PMF Book Review - March2024

Manual of Clinical Microbiology, 13th Edition Carroll, K. C. and M.A. Pfaller (Editors-in-chief) ASM Press/Wiley 2600pp. Hardcopy $460

The first edition of the ASM Manual of Clinical Microbiology was published in 1970 and it is continuously revised and extended. The thirteenth edition appears as four volumes containing 155 chapters and over 2600 pages. An innovation is the publication of an online version with a search function and periodic updates called ClinMicroNow. PMF members should investigate whether you or your company should subscribe to ClinMicroNow as a better option than purchasing a four-volume hardcopy book.

The Manual is recognized the most authoritative textbook in the field of clinical microbiology. As a pharmaceutical microbiologist consulting to industry, I believe I needed up-to-date information on microorganisms that are implicated in infectious disease that I can cite in reports to clients, so I purchased the books. This information especially useful in supporting out-of-specification investigations and determining whether a microbial isolate from a non-sterile drug product is objectionable in that dosage form. This source of information will be useful to my colleagues working in the pharmaceutical industry. A notable feature is how from 2011 to 2024 MALDI TOF mass spectrometry became the first line microbial identification method and the emerging role of next generation sequencing (NGS) in clinical microbiology, which I advocate for QC microbiology laboratories. Also, the Manual uses up-to-date taxonomic changes to species naming.

How is the Manual structured? Content of each of the four volumes is as follows:

Volume 1, Section I Diagnostic Strategies and General Topics and Section II Bacteriology (Gram-positive Cocci and Rods)

Volume 2, Section II Bacteriology (Gram-negative Bacteria, Anaerobic Bacteria, Curved and Spiral-shaped Gram-negative Rods, and Mycoplasma and Obligate Intracellular Bacteria) and Section III Antibacterial Agents and Susceptibility Test Methods.

Volume 3, Section IV Virology and Section V Antiviral Agents and Susceptibility Test Methods

Volume 4, Section VI Mycology, Section VII Antifungal Agents and Susceptibility Test Methods, and VIII Parasitology and IX Antiparasitic Agents and Susceptibility Test Methods.

In Volume 1 the General Topics of most interest to pharmaceutical microbiologists are Molecular Techniques, Investigation of Disease Outbreaks, Procedures for the Storage of Microorganisms, Disinfection and Sterilization, and The Human Microbiome. The chapters directed different types of Gram-positive bacteria are similarly structured with subsections on Taxonomy, Descriptions of Families, Epidemiology and Transmission, Clinical Significance, Collection,

Transportation and Storage of Specimens, Direction Examination, Isolation Procedures, Identification, Typing, Serologic Tests, Antimicrobial Susceptibilities, Evaluation, Interpretation, and Reporting Results, and References. This standardized structure is most useful to the reader. The chapters on Antimicrobial Agents and Susceptibility Test Methods in each Section, although critical for clinical microbiologists, they are of much less interest to pharmaceutical microbiologists, unless they are working on the discovery and development of antibiotics. As expected in a clinical text, there is no discussion of antimicrobial preservatives and pharmaceutical ingredient and drug product testing.

A similar pattern of subsections is found in Volume 2, Section II for Gram-negative bacteria, Volume 3, Section IV for viruses, and Volume 4, Section VI fungi, and Section VII parasites.

As an example, current information can be obtained on the *Burkholderia cepacia* complex, which is an objectionable microorganism in aqueous, multiple-use non-sterile drug products. The chapter includes information of the species in the complex, its role in cystic fibrosis, antibiotic resistance, division between environmental and pathogenic species, and reference to two papers written by FDA microbiologist on the detection in non-sterile drug products.

This reviewer recommends that PMF members obtain access to the Manual. However, it may be likened to owning all the volumes of Encyclopedia Britannica which contains much information, most of which you will never use. The addition of ClinMicroNow to the Manual may limit the haphazard use of search engines to obtain information. Other publications that you should consider purchasing include Clinical Microbiology Procedures Handbook, Multi-Volume, 5th Edition, 2023, Pharmaceutical Microbiological Quality Assurance and Control: Practical Guide for Non-Sterile Manufacturing, 1st Edition, 2019, and Larone's Medically Important Fungi: A Guide to Identification, 7th Edition, 2023.

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