Technical Report No. 73

Prefilled Syringe User Requirements for Biotechnology Applications

PDA Prefilled Syringe User Requirements for Biotechnology Applications Technical Report Team

Authors and Contributors

Ron Forster, Ph.D., Amgen, Team Leader

Ross Allen, Eli Lilly and Company

Khandan Baradaran, Dimension Therapeutics

Sherri Biondi, Genentech

Alfred Breunig, Nipro Glass Germany AG

Charlene Brisbane, GlaxoSmithKline

Anil Busimi, Schott

Rey Chern, Ph.D., Amgen

Piet Christiaens, Ph.D., Toxikon Europe NV

Jean-François DeCoster, UCB Pharma S.A.

Andrew Donnelly, Bespak

Peter Gassmann, Ph.D., Johnson & Johnson

Aarti Gidh, Ph.D., GlaxoSmithKline

Heike Gruen, West Pharmaceutical Services

Olivia Henderson, Ph.D., Biogen

Carl Hitscherich, Ph.D., Biogen

Tibor Hlobik, West Pharmaceutical Services

Colleen Hutter, Merck

Renaud Janssen, Datwyler Pharma Packaging Belgium NV

Laurent Jeanmart, Ph.D., GlaxoSmithKline Biologicals

Akshay Kamdar, Ph.D., Eli Lilly and Company

Suzanne Kiani, Amgen

James Kershner, Eli Lilly and Company

Lei Li, Ph.D., Eli Lilly and Company

Alice Maden, Becton Dickinson

Mary Mathieu, AbbVie

Kingman Ng, Ph.D., Novartis

QuynhNhu Nguyen, U.S. FDA/CDRH

Thomas Nikolai, Hospira

Carlos Ortiz, Eli Lilly and Company

Bruno Reuter, Nipro Europe NV

Julio Rivera, SiO2 Medical Products

Lesbeth C. Rodriguez, Bayer Healthcare Pharmaceuticals, Inc

Andrea Salmaso, Pharma.D., Stevanato Group spa

Thomas Schönknecht, SHL

Jörg Sielemann, F. Hoffmann La Roche AG

Hervé Soukiassian, Becton Dickinson

Kalavati Suvarna, Ph.D., U.S. FDA

Robert Swift, [illegible]

Randy Thackrey, Eli Lilly and Company

Rajaram Thyagarajapuram, Ph.D., Eli Lilly and Company

Simon Toth, Dow Corning Corporation

Li-Chun Tsou, Ph.D., AstraZeneca

Tina Tubbs, Sanofi-Pasteur

Paulo Villaneuva, Genentech

Lee Wood, F. Hoffmann La Roche AG

Jörg Zimmermann, Vetter Pharma

Daniele Zuccato, Stevanato Group spa

Prefilled Syringe User Requirements for Biotechnology Applications

Technical Report No. 73

ISBN: 978-0-939459-82-7

Table of Contents

FIGURES AND TABLES INDEX

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

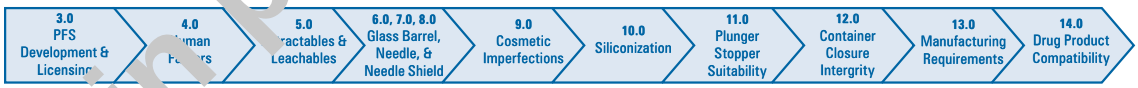
The purpose of this technical report is to present a discussion of requirements for the 1 mL long glass PFS for biotechnology applications (**Figure 1.1-1**). Topics covered are material selection and evaluation for suitability, syringe preparation and handling (including human factors), and drug product 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 ensure 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.