Bioteknologi – Analytiske metoder – Risikobaseret tilgang til metodevalg og validering til hurtig mikrobiel detektion i bioprocesser

Biotechnology – Analytical methods – Risk-based approach for method selection and validation for rapid microbial detection in bioprocesses

DANSK STANDARD
Danish Standards Association

Göteborg Plads 1
DK-2150 Nordhavn

Tel: +45 39 96 61 01
dansk.standard@ds.dk
www.ds.dk

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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Foreword

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This document was prepared by Technical Committee ISO/TC 276, *Biotechnology*.

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Introduction

Patient safety is essential in providing cell-based therapies. However, novel cell-based therapies present many challenges with respect to the timely assessment of microbial contamination. Since many cell-based therapies have short shelf lives, they are administered to patients within hours after formulation. In addition to final product testing, testing on cell banks and product intermediates is common. Microbiological testing includes bacteria, fungi, mycoplasma and viral adventitious agents. Culture-based testing methods (e.g. pharmacopeia methods) have been widely adopted by industry. However, culture-based testing methods can take days to weeks to obtain a result. More rapid methods for microbiological testing are needed to ensure patient safety prior to product administration. The development and use of rapid, validated methods that are sensitive and accurate, and that allow for the detection of a broad range of microorganisms are therefore desired and supported by this document.

Biotechnology — Analytical methods — Risk-based approach for method selection and validation for rapid microbial detection in bioprocesses

1 Scope

This document provides guidance, a framework and a risk-based approach for the selection and validation of methods for rapid microbial detection in cellular therapeutic product manufacturing.

This document provides a flexible risk-based framework for the detection of microbial contamination in cellular therapeutic products and cellular intermediates.

This document provides general requirements and risks associated with cellular therapeutic product manufacturing, with flexibility to address differences in specific manufacturing processes of each unique cellular therapeutic product.

This document primarily addresses sterility testing in cellular therapeutic product manufacturing. This document is applicable to other cell-derived therapeutic product manufacturing.

This document focuses on rapid microbial test methods (RMTMs) used for both in-process and final product testing.

Viral testing in cellular therapeutic product manufacturing is not included in this document.

2 Normative references

There are no normative references in this document.