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This second edition of the ISPE Baseline® Guide: Biopharmaceutical 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 described.

Baseline Guide Volume 1: Active Pharmaceutical Ingredients

The ISPE Baseline Guide® Water and Steam Systems (Third 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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The ISPE Baseline® Guide: Commissioning and Qualification (Second Edition) provides practical guidance on the implementation of a science and risk-based approach for the Commissioning and Qualification (C&Q) of pharmaceutical manufacturing facilities, systems, utilities, and equipment to demonstrate that they are suitable for the intended purpose.

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Mapping Document for ISPE Specification and Verification Guides. This free document explains the relationship between the following ISPE Guides. ISPE Baseline Guide, Volume 5: Commissioning and Qualification (Baseline Guide Volume 5) ISPE Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment (FSE Guide)

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