

# GMP Expert Seminar

EU / US cGMP Compliance  
November 18<sup>th</sup>-19<sup>th</sup> 2010, Shanghai



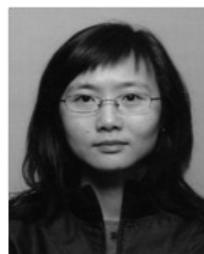
**Ralf Gengenbach**

Managing Director  
gempex GmbH /  
gemro-services Ltd.  
Mannheim, Germany



**Mohsen Masoumi**

Senior GMP Consultant  
APIC certified Auditor  
gempex GmbH Mannheim,  
Germany



**Dr. Joono Wu**

Senior GMP Consultant  
gemro-services Ltd.  
Hongkong, China



**Rick Zhen**

Senior GMP Expert  
gemro-services Ltd.  
GuangZhou, China

## **GMP EXPERT SEMINAR**

### **EU / US cGMP Compliance**

**November 18<sup>th</sup>-19<sup>th</sup> 2010, Garden Avenue Hotel,  
Shanghai, PR, China.**

#### **Purpose of seminar**

Today, the rapidly growing PRC economy provides numerous opportunities for all local industries. The PRC pharmaceutical industry has been benefiting from the economic growth and is selling their products increasingly to Western markets. However, while business is growing in the pharmaceutical area, there are many regulatory hurdles in the Western countries - especially GMP regulations - which must be well known and understood:

- The EU / US basic GMP philosophy
- The differences from EU / US GMP to Chinese GMP
- Current Relevant hot topics of EU/US GMP
- Understanding how Western inspections are conducted
- Typical questions and findings during inspections

This seminar will cover exactly these topics and will provide important practical and relevant details. Our seminar is based on the experiences we have gained carrying out numerous audits in China, Asia and the West. Our GMP experts will expressly teach you how to meet compliance and how to successfully bring your products to the Western market.

#### **Participants**

All managing directors, production managers, quality control and quality assurance managers as well as responsible technical managers who are confronted with regulatory requirements and GMP standards.

#### **Registration Fee**

The registration fee of 2,200 RMB will include the two days of lecture, handouts, certificates, coffee breaks, lunch and one dinner.

**gemro Services Ltd.**  
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## SEMINAR CONTENTS

November 18<sup>th</sup>

<b>08:30 – 09:15</b>	<b>Registration</b>	
<b>09:15 – 09:30</b>	<b>Welcome</b>	<b>Mr. Ralf Gengenbach</b>
<b>09:30 – 10:30</b>	<b>EU/ US regulatory update</b>	<b>Mr. Ralf Gengenbach</b>
	Overview about the actual valid EU and US cGMP rules and regulations; latest trends and discussions of new upcoming guidelines; meaning of ICH Q8, Q9, and Q10 for the pharmaceutical industry; meaning of PIC/S and WHO guidelines for the Western world; meaning of standards like ISO 14644 and ASTM E2500.	
<b>10:30 – 12:00</b>	<b>CEP/ ASMF / DMF*</b>	<b>Dr. Joono Wu</b>
	What is their meaning and interrelation with GMP; when and how to prepare which type of document; filing and certification procedure; typical difficulties in dossier preparation; what about USP certification procedure?	
<b>12:00 – 13:00</b>	<b>Lunch Break</b>	
<b>13:00 – 14:00</b>	<b>Chinese GMP versus Western GMP</b>	<b>Mr. Mohsen Masoumi</b>
	What are the main differences between Western GMP requirements and Chinese GMP requirements and how does it influence the general GMP compliance; what are Western customers willing to accept – experiences from an APIC certified auditor.	
<b>14:00 – 14:15</b>	<b>Coffee Break</b>	
<b>14:15 – 15:45</b>	<b>Qualification and Validation</b>	<b>Mr. Ralf Gengenbach</b>
	What is the actual standard in the Western world; what are the minimum requirements; how do Western pharmaceutical companies carry out qualification and process validation (examples); what is the situation in China and what are the biggest gaps; what about the new FDA validation guideline?	
<b>15:45 – 16:00</b>	<b>Coffee Break</b>	
<b>16:00 – 17:00</b>	<b>Change Control &amp; CAPA</b>	<b>Mr. Mohsen Masoumi</b>
	Why are Change Control and CAPA (Corrective Actions; Preventative Actions) so important tools today; explanation of basic requirements and examples showing how Western companies are realizing those requirements today.	

\* The topics marked with an asterisk will be held in Chinese. All other presentations will be done in English and directly translated into Chinese.



