

Corporate Report

a report by

Laureate Pharma Inc.

Laureate Pharma, a full service biopharmaceutical development and production company, located in Princeton, New Jersey, provides specialized services from process design and development to full-scale current Good Manufacturing Practices (cGMP) production, purification, aseptic filling, testing, validation, analytical services and regulatory support. Laureate Pharma's experienced scientists purify biopharmaceutical proteins, expressed in mammalian cells, using state-of-the-art semi-automated chromatography systems and fill into vials under stringent aseptic conditions. Laureate Pharma is focused on two active segments of the biopharmaceutical industry, monoclonal antibodies and recombinant protein products.

Laureate Pharma's Commitment to Contract Bio Manufacturing

The biopharmaceutical industry is faced with a challenging task; planning, developing, manufacturing, and bringing to market a highly specialized and complex biopharmaceutical product. Competitive pressures, cost, and, above all, the time-to-market issue are of key concern. Laureate Pharma's objective is to offer customers greater confidence in outsourcing their biomanufacturing. Laureate Pharma's expertise spans the area of clinical scale to commercial scale production of monoclonal antibodies, interleukins, enzymes, anti-body conjugates and radio labelled antibodies. Laureate Pharma's mission is "to partner in delivering the future of human health to improve the quality of all the lives we touch".

Laureate Pharma's Bioprocessing Services

Laureate Pharma provides superior bioprocessing services that accelerate new products from development through production.

Cell Line Optimization

Laureate Pharma's highly experienced cell line development team ensures that this first critical step

in the development phase of a biopharmaceutical is improved and maximized to yield cell line productivity in optimal media for downstream processing.

Process Development

Laureate Pharma's development staff have the expertise and experience in bringing protein-based parenterals from lab scale to pilot scale and all the way to commercial production. Laureate Pharma's team conducts small-scale pilot bioreactor runs, which is a vital step enroute to larger-scale production.

Bioreactor Production

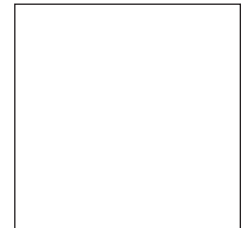
Laureate Pharma's 57,000 sq.ft. (5300m²) facility in Princeton, New Jersey includes development laboratories and manufacturing areas that house both hollow-fiber and stirred-tank bioreactors ranging from 20 to 2500 liters in size. Laureate Pharma's assets include multiple stirred tanks, wave systems and hollow fiber bioreactors. Critical equipment and processes are validated for the production of biopharmaceuticals, and the facilities have been routinely inspected by regulatory agencies.

Purification

To scale up from bench to manufacturing, develop robust well-integrated processes and produce high-purity product with good yield, Laureate Pharma uses automated chromatography development systems. From sample preparation to initial capture to polishing and final product formulation, Laureate Pharma's experienced team can purify any protein product to full cGMP requirements. Laureate Pharma performs process validation, including viral-clearance studies at off-site, qualified laboratories.

Proteing Modification and Conjugation

Laureate Pharma's team of specialists can perform chemical conjugation of molecules with proteins.



Margin Copy

They have experience in performing conjugation for clinical and commercial products, and have special expertise in working with conjugation of chelators to proteins for radiolabelling.

Analytical and Formulation Development

Laureate Pharma's team of scientists, based on clients' requirements, routinely characterize protein properties, develop assays and test methods, transfer in client's methods, develop new methods, adapt Laureate Pharma's methods and formulate product & profile stability of the final product.

Aseptic Filling and Finishing

Laureate Pharma offers aseptic fill and finish services to formulate and fill the final product. Laureate Pharma's facility features a specialized filling machine whose product-contact parts are all single use disposable. It operates within a class 100 filling area and can accommodate vials from 2-100 ml in size, with fill volumes from 0.1 – 100 ml. This equipment can accommodate batch sizes up to 20,000 vials or 200 liters of bulk volume.

