

# ISO/TR 22758:2020-05 (E)

## Biotechnology - Biobanking - Implementation guide for ISO 20387

---

<b>Contents</b>		<b>Page</b>
Foreword		v
Introduction		vi
<b>1</b>	<b>Scope</b>	<b>1</b>
<b>2</b>	<b>Normative references</b>	<b>1</b>
<b>3</b>	<b>Terms and definitions</b>	<b>1</b>
<b>4</b>	<b>Background information for the development of ISO 20387</b>	<b>1</b>
4.1	General	1
4.2	Intended audience for ISO 20387 and this document	2
4.3	Implementation of ISO 20387	2
<b>5</b>	<b>Fitness for the intended purpose (FIP) (ISO 20387:2018, 3.24) in biobanking</b>	<b>3</b>
5.1	General	3
5.2	Fitness for the intended purpose and biological material and/or associated data (BMaD) 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
<b>6</b>	<b>Process landscape</b>	<b>5</b>
<b>7</b>	<b>Conformity with ISO 20387</b>	<b>7</b>
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
<b>8</b>	<b>Guidance on the interpretation of selected ISO 20387:2018 text parts</b>	<b>8</b>
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 (20387:2018, <a href="#">Clause 5</a> )	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
<b>Bibliography</b>		<b>23</b>