Innovation in the Prefilled Syringe Market

Biologics and Autoinjection Devices Shaping Future R&D Trends
GBI Research Report Guidance

The report discusses the innovations made in prefilled syringes market.

- The report begins with an executive summary that captures the key takeaways of the report.
- Chapter three introduces prefilled syringes, discusses their current position in the market along with the drivers and barriers.
- Chapter four details the technology currently employed in the development and manufacture of prefilled syringes and some of the issues that need to be addressed in their use.
- Chapter five analyses the formulation properties to be considered by pharmaceutical companies while manufacturing syringes to store them.
- Chapter six discusses innovative ways of overcoming the current barriers in production of prefilled syringes. Some of these include use of plastic syringes; extractables and leachables; integrated needles; safety innovations and automation.
Innovation in Prefilled Syringes Market - Executive Summary

Move towards Home Healthcare Drives the Use of Prefilled Syringes and Autoinjection Devices

The market for prefilled syringes is being driven by the rise in popularity of autoinjection devices for the home-use market. As health authorities seek to reduce costs, facilitating patients in self-administering their medication is one major way of reducing the strain on resources for providers.

Legislation Regarding Needlestick Injuries Increases Popularity of Prefilled Syringes with Integrated Safety Mechanisms

Safety is one area that has seen increasing innovation in response to regulations and guidelines concerning needlestick injury. This is an area of rising concern as the number of logged needlestick injuries in healthcare workers is high and thought to be considerably under-reported.

The Rise of Biologic Therapies Requires a Concurrent Rise in Prefilled Syringe Technologies

The development of injectable biologic therapies is a major factor in the future prospects of prefilled syringes. Although oral biologics are something that companies are aiming for and there are some in development, many peptides are broken down too quickly in the stomach and are therefore not useful in treatment.
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2 Innovation in Prefilled Syringes - Overview

2.1 Overview

Pre-filled syringes are one of the fastest growing markets in the drug delivery and packaging sectors, driven by a marked rise in the success of biological drugs and vaccines, which require the drug to be injected directly into the bloodstream.

Many companies seek prefilled syringe products as a means of life-cycle extension, offering an update to a product that may be losing its ground or approaching patent expiry.
3 Innovation in Prefilled Syringes - Introduction

3.1 What are Prefilled Syringes?

Prefilled syringes are syringes filled with medication before they are supplied to the healthcare provider or patient; this means that the pharmaceutical or biotechnology company producing the drug has decided to make that medicine available packaged within a syringe rather than as a liquid or powder that needs to be placed into an empty syringe by healthcare providers. There are obvious advantages to offering drugs in this form; a reduction in human error in filling, the ability for untrained people to administer injections, a reduction in time and resources required to prepare an injection, and less waste. As such, their popularity has been growing.

3.2 The Current Position of Prefilled Syringes in the Pharmaceutical Market

Prefilled syringes are becoming the injection mode of choice in the pharmaceutical industry as the emphasis on reduced error, safety and home use come to the fore. The increasing demands made by the US Food and Drug Administration (FDA) and European Medicines Agency (EMA) in terms of approval criteria are also driving the need for safe and error-free products. Prefilled syringes offer pharmaceutical companies a way of ensuring these factors in their drug products due to the reduced opportunity for contamination in a process that removes certain stages of human involvement (for example in mixing up solutions for injection) and in the incorporation of safety needles into prefilled syringe devices to prevent needlestick injuries.

3.3 Factors Fueling Growth of Prefilled Syringes

The attractiveness of prefilled syringes for healthcare providers is partially based around their potential to minimize costs and waste. Costs are rising not only for pharmaceutical companies, faced with a high rate of product failure and in R&D, but also for healthcare providers, as drugs command higher prices in the market place. However, rising costs for healthcare providers has led to increased scrutiny by regulators and reimbursers, and this is driving a need for efficiency in the marketed product. Prefilled syringes have the potential to improve efficiency in that the overfilling of syringes and spillage can be minimized in cutting out the human error present in self-filling. The correct dosage is provided already made up by the company in its manufacturing and filling facilities. Conventional syringes generally have to be overfilled by 20-24% in order to deliver the correct dose, whereas prefilled syringes leave only tiny amounts in the syringe following discharge (Soikes, 2011).
4 Innovation in Prefilled Syringes - Current Device Technologies and Associated Drivers and Barriers

There are a variety of types of prefilled syringe available. The section below details the technology currently employed in the development and manufacture of prefilled syringes and some of the issues that need to be addressed in their use.

4.1 Glass Syringes versus Plastic Syringes

There are two types of prefilled syringe material - the older, more established glass syringes and newer plastic polymer syringes, which have been developed in response to the changing nature of pharmaceuticals.

