



BD Medical  
Pharmaceutical Systems  
The Difference of One Drug Delivered



# Supporting your drug development with a full range of services

Establishing and maintaining our customer's trust is at the forefront of our collaboration effort. Decades of experience working closely with you has provided us with expertise and proven track records regarding:

- Drug/container/device integration
- Product quality and quality-control efficiency
- Supply assurance
- Registration requirements
- Problem resolution

When you partner with BD Medical - Pharmaceutical Systems, you also have access to following benefits :

## Consultative services on drug delivery options

With deep, skills in [human factor engineering](#) and worldwide expertise in developing solutions, BD offers an intimate knowledge of the many issues affecting your product. To support our customers, we ensure the [functionality of the drug delivery system](#), providing consultative expertise to help customers quickly and easily choose the most suitable delivery system.

## Regulatory support to optimize time-to-market

BD Medical - Pharmaceutical Systems Regulatory Affairs team offers regulatory expertise on worldwide registration of pre-fillable delivery systems to support customers with their applications and [optimize time-to-market](#).

Depending on the targeted region(s) for registration, the BD Medical - Pharmaceutical Systems Regulatory Affairs team provides:

- A Letter Of Authorization (LOA) for applications in the United States (CDER, CBER, CDRH, CVM), Canada and Australia.
- A Technical Dossier (TD) of BD container closure system under a signed Confidentiality Disclosure Agreement (CDA), for enabling the preparation of your applications.
- A case-by-case customized regulatory support based on your specific needs.

Request your LOA and TD online in just a few clicks on: <http://www.bd.com/pharmaceuticals/regulatory>.

## Compatibility testing to mitigate risk

BD provides rigorous [compatibility testing](#) of container packaging components well in advance in their marketing. If required, BD can also propose [tailored extractables & leachables \(E&L\) studies](#), mechanical data, and functional data for regulatory or registration purposes.

## Global reach and capacity to ensure business continuity

With offices in more than 50 countries, BD has both the familiarity of the global marketplace and the manufacturing capabilities to ensure [supply continuity](#). Our global reach enables us to minimize the impact of unexpected events. Our global management network and [high-level quality-assurance system](#) ensure consistent processes to meet product specifications.

## (Pre)Clinical and Usability assessment Data to support registrations

The Medical Affairs Department is responsible for the safety of our products. We can support your registration efforts by sharing summaries of preclinical (including toxicology) clinical and Human Factor data generated to assess efficiency and safety of our products. Our Medical Affairs team can also work with you to integrate this evidence in your regulatory strategy and, when needed support you in the development of studies tailored to your combination product development strategy.



# A partner of choice for the pharmaceutical industry

BD Medical - Pharmaceutical Systems is a global leader in supplying the pharmaceutical industry with innovative, high-quality, clinically-proven and customized pre-fillable parenteral drug delivery systems. Our offering includes an extensive portfolio of pre-fillable syringes, self-injection systems, safety and shielding solutions. Our products are designed to protect, package and deliver drug therapies and to maximize healthcare worker and patient safety.

BD Medical - Pharmaceutical Systems is a reliable partner that can provide expertise in highly specific fields to support your drug throughout its lifecycle, from development to launch and beyond. We are uniquely positioned to offer expertise in drug container interactions, primary container selection and container/device

integration for a variety of drug therapies including vaccines, biopharmaceuticals, acute care drugs, anticoagulants and hyaluronic acid. We are committed to building partnership with you and developing product solutions that meet your needs by leveraging our innovative technologies, extensive global manufacturing and advanced technical, scientific, medical and regulatory expertise.

## **Products used by more than 500 Pharmaceutical and Biotechnology companies<sup>2</sup>**

BD is proud to partner with hundreds of pharmaceutical and biotechnology companies that place their confidence in our high performance BD products. BD customers include 27 of the top 30 pharmaceutical companies in the world<sup>3</sup>.

More than 70% of the top 100 pharmaceutical companies around the world use BD Medical - Pharmaceutical Systems pre-fillable drug-delivery systems for a wide variety of therapeutic applications<sup>4</sup>.



