

ISO/TR 22758:2020-05 (E)

Biotechnology - Biobanking - Implementation guide for ISO 20387

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 (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
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 (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