



BD Neopak™

Glass Pre-fillable Syringe

Turning expertise
into advanced solutions for biotech

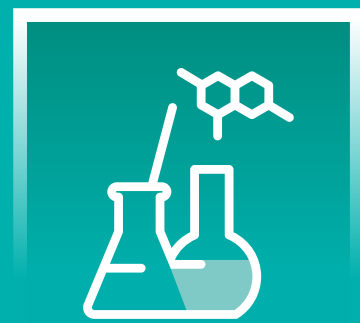
A partner of choice for the pharmaceutical industry

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.

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CHOOSING BD AS YOUR STRATEGIC PARTNER GIVES YOU SIX KEY ADVANTAGES :

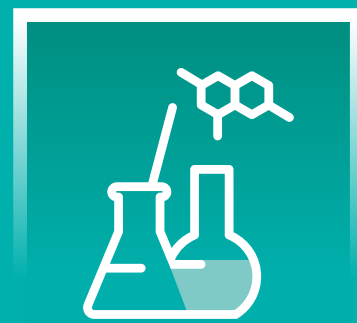


Pre-fill expertise and
consultation
at every stage
of drug development

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Pre-fill expertise and **consultation at every stage** of drug development

Worldwide support and regulatory expertise

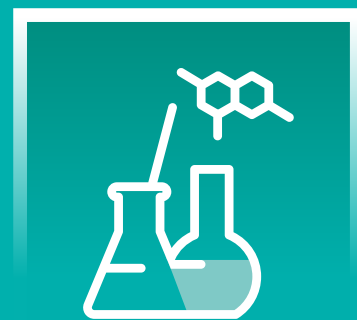
Multifaceted service and **in-depth expertise**



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Multifaceted service and **in-depth expertise**

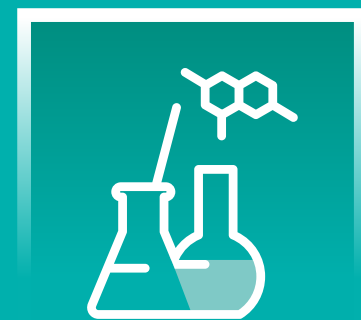


Worldwide manufacturing plants to meet global production demands

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CHOOSING BD AS YOUR STRATEGIC PARTNER GIVES YOU SIX KEY ADVANTAGES :



Pre-fill expertise and **consultation at every stage** of drug development

Worldwide support and regulatory expertise

Multifaceted service and **in-depth expertise**



Worldwide manufacturing plants to meet global production demands

A wide array of pre-fillable drug **delivery systems**

Comprehensive **cross-functional** support and **dedicated teams**



A partner of choice for the pharmaceutical industry

BD Neopak™ has been designed to specifically meet your evolving needs, throughout drug development to launch and beyond



**Biotech drugs that are
breakthroughs or that target
new therapeutic areas**

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Biotech drugs that are breakthroughs or that target new therapeutic areas



Pipeline biosimilars and drugs targeting highly competitive therapeutic areas

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Biotech drugs that are breakthroughs or that target new therapeutic areas



Pipeline biosimilars and drugs targeting highly competitive therapeutic areas



Legacy drugs under life cycle Management

BD Neopak™

Glass Pre-fillable Syringe

Turning expertise into
advanced solutions for biotech

Major biotech
Manufacturers
representing
±80%
of the biotech market
**are using or testing
BD Neopak™ Glass
Pre-fillable Syringe²**



BD Neopak™ Glass Pre-fillable Syringe is built on years of BD's unmatched experience partnering with leading biopharmaceutical companies to support drug development and launch.

BD Neopak™ Glass Pre-fillable Syringe was conceived with a solution finding mindset, allowing you to tangibly meet your current and future needs for biotech drugs.

