

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 is specialized to support the manufacturing of Bioconjugates products from the Conjugation to the Fill-Finish and offers a full and integrated package of services from development to clinical and commercial supply under the same roof.

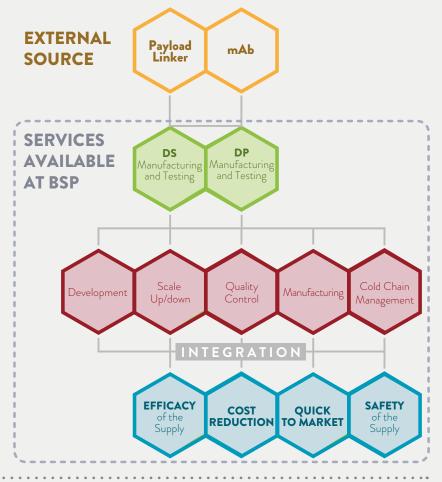
DEVELOPMENTFormulation, Process,
Analytical methods

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

With the aim to facilitate the supply chain of **Bioconjugates**, BSP Pharmaceuticals developed, within the same Facility and under the same Quality system, capabilities to handle conjugation and fill/finish, from the early development up to the commercial scale.









ADCs CONJUGATION CAPABILITIES CLINICAL AND COMMERCIAL MANUFACTURING

CONJUGATION BATCH SIZE:

from 5g to 15kg (mAb scale)

MULTIPLE BUFFER VESSELS

up to 65.000 lt capacity

DIAFILTRATION and **CHROMATOGRAPHY**

SYSTEMS suitable for development, clinical and commercial scales

BOTTLE & BAG FILLING CAPABILITIES

automatic equipment using peristaltic dosing system to fill a wide range of primary packacing configurations

MANUFACTURING OPERATIONS

are performed in a "Class C" area

STORAGE @ 2-8°C, frozen conditions (up to -80°C)











ADCs FILL-FINISH CAPABILITIES

CLINICAL AND COMMERCIAL MANUFACTURING

SEVEN STERILE MANUFACTURING SUITES

equipped to handle liquid and lyophilized vials

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 FREEZE DRYER

to optimize temperature management during lyo cycle

FULL CONTAINED ISOLATION TECHNOLOGY

to have the highest level of sterility

DEDICATED COLD STORAGE AREAS

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

DEDICATED THAWING AREAS

manual, automatic, water bath

TEMPERATURE CONTROL

during manufacturing

LOW LEVEL OF RESIDUAL PEROXIDES

to prevent protein degradation

DEDICATED PRODUCT CONTACT PARTS

(stainless steel, disposable systems)

SPECIFIC CLEANING PROCEDURES

to avoid contamination/degradation

STERILE 1

STERILE 2

STERILE 3 ft 2x323 saft

STERILE 4

STERILE 5

5

STERILE 6

STERILE 7

LYO SURFACE LYO SURI

LYO SURFACE LYO SURFACE

LYO SURFACE

LYO SURFACE

LYO SURFACE

2x323 sqft LYO SURFACE



