

- GMP PUBLISHING RELEASES NEW BOOK -

**GMP MANUAL Volume 1 – Manufacturing
published by Maas & Peither AG – GMP Publishing**

GMP Publishing is launching its new GMP MANUAL Volume 1 – Manufacturing. The book is intended to support staff in the pharmaceutical production field by providing internationally accepted GMP guidance. International GMP experts share their knowledge of GMP implementation according to GMP regulations of the FDA, Europe, ICH, PIC/S and WHO. The reader is learning how leading industry experts solve challenges and improve and refine procedures accordingly. The book answers quality related questions that affect daily business.

The compendium on manufacturing was written by Dr. Helmut Bender, Dr. Christian Gausepohl, Dr. Ralph Gomez, Dr. Michael Hiob, Dr. Josef Künzle, Paolomi Mukherji, Michael Schulte, Dr. Hanfried Seyfarth, and Cornelia Wawretschek, all experts and key opinion leaders in the field of GMP from the US and Europe. The writers' expertise combined with a peer review process ensures up-to-date and authentic guidance in the field of GMP.

The book is an excerpt from the GMP MANUAL, the world's leading comprehensive reference book in the field of GMP and tailored towards people who need a concise and authoritative how-to-do document for daily business. It is helpful to people responsible for GMP in all areas of pharmaceutical manufacturing or in charge of conducting GMP-audits. It offers the perfect tool to keep up-to-date with a constantly changing environment.

The book is divided in four chapters: production, packaging, laboratory and analytical controls, and documentation. Every part starts with an overview of questions that will be answered in the following chapter and ends with a brief summary.

The first chapter on production explains amongst others all aspects of sanitation, personal and production hygiene, environmental monitoring, and in process-control. A special part offers tips on how to deal with deviations and how deviations are documented. Packaging is the topic of the second chapter and covers all aspects of the packaging process on ninety pages. The third chapter contains GMP-related information around laboratory and analytical controls. Last but not least the reader will find a chapter about documentation. According to FDA statistics poor documentation is one of the main issues for audit complaints. The chapter starts with official and legal requirements (US as well as EU) in relation to documentation – which formal aspects must be observed, how should documents be structured, managed, and reviewed. In addition the compendium carries on more than 50 pages of a collection of sample documents which can be adapted for the specific needs of the reader.

GMP Publishing was founded by Anita Maas, Barbara Peither, and Thomas Peither in Germany in 1999 with the vision of providing their colleagues in industry and regulatory authorities with a resource that enables them to implement and maintain GMP regulations. In 2000 they released the first GMP-BERATER in German which soon became a market leader and standard reference work in the pharmaceutical and related industries. In 2006 was the first release of the GMP MANUAL – the English version of the GMP-BERATER. By extending their portfolio GMP Publishing responded to the expanding demand of the international community. Headquartered in Schopfheim (Germany) Maas & Peither – GMP Publishing is strategically located near the heart of the European pharmaceutical industry in Basel (Switzerland). Maas & Peither – GMP Publishing has alliances with partners around the world supporting them with the distribution and shipment of GMP MANUALs. Early this year GMP Publishing has decided to put the growing community of their American customers in the center of their efforts. Opening a new office in Philadelphia, PA the company can now provide immediate, high quality service and respond to all its clients' needs in the US and Canada.

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