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

Supporting your drug development with a full range of services



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

- Consultative services on drug delivery options
- Regulatory support to optimize time-to-market
- Compatibility testing to mitigate risk
- Global reach and capacity to ensure business continuity
- Summaries of preclinical (including toxicology) clinical and Human Factor to support registration

- 1: Chronic Market data 2017 [Internal Business Insight]. Pont-de-Claix, FR: Becton Dickinson and Company; 2017
- 2: BD Neopak™ vs Hypak for Biotech improved specifications [Internal study]. Pont-de-Claix, FR: Becton Dickinson and Company; 2018
- 3: BD Neopak™ designed for superior auto-injector compatibility [Internal Studies]. Pont-de-Claix, FR: Becton Dickinson and Company; 2015-2018
- 4: Neopak™ 1mL Long Term Verification: Glue Extractables [Internal Study]. Pont-de-Claix, FR: Becton Dickinson and Company; 2015
- 5: Customer case study. PDA Universe of Pre-filled Syringes and Injection Devices October 6-8, 2014

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Becton Dickinson France S.A.S - Share capital: 64 719 915 €

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BD Neopak™

Glass Pre-fillable Syringe

When time to market is critical,
invest in the reliability of BD Neopak™



Pipeline biosimilars and drugs in highly competitive therapeutic areas

Biosimilars face the pressure of pipeline drug development in a **highly competitive context**. The critical success factors impacting the process of biosimilar drug development, production and launch on time are:

- Risk mitigation associated to **drug-container interactions**
- Creating **differentiation**
- Anticipating market **demand expansion**

BD Neopak™ Glass Pre-fillable Syringe platform is built on years of BD's unmatched experience partnering with leading Biopharmaceutical companies to support drug development and launch. BD Neopak™ was conceived with a solution-finding mindset, allowing you to tangibly meet your current and future needs for biotech drugs.

> [BD Neopak™ Glass Pre-fillable Syringe platform supporting your time-to-market](#)

BD Neopak™ Glass Pre-fillable Syringe platform supporting your time-to-market

- BD Neopak™ offer unique features and over all tightening of specifications allowing pharma to minimize risks¹

- ✓ **Dead volume** under control (<5μL)
- ✓ **Minimized glue extractibles**
- ✓ **Minimized glass particles**
- ✓ **Certificate of analysis** supplied with **delegation of control**
- ✓ **Autoinjector compatibility** ensured through dimensional precision
- ✓ **Autoinjector performance** through gliding force control (<2.5N)



BD Neopak™ Glass Pre-fillable Syringe platform supporting your time-to-market

- BD Neopak™ offer unique features and over all tightening of specifications allowing pharma to minimize risks¹

BD Neopak™
features **80%**
NEW
or improved specifications
compared
to BD Hypak™
for Biotech²



BD Neopak™ Glass Pre-fillable Syringe platform supporting your time-to-market

- BD Neopak™ comprehensive data package helps you meet combination product regulatory requirements

BD Regulatory Affairs support to customer registration file to help secure time-to-market

- Offering* a **full “container closure system” regulatory data package** ensuring information accuracy and simplifying your CTD** registration process

* On a customer case by case basis
** CTD: Common Technical Document



BD Neopak™ Glass Pre-fillable Syringe platform supporting your time-to-market

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BD Regulatory Affairs support to customer registration file to help secure time-to-market

- Offering* a **full “container closure system” regulatory data package** ensuring information accuracy and simplifying your CTD** registration process
- BD Neopak™ syringe design is **based on current regulatory standards** smoothing registration file approval^{3,4}

* On a customer case by case basis
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BD Neopak™ Glass Pre-fillable Syringe platform supporting your time-to-market

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- BD Neopak™ syringe design is **based on current regulatory standards** smoothing registration file approval^{3,4}
- BD Neopak™ is uniquely supported by a **wealth of data**, that can be leveraged in your combination product development and registration
 - ✓ **Extractables**
 - ✓ **Biocompatibility**
 - ✓ **Stability**
 - ✓ **Device compatibility**

* On a customer case by case basis
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- 1: BD Neopak™ performance characteristics [Internal Studies]. Pont-de-Claix, FR: Becton Dickinson and Company; 2015-2018
- 2: BD Neopak™ vs Hypak for Biotech improved specifications [Internal study]. Pont-de-Claix, FR: Becton Dickinson and Company; 2018
- 3: Technical data sheet for BD Neopak™. Pont-de-Claix, FR: Becton Dickinson and Company; 2018
- 4: ISO11040-4 :2015 compliance statement. Pont-de-Claix, FR: Becton Dickinson and Company; 2018

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Give tomorrow's most demanding biotech drugs the strength of BD Neopak™ Pre-fillable Syringe technology



