



Non-CYTO & HiPo

# Sterile Injectable

**BSP Pharmaceuticals is a Contract Development and Manufacturing Organization focused on innovative cytotoxic and non cytotoxic products for oncology, immuno-oncology, CNS and other relevant therapeutic indications.**

The Manufacturing plant is located in Italy, 40 miles southbound of Rome.

BSP Pharmaceuticals provides a full range of integrated services aimed to support the entire life cycle of a product as described below:



## THE PLANT HAS BEEN DESIGNED TO ACHIEVE AN OCCUPATIONAL EXPOSURE LIMIT (OEL) :

- Handling of highly potent active materials take place within closed systems (isolators), avoiding direct exposure to the surrounding in any step of the manufacturing process.
- Movement of raw materials (including High Potent APIs) and intermediates is managed using closed containers (bins or charge containers).
- Transfer of components in and out of isolators occurs through Rapid Transfer Port (RTP) and High Containment Transfer valves.

OEL < 10 ng/m<sup>3</sup> and Up to OEB 6

### CONTAINMENT GRANTED BY

**INSULATING SYSTEM** FULL CONTAINED ISOLATION TECHNOLOGY TO HAVE THE HIGHEST LEVEL OF STERILITY

**PRESSURE CASCADE FROM OPERATIONAL** TO SURROUNDING AREAS

**CONTINUOUS MONITORING** OF DIFFERENTIAL PRESSURES AND RELATED ALARM SYSTEM

**DEDICATED AIR HANDLING SYSTEM**

**100% EXHAUST AIR (NO RECIRCULATION)**

**ABSOLUTE FILTER** OF EXHAUST AIR

**CONTAMINATED WASTED MATERIAL** SEGREGATION, INACTIVATION AND DISPOSAL



#### HEADQUARTER AND MANUFACTURING PLANT

BSP Pharmaceuticals S.p.A.

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#### FOR TECHNICAL INQUIRIES AND TO REQUEST A QUOTATION

**MAIL** business.development@bsp-pharmaceuticals.com

**BSPPHARMACEUTICALS.COM**



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## DRUG PRODUCT INJECTABLE CAPABILITIES

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** High Potent Drugs as well **the next generation** of products characterized by complex formulations



### CONVENTIONAL CAPABILITIES

LYOPHILIZED VIALS  
LIQUID VIALS BY ASEPTIC FILLING AND TERMINAL STERILIZATION



### IMMUNO-ONCOLOGY DRUGS

(mAbs, CHECKPOINT INHIBITORS, SYNTHETIC VACCINES)



### IMMUNOTHERAPIC DRUGS CNS



### INNOVATIVE PRODUCTS AS SMALL AND LARGE MOLECULES

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

#### 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

	STERILE 11	STERILE 12	STERILE 13	STERILE 14	STERILE 15	STERILE 16	STERILE 18
LYO / LIQ	Lyo / Liq	Lyo / Liq	Liq	Liq	Liq	Liq	Lyo / Liq
LYO SURFACE	1x66 sqft	2x325 sqft	N/A	N/A	N/A	N/A	2x325 sqft



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