

## UNILIFE – DEVELOPING PREFILLED PRODUCTS OF CHOICE

Based in its market driven approach to product commercialisation, Unilife has developed a new prefilled syringe. The Unifill syringe is the first known ready-to-fill syringe which has all safety features fully contained within the glass barrel. Stephen Allan, Vice-President of Marketing and Communications at Unilife, explains.

There are more than 20 pharmaceutical companies using prefilled syringes as a preferred delivery device for at least 50 injectable drugs and vaccines that have total combined annual sales of approximately US\$50 billion. Prefilled syringes are now used across a wide array of therapeutic sectors outside of the traditional domains of anti-coagulants and vaccines (see figure 1). In particular, their usage in areas such as haematology, multiple sclerosis, arthritis, oncology and human growth hormones is expected to accelerate over the coming decade.

For pharmaceutical companies, the advantages of prefilled syringes in minimising drug wastage, increasing product lifecycles and enhancing levels of market share are driving market demand. As such, countless pipeline drugs and vaccines are also targeted to be launched in a prefilled syringe format over the coming decade.

By healthcare workers, prefilled syringes are recognised as an efficient, reliable and convenient method of drug administration. Furthermore, the ease at which patients can self-administer many types of injectable drugs makes prefilled syringes ideal to accelerate the transferral of healthcare treatment out of hospitals and into the home.

Over the past decade, one of the key emerging challenges in the pharmaceutical market for prefilled syringes has been compliance with needlestick prevention laws. The US was the first country to mandate the use of safety-engineered medical devices within healthcare facilities to protect healthcare workers, with the adoption of the Federal Needlestick Prevention Act in 2000 and subsequent amendments to the Bloodborne Pathogens Standard (BPS). Since then, the US Occupational Safety and Health Administration (OSHA) has moved to enforce the BPS aggressively with around one in every

five inspected healthcare facilities issued with citations for non-compliance between 2002 and 2007. OSHA has further stipulated that prefilled syringes should include a safety device when used within healthcare facilities even in pandemic situations.

Other international markets including the European Union, Canada and Australia are also taking steps towards the use of safety products, including prefilled syringes, which can help protect healthcare workers from harm.

Because there is currently no prefilled syringe with integrated safety features, pharmaceutical companies marketing drugs in a prefilled format have two main options to comply with laws seeking to protect healthcare workers from needlestick injuries (see Figure 2).

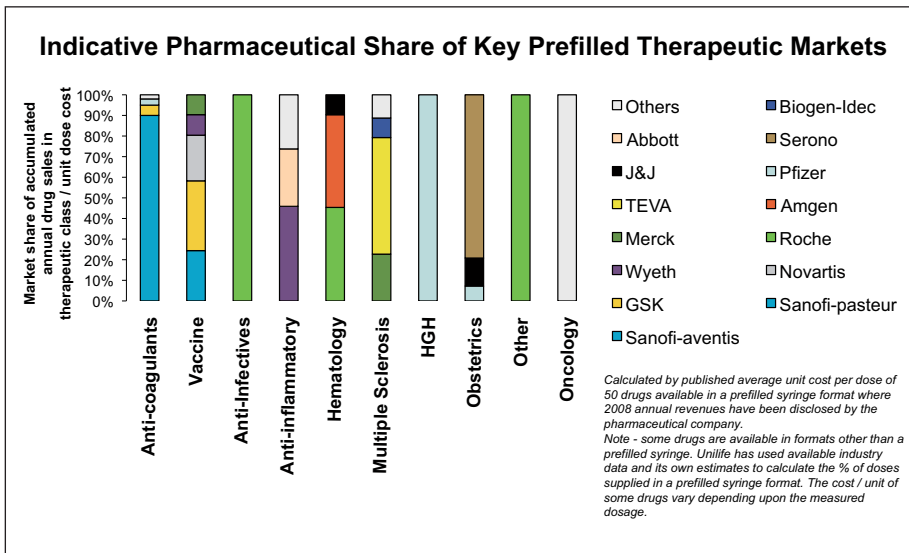
The first and arguably most common option, particularly for drugs supplied with an attached needle and administered via subcutaneous injection, is to fill a standard ready-to-fill syringe as normal then attach an ancillary safety product over the barrel prior to packaging and shipment. To protect those at risk of harm from needlestick injuries, these ancillary safety products typically slide an external plastic sheath over the entire prefilled syringe upon activation of the safety feature.

The primary advantage of these ancillary products is that they serve as a secondary drug container, thus minimising additional pharmaceutical requirements for biocompatibility and stability testing. However, pharmaceutical companies must not only purchase these ancillary safety products, but also invest in the automated assembly systems which attach them onto a prefilled syringe. As these safety products are much larger in size than a standard prefilled syringe, they can significantly increase pharmaceutical costs related to packaging, shipping and storage.

