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

Biotechnologie — Méthodes d'analyse — Approche basée sur les risques pour la sélection et la validation de méthodes pour la détection microbienne rapide dans les bioprocédés

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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.