De-risk. Develop. Deliver.

BD Pharmaceutical Services and Solutions are designed to help you achieve your drug combination product goals, from development to launch.

BD

BD – A long-term industry leader in drug container systems …

BD has a long history of leadership and innovation in the drug delivery marketplace, with more than 60 years of expertise

We provide industry-leading prefillable syringes, safety and shielding systems, and self-injection systems for pharmaceutical and biotech companies across the globe. At BD, we strategically develop our solutions to mitigate risks associated with combination product development and medication administration to enhance the certainty of safe and sound drug delivery.

>2.5 billion/year
of ready-to-administer drug delivery systems produced[1]

>500 Pharmaceutical and Biotechnology companies use our products including **27 of the top 30 in the world**.[2]

~70% of the top 100 pharmaceutical companies around the world rely on BD Medical - Pharmaceutical Systems prefillable drug-delivery systems for a wide variety of therapeutic applications.[3]

… now offering broad expertise and services in drug combination product development

In addition to the large number of industry-leading prefillable syringe systems, we also offer a large variety of professional pharmaceutical services to support our customers in every step of their drug combination product development process.

Decades of experience of working with you has provided us with a proven track record to support you all along your combination product development journey.

Since the official launch of our BD professional services, more than 100 customers have already benefited from our support for their testing, small-scale fill & finish operations or regulatory activities.

20+

20+ years in designing and executing combination product testing and performance evaluations for your registration purposes

60+

60+ unique formulations tested

40+

40+ regulatory submissions supported per year

De-risk your drug combination product development and support acceleration of your market introduction

Did you know?
ZebraSci is BD's independent combination testing and expert advisory platform for pharmaceutical and biotech companies. We can now support you at any step of your development, regardless of the primary container or the delivery system chosen.

BD expands its service capabilities with ZebraSci

ZEBRASCI
Combination Product Experts

- ZebraSci can test both BD and non-BD products
- Confidentiality related to customer data, protocols and results relating to non-BD products are:
  - Safeguarded from the BD organization
  - Only accessible by associates on the ZebraSci side of the firewall

More information at zebrasci.com

We have now over 3500m² of lab and clean room available between our locations

Temecula, CA
- FDA registered and audited
- GMP Quality System
- ISO 17025:2017 Accredited
- ISO 13485:2016 Certified

