ISO 24190:2023-05 (E)

Biotechnology - Analytical methods - Risk-based approach for method selection and validation for rapid microbial detection in bioprocesses

Contents

Page

Foreword v

Introduction vi

1 Scope 1

2 Normative references 1

3 Termsanddefinitions 1

4 General considerations 7

5 Risk management for microbiological contamination 7
5.1 Risk management in manufacturing process 7
5.2 Risk management in microbial testing 8

6 Selectionofafit-for-purposeassay 9
6.1 General 9
6.2 Assay selection 10
6.3 Kit or system selection 10
6.4 Considerations for various test types 11
6.5 User requirement specifications 12
6.5.1 General 12
6.5.2 Speed 12
6.5.3 Sample volume 12
6.5.4 In-process versus final release testing 12
6.5.5 Specificity 12
6.5.6 Sensitivity 13

7 Validation 13
7.1 General concepts 13
7.2 Selection of microorganisms for validation 14
7.3 Quality by design of method validation 15
7.4 Revalidation method 15
7.5 System validation 16
7.6 Use of reference material in validation 16
7.7 Acceptance criteria of targeted validation parameters 16
7.8 Precision 17
7.9 Detection limit 17
7.10 Accuracy 17
7.11 Robustness 18
7.12 Ruggedness 18

8 Use and application of rapid microbial tests 18
8.1 Number and type of samples 18
8.2 Testing environment 18
8.3 Sensitivity 19
8.4 Analytical specificity (microorganism detection) 19
8.5 Comparable test data 19

9 Investigation of positive sterility results 20

10 Training 20

11 Documentation 21

12 Test report 21

Annex A (informative) Exemplary framework for identifying microbial contamination 22

Annex B (informative) Risk analysis with cellular therapeutic products related to input materials -- Donor selection 23

Annex C (informative) Risk analysis with cellular therapeutic products related to input materials -- Cell transformation and expansion 24

Annex D (informative) Risk analysis with cellular therapeutic products related to input materials -- Packaging storage and administration 26

Annex E (informative) Risk-based classification for monitoring practices for cellular therapeutic product manufacturing 27

Annex F (informative) Validation of rapid microbial test methods 28

Annex G (informative) Microorganisms for validation of rapid microbial test methods 30

Annex H (informative) Methods for rapid microbial testing 34

Annex I (informative) Environmental control 41

Bibliography 42