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This Quality Assurance Workbook for Pharmaceutical Manufacturers presents strategies for the set up and management of a Quality Management system within the pharmaceutical industry. Based on the structure of DIN EN ISO 9000, a series of Quality Management sections are shown and it is made clear that these must be realised and continuously improved. These sections regulate the responsibility for quality, show how necessary it is to plan processes at an early stage, what is required in order to attain a high production standard and how it may be maintained. All chapters are presented individually and partly supplemented with practiced order-of-events experience (Standard Operation Procedures [SOPs]).

Starting with the close relationship of Quality Assurance with Good Manufacturing Practice (GMP) and Quality Control and Pharmaceutical Production, a Quality Management system for the pharmaceutical industry is presented and an example Quality Manual is described. Within the 25 chapters the key issues of a good Quality Manual are presented and practices are described that have been developed within a pharmaceutical manufacturing company.

Starting with Management Responsibility, advice is presented on how to provide job descriptions and define management responsibilities. The Quality Management System chapter deals with the establishment, documentation, implementation and maintenance of a Quality Management system, e.g., how to handle manufacturing protocols, testing instructions, measures for calibration and maintenance, etc.

A detailed description of the set up and review of contracts such as Secrecy Agreement, (Contract) Manufacturing Agreement and Quality Assurance Agreement and the measures for amendments thereof are provided. This is followed by descriptions of the process of the planned and documented Research and Development (R&D), ranging from planning, definition of inputs, documentation of the results and inspection and certification of the design, to design validation, which defines the transition into the field of process control.

Control of documents and records is of paramount importance, thus documentation requirements, e.g., design and structure of SOPs and other Quality
Manual documents are described. Measures for *Purchasing* are presented and supplemented by SOPs dealing with vendor qualification programs and audit checklists. The next chapter deals with *Control of Customer-Supplied Product* in which specification requirements of starting materials, packaging materials, etc., and systematic verification, storage and control are described.

Classification of products is important in all phases of production, quality control, and delivery. The requirements for identification and recording for traceability are presented within the topic of *Product Identification and Traceability*. Quality relevant instructions for process steering and Process Control are provided. All manufacturing processes need to be conducted under fully validated conditions and following established specifications. The purpose of the chapter on *Inspection and Testing* is to describe the systematic testing procedure for compliance with stipulated quality requirements. This ensures that tested materials are used in the manufacturing process and are subsequently processed and released as an end-product for launch provided that they satisfy the specifications stipulated in advance. The status of the materials and products must be considered in relation to the results of past and future quality tests.

The chapter about *Control of Non-conforming Products* is provided to show how to process complaints and to trace back raw data. Practical advice is also provided about *Corrective and Preventive Action* dealing with deviation management and deviation report form. The provisions for identifying, collecting, recording and archiving quality records are described in the chapter about *Control of Quality Records*.

Since auditing is a fundamental element of a Quality Management system a company must have an audit procedure and program in place to verify conformity of operations with the principles of Quality Assurance, and the relevant regulatory requirements. The chapter on *Self Inspections and Auditing* deals with regulations about how to conduct audits from the point of view of Quality Assurance, Regulatory Agencies (legal authorities) and contractors. Detailed SOPs are provided for adaptation.

In addition to the need for qualified equipment in the pharmaceutical industry, international and national conditions also demand and regulate staff qualifications (training). The chapter on *Training* provides detailed information about responsibilities, practical aspects on training, e.g., qualification of trainer, training materials, example documentation of training and instructions, etc.

Subsequent chapters deal with the important topics of *Servicing and Statistical Techniques* and this is followed by a chapter on *Hygiene* and maintaining *Hygienic Conditions* with regard to the regulations governing personnel and production hygiene.
The chapter on *Facilities, Utilities, and Engineering* details the regulations and gives an example of the content and structure of a Site Master File and also information about *Validation* of both manufacturing and analytical methods. The structure of a Validation Master Plan and required contents of chapters is discussed followed by introduction into risk analysis according to the HACCP (Hazard Analysis and Critical Control Points) concept and measures for Analytical and Manufacture Transfer Protocols.

Change is inevitable and if there is to be improvement it must be planned, controlled and coordinated if chaos and confusion are to be avoided. Measures to adequately control change are provided within the chapter on *Change Control and Annual Product Review*, which contains example SOPs and formulae dealing with change control management and annual product reviews. Finally a philosophy of the *Continuous Improvement* of a Quality Management system is discussed.
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Dr Michael Jahnke was born on 4 August 1961 in Gronau (Leine) near Hanover in Germany. He is married and has two children. His scientific career started in 1981 at the Technical University of Braunschweig, Germany, and University of Bielefeld, where he passed his Diploma – Pre examination in Biology. Between 1984–1987 he studied Microbiology at the University of Hanover, Germany, where he achieved his Diploma in Biology (B.Sc. Biol.). In 1990 he obtained his doctorate on natural sciences (Dr. rer. nat./Ph.D.) at the Institute of Microbiology/University of Hanover on the topic of mineralisation of xenobiotics.

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