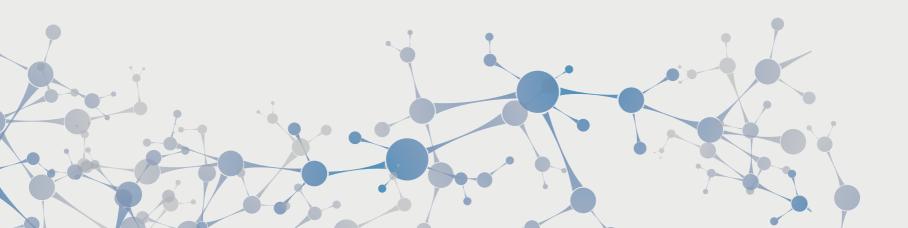


# Sterile Injectable



# ONE STOP SHOP IN THE SUPPLY CHAIN OF ANTICANCER PRODUCTS

BSP Pharmaceuticals is a Contract Development and Manufacturing Organization focused on production of anticancer and cytotoxic drugs as small molecules and ADC compounds.

BSP Pharmaceuticals provides a full range of integrated services aimed to support the entire life cycle of a product.

From the formulation and process development/optimization, through scale up/scale down studies, we can drive the product to cGMP manufacturing for clinical and commercial needs.

QC laboratories are equipped to run all analytical testing (chemical and microbiological) on raw materials, components, in process controls, release and stability testing.

Internal Regulatory Affairs team to manage data collection and document preparation for DMF and CMC to support filing activities.

#### **DEVELOPMENT**

Formulation, Process, Analytical methods

#### SCALE UP/DOWN

and Characterization

#### **QUALITY CONTROL**

Release, Stability, Process comparability testing

#### MANUFACTURING

Clinical and Commercial Supply Regulatory Support for DMF and CMC



With the highest level of technology and the most innovative solutions applied to all manufacturing areas, BSP can fulfill the most stringent requirements for handling conventional cytotoxic High Potent Drugs as well the next generation of anticancer products characterized by complex formulations

#### CONVENTIONAL CAPABILITIES

**SPECIAL** CAPABILITIES



**STERILIZATION** 





## **INJECTABLE**

**CAPABILITIES** 





#### SPECIAL CAPABILITIES

(non conventional formulation)

All Sterile filling lines are equipped to handle Organic Solvent based formulations as well a oxygen-sensitive products.

Lipid-based formulations, such as emulsion and suspension, can be manufactured by using special technologies and equipments, including:

- MICROFLUIDIZER
- HIGH PRESSURE HOMOGENIZER
- EXTRUSION



# AN HIGH CONTAINMENT FACILITY

DESIGNED TO HANDLE HIGH POTENT AND CYTOTOXIC COMPOUNDS





# STERILE SUITES CAPABILITIES

CLINICAL AND COMMERCIAL MANUFACTURING

A UNIQUE MANUFACTURING SYSTEM **SPECIALLY DESIGNED** FOR ANTICANCER DRUGS, WITH THE FLEXIBILITY TO MANAGE **SMALL MOLECULES** AND **THE COMPLEXITY OF ADCs** 

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	STERILE 2	STERILE 6	STERILE 1	STERILE 4	STERILE 5	STERILE 3	W. W. W.
LYO SURFACE	1x16 sqft	2x65 sqft	2x107 sqft	2x215 sqft	2x215 sqft	2x323 sqft	
VIAL SIZES range	from 2 ml to 100 ml	from 2 ml to 100 ml	from 2 ml to 100 ml	from 2 ml to 100 ml	from 2 ml to 100 ml	from 2 ml to 100 ml	
ISOLATOR AND CLOSED RABS to have the highest level of sterility assurance and containment	Isolator	cRABS	cRABS	cRABS	cRABS	cRABS	



ALL THE EQUIPMENT USE FIRST-IN-CLASS TECHNOLOGY WITH AN HIGH LEVEL OF AUTOMATION TO REDUCE THE NEED OF MANUAL INTERVENTIONS.

#### SIX STERILE MANUFACTURING SUITES

equipped to handle liquid and lyophilized vials

## PRODUCT LINES ARE FULLY CUSTOMIZED

and designed according to specific characteristics and criticality of each product and process

#### **FILLING LINES**

designed to minimize shear stress: possibility to use rotary piston pumps and peristaltic dosing systems

#### HIGH SPEED FILLING LINE

designed to manufacture products with short holding times

#### **CRYOGENIC LYOPHILIZERS**

enable a very accurate and efficient temperature's management during each step

### AUTOMATIC LOADING & UNLOADING SYSTEMS (ALUS)

designed for a rapid introduction of the vials into the lyo chamber to minimize product's exposure to room temperature

#### **DEDICATED COLD STORAGE AREAS**

for BDS, mAb, toxin and finish product (+2/+8°C; from -20°C up to -80°C)

#### **DEDICATED AREAS**

for manual/automatic Thawing activities

#### **TEMPERATURE CONTROL**

during manufacturing

#### **CIP AND SIP SYSTEM**

to prevent microbiological and chemical carry over

#### LOW LEVEL OF RESIDUAL PEROXIDE

to prevent protein degradation

#### **DEDICATED PRODUCT CONTACT PARTS**

(stainless steel, disposable systems) and **SPECIFIC CLEANING PROCEDURES** to

avoid contamination/degradation







### DEVELOPMENT

#### CAPABILITIES

**BSP Sterile Department** has dedicated laboratories and skilled scientists to support formulation, process development and process optimization services.

**BSP Development Team** works on both conventional and innovative formulations including ADCs and Lipid Based Formulations such as nano/microemulsion and liposomes.

BSP can also perform all their ancillary studies that can support process characterization and robustness aimed to facilitate the product scale-up delivering the product from R&D to cGMP stage.

#### THERMAL PROFILE

characterization, by DSC and cryomicroscope

#### LYO CYCLE

development, optimization, robustness

#### **2 FREEZE-DRYERS**

of 2.1 sqf and 4.5 sqft installed under isolator

#### STRONG INTEGRATION

between development and cGMP manufacturing

### ANALYTICAL METHODS DEVELOPMENT AND OPTIMIZATION

to support manufacturing during early stages

All the pharmaceutical forms produced, can be manufactured in the development laboratories with pilot scale machines that reproduce the operating conditions of industrial lines

An extended working team that integrates scientific backgrounds and manufacturing expertise supports the characterization of the products transferred within the plant, contributing to an accurate comprehension of the criticality of either process and product.

# ANALYTICAL SERVICES

All conventional analytical testing and instruments are available to support IPC and final release testing

METHODS DEVELOPMENT & OPTIMIZATION

METHODS VALIDATION & TRANSFER

CLEANBILITY & COMPATIBILITY STUDIES

CLEANING METHODS DEVELOPMENT AND VALIDATION

STABILITY & PHOTOSTABILITY STUDIES

IN PROCESS CONTROLS

**RAW MATERIALS TESTING** 

FINAL RELEASE





#### HEADQUARTER and MANUFACTURING PLANT

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CMO
LEADERSHIP
AWARDS2018
COMPATIBILITIES



CMO LEADERSHIP AWARDS2018 RELIBILITY



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DEVELOPMENT