Biotech drugs that are breakthroughs or that target new therapeutic areas

The overriding challenge facing Biopharmaceutical companies today is the **increasing pressure** around **time to market**. Critical success factors influencing pipeline drug therapies development and market launch on time are:

- Risk mitigation associated with **drug-container interactions**
- Anticipation of **combination product development**
- Anticipation of market **demand expansion**


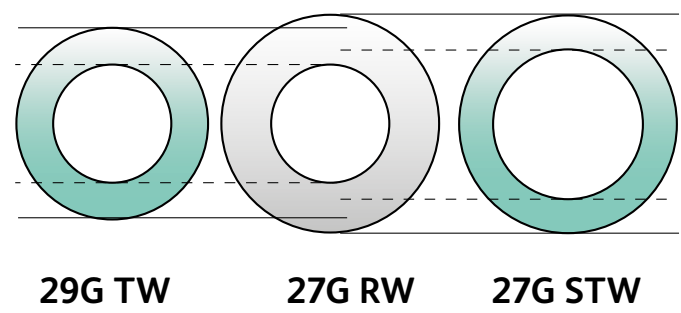
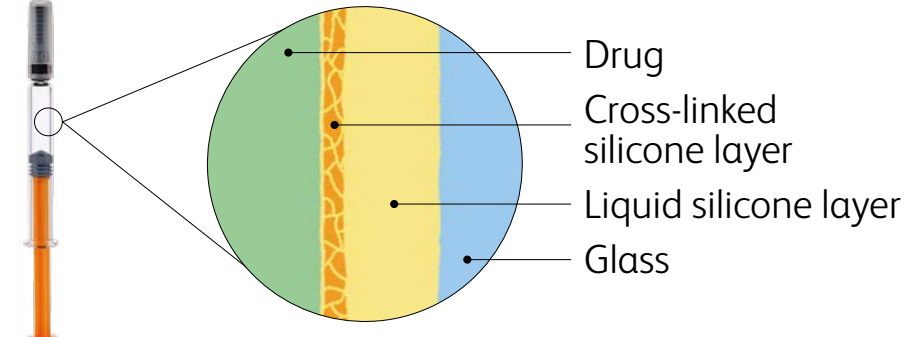

BD Neopak™ Glass Pre-fillable Syringe is built on years of BD's unmatched experience partnering with leading biopharmaceutical companies to support drug development and launch.

BD Neopak™ was conceived with a solution-seeking mindset, allowing you to tangibly meet your current and future needs for biotech drugs.

- > BD Neopak™ Glass Pre-fillable Syringe platform covers a broad design space for agile development, supporting your time-to-market

BD Neopak™ Glass Pre-fillable Syringe platform covers a broad design space for agile development to support your time-to-market

- BD Neopak™ offers a wide portfolio of options

Barrel format	Needles gauge	Needle shield	Flange design
<p>1 mL & 2.25 mL</p> 	<p>BD Physiolis™ BD Hyflow™</p>  <p>29G TW 27G RW 27G STW</p>	<p>Rigid needle shield rubber formulations: BD260, FM30, 4800</p> <p>+ BD Neopak™ gives you access to BD advanced technologies Facilitating implementation of new solutions</p> <ul style="list-style-type: none"> ▶ BD Neopak™ XSi™ Glass Pre-fillable Syringe with silicone immobilization technology ▶ BD VisioGuard™ Stopper Stopper visual-inspection technology  	<p>Cut Flange Small Round Flange Small Extra-round Flange</p>

BD Neopak™ Glass Pre-fillable Syringe platform covers a broad design space for agile development to support your time-to-market

- BD Neopak™ is designed to ensure compatibility with BD injection systems

BD UltraSafe Plus™
Passive Needle Guard



BD Intevia™
Disposable Autoinjector (1 mL-2.25 mL)



BD Libertas™
Wearable Injector



**BD Intevia™, BD Libertas™, UltraSafe Plus™ 2.25, are products in development and are subject to a variety of risks and uncertainties*

BD Neopak™ Glass Pre-fillable Syringe platform covers a broad design space for agile development to support your time-to-market

- BD Neopak™ extensive track record and associated BD services to support your combination product development



>BD Neopak™ is uniquely supported by a wealth of data on extractable, biocompatibility, stability and device compatibility

>BD Regulatory Affairs offer* a full “container closure system” regulatory data package ensuring information accuracy and simplifying your CTD** registration process

