ISO 20399:2022-12 (E)

Biotechnology - Ancillary materials present during the production of cellular therapeutic products and gene therapy products

Contents

Page

Foreword v

Introduction vi

1 Scope 1

2 Normative references 1

3 Termsanddefinitions 1

4 Abbreviated terms 4

5 Strategy 5
5.1 Key concepts on AM 5
5.2 AM-related responsibilities 5
5.3 Qualification considerations of AM 6
5.4 Animal-derived components of AM 7
5.4.1 General 7
5.4.2 Key considerations in the use of animal-derived components 7
5.4.3 Viral inactivation 8

6 Evaluation criteria and risk mitigation for AM containing biological material 8
6.1 Evaluation criteria for AM selection 8
6.2 Mitigation of risk 10
6.2.1 Scientific approach 10
6.2.2 Supplier audit and questionnaires 11
6.2.3 Risk assessment 12

7 AM characteristics and quality attributes 12
7.1 AM components, identity and purity 12
7.1.1 General 12
7.1.2 Identity and quantity of component(s) 13
7.1.3 Purity and impurity 13
7.1.4 Lot-to-lot consistency for AMs containing proprietary components 13
7.2 AM storage and stability 14
7.2.1 General 14
7.2.2 Stability and storage conditions 14

8 AM manufacturing and biosafety 15
8.1 Quality management system 15
8.2 Manufacturing process 16
8.3 Container and closure systems 16
8.4 Animal and human-derived components 16
8.5 Safety to cells and humans 17

9 AM performance 17
9.1 General 17
9.2 Quality and testing 18
9.3 Qualification activity 18
9.4 Performance assay 19
9.5 Performance assay results 19

10 AM documentation 19
10.1 General 19
10.2 Reporting requirements 20
10.3 Certificate of analysis 21
10.4 Additional certificates 22
10.4.1 Certificate of origin 22
10.4.2 Certificate of compliance 22
10.4.3 Certificate of irradiation 22

11 Managing changes to components 22
11.1 Impact of changes to components 22
11.2 Measures for managing changes to components 22

Annex A (informative) Decision chart of AMs 24

Annex B (informative)ExampleworkflowfromAMsuppliertoAMuser 26

Annex C (informative) Information on AM and materials used to produce AMs 27

Annex D (informative) Considerations for the characterization of AMs 29

Annex E (informative) Quality declarations for manufactured biological materials used in the manufacture of a cell-based therapeutic product 30

Bibliography 31