Cambridge Healthtech Institute’s Fifth Annual

GLP Bioanalysis

Creating GLP Structure from the Ground Up

January 7-8, 2009 • The Fairmont • San Francisco, CA

The course will provide detailed information and the current state-of-the-art knowledge on “must know” topics such as writing SOP’s, the do’s and don’ts for the GLP audit, and Quality Assurance.

Ample time is allocated to each speaker in order to provide an interactive, in-depth tutorial with time for questions, detailed coverage of the subject and discussion of individual problems and situations. The audience will be strongly encouraged to interact, bring problems, discussion points or suggestions in order to brainstorm with the experts and share new information. You will be provided with printed handouts to follow along with the speakers and take notes.

✓ Writing SOP’s
✓ Dealing with Regulations
✓ Documentation, Validation and Qualification

⇒ In depth coverage
⇒ Q&A
⇒ Addressing Your Problems
⇒ Printed Course Material

Organized by:
Cambridge Healthtech Institute
250 First Ave, Suite 300, Needham, MA 02494
T. 781-972-5400 or Toll-free in the U.S. 888-899-6288 • F: 781-972-5425 • www.healthtech.com

www.healthtech.com/GLP/overview.aspx
Day One

8:00 am  Registration and Morning Coffee

WRITING SOP’s

8:30 – 11:50  Writing SOP’s (20 minute coffee break included)

Compliance with the requirements of a Good Laboratory Practice (GLP) Study Protocol can only be achieved if the analytical methods and other study conduct operations are properly described in written Standard Operating Procedure (SOP) documents. Failure to have adequate study documentation and SOPs shows up frequently in FDA warning letters to institutions having GLP compliance problems. This seminar will provide attendees with essential tools for the job of creating a compliant SOP system. It will cover:

- How to develop an effective SOP and write clear, practical instructions
- How to set up your SOP process so employees know who’s responsible for what and how often to review and update procedures
- The details to include — and avoid — when drafting a SOP
- Steps for monitoring and auditing SOP compliance

Tutor:
Alex D. Kanarek, Ph.D., Principal, AK Consulting

Dr. Alex Kanarek, Principal of AK Consulting, has more than 30 years of experience in the biopharmaceutical industry with the Wellcome Foundation (now GlaxoSmithKline) in the UK and Connaught Laboratories (now Sanofi Pasteur) in North America. He established his consulting practice in 1993, specializing in regulatory compliance in drug development laboratories and manufacturing plants, technology transfer and biopharmaceutical product development.

Dr. Kanarek has written Guides to Good Laboratory Practice, Good Manufacturing Practice, Good Validation Practice, Good Clinical Practice and to Good Facility Design. He is on the editorial advisory board of the BioProcess International Journal.

Dr. Kanarek received his B.S. in Microbiology from Imperial College, University of London, his Ph.D. on Virus Research from Cambridge University and Membership (MCIM), in International Pharmaceutical Business Development, from the UK Royal Chartered Institute of Marketing.

11:50 – 1:40 pm  Luncheon, provided by CHI

1:40 – 5:00  Dealing with Regulations (20 minute refreshment break included)

PLANNING AND CONDUCTING AN AUDIT—HOW TO AUDIT EFFECTIVELY

- Define: first party, second party, third party audits; significance.
- Defining audit objectives; standard(s) or criteria against which the audit is to be conducted.
- Audit process—document audit, system audit, process audit.
- Audit planning—developing audit checklist; objective vs frequency and schedule.
- Pre-audit meeting—communication.
- Audit findings—observations (opportunity for improvement), minor nonconformance, major nonconformance. What are they? How to address them?
- End of the Audit meeting; initial communication or preliminary report of audit findings.
- Communication exchange between auditor and auditee.
- Final report.
- Follow-up actions: purpose and procedure.

