# BD tools for vaccine combination product developers

# BD Effivax<sup>TM</sup> Glass Prefillable Syringe



BD Effivax™ is a single use Sterile Clean and Ready to Fill syringe (BD SCF™), designed for manual intramuscular or subcutaneous injection of medical products for the Vaccines market segment¹

#### BD Effivax<sup>™</sup> configuration

Talk to your BD representative about options for customization

Volume	1mL
Flange design	Round
Tip cap	PRTC FM30

### **Key benefits**

- New vaccine syringe platform, carrier for future innovation
- A step forward in luer lock PFS performance as compared to previous generation BD vaccine PFS\*:
  - Overall integrity improved due to the reduction of cracks and contamination specifications<sup>1</sup>
  - Stricter glass particles specification<sup>1</sup>
  - 100%-dimensional controls (ISO11040-4)
  - Stricter visible cosmetic defects specifications<sup>1</sup>
  - Control plan harmonized across manufacturing sites for product consistency<sup>3</sup>
- Estimated to improve Total Cost of Ownership (TCO) by 2%<sup>4</sup>
  - Filling and packing optimized, consequently minimizing line stops
- Batch performance documentation (CoA)
- Broad range of value-added services\*\*\*
  - Regulatory expertise in combination product
  - Functional tests in c-GMP compliant labs
  - E&L studies with toxicological assessment
- Multi-sourcing network options for business continuity:
  - 2 plants: in Europe and in North America

#### **Experience**

- Assessed by a major pharmaceutical manufacturer<sup>4</sup>
- BD Effivax<sup>™</sup> is built on years of BD's expertise partnering with leading pharmaceutical companies<sup>5,6</sup>
- BD is uniquely positioned with high volume production capacity delivering hundreds of millions of PFS for vaccines each year<sup>6</sup>

#### **Availability**

- Non For Human Use (NFHU) samples available on demand
- Commercial availability to be evaluated against requirements
- Will benefit from BD long-term capacity extension program with investment of over USD 1.2 billion for ready to fill containers for injectable drugs<sup>7</sup>

<sup>\*\*\*</sup>Non exhaustive list; CoA: Certificate of Analysis; c-GMP: Current Good Manufacturing Practices; E&L: Extractables and Leachables



 $<sup>^*</sup>$  Compared with BD Hypak<sup>™</sup> for Vaccines;

<sup>\*\*</sup> BD Visioguard™: features 100% automated visual inspection to identify defects and support operational excellence;

#### References

- 1. BD internal reference, Customer Quality Specification BD Effivax™ SC000243, BD Hypak™ for Vaccine SC000110, BD Medical Pharmaceutical Systems Le Pont de Claix, France
- 2. BD internal reference, Global Product Manufacturing Specification 442.GPMS.060, BD Medical Pharmaceutical Systems Le Pont de Claix, France
- 3. BD internal analysis, TCO Model, BD Medical Pharmaceutical Systems Le Pont de Claix, France
- 4. BD sales analysis [internal analysis]. Pont-de-Claix, FR: Becton, Dickinson and Company; 2022
- 5. Vaccines Market Size, Share & COVID-19 Impact Analysis, Market Research Report, <a href="https://www.fortunebusinessinsights.com/industry-reports/vaccines-market-101769">https://www.fortunebusinessinsights.com/industry-reports/vaccines-market-101769</a>, February 2022
- 6. BD sales analysis [internal analysis]. Pont-de-Claix, FR: Becton, Dickinson and Company; 2021
- 7. BD-PS external communication to customers BD to Invest \$1.2 Billion in Pre-Fillable Syringe Manufacturing Capacity Over Next Four Years. https://news.bd.com/2020-12-02-BD-to-Invest-1-2-Billion-in-Pre-Fillable-Syringe-Manufacturing-Capacity-Over-Next-Four-Years . Accessed Dec. 2, 2020

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