



CONCEPT
HEIDELBERG



Pharmaceutical Quality
Training. Conferences. Services.



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Helping you to Comply with GMP

Since our foundation on 1 April 1978, CONCEPT HEIDELBERG has been concentrating on providing services for the pharmaceutical (incl. API production) and biotechnology industries.

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). These guides provide information on quality assurance and drug safety and define general requirements relating to documentation, premises, hygiene and process safety. National authorities strictly observe and ensure their implementation through GMP inspections.

In addition to GMP regulations, the services of CONCEPT HEIDELBERG also comprise other quality relevant regulations – such as for the quality part of a marketing authorisation.

It is CONCEPT HEIDELBERG's understanding to provide comprehensive services to facilitate companies in these environments to comply with national and international requirements. Today, we are **Europe's leading provider of advanced training and information services** in the fields of GMP and regulatory affairs. In addition to developing and organising seminars and conferences and in-house training courses in 11 European countries, we also concentrate on the following activities:

- Seminars and conferences
- In-house training
- Consulting
- Literature and Software to implement the regulatory requirements
- APIC Audit Programme

CONCEPT HEIDELBERG is also an associate member of the Heidelberg Technology Park.

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



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 Rudolf Völler, Regierungspräsidium Darmstadt, Germany

The laureates of the past years are:

- 2006: Dr Johannes Krämer, CSL Behring
- 2005: Dr Norman Franklin, Interactive Consulting Associates
- 2004: Dr Michael Pfeiffer, Boehringer Ingelheim
- 2003: Klaus Feuerhelm, Regierungspräsidium Tübingen
- 2002: Dr Michael Hiob, Landesamt für Gesundheit und Arbeitssicherheit, Schleswig-Holstein
- 2001: Dr Ludwig Huber, Agilent Technologies



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 240 events per year and over 8.000 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 Basic Trainings convey GMP 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 seminar demonstrates the practice-oriented implementation of the regulatory requirements. At a GMP 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 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 industry and authorities experienced CONCEPT HEIDELBERG project managers. All of them have been maintaining national as well as international contacts on both sides for years. Moreover, independent speakers from the industry and from authorities like FDA, EMEA, 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 trainings 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).

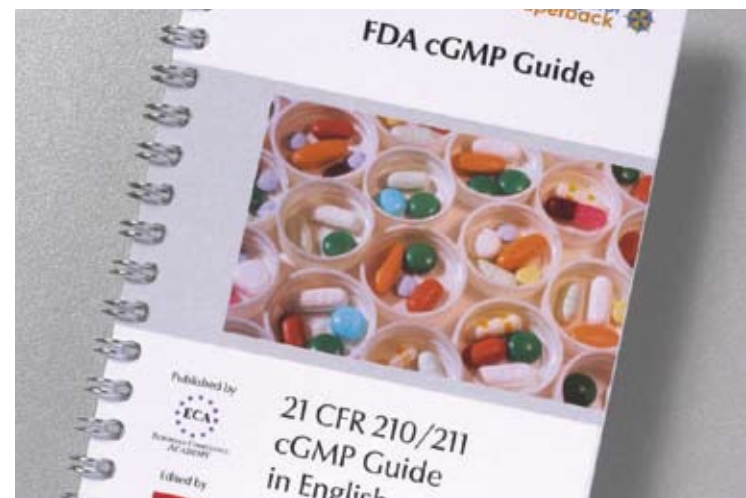


GMP Paperback Series & Publications

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 and II) 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 (formerly ICH Q7A) 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.
- **FDA Navigator with Warning Letters Report** – the FDA Navigator is a guideline database comprising all important GMP regulations of the FDA. More than 200 regulations and guidances are documented in a concise tree structure. The handbook also contains a detailed analysis of FDA Warning Letters, allowing users to identify the most frequent GMP deviations found during FDA inspections quickly and easily and to draw adequate conclusions. The FDA Navigator CD ROM with Warning Letters is also available as an annual update version.



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 20 countries every year prove:

- **GMP seminars and courses** demonstrate the practice-oriented implementation of regulatory requirements. In addition, the ECA **GMP Certificate 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, EMEA, 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 the University of Heidelberg (IPMB): www.pat-conference.org
- with APIC/CEFIC: www.api-conference.org and www.ichq7-week.org
- with the EFCG: www.efcg-conference.org
- with the University of Munich: www.bio-conference.org



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 on a day-to-day basis, promote understanding for following the GMP regulations and foster a positive attitude towards GMP. Discussing current issues also makes your staff aware of GMP regulations and solves existing problems.

Our GMP 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:

- Pharmaceutical Production
- API Production
- Quality Control
- Pharmaceutical Development
- Pharmaceutical Technology
- Storage
- Administration
- Validation
- Computer Validation
- Inspection Preparation

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



GMP Consulting for your Company

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

PCA is an association of leading GMP 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) 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

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 and Regulatory Compliance matters – from GMP 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 APIC 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 Q7A (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 APIC 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 APIC Audit Programme, please visit www.api-compliance.org.





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