



# BD Pre-fillable Syringe Solutions

Why choose a Pre-filled Syringe (PFS) as a delivery system?

## Patient Safety<sup>1</sup>

### Reduction of contamination

PFS can be a solution for reducing reuse & blood borne pathogen contamination  
Pre-filled syringes may reduce the risk of microbial contamination by minimizing preparation steps.

### Right concentration

PFS may reduce the risks associated with improper concentrations

### Right Dosage

PFS is a solution to reducing under/over dose errors

## Efficiency<sup>1</sup>

### Time saving

PFS reduces time to administration, workflow convenience and reducing treatment delays

### Waste reduction

PFS may reduce the cost associated with drug wastage

## User preferences<sup>1</sup>

### Preferred system

PFS are preferred by health care worker (improves workplace satisfaction)

### Patient comfort

PFS may create less anxiety for patients especially for children



# 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 a 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.

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1. "Benefits of Prefilled Syringes" – Global Value Dossier. Becton Dickinson and Company, January 2017.

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