
Biotechnology — Biobanking — Implementation guide for ISO 20387

*Biotechnologie — Biobanking — Guide de mise en oeuvre de l'ISO
20387*

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[ISO/TR 22758:2020](https://standards.iteh.ai/catalog/standards/iso/c941ddf2-8d40-4647-8168-831e3f7cfc05/iso-tr-22758-2020)

<https://standards.iteh.ai/catalog/standards/iso/c941ddf2-8d40-4647-8168-831e3f7cfc05/iso-tr-22758-2020>



iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[ISO/TR 22758:2020](https://standards.iteh.ai/catalog/standards/iso/c941ddf2-8d40-4647-8168-831e3f7cfc05/iso-tr-22758-2020)

<https://standards.iteh.ai/catalog/standards/iso/c941ddf2-8d40-4647-8168-831e3f7cfc05/iso-tr-22758-2020>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2020

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
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Background information for the development of ISO 20387	1
4.1 General	1
4.2 Intended audience for ISO 20387 and this document	2
4.3 Implementation of ISO 20387	2
5 Fitness for the intended purpose (FIP) (ISO 20387:2018, 3.24) in biobanking	3
5.1 General	3
5.2 Fitness for the intended purpose and biological material and/or associated data (BMA) life cycle	3
5.3 Factors affecting fitness for the intended purpose	4
5.4 Determination of the pre-arranged requirements for FIP	5
5.5 Decision whether the biological material and associated data is truly fit for an intended purpose	5
6 Process landscape	5
7 Conformity with ISO 20387	7
7.1 Scopes of Conformity	7
7.1.1 General	7
7.1.2 Determination of the scope of conformity	7
7.2 Conformity Assessment (CA) Practices (General aspects and applicability for biobanks)	8
8 Guidance on the interpretation of selected ISO 20387:2018 text parts	8
8.1 General Requirements (ISO 20387:2018, Clause 4)	8
8.1.1 General	8
8.1.2 Impartiality (ISO 20387:2018, 4.2)	9
8.1.3 Confidentiality (ISO 20387:2018, 4.3)	9
8.2 Structural requirements (ISO 20387:2018, Clause 5)	9
8.2.1 General	9
8.2.2 ISO 20387:2018, 5.1	9
8.2.3 ISO 20387:2018, 5.3	9
8.2.4 ISO 20387:2018, 5.5	9
8.2.5 ISO 20387:2018, 5.7	10
8.2.6 ISO 20387:2018, 5.8, a)	10
8.2.7 ISO 20387:2018, 5.9	10
8.3 Resource requirements (ISO 20387:2018, Clause 6)	11
8.3.1 General	11
8.3.2 ISO 20387:2018, 6.1.2	11
8.3.3 ISO 20387:2018, 6.2.1.2	12
8.3.4 ISO 20387:2018, 6.2.1.4	12
8.3.5 ISO 20387:2018, 6.2.2.1	12
8.3.6 ISO 20387:2018, 6.2.2.3	12
8.3.7 ISO 20387:2018, 6.2.3	12
8.3.8 ISO 20387:2018, 6.2.3.3	12
8.3.9 ISO 20387:2018, 6.3	12
8.3.10 ISO 20387:2018, 6.3.2	13
8.3.11 ISO 20387:2018, 6.3.3	14
8.3.12 ISO 20387:2018, 6.3.5	14
8.3.13 ISO 20387:2018, 6.3.7	14
8.3.14 ISO 20387:2018, 6.4.1.1	14

8.3.15	ISO 20387:2018, 6.4.1.5	14
8.3.16	ISO 20387:2018, 6.4.1.6	15
8.3.17	ISO 20387:2018, 6.5.1	15
8.3.18	ISO 20387:2018, 6.5.3	15
8.3.19	ISO 20387:2018, 6.5.6	15
8.3.20	ISO 20387:2018, 6.5.10	15
8.3.21	ISO 20387:2018, 6.5.11	15
8.3.22	ISO 20387:2018, 6.5.12	15
8.4	Process requirements (ISO 20387:2018, Clause 7)	16
8.4.1	General	16
8.4.2	ISO 20387:2018, 7.1.1	16
8.4.3	ISO 20387:2018, 7.2.1.1	16
8.4.4	ISO 20387:2018, 7.2.3.4	16
8.4.5	ISO 20387:2018, 7.3.1.1	16
8.4.6	ISO 20387:2018, 7.3.2.4	17
8.4.7	ISO 20387:2018, 7.3.2.5	17
8.4.8	ISO 20387:2018, 7.3.3.2	18
8.4.9	ISO 20387:2018, 7.4.2	18
8.4.10	ISO 20387:2018, 7.4.5	18
8.4.11	ISO 20387:2018, 7.6.2	18
8.4.12	ISO 20387:2018, 7.7.1	18
8.4.13	ISO 20387:2018, 7.7.3	19
8.4.14	ISO 20387:2018, 7.7.5	19
8.4.15	ISO 20387:2018, 7.7.7	19
8.4.16	ISO 20387:2018, 7.8.1.2	19
8.4.17	ISO 20387:2018, 7.9.1.1	20
8.4.18	ISO 20387:2018, 7.10.5	20
8.4.19	ISO 20387:2018, 7.12.2.1	20
8.4.20	ISO 20387:2018, 7.13.2	20
8.5	Quality management system requirements (ISO 20387:2018, Clause 8)	20
8.5.1	General	20
8.5.2	ISO 20387:2018, 8.1.1, 8.1.2 and 8.1.3	20
8.5.3	ISO 20387:2018, 8.3.1	21
8.5.4	ISO 20387:2018, 8.4.1, 8.4.2 and 8.4.3	21
8.5.5	ISO 20387:2018, 8.5.1, 8.5.2 and 8.5.3	22
8.5.6	ISO 20387:2018, 8.6.1	22
8.5.7	ISO 20387:2018, 8.8.1 and 8.8.2	22
	Bibliography	23

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).

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).

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.

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

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.

ISO/TR 22758:2020

<https://standards.iteh.ai/catalog/standards/iso/c941ddf2-8d40-4647-8168-831e3f7cfc05/iso-tr-22758-2020>