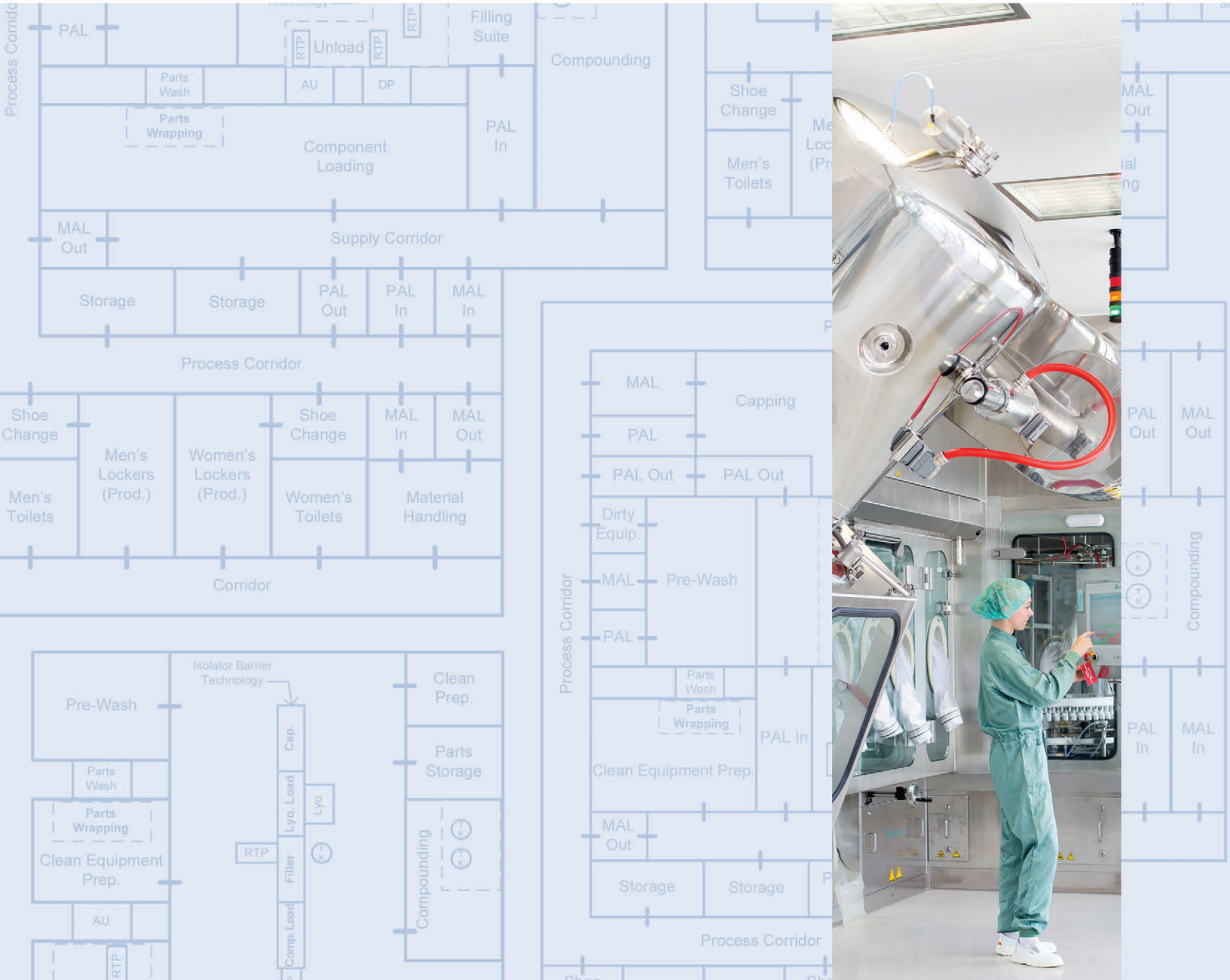


VOLUME 3

Sterile Product Manufacturing Facilities

Third Edition





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This Baseline® Guide focuses on engineering aspects of designing facilities for the manufacture of sterile products. It is intended to offer best practices in the design of a new or renovated facility, by providing an approach that is effective, cost-efficient, and in compliance with existing regulations and related guidance. This Guide is solely created and owned by ISPE. It is not a regulation, standard or regulatory guideline document. ISPE cannot ensure and does not warrant that a system managed in accordance with this Guide will be acceptable to regulatory authorities. Further, this Guide does not replace the need for hiring professional engineers or technicians.