## SEMINAR CONTENTS

November 19<sup>th</sup>

- |                      |  |                                      |
|----------------------|--|--------------------------------------|
| <b>09:00 – 10:30</b> | <b>Risk Assessment / Risk Management*</b><br>Basic requirements and meaning in the Western world; different steps of a risk assessment; when and how to do a risk assessment (examples); differences between risk assessment and risk management; how to keep a risk assessment up to date; meaning in inspections.    | <b>Mr. Rick Zhen</b>                 |
| <b>10:45 – 12:00</b> | <b>Inspection Procedures</b><br>How Western authorities prepare for inspections; inspection guidelines and how to use them for inspection preparation; typical inspection agenda and inspection hot topics; how to train for and how to behave during an inspection (Golden Rules).                                    | <b>Mr. Ralf Gengenbach</b>           |
| <b>12:00 – 13:00</b> | <b>Lunch Break</b>   |                                      |
| <b>13:00 – 14:30</b> | <b>Inspection Findings</b><br>Presentation of a summary of findings during real inspections (US & EU); typical questions collected during inspections; picture reports – based on several case studies.  | <b>Mr. Ralf Gengenbach</b>           |
| <b>14:30 – 14:45</b> | <b>Coffee Break</b>  |                                      |
| <b>14:45 – 15:45</b> | <b>The New Chinese GMP*</b><br>What changes will the new Chinese GMP regulations bring to the local pharmaceutical industry; what are the main differences with the old guidelines; are there still some differences to Western guidelines; how much time do Chinese manufacturer have to adapt to the new guidelines? | <b>Shanghai SFDA</b>                 |
| <b>15:45 – 16:00</b> | <b>Coffee Break</b>  |                                      |
| <b>16:00 – 17:00</b> | <b>Final Discussion</b><br>Open discussion to put your questions to our experts.   | <b>all participants and speakers</b> |

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## OUR GMP EXPERTS – GERMANY & CHINA



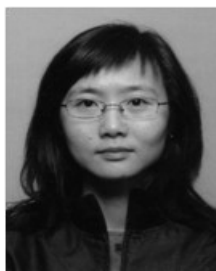
**Ralf Gengenbach | Mannheim, Germany**  
**Managing Director gempex / gemro**

Today more than 20 years experience in all GMP matters focusing on EU / US GMP compliant biotechnological, chemical and pharmaceutical manufacturing plants. Involved in audit execution, preparation of and assistance during FDA / EMA inspections, GMP trainings and regulatory affairs consultancy (CEP, ASMF, DMF). Still active in many national and international associations (ISPE, PDA, BAH, VIP3000, etc.). Permanent speaker on international seminars and congresses. Author of several scientific journals. Beyond others he has published a unique book about “GMP, Qualification & Validation of API plants”.



**Mohsen Masoumi | Mannheim, Germany**  
**Senior GMP Consultant / APIC certified Auditor**

Nearly 20 years of GMP experience. He was deeply involved in the design, planning, and construction of GMP compliant API and final pharmaceutical production plants. This includes but is not limited to projects for liquid, semisolid, and solid dosage forms of medicines as well as projects for sterile products. He was the project manager for a huge vitamin project in Asia responsible for the full GMP implementation and finally for the GMP certification by international bodies. Today he is focusing on third party audits, GMP compliance consultancy and being head of the gempex GMP training centre.



**Dr. Joono Wu | Hongkong, China**  
**Senior GMP Consultant**

More than 10 years of experience in GMP and GMP related processes. She actively worked on numerous Chinese GMP projects doing trainings and consultancy on topics like risk assessment, SOP preparation and handling, qualification and validation, and many more. She guided a lot of Western auditors doing GMP compliance audits and executed third party audits by herself. She is expert in Chinese and Western (EU / US) GMP guidelines respectively and also is involved in CEP/ ASMF / DMF preparation and filing. She gives several trainings and lectures directly for pharmaceutical companies as well as during public seminars.



**Rick Zhen | GuangZhou, China**  
**Senior GMP Expert**

Rick has more than 10 years experience in international GMP regulation. He already has managed a lot of API and final pharmaceutical projects with focus on international, mainly EU and US GMP compliance. Giving training, working on qualification and validation topics as well as on risk assessment projects. He assisted third party audits executed by gemro or by Western companies and guided Chinese manufacturer when upgrading their GMP system to Western standards. He also is experienced in all questions concerning CEP, DMF, and ASMF respectively. He already has given a lot of public speeches and presentations on GMP topics.

## REGISTRATION

Company \_\_\_\_\_  
 Gender \_\_\_\_\_  
 Name \_\_\_\_\_  
 Position \_\_\_\_\_  
 Address \_\_\_\_\_  
 Phone \_\_\_\_\_  
 Fax \_\_\_\_\_  
 E-Mail \_\_\_\_\_  
 Date, Signature \_\_\_\_\_

### Seminar Fee

RMB 2,200/per participant  
 (including two days of lecture, handout, certificate, lunch and one dinner)

### Room Reservation

If you need room reservation services, please fill out the following information. The hotel will contact you.

#### Hotel: ShangHai Garden Avenue Hotel

Single room (RMB 590 / per room)       Double room (RMB 590 / per room)

Name	Nov.17 <sup>th</sup> – 18 <sup>th</sup>	Nov.18 <sup>th</sup> – 19 <sup>th</sup>	Nov.19 <sup>th</sup> – 20 <sup>th</sup>

### Payment Method (only seminar fee – the hotel is to be paid separately)

Wire transfer made payable to gemro services     Other \_\_\_\_\_

### Account Information

Bank                      交通银行上海市瑞南支行  
 Account Name        上海英宏化学品有限公司  
 Account                310066425018010008012

If payment is being made for more than one participant, please complete one registration form for each person and send together.

**Please return this registration form with your payment before 20<sup>th</sup> of October 2010 to Cobby Zhang by Fax: 020-87370005 or E-Mail: c-zhang@gemro-services.com**  
**Upon receipt of your registration and your payment, a confirmation will be sent to you by e-mail.**

### Cancellation Policy

Cancellation is free of charge until 15 days prior to the seminar date. Later you can cancel upon payment of an administrative charge: 10% of registration fee up to 14 days to the seminar date and 50% of registration fee up to 7 days to the seminar date.

