

**Your Partner for Quality Systems**  
***GMP Consulting & Execution***

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Where we come  
from ...



## History

- **2002** Formation of **gempex GmbH**
  - GxP services for API and Pharmaceutical Industry
- **2004** Expanding Services and Management
  - GxP services for Biotech and Medical Devices
- **2005** Globalization
  - Switzerland, Korea, China
- **2006** Qualification & Certification
  - Special in-house education system
  - Certificate acc. DIN EN ISO 9001:2001
- **2007** Formation of a subsidiary in Laufenburg, Switzerland

## Our Team

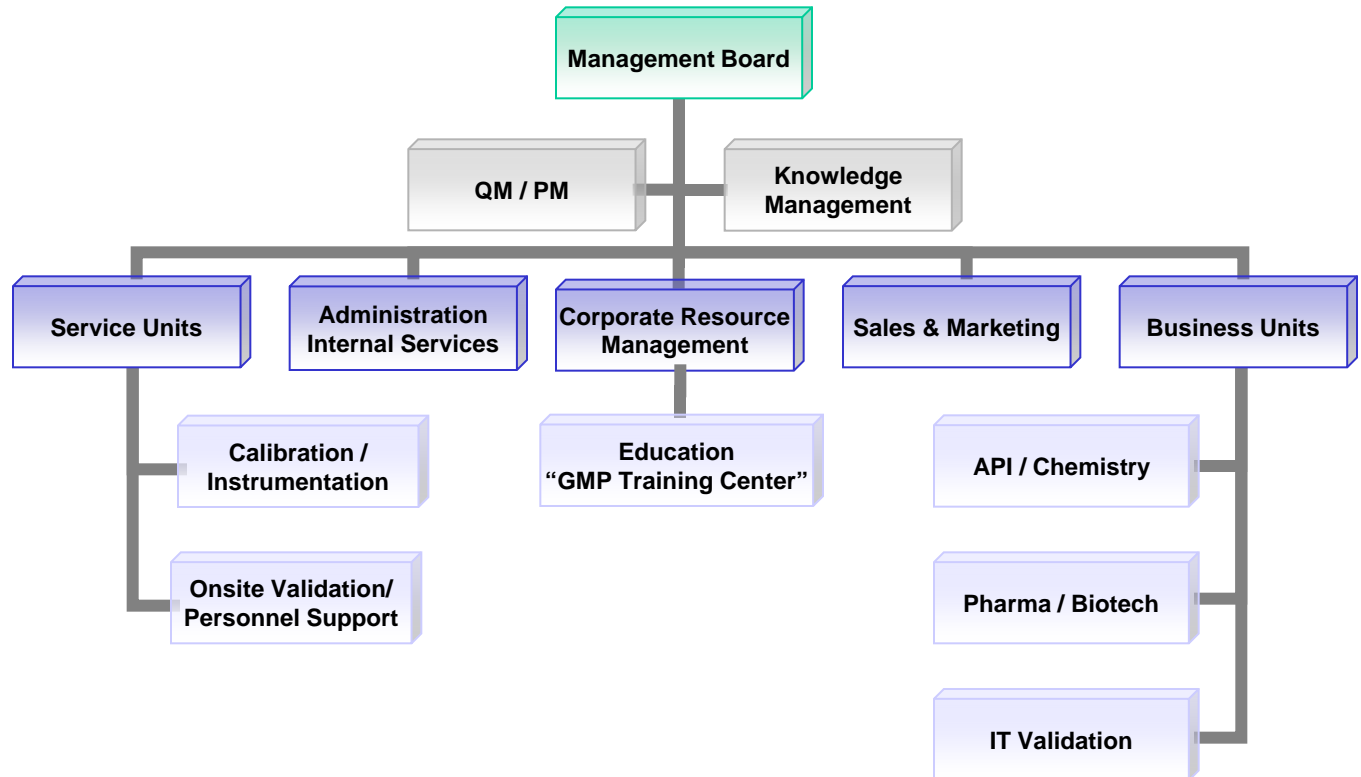
- **gempex GmbH**, located with our main office in Mannheim, Germany, is a continuously growing company actually employing more than 40 experienced GMP specialists of various disciplines such as:
  - Process engineering
  - Chemistry, chemical engineering
  - Pharmacology
  - Biotechnology
  - Food engineering
  - Process control engineering
  - Information technology
- Our specialists are well experienced as a service providers for all topics concerning GMP or equivalent quality assurance systems.
- We keep our knowledge permanently *up-to-date* by internal and external trainings and further education, as well as active memberships in numerous associations.