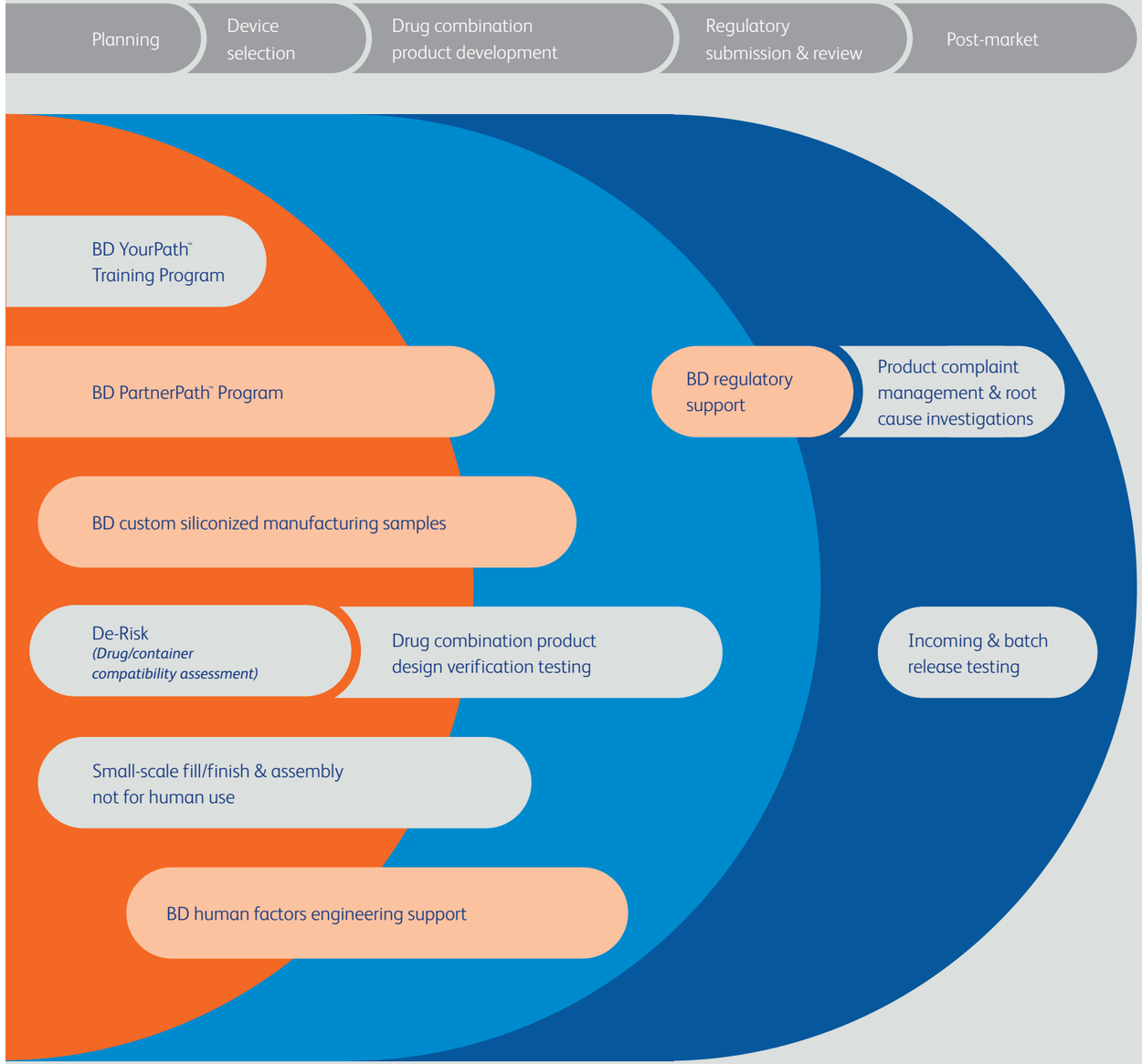
Branchburg, NJ
- FDA registered and audited
- GMP Quality System
- ISO 13485:2016 Certified

Pont-de-Claix, France (BD)
- ANSM and FDA registered and audited
- Accredited 210 / 2011 GMP

Suzhou, China
- ISO 17025 & ISO13485 certified
- Openness to audit for Pharma GMP compliance

China National Accreditation Service for Conformity Assessment
LABORATORY ACCREDITATION CERTIFICATE
(Registration No. CNAS L10697)

No matter where you are in the process of combination product development, we can help you reach your goals



Available for BD Products only

Available for BD and non-BD products

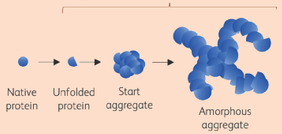
De-risk development by selecting the most appropriate container and delivery system from the start

Did you know?

Many challenges around drug-container interaction for prefilled syringe (PFS) have to be taken into account when selecting your primary container.

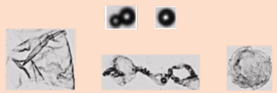
Drug degradation

Denaturation/aggregation induced by physical or chemical interaction[4]



- Drug integrity & efficacy
- Accurate dose delivery
- Compliance to Pharmacopeia

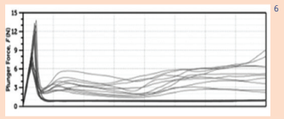
Particle formation



Silicone oil and protein aggregate formation

- Compliance with U.S., Europe and Japanese Pharmacopeia[5]
- Immunogenicity

Alteration of mechanical performance



- Gliding force consistency
- Injection duration & completion

BD can help you anticipate upfront drug-container interaction challenges and functional performances of the system to make data-driven decisions on the most appropriate containment and delivery system

Planning | Device selection | Drug combination product development | Regulatory submission & review

De-Risk | Drug combination product design verification testing

Tests for submission

Primary container & device selection based on data-driven results

De-risk *(Drug/container compatibility assessment)*

Service available for BD and non-BD components

- Anticipate any interaction and possible risk with your drug substance before selecting your primary container with relevant analytical tests based on the specificity of your drug (i.e Drug/Tungsten interactions, drug/silicone interaction...)
- Assess upfront robustness and reliability of the delivery system components or sub-assembly with some functional tests to confirm performance

BD YourPath™ Training Program

Understand drug combination product journey, challenges and key success factors with our experts

BD custom siliconized manufacturing samples

Get key insights in a short time to evaluate different device and siliconization configurations

Small scale fill/finish & assembly NFHU*

Quickly execute small customized filling campaigns for your testing needs

*Not For Human Use

Develop your drug combination product in accordance with regulations and harmonized practices

Did you know?

BD offers a comprehensive end-to-end E&L service with a de-risked approach based on USP guidelines to secure rapid and successful registration.

What we bring you

COMPOUNDS OF INTEREST

Potential extractables database
built on BD's extensive knowledge from our portfolio.

ANALYTICAL METHODS

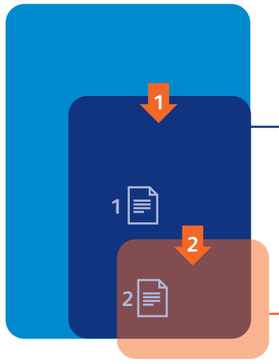
State-of-the art and optimized test methods for reliable compound detection & quantitation based on BD advanced experience.

1. **Wide range screening methods** verified in the extraction medium
2. **ICH Q2(R1) validated methods** in the drug product

END-TO-END OFFER

Analytical evaluation threshold (AET) and toxicological assessment at each stage

1. On extractables **to de-risk your clinical study**
2. On leachables **to consolidate your dossier**



What you need for your file submission

EXTRACTABLES DATA

USP <1663>
- Packaging and delivery system components
- Exaggerated extraction conditions

LEACHABLES DATA

USP <1664>
- Final drug combination product
- Normal conditions of use and storage

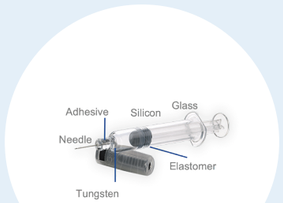
+TOXICOLOGICAL RISK ASSESSMENT

Suitable dossier (compliance with applicable requirements for combination product)

Benefit from BD's robust expertise in analytical and functional testing strategies and results interpretation to verify your drug device combination product development and ensure successful registration

Drug combination product design verification testing

Service available for BD and non-BD components



Analytical testing (drug-container interaction evaluation)

Assess drug compatibility with primary container choice and generate data in a GMP Lab to support drug combination product regulatory submission:

- Sub-Visible Particles formation
- Extractables & Leachables with AET and Toxicological Risk Assessment (TRA)

Functional testing (mechanical performance evaluation)

Verify reliability & performance of the selected system over time and generate data required for registration:

- Prefilled syringes
- Prefilled syringes with needle safety device
- Prefilled cartridges with pen
- Prefilled syringes with autoinjector
- On-body wearable injectors

Container closure integrity testing

Develop a holistic approach to your container closure integrity strategy for quality assurance throughout the entire product life cycle

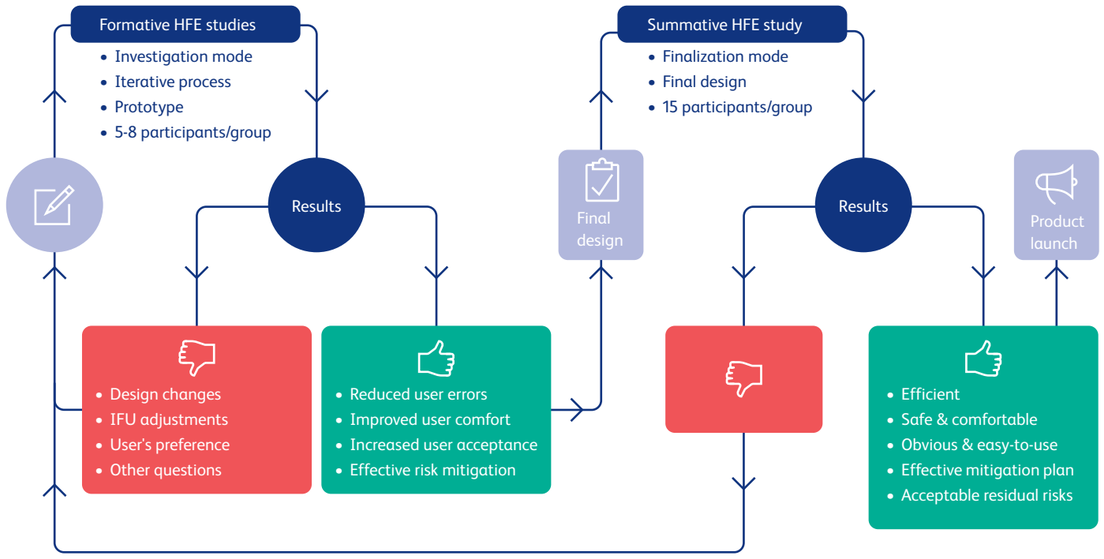
- Helium leak detection (HeLD)
- Vacuum decay detection
- High voltage leak detection
- Dye leak detection

Develop a safe and effective design for your drug combination product

Did you know?

As part of design control and risk management activities, Human Factors Engineering is a critical step scrutinized by authorities for product clearance. You can leverage the available BD platform approach to HFE and complete the dataset for your combination product with the support of the BD services team.

Integrating Human Factors Engineering Activities[7,8,9,10,11]



BD has developed a flexible HFE service offer from consultative review only to full management

Make BD your single point of contact for your HFE activities. Thanks to our partnerships with independent carefully validated HFE vendors selected amongst the biggest names in the industry.

BD human factors engineering (HFE)

- **HFE strategy & planning**
- **Support to threshold (comparative) analyses**
- **HFE study protocol & synopsis**
- **Training development**
- **Studies conduct:**
  - Formative
  - Summative
  - Comparative use
- **IFU development**

- **Leverage BD product expertise and existing data to facilitate study design**
- **Benefit from our 120 years of experience in combination products**
- **Benefit from BD partnerships with carefully validated HFE partners for study operations**
- **Step by step guidance through the entire HFE process as required**

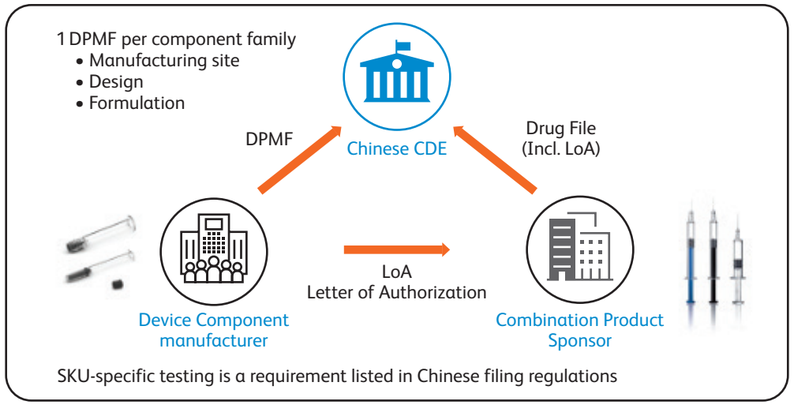
Deliver your drug combination product with confidence and speed

Did you know?

Specific SKU testing is a time-consuming activity listed in Chinese filing regulations* that seems to become an actual requirement from authorities for international companies to enter the Chinese market.

Chinese health authorities can request data on specific SKU (as data on product family in Design Master FIle (DMF) may not be enough).

Co-evaluation of Drug/Biologic File and Drug Packaging Material File (DPMF)



It is important to de-risk registration in China and avoid a minimum of six months' project delay by anticipating request from authorities for specific SKU testing.

*Available for BD products only - select products and product systems
Full offerings not shown. For additional countries of interest, please contact us at PharmaceuticalServices_BDMPS@bd.com

Benefit from BD guidance and long-term worldwide expertise to anticipate market requirements and regulation

BD regulatory support

Canada
- BD can provide you with a Letter of Authorization to BD Canada DMF. **Free of charge**
- In support of your Drug Establishment License (DEL), BD will submit to Health Canada a GMP Clearance dossier for foreign manufacturers for BD and BD-subcontracted sterilization sites. **Free of charge**

Europe
BD can support your preparation of a Global Safety & Performance Requirements (GSPR) dossier for submission to an EU Notified Body (NB) in view of obtaining a Notified Body Opinion in line with article 117 of the Medical Device Regulation (MDR). **For a fee**

Korea
BD can support your registration of a combination product by providing a Korean Technical Document in line with Korean guidelines on examining documents for sterilized needles included in drugs, etc., and Korean standards. **For a fee**

Japan
BD can support your registration of a combination product to Pharmaceuticals and Medical Device Agency (PMDA) by providing a package of documents in line with Japanese Essential Requirements Checklist (ERCL) following the applicable Ministry of Health, Labor and Welfare Notification. **For a fee**

United States of America
BD can provide you with a Letter of Authorization to BD US DMF. **Free of charge**

- 24 Notified Bodies positive opinion in EU for 2022
- More than 40 submissions/year

China
- BD can provide you with a Letter of Authorization (LoA) to applicable BD China DMF in the scope of co-evaluation of BD drug packaging material with your combination product. **Free of charge**
- BD can provide you with testing reports according to Chinese standards (incl. YBB, Chinese Pharmacopeia) on 3 batches for your specific SKU to enable your response to potential NMPA (Chinese authorities) questions on specific SKU. **For a fee**

Malaysia
BD can support your preparation, in line with Malaysian Guideline on Drug-Device Combination Products, of an application to the Malaysian Medical Device Authority (MDA) to obtain an endorsement letter of ancillary component for registration of your combination product. **For a fee**

Get support from BD to ensure continuous quality delivery to your customers

Drug combination product incoming & batch release testing

Get support in managing incoming inspection tests and lot releases

Market complaint support & root cause analysis

Develop a robust and fast complaint management process

Select from our broad range of services that can be tailored to fit your needs

De-risk

BD YourPath™ Training Program
Begin your combination product journey on the right track for your project

BD PartnerPath™ Program
Gain streamlined access to preconfigured BD products sets and supporting documentation

De-risk
De-risk your combination product design verification testing by anticipating upfront drug-container interaction challenges and functional performances of the system

BD custom siliconized manufacturing samples
Support design space verification with silicone level tests at the limits

Small-scale fill/finish & assembly
Flexibility in planning small customized campaigns for your testing

Develop

Drug combination product design verification testing
Validate drug device combination product development with robust analytical and functional testing strategies in accordance with regulation and broader expertise

Functional testing
Evaluate reliability & performance of the selected system

Analytical testing
Assess drug compatibility with primary container choice

Container closure integrity testing
Assess container closure integrity of the system

BD human factors engineering (HFE)
Benefit from BD-wide expertise in HFE studies conducted and from our partnership with independent, carefully validated HFE vendors selected amongst the biggest names of the industry

Deliver

Product complaint management & root cause investigations
Develop a robust complaint management process.

Drug combination product incoming & batch release testing
Get support in managing incoming drug combination product inspection tests and lot releases

BD regulatory support
Anticipate market requirements and regulation changes to expand your reach into target global markets

Partner with us

Partner with BD, like 25 of the top 30 pharmaceutical companies in the world[12]

PharmaceuticalServices_BDMPS@bd.com

https://drugdeliverysystems.bd.com/services-and-solutions/services

Learn more about our Services offer!

Your strategic partner for end-to-end solutions to meet your needs throughout your drug combination product journey

References

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2 BD Customers compared to Evaluate Pharma ranking FY2019.

3 IQVIA: IQVIA dataset extracted on March 11th, 2021, from the IQVIA Smart MIDAS' on-line platform, includes WW sales of injectable drugs. Top 100 Corporation (based on IQVIA standard units 2020) selling PFS, Autoinjectors or Pens. TA included: Acute biologics, Anticoagulants, Chronic, Small molecules, Vaccines

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5 For pharmaceutical products: USP<787>, USP<788>, Ph. Eur. 5th Edition 01/ 2005: 2.9.19, JP 6.07

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8 Draft Guidance for Industry and FDA Staff: Applying Human Factors and Usability Engineering to Medical Devices.2016

9 Draft Guidance for Industry and FDA Staff: Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development. 2016

10 IEC/TR 62366-1 (2020): Application of usability engineering to medical devices

11 IEC/TR 62366-2 (2014): Guidance on the application of usability engineering to medical devices.

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BD, Franklin Lakes, NJ, 07417, U.S.

201.847.6800

drugdeliverysystems.bd.com