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**Figure 1: Indicative Pharmaceutical Share of Key Prefilled Therapeutic Markets**

Compared with the use of standard prefilled syringes, operators may also be required to undertake additional steps or procedures to activate the safety mechanism. For example, one ancillary safety device supplied with a prefilled low-molecular-weight heparin product in the US requires operators to remove the non-sterile needle from the body prior to activation. The operator is then required to activate the safety mechanism manually after the completion of dose delivery to protect themselves and others from the risk of needlestick injury. Should this additional action not be undertaken, the risk of harm remains. Furthermore, it is recommended that the operator point the needle down towards the ground when activating the safety mechanism with this product to minimise the infection risk associated with aerosol (splatter).

The second option for pharmaceutical companies is to place the onus for compliance upon the healthcare facility. Prefilled syringes are

commonly supplied without a needle for drugs and vaccines that are administered via intramuscular (IM) injection. In addition to selecting a needle, healthcare workers are also required to select, attach and activate the needlestick prevention device manually. Typically, these operator-attachable safety products require the operator to remove the needle from the body after dose delivery before electing to slide a plastic guard over the needle to render it safe. This leaves open the possibility that the needlestick prevention device may not be attached or activated at all.

### THE UNILIFE PHILOSOPHY

Traditionally, medical device manufacturers have sought to develop technology-driven solutions designed to address a particular market need such as the prevention of needlestick injuries. Like trying to force a square peg into a round hole, the consequences of such an

approach can be the development of products which do not fully address the operational, safety, usability or functionality requirements of all target stakeholders.

Unilife Medical Solutions was founded on a different philosophy. Unilife strives to design, develop and manufacture innovative safety medical devices via a market-driven approach to product commercialisation. The Company seeks to look beyond a single issue such as needlestick prevention to develop “products of choice” that can help address the specific needs of all relevant industry stakeholders. In this way, Unilife seeks to provide the ‘round peg’ which is perfect for the ‘round hole’ of each target market.

Unilife considers that the market for prefilled syringes will be increasingly driven by pharmaceutical companies, healthcare workers and self-injecting patients for products which can deliver the following core outcomes:

- Serves as a primary drug container with safety features being integrated within the barrel
- Can be inserted into fill-finish systems used for standard ready-to-fill syringes
- Utilises materials in the fluid path which are compatible with the contained drug
- Safety mechanism is passive, requiring little or no operator activation upon dose delivery
- Activation of the safety mechanism does not create additional hazards or infection risks
- Needle is covered permanently after activation, with minimal opportunity for re-exposure
- Operators require minimal training for use compared with conventional products
- Allows safe and convenient disposal, and does not increase sharps waste volumes

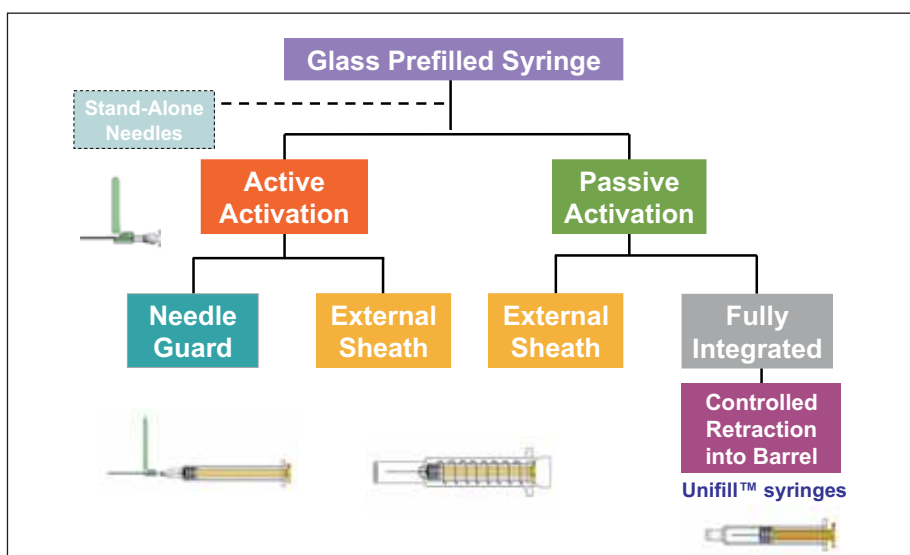
### THE UNIFILL™ SYRINGE

Unilife has worked with its major pharmaceutical partner over several years to develop a ready-to-fill product which is well positioned to attain best-in-class status within the pharmaceutical market for prefilled syringes.

The Unifill™ syringe is the first known ready-to-fill syringe with safety features that are fully contained within the glass barrel.

As a primary drug container, the Unifill™ syringe is designed to be supplied to pharmaceutical manufacturers in three sub-assembly parts (glass barrel, rubber seal and plunger) for insertion into fill-finish systems currently used for standard ready-to-fill syringes. Secondary assembly, packaging and logistical issues relating to the attachment of ancillary safety devices can thus be eliminated, with the Unifill™ syringe similar in size to a standard prefilled syringe.

Unifill syringes are designed for insertion into current fill-finish systems used for equivalent



**Figure 2: Classification of safety options for prefilled syringes**



**Figure 3: Unifill syringes are designed for insertion into current fill-finish systems used for equivalent standard ready-to-fill syringes.**



**Figure 4: Unifill syringes have passive, operator-controlled needle retraction from the body into the barrel.**



**Figure 5: Unifill is ISO 13485 certified with FDA registered manufacturing facilities in Pennsylvania, US.**

standard ready-to-fill syringes. They are supplied in a standard tray (nest) system (see figure 3).

