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Identification and Classification of Visible Nonconformities in Elastomeric Components and Aluminum Seals for Parenteral Packaging

PDA Identification and Classification of Visible Nonconformities in Elastomeric Components and Aluminum Seals for Parenteral Packaging Technical Report Team

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Disclaimer: The content and views expressed in this Technical Report are the result of a consensus achieved by the authorizing Technical Report Team and are not necessarily the views of the organizations they represent.

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1.0 Introduction

Pharmaceutical companies and suppliers of elastomeric components and aluminum seals often make quality decisions based on visual inspections of these packaging components without the aid of universal guidelines or standards. Inconsistency in defining elastomeric component and aluminum seal nonconformities has resulted in a non-uniform approach in meeting regulatory expectations to deliver high-quality pharmaceutical products.

PDA members recognized the need to provide consensus-based best practices for the identification and classification of elastomeric component and aluminum seal nonconformities in the form of a consensus-based Technical Report. A task force, representing a broad cross-section of both suppliers and pharmaceutical manufacturing professionals, was formed to create a consensus document.

Technical Report No. 76 provides an approach to a quality decision-making process; implementation of that approach, however, is the responsibility of each organization. The following represents what the authors believe are best practices for identifying and classifying visual nonconformities for elastomeric components and aluminum seals.

1.1 Purpose and Scope

The purpose of this technical report is to provide consistent and standardized quality criteria that can be used by pharmaceutical and medical device manufacturers for the visual inspection of incoming elastomeric components and aluminum seals, and by suppliers for outgoing inspection. Post-filling inspection for these nonconformity types in filled containers are out of scope and should be established on similar patient risk assessment principles.

Note: In this report, the term "pharmaceutical" is used to designate both pharmaceuticals and medical devices.

Included in scope are elastomeric and aluminum components used for parenteral packaging and delivery, including but not limited to elastomeric vial stoppers, seal liners, and aluminum and aluminum/plastic seals. Out of scope are diagnostics and components, such as blood collection stoppers, and medical device components such as gaskets, diaphragms, and O-rings. Detailed lexicons that visually illustrate commonly observed nonconformities in elastomeric components and aluminum seals are included.

The identification and classification of elastomeric component and aluminum seal visual nonconformities represent only one part of the overall quality requirements. Examples of additional quality requirements may include adherence to dimensional standards, functional requirements, compendial requirements, incoming lot sampling program, and acceptance quality limits. This report provides a building block for developing a comprehensive specification for elastomeric components and aluminum seals.

This report is not intended to establish mandatory standards for the classification and identification of elastomeric component and aluminum seal nonconformities; it is intended to be a single-source overview that complements existing guidelines and standards or documents listed in the reference section of this technical report. For greater detail on various topics throughout this report, suggestions for additional reading have been provided. It is always advisable to consult with the appropriate regulatory authority for agreement on the strategies employed for the identification and classification of visual nonconformities in elastomeric components and aluminum seals, and other similar packaging components.