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Compliance

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Requirements for
Highly Potent Aseptic
Processing *QRM based*
Commissioning and
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Validation in
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Manufacturing

Good Manufacturing
Practices - GMP in
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FDA CFR Part 11, ICH
GCP, GMP, (CSV)-
What's the hype all

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ISPE Pharma 4.0
Operating Model -
~~Presentation IQ OQ PQ |~~
~~Process Validation |~~
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on 10 Principles of
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Manufacturing Practices

*What is
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Commissioning
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overview, important*

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provides practical
guidance on the
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systems, utilities, and
equipment to
demonstrate that they
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Existing risk-based approaches to computerized system compliance and validation as outlined in GAMP® 5 International Society for Pharmaceutical Engineering. GAMP® 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems. North Bethesda, MD:

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builds on the original
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Pharmaceutical

Chemicals). The ISPE
API Baseline Guide also
incorporates and builds
on new regulations and
guidance, such as: ICH
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21 CFR Part 11

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This second edition of
the ISPE Baseline®
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Manufacturing Facilities

intends to further
reinforce the concepts
described in the first
edition of the Guide,
provide examples of
how these concepts can
be put into practice, and
detail the value and
benefits of the approach

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demonstrate that they
are suitable for the
intended purpose. The
process described in this
Guide supports the
application of science
and risk management
approaches, a focus on
product and process ...

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Manufacturing Facilities
(Third Edition) aims to
offer a consistent

interpretation of the 5

latest FDA and EMA
guidance, while

allowing a flexible and
innovative approach to
facility design. The

Guide is based on key
principles such as: the
need to understand
product and process

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requirements, use of risk-based approaches, role of barrier and isolator technology, use of consistent terminology for classified environments, categories for processing (open ...

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initiative, Advancing

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(APQ), a comprehensive

program for assessing

and improving an

organization's quality

management maturity.

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with the design,
construction, operation,
and lifecycle
management of new and
existing water and steam
systems. It is intended to
help meet Good
Manufacturing Practices

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(GMPs) and comply
with regulations and
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The Biopharmaceutical
Manufacturing Facilities
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explores products and
facilities that house
biotechnological
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specifically, it applies to
process design ties to
facility design,
controlled processing,
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released its newest
guide to help
pharmaceutical
organizations achieve
and maintain control in
their critical utility
systems.

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July/August 2012

Rouge in Stainless Steel
tions material storage
conditions, installation
environment,, grinding,
buffing, passivation
state, and treatment,

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etc.). 3. Process

Environment – what
process service
conditions the system is
exposed to (e.g.,
corrosive process fluids,

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Edition) aims to assist with the design, construction, operation, and lifecycle management of new and existing water and steam systems. It is intended to help meet Good Manufacturing Practices (GMPs) and comply with regulations and related guidance.

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engineering aspects of
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modifications of
existing facilities.

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Guide: Risk-Based

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(Risk-MaPP) Second

Edition provides a

scientific risk-based

approach, based on ICH

Q9 Quality Risk

Management, for

managing the risk of

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cross-contamination
within shared facilities.

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course will help you
understand the “why,”
what,” and “how to
use” the ISPE

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