

Industrial Pharmaceutical Microbiology: Standards and Control 2015 Edition
Editors – *Geoff Hanlon and Tim Sandle*

Preface *Geoff Hanlon and Tim Sandle*

Part A: The Role of the Microbiologist and the Microbiology Laboratory

1. Safety in Microbiology

Nigel Silman and John V Daniels

2. Best Practices in Microbiology Laboratory Training

Tim Sandle

3. The Use of Culture Media in Pharmaceutical Microbiology

Tim Sandle

4. Rapid Microbiological Methods and Process Analytical Technology (PAT)

Jeanne Moldenhauer

5. Microbial Risk Assessments for Operational Cleanrooms

Tim Eaton

6. The Role of the Qualified Person in Microbiological Quality Assurance

John Dolman

7. Auditing the Pharmaceutical Microbiology Department

Andy Martin

Part B: Microbiological Control and Industrial Processes

8. Microbiological Environmental Monitoring

Rosamund M Baird

9. Selection and Use of Cleaning and Disinfection Agents in Pharmaceutical Manufacturing

Tim Sandle

10 Microbiology of Pharmaceutical Grade Water

Tim Sandle

11. Biofilm Contamination in Pharmaceutical Facilities

Alex P Blanchard

12. Cleanrooms, Isolators and Rabs: Basic Principles, Design, Testing, Operation and Regulatory Aspects

John Neiger

13. Aseptic Process Simulations/Media Fills

Marco Budini and Francesco Boschi

14. Filtration

Claire Jarmey-Swan

15. Sterilisation Technologies

Eric Dewhurst and Eamonn Hoxey

16. Biological Indicators

Tim Sandle

17. Endotoxins and Dehydrogenation

Karen Zinc McCullough

18. Containment System Integrity: Microbial Challenges for Sterile Products

Tim Sandle

19. Challenges of Bacteriophage Therapy

Alexander Sulakvelidze

Part C: Regulatory Aspects of Industrial Pharmaceutical Microbiology

20. Microbiological Quality and Regulatory Requirements for Biotherapeutics

Daniel Galbraith

21. The Microbiological Quality and Regulatory Requirements for Natural and Nutraceutical Products

Martin Dennison

22. The Regulatory Control and Quality Assurance of Immunological products

Tim Sandle

23. Regulatory Guidelines (Microbiology) for Veterinary Medicinal Antimicrobial Products

Klaus Hellmann and Peter Silley

24. Regulatory Expectations for Non-Sterile Manufacture of Pharmaceutical Dose Forms

Edel Fitzmaurice

25. The Pharmacopoeias and Microbiology

V Fenton-May