Laureate Pharma's Commitment to Quality

Quality Assurance Systems

Laureate Pharma's Quality System consists of Quality Control, Quality Assurance, Microbiology and Validation. The integration of all these functional operations ensures compliance at every step of the cGMP and manufacturing process. The Quality System department works closely with manufacturing groups to assure adherence to quality standards in all systems and processes throughout Laureate Pharma's facilities.

Quality Systems consisting of cGMP Documentation System (batch/fill records, SOPs, specifications test methods), Audit and Review System (batch records, equipment logs, test records, validation data), Approval and Release System (raw materials, intermediates, final product to client), Vendor Approval System (components & outside testing), cGMP Compliance System (training, in-house audits), Change Management System (approved documents, facilities equipment & processes), CAPA system (deviations and incidents, corrective/preventive actions, investigations, remediation plans) and Quality Manufacturing System (QA participation in monitoring of critical parameters during manufacturing and filling).

Analytical and Microbiology Testing

Laureate Pharma offers analytical and microbiology testing for raw materials, in-process and finished protein, anti-body and pharmaceutical products. Laureate Pharma's labs are registered with the Food and Drug Administration (FDA), and licensed by the Drug Enforcement Administration (DEA) and **Nuclear Regulatory Commission (NRC)**. Laureate Pharma's team of validation engineers qualifies equipment and processes for manufacturing of both protein/anti-body and other parenteral pharmaceutical products. Laureate Pharma's analytical testing programs cover biopharmaceuticals, pharmaceuticals and radiopharmaceuticals.

QC Testing is done on raw materials, in-process and intermediates and the final product. Microbiology consists of environmental monitoring including sample collection, speciation tracking & trending data, **Water for Injection (WFI)** sampling and testing, oversight of outside testing and sterility microbial limits (bioburden). Laureate Pharma also monitor additional services such as nitrogen, oxygen, carbon dioxide, compressed air, drains, clean steam, RO/DI spore strips, validation support and investigation support.

Validation

Laureate Pharma's validation program includes Validation Master Plan, **IQ**, **Operator Qualification (OQ)** and **PQs** of all critical equipment, revalidation program, customer-specific equipment and process validation and in-house staff supervision of contractors & consultants.

Laureate Pharma works with clients to ensure that quality agreements are put in place with each client, tailored to the client needs. Specifications are written by Laureate Pharma and approved by the client for each client-specific raw material, packaging component, in-process material and finished product. Master batch & formulation and fill records are written by Laureate Pharma and approved by the client. Audits may be performed by the client at any time for specific issues and once per year globally. Laureate Pharma welcomes a person in the plant.

Facilities

Laureate Pharma's facility is registered with the Food and Drug Administration (FDA), **DMF**, the Drug Enforcement Administration (DEA) state and federal, the Nuclear Reinforcement Commission (NRC) state and federal. Laureate Pharma's team has experience working with the FDA, Canadian and European agencies. Laureate Pharma's staff have

prepared CMCs for INDs, BLAs, NDAs and European dossiers. Laureate Pharma provides the CMC and regulatory support by working closely with the client's regulatory groups. Preparing CMC sections for INDs and other regulatory submissions (site DMF reference letter (Type V).

Expertise and Experience

Laureate Pharma offers a proven, fully integrated cGMP facility staffed with experts and specialists in each critical area. The management and staff combine the unique experience and capabilities of manufacturing with both clinical-trial and commercial biopharmaceuticals for over 20 years and have a proven track record of taking products through development and manufacturing to the market.

Laureate Pharma Facts

Laureate Pharma was formed in 1999, acquired the Princeton facility and hired key employees. Laureate Pharma has ongoing improvements of the facility to accommodate the continuing expansion of service offering. Laureate Pharma, Inc. is a partner company of Safeguard Scientifics (NYSE: SFE). Safeguard provides growth capital as well as a range of strategic, operational and management resources to Laureate Pharma. ■