of which decorates the cover of the book. Following the pore structure with increasing densification is sensitive, but mostly only the volume is followed with increasing applied pressure and described by aid of the Heckel function. The granule porosity and strength, besides secondary factors, mainly affect compactability. 'Modeling the Compression Behavior of Particle Assemblies from the Mechanical Properties of Individual Particles' by W.C. Duncan-Hewitt is a delightful chapter for anyone with a sense for masterly use of language and didactic refinement. It encourages the reader to proceed in looking for meaningful experiments within our real world of many-factor problems. Materials characterization applicates fundamental assumptions of the rate theory of plastic deformation, including the concept of mechanical activation-so intensively propagated by the late Reinhard Huttenrauch, which should be seen in some opposition to the visco-elastic analysis, so comprehensively outlined by F. Muller in chapter 5. Stepwise procedures for predicting compaction behaviour are developed in principle, their power and restrictions demonstrated with examples. A critical evaluation of the state of predicatability arrived at gives hope, since the compaction behaviour so some materials could be predicted from mechanical properties of single crystals.

'Materials for Direct Compaction' by G.K. Bolhuis and Z.T. Chowhan is a plea for direct compression. 'Filler-binders' and important excipients, e.g. celluloses, starches, inorganic slats, polyols, lactoses, other sugars, and *c*-processed products are discussed and compared, along with some d.c. forms of active substances, very valuable for the practitioner. 'Compaction Properties of Binary Mixtures' by J.T. Fell demonstrates the still limited research in this field until 1991 and, that compaction properties of binary mixtures are clearly not yet predictable: 'The complexity of the system and the large influence of experimental variables means that simple theoretical approaches are likely to be grossly misleading'. 'Lubricant Sensitivity' is reviewed by G.K. Bolhuis and A.W. Holzer. The authors very carefully review the particular studies and results, since many studies consider only one or a few factors, which lead to results contradictory to others. They concluded, that 'the susceptibility of a material to lubricants like magnesium stearate is a complex function of a number of factors including surface area, surface texture, flowability, mixing properties, and consolidation behaviour'. Finally, rules are derived to limit the sensitivity of tabletting materials to the still most commonly used lubricant: magnesium stearate. 'The Development and Optimization of Tablet Formulations Using Mathematical Methods' by F. Podczeck outlines how the various possible interactions among the many constituents during tabletting and within the finished product may be taken into account. Many valuable interrogation and question marks, respectively, are given for practical application of statistical design and evaluation. The power of the principal component analysis and of cluster analysis to isolate the most important variables as uncorrelated pricipal components, and of the cluster analysis in grouping a set of objects into classes of similar objects, and canonical analysis are demonstrated, using experimental data as examples. Sections on 'mathematical optimization' and on 'experts systems' finish this part. In 'expert systems' very valuable remarks are given to prevent the novice from expecting too much in relation to his ability to put meaningful facts into the system.

A roughly 15-page index finishes the book, allowing numerous connections between the various contributions. Apparently it has been the purpose of the editors not to press the articles into a common form and style. Even cross-references are given not very frequently. Consequently, some redundant information, as well as some contradictions in attitude result. The literature published in the German language seems widely ignored. Quite a number of typing errors and some deficiencies in the language should be polished in a second edition. The book has great value for scientists as well as industrial pharmacists. It contains very valuable review, discussion, guidelines, and even data which cannot be found elsewhere.

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Good Manufacturing Practices For Pharmaceuticals: A Plan for Total Quality Control, 4th edition.
S.H. Willig, J.R. Stoker (Editors), Marcel Dekker, New York; 1997. 520 pp.; $99.75; ISBN 0-8247-9770-1

This book is a comprehensive and practical reference text that describes in adequate detail some of the most recent FDA guides and guidelines pertaining to current good manufacturing practice (CGMP). The book is logically subdivided into 22 chapters that discuss the CGMP regulations contained in Title 21 of the Code of Federal Regulations, inspection procedures for compliance in the United States, enforcement alternatives in the United States available to the FDA, controlled substances, FDA requirements for bulk pharmaceutical chemicals, FDA pre-approval inspections and investigations, CGMP principles and guidelines for other countries, alternative quality programs such as the Malcolm Baldrige National Quality Award and ISO 9000 series, the import and export of pharmaceuticals and other

products subject to CGMPs. The book is concluded with four relevant appendices that discuss potable water requirements, repackaging of pharmaceuticals and other products, hearing procedures when FDA proposes the imposition of civil money penalties, and guidance for changes currently considered 'important' by FDA.

The chapters are clearly and concisely written, and provide the reader with the current regulations and practical discussions relating to interpretation of the guidelines. The authors offer much insightful information for multinational suppliers of pharmaceuticals specifically related to this era of collaborations (e.g. product licensing agreements and divestitures) between companies. The authors also compare the CGMP guidelines adopted in the United States to those requirements implemented and used in other countries (e.g. Canada and Europe). This book is an invaluable resource for persons involved in manufacturing, quality assurance, and analytical and pharmaceutical research and development.

Also, it is recommended for students because of its subject nature, comparative low cost and readability. I am pleased to add this edition to my bookshelf!

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