ISO 13022:2012-04 (E)

Medical products containing viable human cells - Application of risk management and requirements for processing pra ctices

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 2

3 Termsanddefinitions 2

4 Risk management process 6
4.1 General 6
4.2 Hazards associated with the cellular component 6
4.3 Risk analysis 8
4.4 Risk evaluation 9
4.5 Risk control 9
4.6 Evaluation of overall residual risk acceptability 9
4.7 Production and post-production information system 10

Annex B (informative) Graphic representation of the part of the risk management process for cell-based medical products 12

Annex C (normative) Requirements for donor selection and testing 13

Annex D (informative) Guidance for tissue procurement 17

Annex E (normative) Requirements for handling of cells and tissue during manufacture 20

Annex F (normative) Requirements for packaging and labelling 23

Annex G (informative) Guidance for transport 26

Annex H (informative) Guidance for storage 31

Annex I (normative) Requirements for traceability 34

Annex J (normative) Risk reduction measures relating to contamination with viruses and other infectious agents such as TSE 35

Annex K (informative) Guidance relating to hazards caused by the tumorigenic potential of human cells or tissues used for the production of medical products 38

Annex L (informative) Guidance relating to microbiological contamination 39

Annex M (informative) Guidance relating to potential adverse effects of non-cellular residues of the product 40

Annex N (normative) Requirements relating to potential adverse effects of the cellular components of a medical product 41

Annex O (informative) Guidance for the characterization of the cellular components of a medical product 42

Annex P (informative) Clinical evaluation and testing 45

Bibliography 46