

TO SUSTAIN
THE FIGHT
AGAINST

CANCER
WE

DESIGNED

A MODEL
DRIVEN BY
EXCELLENCE

BSP PHARMACEUTICALS



OUR MISSION STATEMENT

A VALUABLE AND TRUSTED NEIGHBOR
IN THE ONCOLOGY COMMUNITY, OFFERING
THE BEST TECHNOLOGY AND PROVEN
EXPERIENCE TO INNOVATORS
AT THE FOREFRONT OF THE FIGHT
AGAINST CANCER.

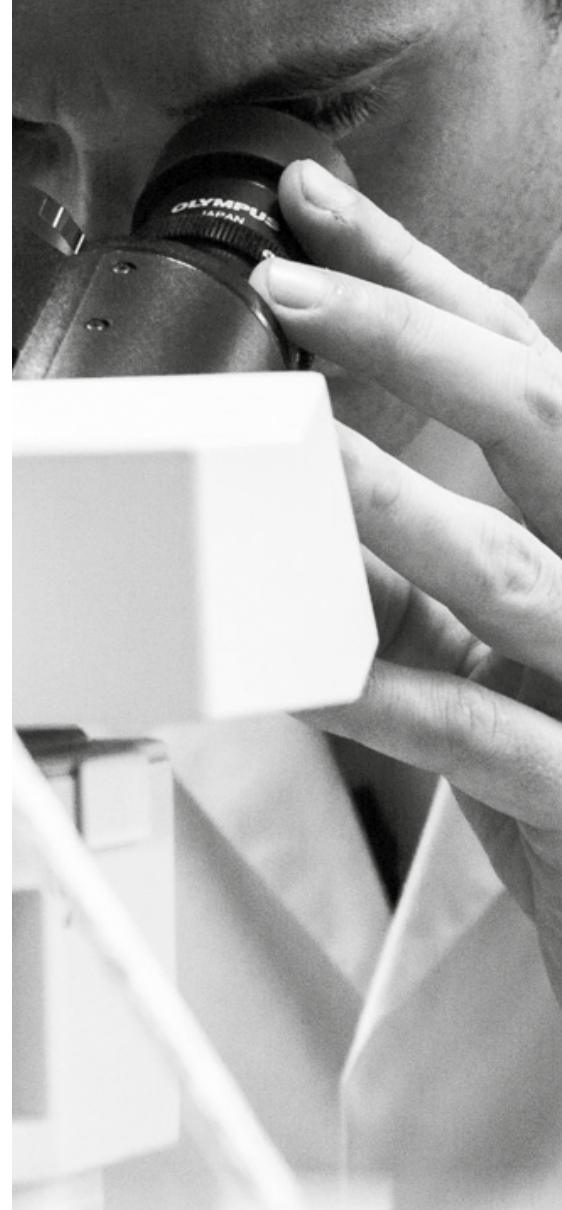
THE FIGHT AGAINST CANCER IS OURS TOO

Every day our experience and technology are put to the service of all those forefront of the fight against cancer with determination and innovation

FACED WITH SUCH A TOUGH CHALLENGE, ONLY REAL DEDICATION IS CALLED FOR

The contribution of BSP to the research and development of drugs for the treatment of serious pathologies like cancer is the driving force in striving to achieve excellence

In the constant evolution of anticancer drug research, the distinctive feature of the market in which BSP operates requires high specialization and continuous updating. For the company to continue in its growth it sets out to focus on the essential elements of its supply chain safety, clinical and commercial production.





**BSP HAS BEEN AT THE
FOREFRONT IN THE FIGHT
AGAINST CANCER SINCE
IT WAS FOUNDED 2006**

BSP IS A CDMO, focused on the development and manufacturing of anticancer drugs with High Potency and Cytotoxic characteristic and It is specialized on formulation and manufacturing of Small Molecules and ADC product

BSP clients can avail of this integrated services:

- **DEVELOPMENT SERVICES**
- **CLINICAL SUPPLY**
- **COMMERCIAL SUPPLY**

A CDMO

technologically developed to meet the needsof innovators, with its high containment facility designed to offer services for pre-clinical glp, clinical and commercial supply

MANUFACTURING

Sterile Injectable, Oral Solid Dosage Forms and Bulk Drug Substance

WIDE RANGE OF SERVICES

Development, Clinical and Commercial Supply

ORGANIC SOLVENT

Usage allowed on both Sterile Injectable and Oral Solid Formulations

CAMPUS

Approx. 58 Acres

BUILDING

480,000 sqft

MANUFACTURING PLANT

Located in Italy
40 miles south of Rome

BUSINESS OFFICES

BSP Pharmaceuticals S.p.A., Latina, Italy
BSP USA Inc. Princeton, NJ

PRODUCTION EXPORTED

To more than 70 countries

CUSTOMER QUALITY AUDIT

Average 2 Client's Audit per Month

FACILITIES INSPECTED BY

EUROPE
USA
JAPAN
BRAZIL
KOREA
TAIWAN
TURKEY
SAUDI ARABIA
RUSSIA
IRAQ
KENYA
BIELORUSSIA



The image shows a high-containment facility with several glove boxes. On the left, two large circular glove ports are visible, labeled 21 and 22. On the right, a larger rectangular glove box is labeled 3, and another one further right is labeled 4. Inside the glove boxes, various pieces of laboratory equipment, including flasks and tubing, are visible. The facility is constructed from stainless steel and has a clean, industrial appearance. A dark blue semi-transparent banner is overlaid on the left side of the image, containing the text 'AN HIGH CONTAINMENT FACILITY' in large white capital letters, and 'DESIGNED TO HANDLE HIGH POTENT AND CYTOTOXIC COMPOUNDS' in smaller white capital letters below it.

