



Validation: Step by Step - B (Bologna)

GAMP Good Practice Guide: Validation of Process Control Systems from ISPE

Reviewed by Nick Sands

A committee of the GAMP Forum Process Control Special Interest Group wrote this good practice guide on validation of process control systems (VPCS) to expand on the principles of validation in GAMP 4 (Good Automated Manufacturing Practices). I divide the book into three parts, the main text, the first 7 appendices which are sample documents by the writers, and the last two appendices which are sample documents from GMA/NAMUR and JETT. Since I am not actually doing system validation, perhaps I judged this book more harshly than I should. Still, no matter what industry you are automating, it's a good idea to be familiar with anything called good automated manufacturing practices.

The VPCS text is mostly an outline of the validation process. It covers key concepts like critical components of a system, GxP critical parameters, direct and indirect impact on product quality, the types of control systems, and the types of configuration or programming. Control systems can be configurable, like single loop controllers or weighers, embedded, like packaging machine controls, or stand-alone, like PLC-SCADA or DCS systems. The GAMP category and validation requirements are different for each system type. The GAMP "V" model is used to outline the lifecycle and how validation confirms performance against the specifications such as the user requirements, functional requirements and design requirements. One interesting concept is a traceability matrix used to track a requirement from stage to stage through design and validation.

The first set of appendices give some examples of forms used for inventories, supplier audits, validation review, and further guidance on control systems. The forms and guidance are limited in depth, more outlines than details really.

The last two appendices are very detailed. The first is really the GMA/NAMUR validation guide, complete with the validation checklist, and procedural outlines for management of change, calibration, system failures, and training. GMA is the German association of Engineers and Electrical Engineers Society for Measurement and Automatic Control and NAMUR is the Standardization Association for Measurement and Control in Process Industries. The procedures are simple outlines. The final appendix contains examples provided by JETT, the Joint Equipment Transition Team, another GAMP special interest group. A template is included as an example of a user requirement specification, the key to the entire GAMP cycle.

After reading the VPCS guide, published by the International Society for Pharmaceutical Engineering (ISPE), it makes me appreciate even more the books published by ISA. ISPE is awfully proud of their books. The 43 pages of text and 175 pages of appendices in the VPCS, available to non-members for a mere \$215, do provide some good guidance on validation, but the same advice can be gathered from a few magazine articles at almost no cost. For that reason I rate this book less than a borrow and more like bologna (B).