

Invitation to Join OECD GLP Training Program

Dear members,

Greetings from Chemlinked.

Chemlinked.com was launched in October 2012 by REACH24H Consulting Group to provide regulatory updates and in-depth analysis for the Chinese market. Since then, Chemlinked has become China's premier compliance information and registration service provider with focusing on chemical regulations and safety assessments in China, Japan and South Korea. It has gained worldwide popularity among professionals in the chemical industry and has become an indispensable information and interaction platform covering the Asia-Pacific Region.

At REACH24H we are proud to invite Mr. Hedwig Beernaert, a veteran in OECD GLP with over 20 years expertise to offer training on GLP quality systems. . Mr. Beernaert's has been a constant in the world of OECD GLP and has been integrally involved in 200+ OECD sanctioned inspections.

The course is aimed at quality engineers and study personnel involved in all things GLP. The training course will provide a chance to meet one of the world's foremost GLP experts. This training event is a rare opportunity to discuss practical issues involved in QA development, GLP implementation and preparation for GLP inspections.

The training is designed to provide participants with in depth knowledge on OECD principles of GLP. As per Mr. Beernaert suggestion the course will be limited to 20 people and take place over a period of 5-days to maximize training utility.

Table 1 - Budget table of the training program

	Item	Budget (RMB)
1	Trainer (including round-trip air tickets)	105,000
2	Venue	50,000
3	Accommodation of the trainer	7,500
4	Meals (including lunch and supper)	18,000
5	Training materials, snacks, and miscellaneous	20,000
	GRAND TOTAL	205,5000

* The budget is made based on the assumption of 5-day training with 20 participants.

Course Details:

Date: August 25th~29th, 2014 (Mon~ Fri)

Venue: Sheraton Xixi Hotel, Hangzhou, China

Trainer:



Mr. Hedwig Beernaert
Belgian GLP expert, consultant, GM of EuroQAM

Mr. Hedwig Beernaert is the quintessential GLP expert, author or coauthor of some 100 peer reviewed publications, Chairman of the EU's mutual joint visit program steering group, organizer and developer of multiple GLP courses and vice president of Belgium's GLP accreditation board are just a taste of the accolades that decorate his outstanding career.

During his 20 year tenure, Mr. Beernaert racked up an impressive list of achievements specifically relating to implementation of OECD principles of GLP, and personally was involved in more than 200 OECD sanctioned inspections. Globally renowned as an expert in the field of OECD GLP, Mr. Beernaert started his own consultancy firm "EuroQAM" in 2009, providing quality and dependable advice and consultancy on all things GLP.

Laboratories inspected by Mr. Beernaert in China include Nutrichem (Beijing), FMC (Shanghai), Pilarquim (Shanghai), Covance (Shanghai) and Jiangsu Agrochem (Changzhou).

Training Overview & Course Schedule

The course will be highly interactive with intensive case studies and exercises to enhance its effectiveness.

Schedule	Morning Session (9:00~13:00)	Afternoon Session (14:00~18:00)
Day 1	<ul style="list-style-type: none">● Introduction● General GLP aspects● What is GLP?● Relationship between Receiving and Monitoring Authority● Scope of GLP: trends in the OECD GLP	<ul style="list-style-type: none">● Critical points concerning responsibilities of<ul style="list-style-type: none">• Sponsor• Test Facility Management (TFM)• Study Director (SD)• QA staff

	<p>Principles</p> <ul style="list-style-type: none"> ● Legal Framework (Differences between OECD, USA and Japan) ● Inspection preparation: how to survive an inspection? <p>Questions (trainees) and answers (trainer)</p> <p>Individual exercise: general GLP aspects</p>	<ul style="list-style-type: none"> • Archivist • Study personnel <p>Questions (trainees) and answers (trainer)</p> <ul style="list-style-type: none"> ● Master schedule of GLP studies <p>Group exercise: set-up and deficiencies of a master schedule</p>
Day 2	<ul style="list-style-type: none"> ● Critical points QA Program ● What is a processed based inspection? <p>Questions (trainees) and answers (trainer)</p> <p>Group exercise: preparation of test-facility inspection</p>	<p>Group exercise: performance and reporting a test facility inspection</p>
Day 3	<ul style="list-style-type: none"> ● Critical points of facilities: floor plan, separation of activities, environmental conditions, waste disposal, housekeeping <p>Questions (trainees) and answers (trainer)</p> <p>Individual exercise: facilities <ul style="list-style-type: none"> ● Critical points apparatus, materials and test systems: purchase, use of terms maintenance, calibration and validation <p>Questions (trainees) and answers (trainer)</p> <p>Individual exercise: equipment</p> </p>	<ul style="list-style-type: none"> ● Critical points computerized systems ● IT policy: responsibilities, training, security, SOPs, archiving ● Master validation plan (DQ, IQ, PQ, OQ) of computerized systems <p>Questions (trainees) and answers (trainer)</p> <p>Group exercise: computerized systems</p>
Day 4	<ul style="list-style-type: none"> ● Critical control points of test and reference items <p>Questions (trainees) and answers (trainer)</p> <ul style="list-style-type: none"> ● Critical points standard operating procedures (SOPs) <p>Questions (trainees) and answers (trainer)</p> <ul style="list-style-type: none"> ● Critical points archives <p>Questions (trainees) and answers (trainer)</p> <p>Individual exercise: test and reference items, SOPs, archiving</p>	<ul style="list-style-type: none"> ● Critical points performance of a study <p>Group exercise: case study set up (SD) and audit (QA) of a study plan</p>
Day 5	<p>Group exercise: open discussion results case study plan</p> <ul style="list-style-type: none"> ● Critical points reporting of a study 	<p>Group exercise: open discussion results case study final report</p>

	Questions (trainees) and answers (trainer) Group exercise: case study set up (SD) and audit (QA) of a final report (QA)	
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Target Group:

- Sponsor
- Management
- Study Director
- Study Personnel
- Principal Investigator
- Quality Assurance Unit (QAU)

The course will be conducted in English.

How to Register

Registration Fee: 9,800 RMB for 5 days' training (excluding accommodation, contact us for hotel reservation if necessary)

To register for the course

Please send back the application form in the attachment by fax or email.

May 9th, 2014 - Chemlinked
REACH24H Consulting Group



Contact: Olivia Sun
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OECD GLP Training Course – Application Form

Please send us by **July 31st, 2013** via Fax: **0571-87007566** or Email: **CHEMLINKED@Gmail.com**

Organization:					
Name		Dept.		Job Title	Mr./Ms.
Tel.		Mobile		Email	
Name		Dept.		Job Title	Mr./Ms.
Tel.		Mobile		Email	
Name		Dept.		Job Title	Mr./Ms.
Tel.		Mobile		Email	
Name		Dept.		Job Title	Mr./Ms.
Tel.		Mobile		Email	
Name		Dept.		Job Title	Mr./Ms.
Tel.		Mobile		Email	
Name		Dept.		Job Title	Mr./Ms.
Tel.		Mobile		Email	

Special note: The training course only accepts 20 participants, please send back the application form as soon as possible and we will reserve your seats.

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