

## **THE FUTURE OF SYRINGES**

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The prefilled syringe is a relative newcomer to the syringe market. The advantages of prefilled syringes include ease of use and lower administration costs, fewer medication errors and higher dose accuracy, greater control over potent or addictive drugs, reduced overfill compared with conventional syringes, the potential to eliminate toxic preservatives in vaccines, lower likelihood of bacterial contamination, and product differentiation.

Convenience and ease of use are beneficial both in self-administration and in formal healthcare settings. Prefilled syringes are rapidly becoming the preferred administration mechanism for diabetics and family caregivers. Peel-off labels on prefills facilitate medication tracking in hospitals, while bar-coding and fixed labels prevent dosing errors common with conventionally filled syringes – those that are filled but not immediately used, for example.

Manufacturers go to great lengths to demonstrate that their construction materials are inert and must do so for an ever-expanding range of injectable drug substances. Nevertheless, the burden of demonstrating safety falls on the formulator and, ultimately, on the product sponsor.

Stability studies should include testing of those attributes of the pharmaceutical product that are susceptible to change during storage and are likely to influence quality, safety, and efficacy. The testing should cover, as appropriate, the physical, chemical, biological and microbiological attributes, preservative content (e.g. antioxidant, antimicrobial preservative). Analytical procedures should be fully validated and stability indicating.

Quality of prefilled syringe formulations is covered under several International Conference on Harmonisation guidances:

- Q1C Stability Testing for New Dosage Forms
- Q1A(R2) Stability Testing of New Drug Substances and Products
- Q3B(R2) Impurities in New Drug Products
- Q5C Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products

The world is moving to prefills, and, to stay competitive, you need to move with it.

The prefilled syringe is a lower overfill, which helps to reduce costs and maximize yield, enhanced differentiation, greater efficiency, increase patient compliance, ease of use and convenience for healthcare professionals and patients, reduce risk of dosage error and contamination.