Who we are ...



## Organization

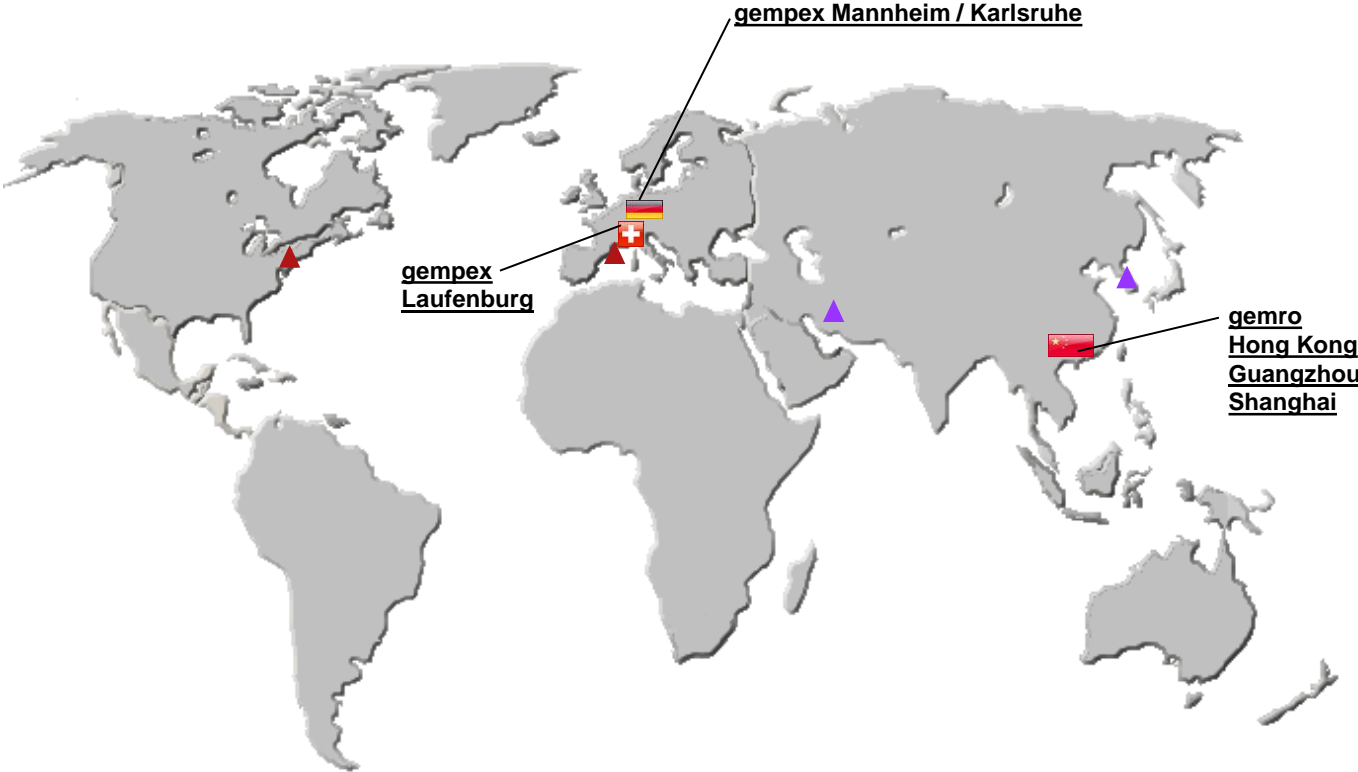
How we are organized ...



## Locations

Associates ▲  
Cooperation's ▼

We are active all over the world. Our associates in the US and in Switzerland have the direct contact to US FDA and EMEA respectively



gemro is a joint venture of gempex & HeRo ([www.gemro-services.com](http://www.gemro-services.com))

