



Technical Report No. 73

Prefilled Syringe User Requirements for Biotechnology Applications

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PDA Prefilled Syringe User Requirements for Biotechnology Applications Technical Report Team

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Technical Report No. 73

ISPN: 18-0-939459-82-7

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1.0 Introduction

Since the mid-2000's, a large number of subcutaneously injected biotechnology drug products have been packaged in prefilled syringes (PFSs) because of significant benefits compared to vials or ampules. PFSs reduce medical dosing errors and the risk of microbial contamination by decreasing the number of necessary manipulations prior to injection, and they improve compliance due to ease of use. In addition to the patient benefits, PFSs often have lower overfill regulatory requirements than vials, thereby reducing product waste.

1.1 Purpose/Scope

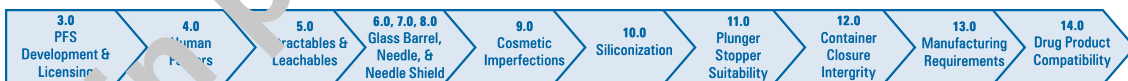
The purpose of this technical report is to present a discussion of requirements for the 1 mL long glass PFS for biotechnology applications (**Figure 1.1-1**). Topics covered are material selection and evaluation for suitability, syringe preparation and handling (including human factors), and drug product compatibility (physical and chemical) with the syringe materials and mode of delivery. Plastic syringes and ancillary devices, such as autoinjectors, are not within scope.

The terms “end user,” “customer,” and “user” are used interchangeably throughout this report. However, the definitions of these terms change according to the topic under discussion as the report progresses through the product life cycle of the PFS. For example, during development, the end user or target population may be the target patient, while the customer or user during production and delivery may be the supplier or manufacturer. Additionally, while this technical report provides more specific information related to the U.S. and European regions, requirements for different regulatory agency jurisdictions may vary, and applicants and manufacturers should be aware of the proper qualification and validation expectations for the intended market.

While the focus of this report is on 1 mL long glass PFSs for biotechnology (large molecule) drug products, the concepts presented may be applied to other products and applications (e.g., small molecule drug products, luer, luer-lock, and plastic syringes). Every attempt has been made to provide comprehensive content, but some particular techniques and technologies may not be included.

The task force that prepared this report consisted of members representing global companies and representatives from regulatory bodies to create a consensus on the methods, terminology, and practices described. Experts in PFSs and PFS manufacturing performed technical reviews.

The information in this technical report appears in the general order of operations for developing and manufacturing 1 mL long glass PFSs. Throughout the report, the chevron diagram (below) serves as a guide for the reader and reflects the focus of each chapter.



The glossary contains a list of definitions and acronyms used in this report. When available, same or similar definitions to those included in FDA or ICH guidelines are used.