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PHARMACEUTICAL ENGINEERING GUIDE
FOR NEW AND RENOVATED FACILITIES

VOLUME 2

Oral Solid Dosage Forms

Third Edition

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As a contributor to the OSD Baseline Guide Volume 3, CRB is honored to take part in developing a key tool that assists companies in OSD manufacturing. Staying ahead of the ever-changing regulations in the life sciences industry, CRB is committed to finding the right solutions to our clients' most technically challenging problems.

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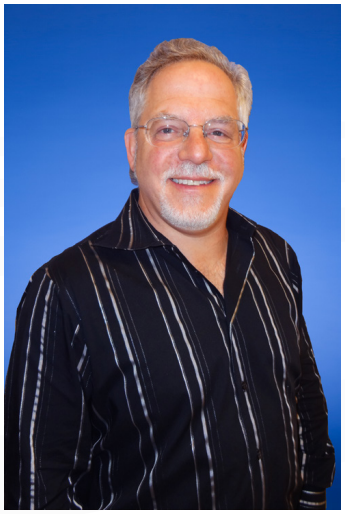

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"The ISPE OSD Baseline Guide is one of the key, go-to international industry documents that provides valuable guidance on topics including, but not limited to: Regulatory Philosophy, Risk Management, Product/Processing, Containment, Architectural, HVAC, Process Utilities, Electrical/I&C, and other. This update highlights the "c" in cGMP and will be a tool everyone involved in OSD facilities will want to have in their tool box."

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Disclaimer:
This Baseline® Guide addresses facilities for the manufacture of Oral Solid Dosage (OSD) Forms, including tablets, capsules, and general powders. It is intended to be used for the planning, design, engineering, construction, commissioning, qualification, and operation of both new and renovated pharmaceutical OSD forms manufacturing facilities. 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

Although many discussions focus on the high-growth area of biopharmaceuticals, Oral Solid Dosage (OSD) forms maintain a large sales volume within the global market. It also continues to be an important segment within the Pharmaceutical Industry. OSD manufacturing is mature and has been slow to change. It is the time to embrace the digital-age technologies for next-generation pharmaceutical manufacture, which should be more efficient, lower cost, and faster to market, while continuing to maintain and improve drug product quality, safety, and efficacy.

This new edition of the ISPE Baseline® Guide on OSD Forms considers both current and new technologies, such as Process Analytical Technology (PAT); continuous manufacturing processes, and other innovative approaches to help meet regulatory requirements and pursue industry best practices. For example, this new edition focuses on product, process, and protection, based on the increased regulatory requirements for OSD forms manufacturing. A new chapter has been added to address containment and cross-contamination in support of the increasing use of highly potent APIs. In addition, this new edition presents an innovative design approach for OSD manufacturing facilities and critical utilities that includes smaller production footprints and space classification considerations and applications.

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TO THE USERS OF THIS GUIDE… We hope you find the materials herein useful and of value to you in your OSD activities.

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

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1 Introduction

1.1 Background

This *ISPE Baseline® Guide: Oral Solid Dosage (OSD) Forms* is intended to offer a tool for consistent framework for regulatory interpretation, while still allowing a flexible, innovative and compliant approach to facility design, construction, commissioning, and qualification. This approach is intended to allow manufacturers to better serve their customers by helping to reduce costs and improve product quality. Additionally, this Guide will provide an overview of potential new technologies, which are being applied selectively in the industry.

The reader should consider this ISPE Baseline® Guide as a tool, to be used in conjunction with other design guides, industry guidance and regulatory requirements that are already available in the industry.

This is the third edition of the ISPE Baseline® Guide for new for new and renovated OSD facilities. It focuses on compliance with the US FDA current Good Manufacturing Practice (cGMP) regulatory expectations, as well as other international regulatory bodies, where applicable.

Some of the major changes/enhancements and revisions to this third edition include:

- Reorganization of the existing chapters and general flow of the document
- Expanded discussion related to Risk Management (see Chapter 3) with content including the topics of: Principles, Processes and Tools
- Significant expansion of Product and Processing (see Chapter 4) including discussion on “ATmospheric EXplosibles (ATEX)”, a European directive focused on equipment intended for use in potentially explosive situations. was created by the European Directive 94/9/EC (ATEX 95) [1], and it applies to both equipment manufacturers and equipment users
- Addition of a new chapter entitled Product Isolation and Containment: Principles of Product, Operator, and Environmental Protection. This chapter provides further detail on the challenges, and considerations relating to containment and cross-contamination issues faced by OSD manufacturers
- Numerous updates and considerations relating to modern OSD forms manufacturing facilities in the areas of Architectural (layout, functional areas, etc.), Process Support Utilities (approach, critical systems, and code issues), Heating, Ventilation, and Air Conditioning (HVAC) (further aligned with the ISPE Good Practice Guide on HVAC [2]), Electrical (classified areas, systems and preventive maintenance), Controls and Instrumentation (Process Analytical Technology (PAT)), Manufacturing Execution Systems (MESs), Electronic Batch Records (EBRs), and Other Considerations (Non-cGMP risks, exposure, life/safety, hazardous operations, environmental, emergency preparedness).
- Addition of easy to use graphics, tables, and visual aids

1.2 Purpose of This Guide

This OSD Baseline® Guide is intended to be used by various industry professionals for the planning, design, engineering, construction, commissioning, qualification, and operation of both new and renovated pharmaceutical OSD facilities. It is intended to be used to develop technically sound and compliant solutions while offering flexibility to meet specific facility and project needs.