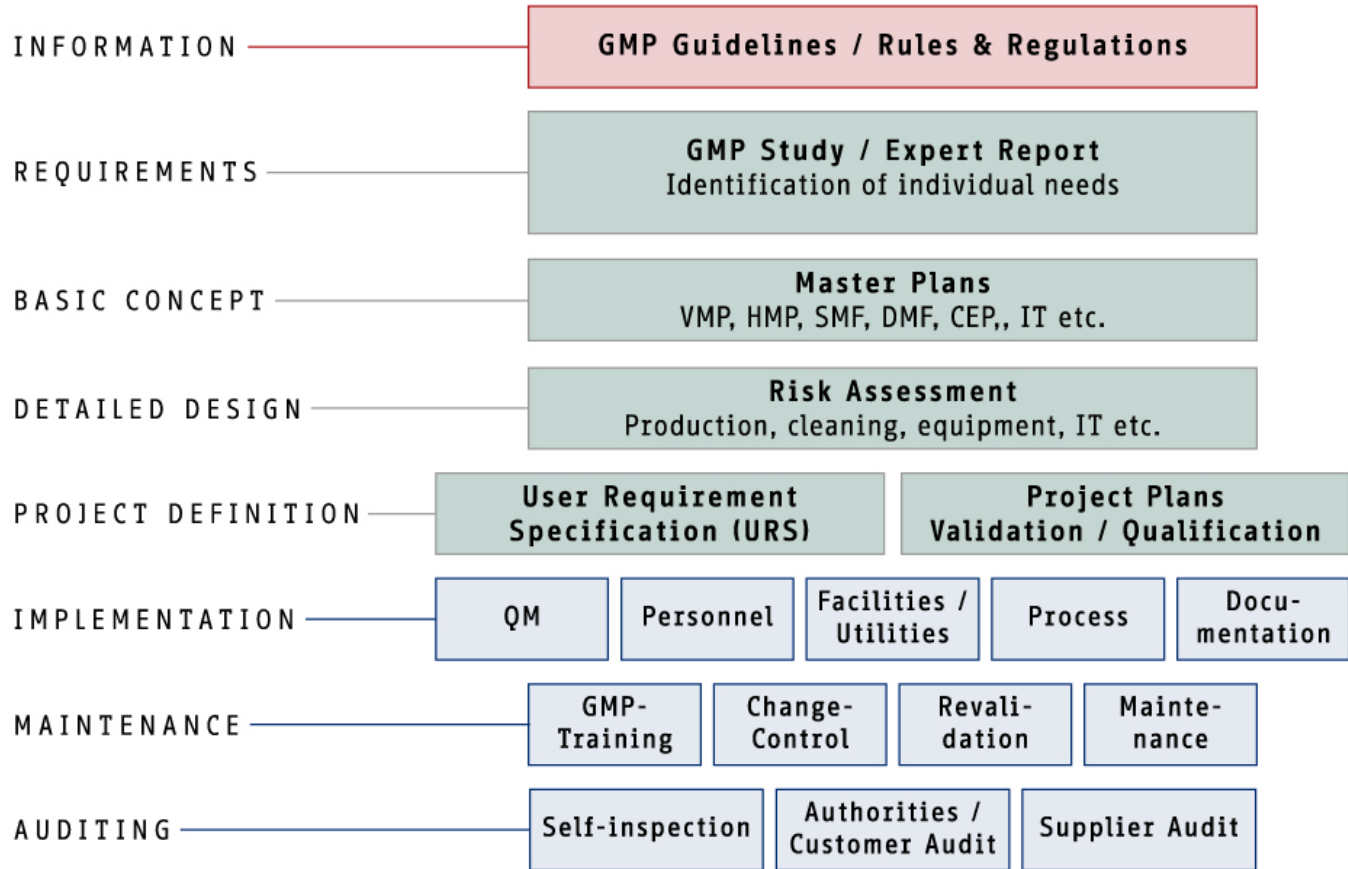
What we offer ...

## Our Services

- **Consultancy services**
  - supporting new projects from the beginning
  - accompanying running projects
  - special trainings and seminars
- **Project execution**
  - complete GMP system implementation
  - defined projects or sub-projects (e.g. qualification, validation)
- **Ongoing servicing (external GMP office)**
  - personnel support
  - information center
  - continuous communication with relevant authorities
  - permanent training and education
  - ...

## How we proceed

Modular approach ...



... meeting your individual needs

## **Our Services in Detail**

Services meeting  
your needs ...

- **Basic concepts**
- **Risk assessment**
- **GAP analysis**
- **Qualification**
- **Calibration of quality-relevant measuring systems**
- **Validation**
- **Validation of computerized systems**
- **Documentation**
- **Training**
- **Audits**
- **Preparation for inspections**

## Basic Concepts

### What we offer ...

- Consulting, personnel support and realization of basic concepts for
  - master plans
  - qualification
  - validation

### What we do ...

- Based on proven experience we develop the qualification/validation concept that fits your needs and goals. Needless to say, it reflects your opinion of the topic (within the framework of area, division or whole company). According to your preferences we either support you in, or take over the preparation of master plans. These conceptual documents coordinate and control the individual projects, name responsible persons and list all qualification and validation activities.

