

# THE WBF BOOK SERIES: ISA 88 and ISA 95 in Life Science Industries

The World Batch Forum



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### THE WBF BOOK SERIES: ISA 88 and ISA 95 in Life Science **Industries**

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THE WBF BOOK SERIES: ISA 88 and ISA 95 in Life Science Industries The World Batch Forum The ISA (International Society of Automation) standards 88 and 95 are manufacturing standards established in the late 1990s and periodically updated by the governing bodies responsible for them the ISA and the WBF (World Batch Forum). The two standards set up protocols and uniform specifications for batch control systems, including types of control equipment, design of control systems and interpretation of batch control data. ISA 88 and 95 are explained in this volume in the context of the pharmaceutical and medical industries. Examples of such batch processing procedures as fermentation, separation, and refinement are discussed and how the two standards affect the design of facilities and systems for performing these procedures. It features: How to set up a pharmaceutical module library using ISA 88 and how to implement ISA 88 across life Science Development Operations; understanding Product life-cycle batches; and case Studies on Risk-based engineering assessment and qualifications, a SCADA upgrade project, and more



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