

This is a preview of "ISO/TS 20399-1:2018". [Click here to purchase the full version from the ANSI store.](#)

First edition  
2018-11

---

---

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

## Part 1: General requirements

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

*Partie 1: Exigences générales*



Reference number  
ISO/TS 20399-1:2018(E)

© ISO 2018



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Fax: +41 22 749 09 47  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

This is a preview of "ISO/TS 20399-1:2018". [Click here to purchase the full version from the ANSI store.](#)

## Contents

	Page
<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Abbreviated terms</b> .....	<b>3</b>
<b>5 Considerations</b> .....	<b>3</b>
5.1 General considerations .....	3
5.2 Animal-derived components of AM .....	3
5.2.1 General .....	3
5.2.2 Levels of ADCF .....	3
5.2.3 Key considerations in the use of animal-derived components .....	4
5.2.4 Viral inactivation .....	4
5.3 Mutual responsibilities for AMs .....	4
5.4 Example workflow .....	5
<b>6 Ancillary material requirements</b> .....	<b>6</b>
6.1 Quality management system .....	6
6.2 Information on ancillary material products and materials used to produce ancillary materials .....	6
<b>Annex A (informative) Example of workflow from AM supplier to AM user</b> .....	<b>7</b>
<b>Annex B (informative) Information on AM products and materials used to produce AM</b> .....	<b>8</b>
<b>Bibliography</b> .....	<b>10</b>

## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

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](http://www.iso.org/members.html).

This is a preview of "ISO/TS 20399-1:2018". [Click here to purchase the full version from the ANSI store.](#)

## Introduction

Ancillary materials (AMs) 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 and growth factors, among other biological and non-biological components. They can be a complex mixture of many components, and a variation in their lot-to-lot composition can hamper the ability to produce consistent cellular therapeutic products with specified quality attributes.

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

This document specifies definitions and general requirements for AMs and contributes to their control by suppliers and users of such materials.

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 products and documentation provided by the suppliers can help AM users.

It is intended to ensure the quality and consistency of AMs used in the manufacturing of cellular therapeutic products. Good manufacturing practice (GMP) is taken into account, when necessary.