



# Technical services

BD Medical–Pharmaceutical Systems



# Trusted technical expertise and a comprehensive service offering

Each of our services is delivered intentionally and carefully to directly result in significant benefits for your drug throughout its lifecycle, from development to launch and beyond.

Our Technical Services team will collaborate with you to increase your chances of a successful launch through:



**Analytical testing**, ensuring long-term compatibility and stability of your drug product

**World-class lab capabilities**, including a cGMP-compliant testing lab, a wide range of state-of-the-art equipment and proprietary testing methods

**Technical documentation support**, to help you successfully file with relevant regulatory bodies

**Combination product testing**, which is an array of tests that demonstrate the performance of your drug combined with the delivery solution(s)

**Value-added fill/finish services**, such as not-for-human-use filling at our cGMP-compliant laboratory and associated fill/finish support such as Contract Manufacturing Organization (CMO) recommendation and secondary device assembly equipment rental

# Technical services

Our team of experts is able to provide a comprehensive range of tests depending on customer needs. These include but are not limited to:

## Analytical and bioanalytical testing

- Extractable and leachable custom studies\*
- Tungsten pin extract preparation
- Tungsten-drug/placebo interaction
- Silicone interaction/migration studies

## Feasibility and optimization testing

- RapID
- Interfacial tension for silicone oil interactions
- Predictive modeling for extractable sensitivity
- Injection time modeling
- Formulation characterization (*e.g., viscosity*)
- Formulation optimization
- Functional performance testing

## Fill/Finish services

- Fill/Finish consultation
- Contract manufacturing organization (CMO) selection/vendor recommendations
- Not-for-human-use filling services
- Stoppering tool sales
- Assembly equipment rental



## Combination product functionality and performance<sup>+</sup>

- Activation and gliding force
- Rigid cap unscrewing torque and pull off force
- Needle shield pull off force
- Luer lock adaptor torque resistance
- Needle/connector assembly
- Needle cover lock out
- Cap torque and removal force
- Syringe spin test
- Injection time
- Dose accuracy
- Free fall
- Compression force
- Triggering test
- Needle shield device deployment force

## Container closure integrity

- Dye test on stopper and cap
- Leak test under pressure
- Bacterial ingress test
- Secondary packaging integrity tests

## Technical documentation support

- System and component level entity relationship diagrams (ERDs)
- Extractable and leachable reports\*
- Potential extractable lists
- Generic extractables reports

\*Offered at both component and combination product level

<sup>+</sup>Partial listing of services in this category



# Analytical and lab capabilities

Our state-of-the-art equipment coupled with our highly experienced team results in the creation of methods designed and validated to provide relevant, consistent, quality results according to your needs

## Elemental analysis

- Dynamic reaction cell inductivity coupled plasma mass spectrometry (DRC-ICP/MS)
- Atomic absorption spectrometry
- Ion chromatography
- Feasibility and optimization testing

## Volatile and semivolatile compound analysis

- Head space-gas chromatography with:
  - Mass spectrometry
  - Flame ionization detector
- Gas chromatography with:
  - Mass spectrometry
  - Flame ionization detector

## Organic compound analysis

- Liquid chromatography with:
  - Diode array detector
  - Mass spectrometry
  - Mass spectrometry/Mass spectrometry

## Protein analysis

- Size exclusion chromatography with ultra-violet/fluorescence detector
- Dynamic light scattering (DLS)
- Nanozetasizer
- Circular dichroism
- Differential scanning calorimetry

## Particle analysis

- Laser particle counter
- Micro-flow imaging (MFI)
- High-accuracy liquid particle counter (HIAC)
- Scanning electron microscopy (SEM)

## System functionality and performance

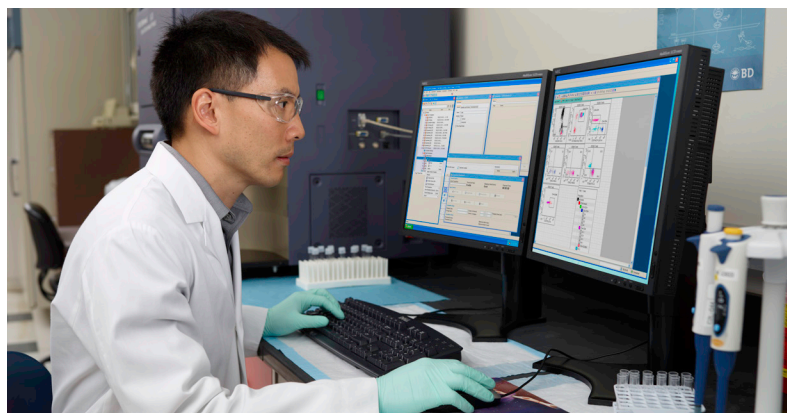
- Lloyd bench
- Instron bench
- RapID

## Dedicated laboratories

- cGMP-compliant analytical chemistry lab
- Material characterization lab
- cGMP-compliant functional testing lab

## Storage capabilities

- 5°C
- 25°C/40%RH and 25°C/60%RH
- 30°C/65%RH
- 40°C/NMT 25%RH and 40°C/75%RH



# As combination product regulations evolve, working with the right service provider becomes even more critical





With the Technical Services team in BD Medical–Pharmaceutical Systems, you gain high-quality, customized laboratory testing, fill/finish and consultation services. In addition, our team of cross-functional experts will collaborate with you to help design, execute and troubleshoot your combination product strategy.

## **Our Technical Services team provides you with an unparalleled partnership in developing your drug delivery system by leveraging our:**

- Experience working with more than 500 pharmaceutical and biotech companies across a wide range of molecules at various stages of a drugs' lifecycle
- 60+ years of expertise and innovation in the drug delivery industry
- 20+ years of experience designing and executing successful testing strategies for over 100 pharmaceutical and biotech customers
- State-of-the-art laboratory facilities and a team of highly experienced pharmacists, PhDs, engineers and technicians
- Supportive, regulatory-compliant data and documentation packages



# Partner with us today

-  **Save time** by leveraging our tried and tested expertise and methods
-  **Save money** by eliminating the need to invest in costly machinery and other resources
-  **Gain confidence** by working with an organization that has successfully helped launch hundreds of drug products
-  **Free-up valuable internal resources** that may be deployed to other critical activities

For more information, contact [TechnicalServices\\_BDMPS@bd.com](mailto:TechnicalServices_BDMPS@bd.com)

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