tion. He points out that the most essential principle in adapting a DCS into a CSDCS is to segregate process and equipment functions. A number of user and application interfaces allowing for an optimal use of CSDCS are presented. The recipe definition language (RDL) is considered as an additional element in the management of the manufacturing control domain. B. Korkmaz analyses the potential of distributed client/server-based batch control systems applied as part of the enterprise solution suite using technology. In this context the industry standard S88.01 are a great help in defining the next generation enterprise and control models. In two chapters the editor, J.F. deSpautz, outlines 'a computer integrated manufacturing (CIM) architecture for validated manufacturing systems' as well as a 'system implementation plan for validated manufacturing systems'. Based on the FDA's general definition of process validation on one hand and the Purdue enterprise reference architecture (PERA) he develops a unified validation master plan consisting of seven phases. This plan 'allows the developer to integrate into a single plan the mutually independent architectures of manufacturing equipment, human and organisational as well as information'. The various concepts are explained by means of detailed flow diagrams. T. Stokes contributes two chapters on 'GMP regulations and computer validation' and 'management's role in computer validation'. In the first chapter she discusses the FDA guideline 'guide to inspection of computerised systems in drug processing (1983)', the GMP guide released by the European Commission in 1992, which includes an annex 11 on computerised systems, the guideline (1993) of the Japanese Ministry of Health and Welfare, 'guideline on control of computerised systems in drug manufacturing' and the OECD GLP consensus for computerised systems which was published in 1995. Whereas the FDA guideline teaches the inspectors on how to audit companies the other guidelines line out what the pharmaceutical manufacturer has to do in order to comply with validation requirements. The role of the senior management in computer validation is seen in setting policies, in establishing procedures for their implementation, in training personnel in policy and standard operating procedures, and in monitoring compliance to the policy over time. Together with K.S. Kovacs, J.F. deSpautz (editor), contributes three additional chapters dealing with a 'system implementation plan for validated manufacturing systems', 'validation concepts for manufacturing systems', a 'validation plan for process automation', and 'performance qualification testing of integrated manufacturing resource planning/manufacturing execution systems (MRP/MES)'. The wide correspondence seen in the headlines is also found in the content of the chapters. Based on the PERA and the validation life cycle approach activities characteristic for the various phases of the life cycles in the different fields are discussed. Check lists and flow diagrams summarise the procedures proposed in performing validation of computerised systems. 'One keyboard pounders's view on validation' contributed by J.A. Hercamp was more than confusing. For the reviewer it was impossible to understand why this chapter was included. In his contribution on 'research and development automation' J.S. Gramm points out that the R&D spending of pharmaceutical companies has been doubling every 5 years. He concludes that this trend can not sustain itself indefinitely. Automation is addressed as a measure to make R&D more efficient. The examples however discussed in this context make clear that the author is thinking in terms of late development phases where for example fermentation processes have to be transferred into production. In their first contribution 'enhanced regulatory compliance using manufacturing execution systems' F.R. Bickel and R.E. Blanchette discuss the benefits from the implementation of such systems, e.g. 'the elimination of deviations from current operating standards, the reduction of levels of non-conforming products as the result of better enforcement of cGMPs, or the simplification of functions or processes by reducing or eliminating paperwork and redundant data entry, manual review and approval or manual procedures and administrative tasks'. The content of their second contribution 'applied computer validation plan' repeats to a large extent the concepts developed by Kovacs and deSpautz in other chapters. The chapter 'plant design and engineering' by J. Conaway informs about instruments used by architects and engineers in designing plants. It is hardly covered by the title of the book. Most of what has been written in the chapters 'client-server batch control' by A.R. Gonzales and M. Castro and 'batch process automation' by T.H. Tom and K.S. Kovacs was already outlined in former chapters.

Based on his long term experience in pharmaceutical industry the reviewer comes to the conclusion that the book 'automation and validation of information in pharmaceutical processing' addresses an actual and important issue. Especially the contributions made by deSpautz contain a series of interesting aspects which may be of help to people in charge of the implementation of such systems or of their validation. The elimination of a huge number of common place statements as well as of the redundancies would have improved the overall impression of the book. A price of $175 is hardly justified by the book.

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