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

    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*

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**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*