### What you get ...

- A company specific qualification/validation concept and a project specific master plan in compliance with GMP requirements.

## Risk Assessment / Risk Management

### What we offer ...

- Preparation, discussion and execution of risk assessment according to the following standards (e.g.)
  - HACCP
  - FMEA
  - FTA

### What we do ...

- Risk assessment / management enables you to determine which qualification/ validation measures are necessary and perform your activities according to, e.g. GMP requirements. We teach you how to execute risk assessment in an easy and effective way and provide support with the implementation of results for corresponding processes and equipment.

### What you get ...

- Elaboration of
  - equipment to be qualified
  - process steps, cleaning steps to be validated
  - analytical methods to be validated
  - computerized systems to be validated
  - quality relevant control points to be calibrated
  - functioning risk management system

## GAP-analysis

### What we offer ...

- GAP-Analysis is a management tool used in evaluation of complex settings or for detailed planning of changes. Based on experience taken from numerous examples executed by our company we offer professional and competent processing of this exercise.

### What we do ...

- We plan, handle and state our results in compliance with requirements defined in direct interaction with our clients. Clarification of basic conditions for the relevant task is first step. Thereafter, detailed and effective onsite analysis take place. Deviations are directly annotated, reliably evaluated and discussed in depth. The final step consists of preparation of a formal report accompanied by a list of measures.

### What you get ...

- A precise description displaying firm evaluation of the analyzed process together with a list of relevant measures suitable as the basis for generation of a project plan for further scheduling.

## Qualification

### What we offer ...

- Consulting, personnel support and execution of
  - DQ - Design Qualification
  - IQ - Installation Qualification
  - OQ - Operational Qualification (incl. calibration)
  - PQ - Performance Qualification

### What we do ...

- Based on proven concepts or on your individual guidelines, our experts develop and prepare all qualification protocols and relevant SOPs for discussion within the validation team. Our engineers will accompany and support you during subsequent qualification. Upon request, we also execute projects independently and on our own responsibility. We collect and collate records, raw data and individual results and summarize them in final qualification reports.

### What you get ...

- A comprehensive GMP compliant documentation describing whole qualification activities for your plant.

## Calibration of quality-relevant measuring systems

### What we offer ...

- Consultation, implementation or personnel support in
  - creation of measuring point indices and lists
  - critical consideration of the measuring systems considering GMP
  - preparation of a calibration concept with inspection templates
  - implementation of traceable and repeatable calibrations

### What we do ...

- We acquire and identify your quality-relevant measuring systems, ensure GMP-compliant labeling onsite and collate the relevant data in specification sheets. Experienced staff create the necessary documentation for calibration in line with standards using proven templates or according to your wishes. In principle, calibration can be traced and reproduced with your own, calibrated and qualified measuring equipment.

### What you get ...

- GMP-compliant, traceable and repeatable calibration of quality-relevant measuring systems.

## Validation

- Consulting and personnel support in
  - process validation
  - cleaning validation
  - validation of computerized systems
  - validation of analytical methods
- We advise you regarding all technical questions and support you with manpower for preparation of validation protocols and reports and for execution. We work with proven templates and check lists. Additionally, we provide necessary validation SOPs and adapt them to your individual needs.
- Validated processes and systems including all required SOPs, protocols and reports.

What we offer ...

What we do ...

What you get ...

## Validation of computerized systems

### What we offer ...

- Consulting, provision of human resources and project execution concerning the validation of computerized systems according to current regulatory directives and guidelines (e.g. Annex 11, 21 CFR Part 11, PIC/s PI-011, GAMP 5).

### What we do ...

- Trained and experienced specialists for IT-validation prepare the required documents for software validation and hardware qualification on the basis of our well-proven templates or according to your individual demands. We accompany and support you from validation planning through the development and execution of test specifications to the analysis of results and the creation of validation reports.

### What you get ...

- Validated IT-systems with related SOPs, validation plans, risk analyses, test specifications and final reports.

