

## **Baxter Pharmaceutical Solutions LLC Technology Overview**

### **Scope:**

BPS is a fully integrated parenteral (injectables) contract service business that can move sterile products from a novel idea through development and clinical trials, to full-scale manufacturing. BPS manufactures drug products for human and veterinary applications encompassing small molecule, biologic, vaccine, and protein pharmaceuticals. BPS also provides a variety of sterile product dosage forms including solutions, suspensions, emulsions, and freeze-dried powders.

### **Syringe Filling**

BPS syringe capacity of 45,000 syringes per hour (3 high-speed lines) helps meet the challenge of a growing pre-filled syringe market. Depending on your specifications, we can aseptically formulate product and fill syringes as well as provide additional options, such as terminal sterilization, plunger rod and backstop insertions, and blister packaging.

BD HYPACK® SCF® glass syringes in 0.5mL, 1mL, 1.5 mL, 2.25 mL, 3 mL, 5 mL, 10 mL and 20 mL sizes

BD READYFILL™ glass syringes in 1 mL, 3 mL and 5 mL sizes

### **Vial Filling**

Fill 18,000 vials per hour in a wide spectrum of sizes and closures. Two filling suites can process vials in sizes ranging from 2 mL to 100 mL. Automatic and semi-automatic equipment ensures accuracy and quality during the validation process of vial and stopper washing.

### **Lyophilization**

Developmental and clinical-scale freeze-dryers contain 33 square feet of shelf space. Three commercial-size freeze-dryers each provide 220 square feet of shelf space. The commercial-size freeze dryings are loaded and unloaded automatically.

### **Labeling and Packaging**

Label vials ranging in size from 2 mL to 100 mL in multiple languages and in a variety of label stocks. Package in single-printed cartons or multiple and bulk packs. We label and package pre-filled syringes ranging in size from 0.5 mL to 20 mL using clear acetate label stock with or without graduation marks and offer syringe packaging in blister trays or printed cartons. We offer blinded labeling and packaging, study design support, packaging configurations, and the provision of case report forms and randomization tables for clinical trials.

### **Formulation Development**

Expertise in biomolecule and small molecule parenteral product formulation as well as processing solution, lyophilized, and dispersed system dosage forms. Analytical development includes developing, optimizing and validating analytical methods that meet regulatory requirements. BPS has developed dosage forms and manufacturing processes for numerous FDA/EMA-approved sterile products. We utilize project-specific protocols to ensure that all formulations meet our clients' expectations. Services include:

- Stress studies
- Photostability
- Evaluation of methods for transfer to QC Chemistry Laboratories
- Freeze-dry cycle development and optimization

**Analytical Capabilities:**

- Karl Fischer
- Differential Scanning Calorimetry
- Fourier Transform Infrared Spectroscopy
- Near Infrared Spectroscopy
- UV/Vis Spectrophotometry
- Protein assay (includes ELISA, SDS-PAGE, Western Blot assays)
- High Pressure Liquid Chromatography
- Freeze Dry Microscopy
- Atomic Absorption Spectroscopy

**Quality Control Laboratory Support**

Our Quality Control (QC) Chemistry Laboratories conduct a wide variety of analytical tests on all items from raw materials to finished products. Procedures include:

- High Pressure Liquid Chromatography
- Gas Chromatography
- UV/Vis Spectrophotometry
- USP<788> Particulate analysis
- Bacterial Endotoxin (chromogenic and kinetic turbidimetric) analysis
- FTIR Spectroscopy
- Real time and accelerated stability testing
- Bacteriostasis/Fungistasis testing (EP, JP, and USP)
- Microbial identification
- Bioburden
- Biological Indicator verification (population and D-value)
- Environmental monitoring