AN HIGH CONTAINMENT FACILITY

DESIGNED TO HANDLE HIGH
POTENT AND CYTOTOXIC
COMPOUNDS

The plant has been designed to achieve an Occupational Exposure Limit (OEL) :

<10 nanograms/m³

CONTAINMENT GRANTED BY

INSULATING SYSTEM

ISOLATOR, cRABS, CONTAINMENT VALVES

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

BSP has been conceived starting from a basic but essential operating requirement: **segregate** the high potent components from the surrounding and create a system suitable to manage pharmaceutical processes.

With this primary idea in mind, layouts, flows of materials and personnel, air flows have been designed to **minimize** the risk of contamination for the environment, for the employees and for the product that is intended for patients with low level of immune defenses.

CAPABILITIES OVERVIEW

BSP Pharmaceuticals offers a wide range of Sterile Injectable and Oral Solid dosage forms from the early stage of formulation development through product commercialization in order to fit the needs of its clients.

BSP has capabilities to manufacture conventional and special **Sterile Injectable** Formulations on development, clinical and commercial scale.

BSP is specialized to support the manufacturing of **ADC PRODUCTS** from the Conjugation to the Fill-Finish and offers a full and integrated package of services from Development to Clinical and Commercial supply

BSP has capabilities to manufacture conventional and special **Oral Solid** Formulations on development, clinical and commercial scale.



- LYOPHILIZED VIALS
- LIQUID VIALS BY ASEPTIC FILLING AND TERMINAL STERILIZATION



- LIPID BASED FORMULATIONS
- ORGANIC SOLVENT BASED FORMULATIONS



- ADCs FROM CONJUGATION TO FILL-FINISH



TABLETS COATED AND UNCOATED



CAPSULES



LIQUID FILLED HARD GELATINE CAPSULES



QUALITY CONTROL LABORATORIES

THE FACILITY HOUSES CHEMICAL, BIOCHEMICAL AND MICROBIOLOGICAL LABORATORIES TO PERFORM:

- ANALYTICAL METHODS:
Development & Optimization
Transfer/Validation product release testing and stability
- CLEANING CONTROLS:
Cleanability & Compatibility studies
Cleaning methods development and validation
- STABILITY & PHOTOSTABILITY STUDIES
- ENVIRONMENTAL MONITORING
- RAW MATERIALS TESTING
- IN PROCESS CONTROLS
- FINAL RELEASE

CHEMICAL & MICROBIOLOGICAL

Support the cGMP manufacturing of clinical and commercial anticancer drug products

BIOCHEMICAL

Has experience in establishing, validating and conducting routine bioassays according to cGMP standards.

Fully validated assays suitable for regulatory submission are provided. Characterization work includes the determination of physicochemical and structural properties, purity, impurities and quantity of the mAb, in line with ICH Q6B.

Dedicated capabilities are installed to support ADC characterization and manufacturing activities (IPCs as well as full release of the product)





PEOPLE ARE THE DRIVING FORCE BEHIND ANY OF OUR ACHIEVEMENTS

BSP BELIEVES IN THE IMPORTANCE
OF EACH INDIVIDUAL AND ITS TALENTS,
ENTREPRENEURIAL SPIRIT AND DEDICATION,
BECAUSE THERE IS NO INNOVATION WITHOUT
DARING, WITHOUT TAKING INITIATIVES



HEADQUARTER AND MANUFACTURING PLANT

BSP PHARMACEUTICALS S.p.A.

Via Appia km 65,561
04013 Latina Scalo - Italy

Phone +39 0773 822 1

Mail info@bsppharmaceuticals.com

COMMERCIAL BRANCH

BSP USA Inc.

100, Overlook Center Suite 200
08540 Princeton, NJ - USA

Phone +1 609 375 2700

Mail info@bsppharmaceuticals.com

FOR TECHNICAL INQUIRIES AND TO REQUEST A QUOTATION

Mail business.development@bsppharmaceuticals.com

bsppharmaceuticals.com



BEST CONTRACT MANUFACTURING
(CMO) PROVIDER



CMO

LEADERSHIP AWARDS 2019

CAPABILITIES, EXPERTISE, RELIABILITY, SERVICE

LEADERSHIP AWARDS 2018

CAPABILITIES, COMPATIBILITIES, EXPERTISE
RELIABILITY, QUALITY, DEVELOPMENT