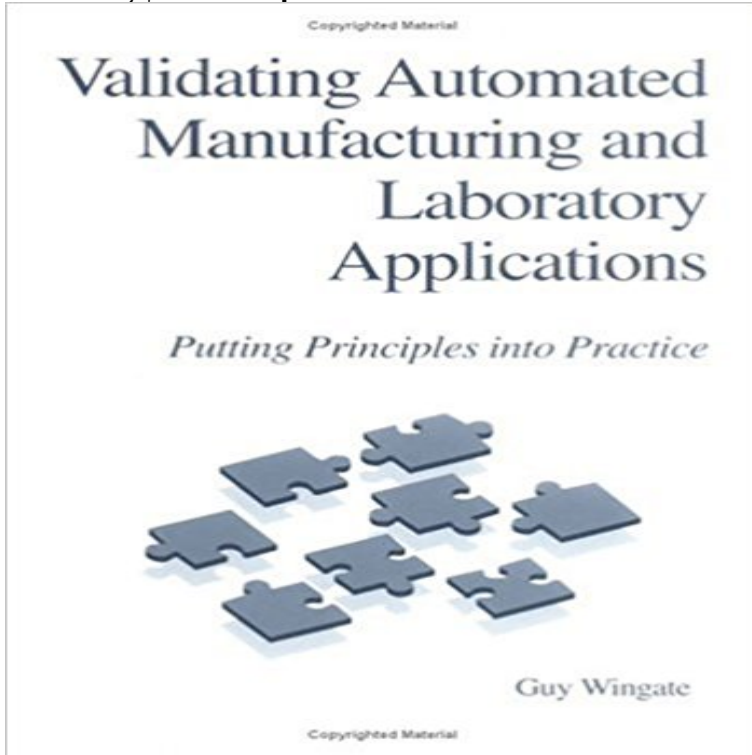


Validating Automated Manufacturing and Laboratory Applications: Putting Principles into Practice



Since 1994, the German GMA-NAMUR, German APV, ISPE-Baseline, OECD, UK GAMP Forum, UK IQA-PQG, US DIA, ISPE, and PDA initiatives have supplemented the regulations governing the validation of automated systems with high-level guidelines. The result has been a broadly accepted industry framework for validating automation systems. It includes Good Automated Manufacturing Practice (GAMP), Good Automated Laboratory Practice (GALP), and Good Information Technology Practice (GITP). This book deals directly with project problems and their resolutions based upon the experience of established industry practitioners. The first part introduces the principles of good practice and why validation is needed, concluding with the Ten Commandments for Validating Automation. The second part presents a comprehensive selection of case studies (provided by industry experts).

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