# BD offers a wide array of customizable drug delivery systems

BD Medical -  
Pharmaceutical  
Systems  
**at a glance**

Pre-fillable Syringes\* (PFS)  
manufactured per year

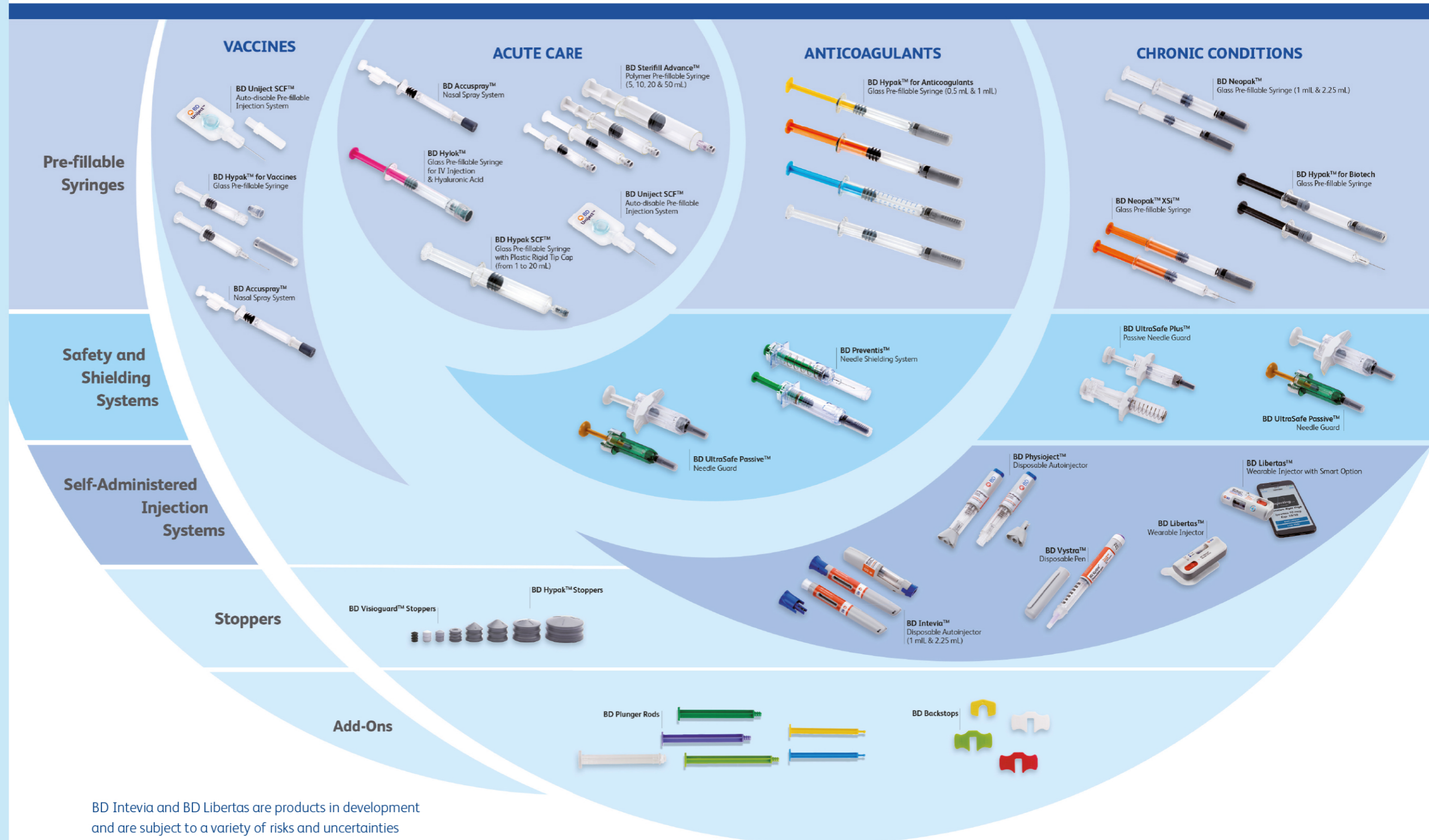
**>2,3  
billion**

Associates globally

**4,700**

Manufacturing  
plants worldwide

**7**



BD Intevia and BD Libertas are products in development and are subject to a variety of risks and uncertainties

\* Barrels

# Choosing BD as your strategic partner gives you six key advantages

- Prefill expertise and consultation at every stage of drug development
- A wide array of pre-fillable drug delivery systems
- Multifaceted service and in-depth expertise
- Worldwide manufacturing plants to meet global production demands
- Worldwide support and regulatory expertise
- Comprehensive cross-functional support and dedicated teams

1 - Syringes manufactured per year > 2.3 billion – BD Internal systems (SAP ECC, SAP Legacy, Tracis, Nodum) – January 2018

2 - SAP Legacy, Tracis, Nodum) – January 2018

3 - IQVIA-based analysis & BD Internal systems (SAP ECC, SAP Legacy, Tracis, Nodum) – 2016 update

4 - IQVIA-based analysis & BD Internal systems (SAP ECC, SAP Legacy, Tracis, Nodum) – 2016 update

## **BD Medical**

Pharmaceutical Systems

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