



CONCEPT
HEIDELBERG

Pharmaceutical Quality
Training. Conferences. Services.



Helping you to Comply with GMP/GDP

Since our foundation on 1 April 1978 we have been concentrating on the pharmaceutical industry (incl. API production) and on biotechnology.

In these industries companies are obliged by law to comply with strict quality standards based on national and international regulatory guidelines like the GMP guides (Good Manufacturing Practice), providing information on quality assurance and drug safety. In these guides companies manufacturing drug products find the general requirements relative to documentation, premises, hygiene and process safety. Regulatory Authorities strictly observe and ensure their realisation through GMP inspections and audits. In addition, the GDP Guidelines (Good Distribution Practice) define the requirements regarding transport and storage of medicinal products.

To comply with these requirements companies need highly qualified staff in all business areas. They have to know, understand and realise binding regulations – making it necessary to train staff continuously.

Europe's leading advanced training and information services provider for GMP and GDP Compliance

As Europe's leading advanced training and information services provider in the area of pharmaceutical quality assurance and drug safety (Good Manufacturing Practices and Good Distribution Practices) Concept Heidelberg develops and organises more than 280 seminars and conferences in 10 European countries.

In addition to own events, Concept Heidelberg also organises events on behalf of and in cooperation with various institutions.

Furthermore, our services also comprise GMP/GDP in-house trainings and GMP consulting to support pharmaceutical businesses in realising regulatory compliance on a day-to-day basis.

For more information, please visit the website www.concept-heidelberg.com



Concept Heidelberg office building in Heidelberg, Germany

Rewarding high-level Knowledge Transfer

Since 1987 CONCEPT HEIDELBERG has been conferring the Wallhäußer Award every year. This award is endowed with € 5,000.

The award is given to personalities who have specifically supported the knowledge transfer through publications, their commitment and their life's work. In particular, it honours outstanding accomplishments in the fields of pharmaceutical production, technology and quality assurance.

With the award, CONCEPT HEIDELBERG wants to remind of Professor Wallhäußer's exceptional achievements in production hygiene and microbiological quality assurance. Through many publications and through his book "The Practice of Sterilisation, Disinfection and Conservation", he earned a remarkable reputation across Europe.

He significantly influenced a practical implementation of pharmaceutical quality assurance and Good Manufacturing Practice (GMP) and also promoted the information transfer to further develop pharmaceutical quality assurance at many CONCEPT HEIDELBERG conferences. Professor Wallhäußer died in 1996.

Every year, a jury of acknowledged experts from industry and authority choose the laureate.

Members of the jury are:

- Dr Wolfgang Schumacher, F. Hoffmann-La Roche, Basle, Switzerland
- Pharmaziedirektor a.D. Rudolf Völler

The laureates of the past years are:

Dr. Gero Beckmann, Institut Romeis Bad Kissingen GmbH
Dr. Michael Rieth, Merck KGaA
Dr. Klaus Haberer, Compliance Advice & Services in Microbiology GmbH
Dr. Thomas Trantow, Analytik-Service Dr. Trantow
Dr. Michael Jahnke, Haupt Pharma Wülfig GmbH
Alexandra Stärk, Novartis Pharma Stein AG , und Volker Sigwarth, Skan AG
Dr. jur. Martin Wesch, Wesch & Buchenroth



Prof Dr Wallhäußer

Europe's Advanced Training Services Provider

Number, scope, depth and complexity of regulatory requirements in the pharmaceutical and adjacent industries are constantly increasing. CONCEPT HEIDELBERG thus facilitates management and staff across Europe in receiving the necessary qualification to fulfil these requirements in their day-to-day work.

With more than 260 events per year and over 10.000 participants from more than 20 countries, CONCEPT HEIDELBERG is Europe's largest advanced training provider in the field of GMP and regulatory compliance. Right from the start, CONCEPT HEIDELBERG set standards by developing trainings with experts from the industry and from authorities. The trainings cover the entire spectrum:

- GMP/GDP Basic Trainings convey GMP/GDP basics in specific areas like production, quality control or packaging.
- Seminars and conferences pick up currently discussed issues, introduce latest regulatory requirements and demonstrate solution approaches. A GMP/GDP seminar demonstrates the practice-oriented implementation of the regulatory requirements. At a GMP/GDP Conference or Regulatory Affairs Conference, the current regulatory developments and trends are presented by the leading experts from industry and authority. Various seminars are also offered as webinars. They allow attendees to get the latest developments quickly and easily – online from their desk.
- Various GMP/GDP courses allow professionals to assemble a course programme according to their personal interests and needs and to obtain an acknowledged certificate.