4.1.1 Fragility

Glass syringes suffer from numerous problems that are expected to encourage a gradual move towards plastic polymer syringe materials.

4.1.2 Dimensional Variability

Glass syringes are also subject to issues of dimensional variability, in that they are formed by a process which can lead to slight alterations in the size or shape of the product (DeGrazio and Paskiet, 2012).

4.1.3 Siliconization

A coating of silicone fluid (polydimethylsiloxane or PDMS) is often used in glass syringe technology for a variety of reasons. It is useful for lubrication, it prevents contact between the glass of the syringe and the liquid within, and aids drainage from the syringe barrel. As such, it has been a mainstay of syringe design for decades. Any alterations to the silicone layer must maintain the functionality of the coating in facilitating the sliding mechanism of the syringe.
7 Appendix

7.1 Market Definitions

Prefilled syringes: syringes filled with medication before they are supplied to the healthcare provider or patient.

Autoinjectors: spring-loaded syringe devices designed to deliver a single dose of a drug product.

7.2 Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AEB</td>
<td>Advanced Electron Beam</td>
</tr>
<tr>
<td>COC</td>
<td>Cyclic Olefin Co-polymer</td>
</tr>
<tr>
<td>COP</td>
<td>Cyclic Olefin Polymer</td>
</tr>
<tr>
<td>E-Beam</td>
<td>Electron Beam</td>
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<tr>
<td>EMA</td>
<td>European Medicines Agency</td>
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<tr>
<td>ETO</td>
<td>Ethylene Oxide</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
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<tr>
<td>HPLC</td>
<td>High Performance Liquid Chromatography</td>
</tr>
<tr>
<td>RABS</td>
<td>Restricted Access Barrier Systems</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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7.3 Bibliography


### Research Methodology

GBI Research’s dedicated research and analysis teams consist of experienced professionals with a pedigree in marketing, market research, consulting backgrounds in the medical devices industry, and advanced statistical expertise.

GBI Research adheres to the codes of practice of the Market Research Society (www.mrs.org.uk) and the Strategic and Competitive Intelligence Professionals (www.scip.org) .

All GBI Research databases are continuously updated and revised.

#### Coverage

The objective of updating GBI Research’s coverage is to ensure that it represents the most up-to-date vision of the industry possible.

Changes to the industry taxonomy are built on the basis of extensive research of company, association and competitor sources.

Company coverage is based on three key factors: market capitalization, revenues, and media attention/innovation/market potential.

- An exhaustive search of 56 member exchanges is conducted, and companies are prioritized on the basis of their market capitalization;
- The estimated revenues of all major companies, including private and governmental, are gathered and used to prioritize coverage; and,
- Companies which are making the news, or which are of particular interest due to their innovative approach, are prioritized.

GBI Research aims to cover all major news events and deals in the medical industry, with its databases updated on a daily basis.

The coverage is further streamlined and strengthened with additional inputs from GBI Research’s expert panel (see below).
7.4.2 Secondary Research

The research process begins with exhaustive secondary research on internal and external sources being carried out to source qualitative and quantitative information relating to each market.

The secondary research sources that are typically referred to include, but are not limited to:

- Company websites, annual reports, financial reports, broker reports, investor presentations and US Securities and Exchanges Commission (SEC) filings
- Industry trade journals, scientific journals and other technical literature
- Internal and external proprietary databases
- Relevant patent and regulatory databases
- National government documents, statistical databases and market reports
- Procedure registries
- News articles, press releases and webcasts specific to the companies operating in the market

7.4.3 Primary Research

GBI Research conducts hundreds of primary interviews each year with industry participants and commentators, in order to validate its data and analysis. A typical research interview fulfills the following functions:

- It provides first-hand information on the market size, market trends, growth trends, competitive landscape, and future outlook.
- Helps in validating and strengthening the secondary research findings; and,
- Further develops the analysis team’s expertise and market understanding

Primary research involves email interactions, telephone interviews, and face-to-face interviews for each market, category, segment and sub-segment across geographies.

The participants who typically take part in such a process include, but are not limited to:

- Industry participants: CEOs, VPs, marketing/product managers, market intelligence managers and national sales managers
- Hospital stores, laboratories, pharmacies, distributors and paramedics
- Outside experts: Investment bankers, valuation experts, research analysts specializing in specific medical equipment markets; and,
- Key Opinion Leaders: Physicians and surgeons specializing in different therapeutic areas corresponding to different kinds of medical equipment

7.4.4 Expert Panel Validation

GBI Research uses a panel of experts to cross-verify its databases and forecasts.

GBI Research’s expert panel comprises marketing managers, product specialists, international sales managers from medical device companies, academics from research universities, and key opinion leaders from hospitals.

Historic data and forecasts are relayed to GBI Research’s expert panel for feedback and adjusted in accordance with their feedback.
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