To assist with pharmaceutical drug validation processes, the Unifill™ syringe contains components in the fluid path which utilise a number of materials commonly used with standard vials and ready-to-fill syringes. Unifill is also building relationships with a number of trusted names within the prefilled syringe market to enhance material choices for pharmaceutical customers.

To strengthen its supply chain further, Unifill has designed the glass barrel of its Unifill™ syringe so that it utilises glass cartridges which are shaped at only one end. This differs from the more challenging manufacturing process used for traditional ready-to-fill syringes, whereby the glass barrel must be shaped at both ends (needle and the finger flanges).

Being a fully integrated medical device, the Unifill™ plunger contains the proprietary safety mechanism which is activated automatically (passively) upon full dose delivery (see figure 4). The operator is able to control the speed of needle retraction directly from the body into the barrel of the syringe simply by relieving thumb or finger pressure on the plunger. Upon full retraction of the needle into the barrel, the plunger is automatically locked to prevent needle re-exposure or product tampering.

The unique combination of passive activation of the safety mechanism and the ability for operators to control the speed of needle retraction into the barrel can virtually eliminate potential infection risks associated with needlestick injuries or aerosol. Further to accommodate healthcare procedures which seek to minimise contaminated medical waste disposal volumes, operators may also snap off the end of the plunger rod after use as it has not been in contact with the fluid path.

The Unifill™ syringe delivers the same core outcome to all target stakeholders—a device nearly identical in size, shape and similar steps of use to standard prefilled syringes. The integration of fully passive safety features, however, takes this device class into a new generation of convenience, passive functionality and safety.

With the Unifill™ syringe, it is possible for pharmaceutical manufacturers to utilise current fill-finish processes with minimal changes, contain packaging and logistical costs; comply with needlestick prevention laws; and expand levels of product differentiation in competitive therapeutic markets. Healthcare workers and patients who self-administer prescription medication who are using the Unifill™ syringe also require minimal training compared with other safety prefilled syringes, yet can be fully protected against infection from needlestick injuries or splatter.

## THE UNIFILL™ SELECT

Unifill filed patent applications in the US last year for a new ready-to-fill syringe product to be marketed as the Unifill™ Select. This new pipeline product is designed to complement the Unifill™ syringe, and is targeted at addressing the requirements of pharmaceutical companies that manufacture injectable drugs and vaccines indicated for administration via IM injection.

Unifill™ Select syringes will allow healthcare workers to attach needles of up to 1 ½ inches in length and inject the dose into the patient as per routine procedures for IM administration. Unifill is not aware of any ancillary safety product currently used by pharmaceutical companies which can accommodate needles of 1 ½ inches in length.

Upon full dose delivery, the needle retraction mechanism is activated automatically with the operator being able to control the speed of needle withdrawal directly from the body into the barrel.

Pharmaceutical companies may elect to supply the Unifill™ Select to healthcare facilities in a compact and convenient kit format which is ready for injection by healthcare workers.

Like its companion product the Unifill™ syringe, the Unifill™ Select would also be designed for insertion into the fill-finish systems currently utilised by pharmaceutical companies manufactured for use with standard ready-to-fill syringes.

## BUILDING A WORLD-CLASS BUSINESS

Unifill is a fast-growing company and an emerging industry leader committed to building a team with the technical expertise to make it a preferred and trusted partner for pharmaceutical customers. The US based company is ISO 13485 certified and employs more than 100 people at its FDA-registered facilities in Pennsylvania. To support its continued global expansion, the company is redomiciling from Australia to the US and is now finalising its application to list on NASDAQ as Unifill Corporation (figure 5).

As a demonstration of the calibre of the industry leaders now joining Unifill, the management team includes the former SVP of Operations for Bayer AG, the former head of medical devices for the World Health Organization and other senior professionals from companies including Safety Syringes Inc, Teva and CR Bard.

Given its plans to manufacture more than 400 million units per year beyond 2014, Unifill has also outsourced the development of its automated assembly systems to Mikron. Following the completion of proof-of-principle activities which successfully manufactured the Unifill™ syringe on proven assembly systems, Mikron has commenced development of the first commercial assembly line for the Unifill™ syringe with scheduled completion during the second half of 2010.

The first commercial line will have an annual capacity of 60 million Unifill™ syringes, and is to be installed in Unifill's new 165,000 square foot global headquarters and manufacturing facility currently being developed in York, Pennsylvania. High-volume assembly lines with a capacity of 150 million Unifill™ syringes will also be developed to support additional pharmaceutical demand.

Unifill has retained the right to negotiate with other pharmaceutical companies seeking to use its Unifill™ syringe in areas outside of those secured by its major pharmaceutical partner.

Unifill welcomes enquiries regarding its Unifill™ range of ready-to-fill syringes via its website at [www.unifill.com](http://www.unifill.com) or at its booth (A34) at Pharmapack, Paris between February 1 and 2, 2010.