All events are planned and organised by CONCEPT HEIDELBERG project managers (Pharmacists, Chemists, Microbiologists with longtime experience in the pharmaceutical industry). Moreover, independent speakers from the industry and from authorities like FDA, EMA, PIC/S or WHO also guarantee a maximum know-how transfer. Therefore you benefit from events planned with expert knowledge and allowing you to get first-hand information and to exchange your experience with experts.

Various institutions accept our training courses and conferences as advanced training, also proving the high quality of our events.

Further information is available at www.concept-heidelberg.com. An events calendar can be found at www.gmp-navigator.com (in German language).



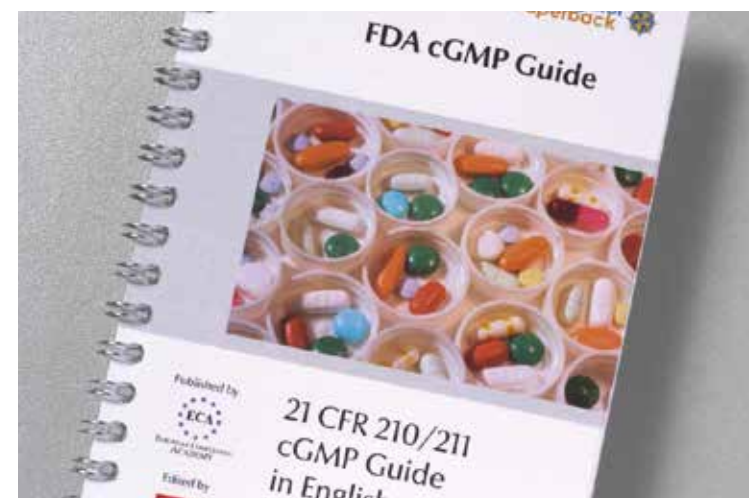
GMP/GDP Paperback Series & Publications

The Good Manufacturing Practices (GMP) are defined in a variety of laws, regulations and guidelines.

To help pharmaceutical companies ensure a GMP compliant manufacture of medicines and active pharmaceutical ingredients (APIs) CONCEPT HEIDELBERG publishes a series of GMP handbooks and publications with the most important regulations, check lists and analyses:

- **EU GMP Guide (Parts I, II and III) and its Annexes** – the basis for supervision by the competent authorities in Europe is the.
- **FDA cGMP Guide** – in the US, the Food & Drug Administration (FDA) has defined the GMP requirements in the Code of Federal Regulations (CFR). The 21 CFR 210/211 describes GMP requirements for medicinal products. In addition, the FDA has published interpretations of the cGMP Guides in a variety of guidance documents. Due to the strict requirements in aseptic processing, the FDA guidance „Sterile Drugs produced by Aseptic Processing“ has a special meaning.
- **ICH Q7 „GMP for Active Pharmaceutical Ingredients (APIs)“** – GMP requirements for the manufacture of APIs are universally harmonised through the International Conference on Harmonisation (ICH). The document ICH Q7 defines the requirements in the most important pharma markets – the US, Europe and Japan.
- **Check Lists** – in addition to the paperbacks, GMP check lists on the basis of the EU GMP Guide and the FDA cGMP Guides help pharmaceutical companies to review GMP regulations in an audit/an inspection.
- **Good Distribution Practice (GDP)** of medicinal products for human use (Text with EEA relevance) (2013/C 343/01) . The EU GDP Guidelines have been extensively revised to take into account the changing nature of the globalised supply chain. The new requirements have been effective since 2013. The booklet contains the original English wording and the official Germany translation.
- **GMP REPORT** - is a new publication series. It is published in English language. The reports support the implementation of current GMP guidelines in pharmaceutical operations. There are no fixed publishing intervals or periods; as a rule, two volumes per year are issued.

To order GMP handbooks and publications, please go to www.concept-heidelberg.com/publications



Events for International Not for Profit Organisations

In addition to conducting own courses and conferences in Germany many international organisations rely on CONCEPT HEIDELBERG's services for planning and organising international events – like the European Compliance Academy (ECA), the CEFIC/APIC, the European Fine Chemicals Group (EFCG), the Paul-Ehrlich-Institut as well as the University of Heidelberg's Institute of Pharmacy and Biotechnology (IPMB) and the University of Munich.

