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:

DEVELOPMENT
Formulation, Process, Analytical methods

SCALE UP/DOWN
Process Robustness and Characterization

QUALITY CONTROL
IPC, Release, Stability Process comparability testing

MANUFACTURING
Pre-Clinical, Clinical and Commercial Supply

REGISTRATION
Regulatory Support for DMF and CMC Preparation

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/m3 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
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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

SPECIAL CAPABILITIES
- LIPID BASED FORMULATIONS
- ORGANIC SOLVENT BASED FORMULATIONS

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 1	STERILE 2	STERILE 3	STERILE 4	STERILE 5	STERILE 6	STERILE 7
LYO / LIQ	Lyo / Liq	Lyo / Liq	Lyo / Liq	Lyo / Liq	Lyo / Liq	Lyo / Liq	Lyo / Liq
LYO SURFACE	2x107 sqft	1x16 sqft	2x323 sqft	2x215 sqft	2x215 sqft	2x65 sqft	2x323 sqft

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