LABORATORY DESIGN

ESTABLISHING THE FACILITY AND MANAGEMENT STRUCTURE



Edited by Scott Sutton

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I The Role of Microbiology in a Pharmaceutical Quality Program

Anthony M. Cundell

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5 Training Personnel in the Microbiology Laboratory 00 Michele M. Conway

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- 6 Safety Considerations in the Quality Control Microbiology Laboratory Scott Sutton

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General Safety Considerations

Biosafety Considerations General issues **Biological risk levels Biological safety levels** Leadership The Biological Safety Cabinet **Clean Benches** HEPA Filtration of Air Cleaning and Sanitization of a BSC Standard Operating Procedures (SOP) Support - Recommended Instruction to the Technician **Biosafety Biosafety** manual **Biohazardous spills** Decontamination of microorganism Eating, drinking smoking, and the application of makeup in the lab Laboratory hygiene procedures Transferring cultures Use of PPE Clean benches and biosafety hoods Shipping infectious materials General Safety Summary References About the Author

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	Linda Skowronsky	
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In-process control strategy Environment, process water, and cleaning strategies Microbiologibal Control Strategy Manage Product Lifecycle, Including Continual Improvement Technology Transfer Test Method Transfer Microbiological Control Development Report Change Control/Change Management — General Changes that can Impact the Microbial Bioburden of a Formula Conclusion References Appendix About the Author

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Building and Equipping a Microbiology Laboratory: How to Budget Size and Cost Bob Ferer and Scott Sutton Introduction Know Your Process Non-Routine Testing Equipment Needs Common Equipment Needs Storage Needs Quantify the Number of Samples Quantify the Number of Samples for Stability and Retain Contract Laboratory Support Costs Equipment costs Facility finishing costs

Alternate calculation method

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10 Laboratory Water

T.C.Soli

Introduction Determining the Required Water Quality General lab operation requirements Microbiology lab operation requirements Facility housekeeping Equipment and labware cleaning Growth media preparation General assay reagent preparation Special methodologies System Design and Distribution Considerations Shared vs. dedicated systems Extension of manufacturing water system to laboratories Cross-connection of the manufacturing and laboratory systems Dedicated laboratory systems Cost consideration Cost/budget overruns Optimizing water availability costs System qualification needs Source water impact

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Tim Sandle

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Introduction Culture Media Complex culture media Enriched media Defined culture media Selective media Design of the Media Kitchen Design of the facilities Utilities Water Steam quality and autoclave operation **Incoming Materials** Media Manufacturing Batch records Equipment Weighing Preparation Initial preparation Rehydration Sterilization Addition of supplements Filling Labelling

Secondary Sterilization Media Quarantine and Release Quarantine Release Physical characteristics pН Contamination/reality Gel strength Growth promotion Qualitative techniques **Quantitative techniques** Quality control of purchased media and reduced testing Storage and Expiry Disposal Documentation Troubleshooting Conclusion References About the Author

12 Environmental Monitoring of Microbiology Laboratories 00

Frank Settineri

Introduction Training Laboratory Design and Flow Sample receipt area Sample staging and holding area Biohazard waste area Media preparation areas General testing area Live organism area (for identification, growth promotion, and culture preparation Cleanroom areas (suites or isolators) for sterility testing Documentation Standard Operating Procedures (SOPs) Protocols Reporting of data Sample number Raw data form **Specifications**

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13 The Laboratory Design and Layout for Microbial Identification

Anthony M. Cundell

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14 Microbiology Manufacturing Support Laboratory

David A. Porter

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15 Building or Remodeling a Laboratory for the Bacterial Endotoxin Test

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Karen Zink McCullough Your Constraints: Timelines and Budgets Timelines **Budgets** User Requirements and Specifications What assays are you doing? What equipment do we need to perform these tasks? What utilities and provision for information technology (IT) do you need? What furniture or finishes are required? What kind of floor plan do you need to accommodate sufficient workspace, proper flows, convenient support areas, etc.? Lab space Support areas Office space Create and Execute a Validation Master Plan Standard Operating Procedures and Training Summary References About the Author