On behalf of the ECA, for instance, we organise more than 50 international events throughout Europe – like in Amsterdam, Barcelona, Basle, Brussels, Budapest, Copenhagen, Lisbon, Madrid, Milan, Prague, Stockholm, Vienna and Warsaw. The courses and conferences cover the most diverse needs – as participants from more than 50 countries every year prove:

- **GMP/GDP seminars and courses** demonstrate the practice-oriented implementation of regulatory requirements. In addition, the ECA **GMP/GDP Certification Programme** enables participants to complete an internationally accepted qualification.
- At **conferences**, leading experts from industry and authority present current regulatory developments and trends, allowing delegates to get an update on the latest issues and regulatory requirements as well as to receive potential solution approaches. They further provide delegates with the opportunity to exchange their experience with colleagues from other companies and representatives from international authorities like FDA, BfArM, EMA, PIC/S, SwissMedic, and WHO.

To find out more about international events organised in co-operation with other organisations, please visit the following websites:

- with the European Compliance Academy (ECA): www.gmp-compliance.org
- with APIC/CEFIC: www.api-conference.org and www.ichq7-week.org
- with the European QP Association: www.qp-association.eu



Training „On site“

CONCEPT HEIDELBERG also specifically develops and conducts in-house training courses for your company. These training courses are also offered on behalf of the ECA and enjoy a great reputation at both industry and authorities. They concentrate on an overview of the comprehensive national and international regulations as well as on relevant GMP guidances in your environment. What is exactly defined? Where is room for interpretation? Which procedure is common and accepted? What is mandatory, and what is too much?

By answering these questions, we facilitate implementing GMP/GDP on a day-to-day basis, promote understanding for following the GMP/GDP regulations and foster a positive attitude towards GMP/GDP. Discussing current issues also makes your staff aware of GMP/GDP regulations and solves existing problems.

Our GMP/GDP training differentiates between basic and special training courses. While basic training courses provide GMP fundamentals, special training courses help to advance knowledge or to gain knowledge in one specific area. The following training courses are available:

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|------------------------------|-----------------------------|--------------------------|--------------|
| ■ Pharmaceutical Production | ■ Pharmaceutical Technology | ■ Validation | ■ Wholesaler |
| ■ API Production | ■ Storage | ■ Computer Validation | ■ Logistics |
| ■ Quality Control | ■ Administration | ■ Inspection Preparation | ■ GDP |
| ■ Pharmaceutical Development | | | |

The training courses are conducted on site – taking into account your individual requirements and ideas. The programme also takes site-specific issues or instructions (SOPs) as well as recent incidents into account. As a result you will receive an individual training whose form, content and level is exactly tailored to the target audience – even considering group dynamics. Ideally, a group is comprised of 20 individuals, but should definitely not exceed 30.

The detailed GMP/GDP in-house training programme can be found on ECA's website at www.gmp-compliance.org/eca_inhouse.html



GMP/GDP Consulting for your Company

CONCEPT HEIDELBERG also manages the comprehensive consulting services in the field of GMP/GDP and Regulatory Compliance for the Pharmaceutical Consulting Alliance (PCA).

PCA is an association of leading GMP/GDP experts from various areas of the pharmaceutical and active pharmaceutical ingredients (API) industry. All of them are recognised specialists with long-standing practical experience – e.g. as Qualified Persons, QA/QC Managers, Production and Development Managers. Clients therefore benefit from consultants who can discuss their situation with further experts. Moreover, PCA's international presence – the consultants come from England, Switzerland and Germany and have established networks of contacts – enables you to quickly contact various European supervisory authorities. These contacts are often the key to the solution of (GMP/GDP) problems.

The Pharmaceutical Consulting Alliance offers counsel for all relevant departments and fields of expertise:

- Aseptic / sterile manufacture
- Biotechnological production
- Solids production
- Production of APIs
- Production of excipients
- Quality Assurance
- Quality Control
- IT/EDP
- Engineering (water systems, HVAC systems)
- Pharmaceutical development
- Distribution
- Logistics
- GDP Implementation

PCA services are based on the following standards:

- FDA
- EU/EMA
- WHO
- PIC/S
- Pharmacopoeias (EP/USP)

Benefit from a consultants team supporting you on all GMP/GDP and Regulatory Compliance matters – from GMP/GDP audits (current state analysis) to overarching advice and inspection preparation. To find out more about the Pharmaceutical Consulting Alliance, please visit www.pca-gmp.com



GMP Compliance Audits for API Manufacturers

The API Audit Programme is a third-party audit programme for auditing manufacturers of Active Pharmaceutical Ingredients (APIs).

This programme was founded by APIC, a sector group of the European Chemical Industry Council (CEFIC), in co-operation with CONCEPT HEIDELBERG. It was established to create independent and harmonised audit reports. By forwarding these reports to pharmaceutical companies for their supplier qualification, API manufacturers can reduce costs and audit frequency. The audits are conducted on the basis of ICH Q7 (Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients) and with regard to the APIC Auditing Guide. Participation is voluntary and not limited to APIC members.

