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International Society for ...

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

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Computerized Systems. North
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Baseline® Guide Volume 1,
Active Pharmaceutical
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The ISPE API Baseline Guide also
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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 described.

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Approaches, a focus on product
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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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Baseline Guide Vol 7: Risk-Based
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regulations and guidance, such
as: ICH Q7 ICH Q9

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to help pharmaceutical organizations achieve and maintain control in their critical utility systems.

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material storage conditions,
installation environment,,
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state, and treatment, etc.). 3.
Process Environment - what
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system is exposed to (e.g.,
corrosive process fluids,

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risk of cross-contamination within
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Introduction to ISPE's Risk-MaPP
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