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Preface

The global pharmaceutical industry and regulators are responding to the challenge of significantly improving the way drug development and manufacturing is managed. New concepts are being developed and applied including science-based risk management approaches, a focus on product and process understanding, and modern Quality Systems that still focus on drug product safety, integrity, purity, and identity from development through distribution.

Uncertainty about the requirements for regulatory compliance may discourage innovation and technological advancement, and can drive up costs. ISPE Guides aim to describe current good practices that can help a company to develop an approach that is effective, cost-efficient, and in compliance with existing regulations and related guidance.

This Baseline® Guide covers engineering aspects of designing new sterile products manufacturing facilities and modifications of existing facilities. This Guide is intended to offer recommendations to help facilitate compliance with the latest FDA and EMA guidance. This third edition of the Guide is updated to include a global design approach, harmonized area classifications, and additional information about local protection/Grade A air supply and particulate monitoring.

During the development of this Guide, for previous editions as well as this third edition, the FDA was involved in reviews and discussions with ISPE to ensure that the Guide aligns with GMP requirements.

It is recognized that industry standards evolve, and this document reflects an understanding of them as of the publication date. It is also recognized that **a draft revision of Annex 1 of the European Union GMPs [1] was issued on 20 December 2017; after the Annex 1 revision is finalized, respective alignment updates will be made to this Guide.**

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This Baseline® Guide Third Edition was produced by a Task Team led by Gordon Leichter, PhD (Belimed, Inc., USA). The work was supported by the ISPE Sterile Products Processing Community of Practice (CoP).

Core Team

The following individuals took lead roles in the preparation of this Guide:

Vincent J. Cebular	IPS	USA
Jason S. Collins, AIA	IPS	USA
Norman A. Goldschmidt	Genesis Engineers Inc.	USA
Thomas M. Huber	Skan AG	Switzerland
Christa B. Myers	CRB	USA
Patrick J. Poisson	United Therapeutics Corp.	USA
Robert L. Roy, PE	IPS	USA
Matthew P. VonEsch	Exelead	USA

Other Contributors

The Team wish to thank the following individuals for their significant contribution to the document.

Kevin Debbs	CRB	USA
Ty Duginske	Regulatory Compliance Associates Inc.	USA
Charlotte Enghave Fruergaard, PhD	NNE	Denmark
Todd Vaughn	CRB	USA

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The Team Leads would like to express their grateful thanks to the many individuals and companies from around the world who reviewed and provided comments during the preparation of this Guide; although they are too numerous to list here, their input is greatly appreciated.

Company affiliations are as of the final draft of the Guide.

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These acknowledgments are provided here as they were in the second edition at time of publication.

This Guide was developed by an integrated US-European team under the leadership of Bruce Davis of Bruce Davis Global Consulting.

Chapter Writers and Reviewers

The following individuals took lead roles in the preparation of this document and the co-leaders of this Guide recognize these participants, who went above and beyond expectations to meet deadlines and keep the effort on track. The company affiliations are as of the final draft of the Guide.

Jeff Biskup, CRB Consulting Engineers, Inc., USA
Mel Crichton, Eli Lilly & Company (retired), USA
Bruce Davis, Bruce Davis Global Consulting, United Kingdom
Gordon Farquharson, Critical Systems Ltd., United Kingdom
Russell Madsen, The Williamsburg Group, LLC, USA
Mark Von Stwolinski, CRB Consulting Engineers, Inc., USA

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FDA Reviewers

We would like to thank the following FDA representatives for providing comments on this Guide:

Kristen Evans, FDA Investigator/CDER Compliance Officer, retired and now employed by Amgen, USA
Richard Friedman, Director, CDER/OC/DMPQ/FDA, USA
Diane Raccasi, Microbiologist, CDER/OC/DMPQ/FDA, USA
Brenda Uratani, Consumer Safety Officer, CDER/OC/DMPQ/FDA, USA

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