TECHNICAL SPECIFICATION

ISO/TS 20399-2

First edition
2018-11

Biotechnology — Ancillary materials present during the production of cellular therapeutic products —

Part 2: Best practice guidance for ancillary material suppliers

Biotechnologie — Matériaux auxiliaires présents lors de la production de produits thérapeutiques cellulaires —

Partie 2: Lignes directrices de bonne pratique pour les fournisseurs de matériaux auxiliaires

Reference number
ISO/TS 20399-2:2018(E)

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Published in Switzerland

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Foreword

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

A list of all parts in the ISO/TS 20399 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Ancillary materials (AM) are materials that come into contact with the cellular therapeutic product during the manufacturing process, but are not intended to be in the final product.

AMs include culture media, growth factors, and other biological and non-biological components. They can be a complex mixture of multiple components and variation in their lot-to-lot compositions can hamper the ability to produce a consistent product based on therapeutic cells with specified quality attributes.

As such, AMs can have implications with regard to the safety and effectiveness of a therapeutic product. Appropriate control of ancillary material may be determined by a risk-based approach.

This document provides guidelines to AM suppliers on best practice to ensure consistent manufacture of AM products. It also describes the information that should be obtained and provided to the AM user to demonstrate lot-to-lot consistency of the AM product with respect to AM characteristics and quality attributes, biosafety, and performance.

A number of standards and guidance documents define the proper processing of cell based therapeutic products to ensure safety and efficacy. However, these standards only indirectly relate to the suppliers of AM products. This document clarifies the expectations for AM suppliers which are distinct from the standards governing cell processing requirements.

The ISO/TS 20399 series provides general requirements and guidance regarding ancillary materials to maintain a high level of lot-to-lot consistency, as well as the accompanying documentation, so that consistent ancillary materials (AM) products and documentation provided by the suppliers can help AM users.