To implement the programme, APIC and CONCEPT HEIDELBERG signed an agreement and founded the “API Compliance Institute” in December 2002. It is the aim of the API Compliance Institute to standardise GMP audits of API manufacturers and thereby to minimise the costs of compliance audits.

The objectives of the API Audit Programme are:

- Standardisation of GMP audits of API manufacturers
- Cost minimisation through
 - reducing the frequency of audits, since the audit report is available to pharmaceutical companies
 - standardised costs for the audits

If you would like to learn more about the API Audit Programme, please visit www.api-compliance.org



PHARMSCHUL® - The GMP Software for Training Management

The legislator requires an efficient training management and documentation from manufacturers of medicinal products: "The manufacturer should provide training for all the personnel whose duties take them into production areas or into control laboratories...." (EU GMP Guide).

Originally developed by Boehringer Ingelheim GmbH (today Roche Diagnostics GmbH) and today used by many international pharmaceutical companies, the software PharmSchul® supports the planning, administration, analysis and documentation of pharmaceutical trainings. Due to the possibility to follow and verify the training status for every employee prior to or during a GMP inspection the software ensures a structured training planning and assessment of demands.

Flexibility for Customisation

PharmSchul is based on a powerful and flexible data structure. The modular concept allows to customise boxes, masks and data structures without changing the PharmSchul system itself – ensuring more security for future updates that are also validated.

Take further advantage of the new user administration. Display your company's structure and define department administrators who take care of the trainings and staff in their area. Powerful reports show potential training deficits any time.

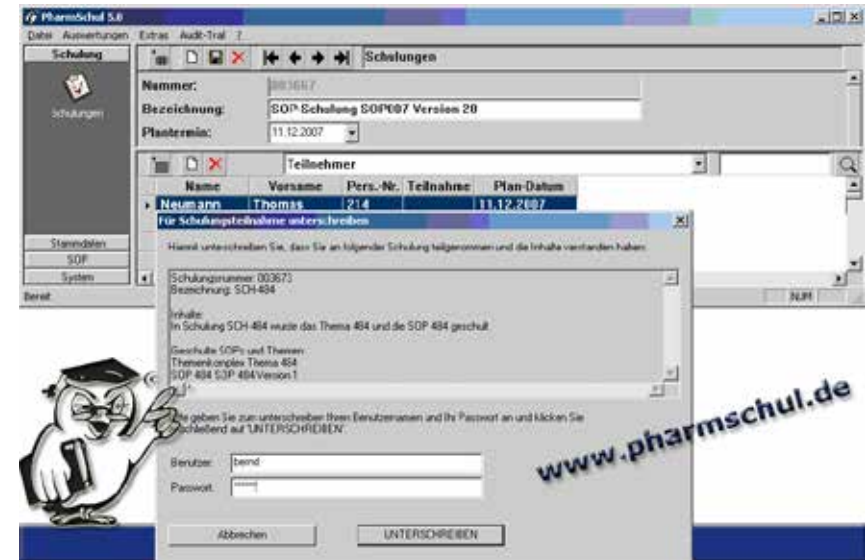
Part 11 Compliance

In 21 CFR Part 11 the FDA defined the requirements with regard to electronic records and electronic signatures. The compliance with these requirements is the precondition for the use in the FDA-regulated environment. PharmSchul 5.0 also translates these requirements systematically, e.g. through:

- Installation of a client/server architecture
- PharmSchul Audit-Trail for documenting every change implemented
- Additional security policies in the user administration

More information – as e.g. with regard to performance features and system requirements – as well as a PharmSchul demo version is available at www.pharmschul.de.

PharmSchul® is registered trademark of CONCEPT HEIDELBERG GmbH, Heidelberg.



GMP/GDP eLearning offers the possibility to provide cost-efficiently the Basics of GMP/GDP requirements to new employees and external collaborators. This is the basis for a GMP qualification.

Beside a webcast-based system which delivers GMP/GDP contents, Concept Heidelberg has extended its service portfolio on 1st October 2011 to the GMP/GDP eLearning System of MediaVision.

Through this acquisition, Concept Heidelberg will be able to provide pharmaceutical and API manufacturers with GMP/GDP eLearning courses available with a company licence. More than 300 companies in 30 countries already use the system. What makes the eLearning courses unique is the availability in 11 languages.



As the programme is available online (through a media server), you only need to open the Internet browser Internet Explorer to start a session. In a word, you can use the GMP/GDP eLearning system at each desk in your company. No need for local setup. The licences are available for a whole site without limitation regarding the number of participants.

More information at www.gmp-elearning.com

The connection to Training Management Software like PharmSchul® is possible.



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