Tutor:
Lokesh Bhattacharyya, Ph.D., Certified ISO/IEC 17025 Lead Assessor, Interdisciplinary Scientist/Quality Manager, Division of Product Quality, Office of Vaccine Review and Research, Center for Biologics Evaluation and Research, Food and Drug Administration
Product Quality (DPQ) of the Office of Vaccine Review and Research (OVRR), Center for Biologics Evaluation and Research (CBER) of the US Food and Drug Administration (FDA) since August, 2006. I served as the Validation Manager until November 2007 and as the Quality Manager since July 2007. I was a faculty at the Albert Einstein College of Medicine, New York (1986-1992), and obtained his Ph.D. (1983) from Calcutta University, India. I published several original research papers and review articles in peer-reviewed journals and presented in several conferences.

Disclaimer: This presentation represents the tutor’s opinion and not the position of the FDA.

5:00  End of Day One

DAY TWO

8:30 – 10:00  GLP BIOANALYSIS

- Prerequisite and Requirements for GLP-Bioanalysis
- Establish GLP Bioanalytical Lab
- Develop Bioanalytical Methods
- Validate Bioanalytical Methods under GLP Regulations
- Perform GLP-Bioanalysis in regulated environment
- Course will present material from conducting GLP-bioanalysis in modern state of the art bioanalytical facility operating under industry highest standards and practices.
- Course participants will gain inside knowledge into working procedures of GLP-bioanalysis in support of IND-enabling and clinical studies and their impact on drug development program

Tutor: Eckhardt Schmidt, Ph.D., Principal Scientist, Clinical Pharmacology and DMPK, AstraZeneca Pharmaceuticals LP

Dr. Eckhardt Schmidt earned his Ph.D. in chemistry at Philipps University/Germany and attended Kansas and PennState University for postgraduate research. Dr. Schmidt has held senior scientist and managerial positions with contract research organizations and major pharmaceutical companies at Ricerca Biosciences, IVAX, Metabais Therapeutics and AstraZeneca. His proven track record of 13 years has provided a unique “hands-on” perspective on bioanalytical applications. He has been recognized by problem solving and extensive accomplishments in GLP Bioanalysis to support drug discovery efforts. Dr. Schmidt manages at AstraZeneca the GLP LC/MS/MS laboratory by developing and validating methods and overseeing bioanalysis to deliver nonclinical, in vitro and clinical studies. His work experience include dose-ranging, relative bioavailability and drug drug interaction studies on small molecules in a high-throughput environment.

10:00– 11:30 am Building a GLP Compliant Business from the Group up - Avoiding Common Pitfalls
Ray I. Nunnally, Ph.D., Invivometrics

11:30 – 11:45 Coffee Break

11:45 – 1:15 pm Current Trends in Bioanalytical Method Validation or Validation of Computerized Systems - A Risky Business?

- Current requirements/process: Method development/validation Setting up a method validation protocol Update on the “Crystal City” requirements Method transfer/revalidation - how to Current trends from the OECD or Primer on validation of computerized systems - requirements by the GLPs GAMP5, PIC/s and other guidelines Red Apple II - current concepts for validation of computerized systems FDA, 21 CFR Part 11 and the risk based approach

- The tutorial gives a comprehensive way an up-to date picture of method validation and validation of computerized systems in a GLP setting.

- Attendees will be able to implement and use the concepts and principles associated with bioanalytical method validation and validation of computerized systems in their own GLP environments.

Tutor: Wolfgang Seidel, Ph.D., MRQA, Head of QA DMPK, MSR Nonclinical Development, Merck KGaA

Dr. Seidel received his Ph.D. in food chemistry and has 8 years of experience in several QC/QA functions in the biotech/pharmaceutical industry Currently head of QA for the GLP test facility DMPK Merck KGaA Member of the BARQA, DGGF, GDCh and DGQ Speaker at various national/international CSV/GLP conferences.