## Documentation

### What we offer ...

- Consulting, personnel support and execution of
  - documentation concepts
  - Standard Operating Procedures (SOPs)
  - production documentation
  - technical documentation
  - documentation review

### What we do ...

- Based on our standards we give advise and support in the implementation of a documentation system that fulfills requirements of GMP as well as other quality management systems (e.g. ISO, GxP, safety guidelines). We create, independently or according to your specifications, all necessary documents or check yours for completeness, current validity and integrity, especially with regard to inspections.

### What you get ...

- A uniform and clearly structured documentation system that contains all documents required to run a plant in accordance with GMP.

## Training

### What we offer ...

- Dependent on your needs we support you in
  - identifying your training needs
  - preparing training concepts and schedules
  - the execution of basic training programs
  - the execution of specialist seminars

### What we do ...

- During an analysis of the current status at your site we will determine your immediate need for trainings and prepare specific training schedules. We carry out general or division/group-specific trainings within your company in accordance with modern methods of adult training. Upon request we will integrate your company's specific procedures or documents into the training seminars. The participants will receive detailed handouts as well as an individual certificate as documented evidence of participation.

### What you get ...

- Qualified personnel and training system documentation as required.

## Audits

### What we offer ...

- Implementation, consultation and personnel support for
  - GAP analysis
  - compliance audits
  - follow-up audit

### What we do ...

- For audits, which you implement (supplier audits, audits at subcontractors) we provide you with the necessary tools in several variations in the form of sample instructions, which, in coordination with you, are adjusted to your individual demands. We accompany you or implement the necessary audit for you on request, including the associated reporting and re-inspection.

### What you get ...

- Efficient, well-founded preparation that ensures success for each audit. Meaningful audit reports, which help to improve the system for the future.

## Preparation for Audits & Inspections

### What we offer ...

- Preparation, support and/or execution and follow-up of
  - authorities inspections
  - customers audits
  - suppliers audits
  - self inspections

### What we do ...

- We provide you with SOPs and useful checklists for each kind of audits and / or inspections. At your request we take part in, or perform audits and take over the task of preparation of the audit report. In advance to customer or authority audits & inspections we help you to prepare the documents and place our knowledge and professional manpower at your disposal.

### What you get ...

- Comprehensive preparation for successful audit & inspection performance. Detailed audit reports that help to continuously improve the GMP system.

## For Us a Matter of Course ...

Our work due to  
your needs ...

- **We do what has to be done, not what could be done**
  - taking into account what already exists
  - implementing what is really required
  - effective, timely and individual execution of your project
- **We protect you from reinventing the wheel**
  - using proven templates and concepts
  - using synergies
- **We put emphasis on pragmatism rather than formalism**
  - practical solutions to create efficient work flows
  - formality only when it is necessary and helpful
- **We provide integrated project management**
  - for the reinforcement of the knowledge of your team
  - to develop appropriate decisions
  - to cover high manpower requirements
  - to provide relief from routine work



## Some Regulations and Guidelines we are Experts in...

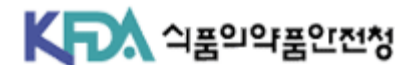
FDA  
ICH  
EMA  
PIC/S  
and others



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
**FOOD AND DRUG ADMINISTRATION**



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



More information:  
[www.gempex.com](http://www.gempex.com)

## For whom we work ...

Our customer is the  
Life Science Industry  
and their suppliers

> 200 customers

> 1000 projects



**Chemistry**



**Pharma / Biotech**



**Food / Feed**



**Cosmetics**



**Medical Devices**



*Abbott GmbH & Co. KG • BASF SE • B. Braun Melsungen AG • Biomeva GmbH • Biotest Pharma GmbH • BBI Sartorius GmbH • Boehringer Ingelheim • CIBA SC • CU Chemie Uetikon GmbH • CSL Behring AG • DIL Ltd. India • Evonik • Gosun China Pharmaceuticals Co., Ltd. • Grünenthal GmbH • Merck KGaA • Messer Group GmbH • Myriad Pharmaceutical Inc. • Novartis Vaccines & Diagnostics • Rentschler Biotechnologie GmbH • Roche Diagnostics GmbH • Rockwood Italia • RP Scherer GmbH & Co. KG. • Solvay Pharmaceuticals GmbH • Vetter Pharma-Fertigung GmbH • Wacker Chemie • Welding GmbH • Wiewelhove GmbH • Wrigley China • Yancheng Xinyi Pharm & Chem Co. Ltd. • Zhejiang Garden Biochemical Ltd. • and many others ...*



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