibility, experience, reliability and value to our clients' challenging programs. The company's cGMP and non-cGMP products have passed rigorous international regulatory reviews. VGXI's patented manufacturing process and cGMP production facilities give us the ability to work with your unique requirements. The unsurpassed knowledge and ingenuity of our team can be leveraged to create a custom manufacturing solution for the benefit of your organization.

VGXI can build a solid foundation for your program with our research production service. This recent offering extends our scope in response to the overwhelming requests of our clients for high-quality, research grade materials. This rapid turnaround program ensures our clients' pre-clinical and clinical products are produced utilizing the same efficient process, personnel, and facility. Our process provides materials you can trust to build a reliable pre-clinical dataset for your development plans.



THE VGXI PROCESS



RESEARCH PRODUCTION / PROCESS DEVELOPMENT



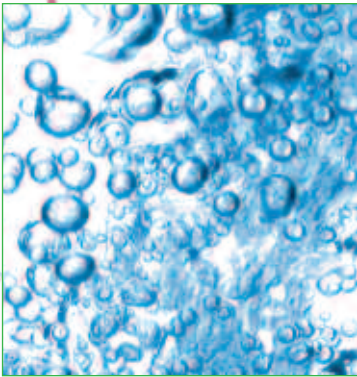
- Allows our clients to have a single source supplier for all plasmid needs
- Ensures efficient transition of your program from pre-clinical to clinical evaluation
- Strain selection, clone selection, fermentation and purification development ensure maximum quality and yield at a cost-effective scale of operation
- Verifies VGXI's ability to meet your critical stability and quality specifications

CELL BANKING / FERMENTATION



- cGMP cell banking performed in-house
- 0.5L, 10L, 100L, and 500L installed; 3,000L planned
- Process simulation up to 10,000L
- Standard growth conditions optimized for each plasmid
- Experience with *E. coli* fermentation up to 3,500L

LYSIS / SEPARATION



- Cell lysis is the critical step for plasmid production
- VGXI utilizes a proprietary Continuous Capture Method
 - Effectively lyses cells at a continuous high rate without damaging cellular contents*
- Fully automated process
- No centrifugation or any high shear on the resulting lysate to minimize genomic contamination
- No animal-derived enzymes
- Process performed at multiple production scales

PURIFICATION / ULTRAFILTRATION



- VGXI uses disposable processing technology to increase process throughput and compliance
- Provides 20x the binding capacity of conventional resins
- No gradients required
- Disposable units require no cleaning validation
- Eliminates the use of organics, carcinogens, and flammables

FILL / FINISH



- VGXI has in-house fill capabilities in a clean room environment
- Vial fills from 0.5 ml up to 100 ml
- 5,000 vial per shift capability
- Validated filling operation
- High concentration plasmids up to 15 mg/mL
- Multi-plasmid DNA vaccine formulations





VGXI's patented processes and purpose built facility deliver world-class results. Our typical first project can be completed in about 5 months but will typically occur over 12 to 18 months to match client product development milestones.

VGXI ADVANTAGES

- Research production service allows single source supply for all plasmid needs
- Ownership and control of in-house manufacturing capability from master cell bank (MCB) to final drug product
- Flexible, purpose-built facility used for research, development, and clinical supply
- Key personnel with expertise allowing for rapid development of products
- Quality Systems in place to meet regulatory requirements
- A cost-effective process that has been scaled to meet clinical and commercial needs
- Process easily transferable to alternate locations if required
- A track record of success in meeting goals and supplying clinical studies



AVAILABLE SERVICES

- Process Cost Analysis
- Strain Selection
- Research Batch Production
- Assay Development
- Fermentation Development
- Cell Bank Characterization
- Purification Development
- Complete Release Testing
- Formulation Development
- Sterility Testing
- MCB, WCB Generation
- CMC Preparations
- cGMP Batch Production
- Validation Services
- cGMP Compliance Audits/Consulting
- Stability Testing
- Fill / Finish Services



VGXI, Inc.

2700 Research Forest Drive, Suite 180
The Woodlands, Texas 77381

T: 281.296.7300

F: 281.296.7333

Email: manufacturing@vgxii.com

VGX International

#701 Jung-Hun Bldg.
944-1 Daechi3-dong
Kangnam-gu
Seoul
Korea

T: +822.2222.3450

F: +822.2222.3497

