

Biologic Manufacturing



We give your biologic the right environment for success.

At Baxter, we understand that every biologic is unique, with specialized requirements that are critical to its commercial success. Our recent \$100 million expansion in Bloomington, Indiana, features state-of-the-art lyophilization and filling lines for vials, syringes, and cartridges specifically designed to protect sensitive biologics and overcome commercialization challenges with speed and efficiency.

CONTINUOUS TEMPERATURE CONTROL.

Complete cold-chain filling prevents temperature fluctuations during filling and lyophilization to optimize product quality and minimize loss. Precise temperatures are maintained from filling tank to manifold and from filling head through accumulation table and lyophilization load/unload.

DUAL FILLING OPTIONS.

Our new filling line is equipped with both time-pressure and peristaltic technologies, allowing us to customize the filling process and minimize stress on your molecule.

FULLY CONTROLLED ASEPTIC MANUFACTURING.

Formulating and filling are conducted in a Class 100 environment, ensuring the highest levels of sterility and product quality.

HIGH-YIELD PROCESS DESIGN.

Each product procedure is individually tailored to provide optimum yield of your valuable API.

- **Improved homogeneity**—unique procedures such as product recirculation guard against product separation in vaccines and other suspensions.
- **Fewer line stoppages**—vial-filling line design minimizes holding of product during final manufacturing stages.
- **Less overfill**—precise filling of syringes, cartridges, and vials significantly reduces overflow and unnecessary product loss during filling.

LOW-SHEAR MAGNETIC MIXING.

Tanks are specially designed with bottom-mounted magnetic mixers to reduce shear forces vs traditional fixed-motor processing.

The right resources to improve your molecule's return on investment.

EXPERTISE TO OVERCOME CHALLENGES.

The Baxter biologic team is led by experts in biopharmaceutical research and development. Their expertise in anticipating and solving critical challenges in all phases of biologic manufacturing helps keep your product moving smoothly to market.

Our comprehensive menu of research and development services includes

- **Analytical methods development and validation** including stress and stability assays; degradation studies; and methods development, validation, and transfers
- **Formulation development** for liquid and lyophilized products and suspensions
- **Lyophilization process optimization** utilizing exclusive freeze-dry microscopy to help improve capacity and deliver more doses from valuable API
- **Packaging development** for expanded delivery methods and market potential:
 - Reformulation from lyophilized to liquid state
 - Packaging validation for conversion from vials to prefilled syringes



AWARD-WINNING TECHNOLOGY FOR RELIABLE SUPPLY.

Baxter recently earned the Facility of the Year Award, sponsored by the International Society for Pharmaceutical Engineering, in recognition of our dramatically increased production capacity and cutting-edge technology in Bloomington, Indiana. With equipment specially designed to maintain the integrity of biologic molecules, this unique facility helps ensure both a seamless path to market and the product supply you need to meet demand.



MEASURABLE BOTTOM-LINE RESULTS.

Baxter's investment in advanced biologic capabilities helps you manufacture your complex molecule successfully and efficiently—without the need for costly investment in specialized facilities, technology, and people.

- **Enhanced product yield**—unique systems such as nondestructive, in-line check weighing enhance product stability and increase yields.
- **Life cycle management solutions resources**—from methods development to packaging, world-class technologies in one streamlined location optimize your product quality and production costs.

Find out how Baxter can help your biologic molecule succeed.
Call 1-800-4-BAXTER today for more information on our dedicated biologic resources and solutions or visit www.baxterbiopharmasolutions.com.

BioPharma Solutions

Connect to the resources you need.

Baxter