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Contract Manufacturing Services Sterile Injectable Products



BioTechnique has rapidly responded to the current high level of demand for cytotoxic and other high-potency filling capabilities by leveraging our existing alliances and strategic partnerships in life science and investment advisory services to develop a contract manufacturing organization (CMO) for cytotoxic and high-potency sterile injectable fill-finish services in the United States.

BioTechnique's new cytotoxic and high potency fill and finish capabilities will surpass customer needs for sterile injectable fill-finish services in all stages of the drug life cycle - from investigational/clinical to final marketed product. By manufacturing these medicines and others that are in high demand in the United States BioTechnique provides a much needed capacity, shortens the supply chain to the patient, and literally helps to save lives.





### **CAPABILITIES**

Aseptic Fill and Finish

Aseptic Lyophilization

Cytotoxic and High-Potency Drugs

Drug Compounding & Formulation

### **CAPABILITIES**

Process Light-, Temperature-, & Oxygen-Sensitive Products

Environmentally-Controlled Storage

Uni-Directional Processing

Closed Manufacturing
Process

Barrier Isolation Technologies

Unit Operation Segregation

Single-Use Disposable Processing System

Research Development & Support

Full Service Laboratory

Regulatory Affairs Management

# Highly Proficient

BioTechnique's contract manufacturing facility is capable of controlling the fill-finish production process from start to end. We have the ability to compliantly manufacture, inspect, and store product at any stage of the drug life cycle. With BioTechnique quality is not a goal, it is the standard. We back our guarantee with the experience and knowledge of our quality assurance team who continually monitor all quality standards.

BioTechnique offers the use of our environmentally-controlled warehouse for confident and consistent storage. BioTechnique's manufacturing facility is fully operational and able to accommodate various manufacturing requirements from standard procedures to custom requirements - ensuring that customer needs are not just met but surpassed every time.



# The Proper Priorities

BioTechnique understands the importance of business relationships in the contract manufacturing industry. Underlying every successful contract manufacturing operation is a high level of trust between the production facility and its clientele. We value our contractual obligations and fervently strive to grow meaningful connections.

BioTechnique will flexibly accommodate customer requests. Custom configuration is not only welcomed, but is addressed with care and efficiency. With BioTechnique clients rest assured knowing that no matter the product or batch size, the manufacturing process will be carried out to the highest standards. Our promise of quality is backed by a comprehensive quality and compliance management software known as Adaptive Compliance Engine™, or ACE. ACE was originally developed and is continually monitored by PSC Software's experienced technical staff.



### **PRIORITIES**

Supply Chain Integrity

Relationship-Focused

Project Management

Customizable Configuration

Customer Request Handling

Complete Contract Confidentiality

Time-Honored Partnerships

Open & Ongoing Communication

## PSC DIVISIONS

# Professional Services





# Investment Consulting Services



# Contract Manufacturing Operations



# Enterprise Software



BioTechnique is a division of PSC, an industry leader in validation, compliance, and calibration services that delivers in-depth investment consulting and quality & inspection management software solutions for the biotechnology, medical device, pharmaceutical, and diagnostics industries. We focus on engineering, compliance, commissioning, qualification, validation, information technology, computerized system validation, regulatory affairs, quality control, investment consulting, and enterprise software services.

Our firm is a catalyst that helps emerging life science companies to achieve their full potential. We provide the professional consulting and investment advisory services, quality management systems, and contract manufacturing operations that help companies get their products approved by the world's regulatory bodies with the highest level of quality and compliance oversight.

By improving the safety and quality of the supply chain we not only reduce the time span from product to patient but can do so at lower costs; these advantages are then passed down to patients in the form of more affordable medicines in shorter time frames. When we ensure the supply of critical medicines we help health professionals save lives.



# Medicine Preserves Life, We Preserve Medicine.

### **CONTACT US**

Madison, Wisconsin

5501 Research Park Blvd Madison, WI 53719

Time Zone: GMT-6

TEL +1.608.204.9224

EMAIL info@biotechnique.com

### **US OFFICES**

Pomona, California

PSC Headquarters 700 Corporate Center Dr Suite 201 Pomona, CA 91768

Time Zone: GMT-8

Alameda, California

2183 Harbor Bay Pkwy Alameda, CA 94502

Time Zone: GMT-

Dallas, Texas

(909) 643-7251

Time Zone: GMT-6

Boston, Massachusetts

(617) 279-3818

Time Zone: GMT-5

### **GLOBAL OFFICES**

Singapore City, Singapor

26 Boon Lay Way, #01-92 Trade Hub 21 Singapore 609970

Time Zone: GMT+8

Beiiina. China

Room B537, No. 16 East Yong'anli Chaoyang District Beijing, China 100022

Time Zone: GMT+8

Shanghai, China

Unit 702, No. 167 Jiangning Road Jing'an District Shanghai, China 200041

Time Zone: GMT+8

Ireland

PSC European Headquarters Cork +353 (21) 601-0707 Dublin + 353 (1) 901-1707

Time Zone: GMT+0

andan United Kinadar

UK +44 (0) 20 34758107 US 1(752) 523-2727

Time Zone: GMT+

Pan Juan Duarta Dia

400 Rafael Lamar St Urb. Ext. Roosevelt San Juan, PR 00918

Time Zone: GMT-4