1:15  End of Course
HOTEL INFORMATION

SAN FRANCISCO, CA
The Fairmont San Francisco Hotel
950 Mason Street
San Francisco, CA 94108
Tel: 415-772-5000 • Fax: 415-391-4833
Discounted Room Rate: $219 s/d
Discounted Reservation Cutoff: December 5, 2008

To reserve your hotel room please call the hotel directly and ask for the Cambridge Healthtech Institute group rate. Reservations made after the cut-off date or after the group room block has been filled (whichever comes first) will be accepted on a space-and-rate-availability basis. Rooms are limited, so please book early.

TRAVEL INFORMATION

Flight Discounts:
To receive a 5% or greater discount on all American Airline flights please use one of the following methods:
Call 1-800-433-1790 (authorization code A4819SS). Go online at www.aa.com (enter A4819SS in promotion discount box).
Contact our designated travel agent, Wendy Levine, at 1-800-336-5248 ext. 137.

Car Rental Discounts:
Special discount rentals have been established with AVIS for this conference. Please call AVIS directly at 800-331-1600 and reference Avis Worldwide Discount (AWD) Number J868190 or go to www.avis.com

GROUP DISCOUNTS AVAILABLE

Discounts will be deducted from total registration fees.
3-5 people from the same organization .................. 20% reduction
6-9 people from the same organization...............25% reduction
10 people and above ........................................30% reduction

Organizations wishing to register multiple employees, for any of the GLP course dates, please contact Rose LaRaia at 781-972-5444 or email rlaraia@healthtech.com to receive an invoice/pay by check.

SPONSORSHIP AND EXHIBIT OPPORTUNITIES

This is an outstanding opportunity to network with scientists needing to work according to GLP regulations. These scientists work in all segments of the research market including pharmaceutical, biotech, academic, and government.

The Cambridge Healthtech Institute offers an array of sponsorship packages and exhibit space for you to reach this targeted audience. Make a lasting impression as a thought leader by taking advantage of these marketing tools.

For additional information, please contact Angela Parsons by phone: 781-972-5467 or email: aparsons@healthtech.com

Media Partners

www.healthtech.com/GLP/overview.aspx
Yes! Register me for GLP Bioanalysis

REGISTRATION INFORMATION

Name
Job Title
Company
Address
City/State/Postal Code
Country
Telephone
Fax
Email*  

*Email is not a mandatory field. However, by excluding your email you will not receive notification about online access to pre-conference presenter materials, conference updates, networking opportunities and requested eNewsletters.

How would you prefer to receive notices from CHI: EMAIL: ☐ Yes ☐ No FAX: ☐ Yes ☐ No

PRICING INFORMATION

Fill out the appropriate pricing section for the course date/location you would like to attend:

<table>
<thead>
<tr>
<th>Commercial</th>
<th>Academic, Govt.</th>
<th>Hosp.-Related</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Register me for the January 7-8, 2009, San Francisco, CA GLP Course</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Early Registration Discount until October 17, 2008</td>
<td>$1295</td>
<td>$875</td>
</tr>
<tr>
<td>Advanced Registration Discount until December 5, 2008</td>
<td>$1445</td>
<td>$945</td>
</tr>
<tr>
<td>Registrations after December 5, 2008</td>
<td>$1645</td>
<td>$1045</td>
</tr>
</tbody>
</table>

☐ Please send information on exhibiting and opportunities to present workshops.

PAYMENT INFORMATION

☐ Enclosed is a check or money order payable to Cambridge Healthtech Institute, drawn on a U.S. bank, in U.S. currency.

☐ Invoice me, but reserve my space with credit card information listed below.

Invoices unpaid two weeks prior to conference will be billed to credit card at full registration rate. Invoices must be paid in full and checks received by the deadline date to retain registration discount. If you plan to register on site, please check with CHI beforehand for space availability.

☐ Please charge: ☐ AMEX (15 digits) ☐ Visa (13-16 digits) ☐ MasterCard (16 digits)

Card # Exp. Date

Cardholder
Signature

Cardholder’s Address (if different from above)

City/State/Postal Code

Country

Please refer to the Keycode below: