



# BD Custom Support Solutions

BD expertise for every stage across the co-packed drug development pathway



# 125 years

*of advancing the world of health™*

For over a century, BD has pioneered healthcare innovations that transform lives. Our expertise spans BD solutions and drug delivery – from regulatory navigation and device selection to kitting solutions and registration support. As a global partner, our network of regional manufacturing sites ensures that wherever your healthcare innovation is needed, **BD is there to support it.**



# Your goals are unique, your support should be, too.

Where you are and where you want to go will shape the level of support you need. Your challenges require more than a one-size-fits-all approach, they require a partner who tailors solutions to your specific needs.



## From concept to patient-ready

Whether you're involved in pharmaceuticals, medical devices, compounding, or final packaging, we're here to support you with precision, safety and reliability.

# Extensive services to support your needs

Our experts understand the drug development pipeline and the hurdles you may face. We're here to share our knowledge of BD solutions and simplify the process with a full range of services, from co-development through kitting. Any fees associated with services can be discussed with your local sales rep.

## Core support services



### ✓ Regulatory compliance and certification

- CE certificate
- Certificate of conformity
- Declaration of conformity
- ISO 13485 certificates
- Label and instructions for use (IFU), external
- Manufacturing information
- Technical data sheet

### ✓ Additional compliance documentation

- Customer drawing\*
- Customer specification\*
- Environmental impact survey\*
- Quality self-survey\*
- Registration list\*

## Development support services



### ✓ Nitrosamine compliance statement

### ✓ Dead space calculation

### ✓ Memos

- ISO compliance list memo
- Biocompatibility testing summary memo
  - Acute systemic toxicity
  - Cytotoxicity
  - Irritation or intracutaneous reactivity
  - Material-mediated pyrogenicity
  - Sensitization
- Sterilization summary memo
  - Method
  - ISO compliance and validation statement
  - Summary of cycle (e.g., time, temperature)

\* Requires a confidential disclosure agreement. Please note that items are provided as applicable, with certain documents specific only to products registered within the EU.



## Quality and regulatory support services



- ✔ **Customer change notifications**  
Proactive communication of critical changes impacting product compliance
- ✔ **Prioritized complaint management**  
Priority handling of adverse events, recalls, or regulatory reporting
- ✔ **One-day audits**  
Onsite or remote with 1 or 2 auditors
- ✔ **Third-party audits**  
Onsite or remote with 1 or 2 auditors
- ✔ **SQA audit report**  
SQA compliance verification

## Submission support services



- ✔ **Letter of authorization**
- ✔ **Regulatory authority question support**
- ✔ **Certificate of Foreign Government/  
Free Sale Certificate**

## Flexible support services



**Whether you need one service or a combination, BD partners with you to provide flexible support solutions designed to adapt.**

Choose exactly what you need, when you need it. Our services are not limited to those listed—we welcome custom testing, projects and other collaborative opportunities.

# Our expertise, your advantage

We're not just focused on helping you navigate the complexities of co-packing BD devices with your drug – we're committed to offering BD solutions that extend to all phases of drug development. From the early stages of compliance and regulatory support to the final steps of submission and market readiness, we aim to make your journey as seamless as possible.

## Reconstitution



## Preparation



## Administration

# Product portfolio

A full lineup of products supporting you from development through delivery.

## Vascular access



IV care and maintenance



Vascular access devices

## IV administration



Gravity administration sets



Needle-free empty IV bags

## Hypodermic solutions and safety products



Hypodermic needle and syringe solutions



Hazardous drug solutions

# Let's partner for what's next.

Learn more at [bd.com/b2b](https://bd.com/b2b) or contact your local sales rep.

BD, Franklin Lakes, 07417 U.S.  
800.323.9088

[bd.com](https://bd.com)

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