* On a customer case by case basis

** CTD = Common Technical Document

>BD Technical Services offer drug-container compatibility testing, using validated methods and BD state-of-the-art equipment

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Change to the reliability of BD Neopak™
platform to accompany your brand strategy



Legacy drugs under Life Cycle Management

Anticipating and managing change through life cycle management strategy is a key success factor for all major biopharmaceutical companies. Pharma companies considering life cycle management solution options need to reconcile:

- Brand strategy and **differentiation**
- Optimizing manufacturing **process** and **cost**
- Risk mitigation associated to **combination product interactions**

BD Neopak™ Glass Pre-fillable Syringe platform is built on years of BD's unmatched experience partnering with leading biopharmaceutical companies to support drug development and launch. BD Neopak™ was conceived with a solution finding mindset, allowing you to tangibly meet your current and future needs for biotech drugs.

- > BD Neopak™ platform options and product features to support your life cycle management brand strategy.

BD Neopak™ platform options and product features to support your life cycle management brand strategy

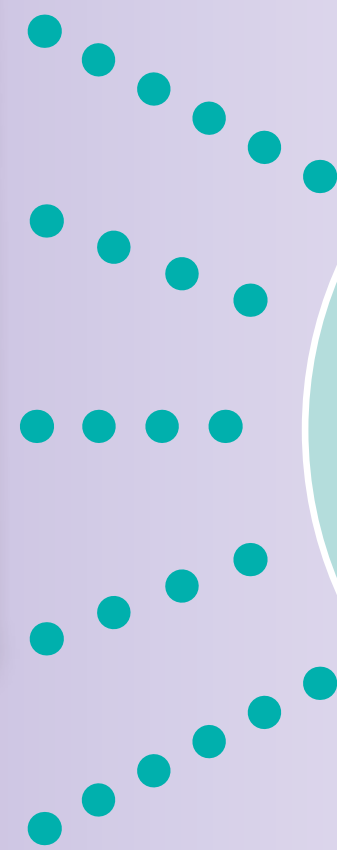
- BD Neopak™ provides a wealth of portfolio options and compatibility with BD injection solutions

Barrel formats
1 mL, 2.25 mL

Needle gauges
27G Special Thin Wall,
29G Thin Wall, 25G Thin Wall

Needle shield rubber for-
mulations
BD260, FM30, 4800

Flange designs
Cut Flange
Small Round Flange
Small Extra-round Flange



68

**BD Neopak™
references**

26 already available
42 are being developed



BD Safety Systems

BD UltraSafe Passive™
Needle Guard



BD UltraSafe Plus™
Passive Needle Guard



Self-Administered Injection Systems*

BD Physioject™
Disposable Autoinjector



BD Intevia™
Disposable Autoinjector



BD Libertas™
Wearable Injector



*BD Intevia™, BD Libertas™, UltraSafe Plus™ 2.25, are products in development and are subject to a variety of risks and uncertainties

BD Neopak™ platform options and product features to support your life cycle management brand strategy

- BD Neopak™ offers unique features¹ allowing to contain costs and minimize risks

- ✓ **Dead volume** under control (<5µL)
- ✓ Minimized **glue extractibles**
- ✓ Minimized **glass particles**
- ✓ **Certificate of analysis** supplied with **delegation of control**
- ✓ **Autoinjector compatibility** ensured through dimensional precision
- ✓ **Autoinjector performance** through gliding force control (<2.5N)

BD Neopak™ offer can potentially reduce your total cost of ownership by delivering savings against existing syringe types.

Customer case study showed:

BD Neopak™ displayed

90% reject rate reduction

compared to standard pre-fillable syringe offer²

BD Neopak™ platform options and product features to support your life cycle management brand strategy

- Shifting to BD Neopak™ BD Regulatory Affairs service supports smooth transition to

General assessment of customer's regulatory impact of a switch*

e.g. BD Hypak™ for Biotech to BD Neopak™ Pre-fillable Syringe

- Explains the change & regulatory impact
- Clarifies how to handle change and what supportive documentation to generate



1: BD Neopak™ performance characteristics [Internal Studies]. Pont-de-Claix, FR: Becton Dickinson and Company; 2015-2018
2: Customer case study. PDA Universe of Pre-filled Syringes and Injection Devices October 6-8, 2014

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