

# Suggested Resources

National Registry of Certified Microbiologists  
SM: Pharmaceutical and Medical Device

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### **About the Resources Lists**

The resources listed are NOT meant to be comprehensive guides to the examination. They are merely suggested resources for review. Use the **exam content** list to identify the areas for which you need to prepare.

## **SUGGESTED RESOURCES**

**AOAC International.** 2001. Accreditation criteria for laboratories performing microbiological and chemical analyses in food, feeds, and pharmaceutical testing. AOAC International, Gaithersburg, Md.

**Association for Advancement of Medical Instrumentation (AAMI).** Selected titles, especially, Sterilization of health care products; Requirements for validation and routine control; Industrial moist heat sterilization. ANSI/AAMI/ISO 11134:1993. Association for Advancement of Medical Instrumentation, Arlington, Va.

**Clesceri, L. S., A. E. Greenberg, and A. D. Eaton (ed.).** Part 9000, Microbiological examination: 9010-9060, 9212, 9215, 9221-9222, 9260. *In* Standard methods for the examination of water and wastewater, 20<sup>th</sup> ed. American Public Health Association (APHA), American Water Works Association, and Water Environment Federation, Washington, D.C.

**Cosmetic, Toiletry, and Fragrance Association (CTFA).** CTFA microbiology guidelines. Cosmetic, Toiletry, and Fragrance Association, Washington, D.C.

**Cunniff, P. A., et al. (ed.).** 2000. Microbiological methods. *In* Official methods of analysis, 17<sup>th</sup> ed. AOAC International, Gaithersburg, Md.

**Difco Manual.** Difco Laboratories, Inc., and Becton Dickinson and Co., Sparks, Md.

**Environmental Protection Agency (EPA).** 2001. Summary of requirements. *In* Managing your hazardous waste: a guide for small businesses. EPA530-K-01-005. Environmental Protection Agency, Washington, D.C.

**Miller, Brinton M., et al.** 1986. Laboratory Safety: Principles and Practices. Chapters 1, 2, 19 and 22. ASM Press, Washington, D.C.

**Murray, P. R., E. J. Baron, M. A. Pfaller, F. C. Tenover, and R. H. Tenover (ed.).** 1999. Chapters: Microscopy, Quality control of media, and Culture media. *In* Manual of clinical microbiology, 7<sup>th</sup> ed. ASM Press, Washington, D.C.

**Olsen, W. P., and M. J. Groves (ed.).** 1987. CIP/SIP system validation. *In* Aseptic pharmaceutical manufacturing. Interpharm Press, Prairie View, Ill.

**Parenteral Drug Association.** 1978. Validation of steam sterilization cycles. Technical report 1. Parenteral Drug Association, Bethesda, Md.

**Pearson, F.** 1985. Pyrogens, endotoxins, LAL testing, and depyrogenation. Marcel Dekker, New York, N.Y.

**United States Pharmacopeial Convention.** Chapters 51, 61, 71, 85, 1035, 1111, 1116, 1208, 1211, 1227, and 1231. *In* United States Pharmacopeia and National Formulary. United States Pharmacopeial Convention, Rockville, Md.

**U.S. Food and Drug Administration.** Current good manufacturing practice for finished pharmaceuticals. 21 CFR 211. U.S. Government

Printing Office, Washington, D.C.

**U.S. Food and Drug Administration.** Good laboratory practice for nonclinical laboratory studies. Title 21, Code of Federal Regulations, section 58 (21 CFR 58). U.S. Government Printing Office, Washington, D.C. [www.gpoaccess.gov/cfr/index/htm](http://www.gpoaccess.gov/cfr/index/htm).

**U.S. Food and Drug Administration.** Guidance for industry; electronic records; electronic signatures. 21 CFR 11. U.S. Government Printing Office, Washington, D.C.

**U.S. Food and Drug Administration.** 1995. Microbiological methods for cosmetics. *In* Bacteriological analytical manual (BAM), 8<sup>th</sup> ed. AOAC International, Arlington, Va.

**U.S. Food and Drug Administration.** Quality system regulation. 21 CFR 820. U.S. Government Printing Office, Washington, D.C.

### ***Internet Resources***

USP.	<a href="http://www.usp.org">http://www.usp.org</a>
AAMI.	<a href="http://www.cssinfo.com/info/aami.html">http://www.cssinfo.com/info/aami.html</a>
AOAC International.	<a href="http://www.aoac.org">http://www.aoac.org</a>
APHA.	<a href="http://www.apha.org">http://www.apha.org</a>
CFR.	<a href="http://www.access.gpo.gov/nara/cfr">http://www.access.gpo.gov/nara/cfr</a>
FDA-BAM.	<a href="http://www.cfsan.fda.gov/~ebam/bam-toc.html">http://www.cfsan.fda.gov/~ebam/bam-toc.html</a>