DIA-ACT-CST毒理学专题负责人研修班

中国 • 北京 • 新云南皇冠假日酒店
2010年10月18日 至 20日

组织委员会

William J. BROCK 博士
组委会主席，布洛克科技咨询公司

付立杰 博士
共同主席，中国毒理学会(CST)

Mary Ellen COSENZA 博士
阿目金制药

Kenneth A. HASTINGS 博士
赛诺菲-安万特

Barbara MOUNHO 博士
阿目金制药

授课专家

Carol AULETTA
美国毒理学院（ACT)理事长;
亨廷顿生命科学研究中心项目管理主任

付立杰 博士
中国毒理学会(CST)副理事长

Byungja MARCIANTE
美国FDA检察员，FDA上海办公室助理主任

Johnnie J. EIGHMY
科文斯(上海)公司病理学总监

Anthony L. KIORPES 博士
药明康德(苏州)有限公司执行总监，毒理学负责人

Kevin S. McDORMAN 博士
查士睿华病理学总经理

Suzanne WOLFORD 博士
科文斯公司毒理学专题负责人

DIA中国顾问委员会成员

金克文 博士
上海查士睿华生物医药科技有限公司总经理

Worldwide Headquarters
Drug Information Association, Inc.
800 Enterprise Road, Suite 200
Horsham, PA 19044, USA
Regional Offices
Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China

近年来，随着国际上服务外包的发展趋势和中国经济的快速发展，以及人们对化学品健康危害关注的日益增加，中国越来越迫切地需要更多的专题负责人熟悉并按照国际规范进行药品、农药,工业和日用化学品的毒性试验研究和安全性评价。本研修班旨在使参加者全面详细了解如何严格按照国际规范和经验，指导、实施和监督毒理学的实验研究研究。内容包括GLP规范，试验设计和试验方案的撰写，剂量设计和动物种属选择,实验实施与结果评价,临床病理学与病理学评价，研究报告起草与撰写等等。

本研修班的主要对象是直接从事毒理学试验研究的专业人员，包括专题负责人、QA、机构负责人以及其他研究人员，也适合于其它包括医药、农药、食品添加剂、生物制品、工业和日用化学品等行业的研发管理人员，临床试验安全评价，以及从事上述健康相关产品与环境危害管理的人员。

本次研习班将提供同传服务
参会者均可获得由DIA、ACT、CST联合出具的结业证书

www.diahome.org

第一天　星期一 10月18日

7:30 – 8:30 注册

8:30 –12:00 （茶歇：10:00 - 10:15）

A. 研修班简介/专题负责人的角色与作用（即:GLP法规对专题负责人的定义）
主讲人：**付立杰**

B. GLP法规就专题负责人,管理 及质检的概况
主讲人：**付立杰**

C. 研究方案的撰写、修改、偏差及保存
主讲人：**Carol AULETTA**

12:00 –13:00 午餐

13:00 –17:00（茶歇：15:00 –15:15）

D. 研究前准备–课题要求与技术考虑
主讲人：**Carol AULETTA**

E. 研究课题的实施–研究的督导与管理
主讲人：**Carol AULETTA**

F. 课题分包–多场所研究及其特别考虑
主讲人：**Suzanne WOLFORD**

成果

第二天　星期二 10月19日

8:30 –12:00 （茶歇：10:00 –10:15）

G. 临床检验–研究终点与测定
主讲人：**Kevin S. McDORMAN**

H. 病理学尸解与肉眼病变检查
主讲人：**Johnnie J. EIGHMY**

I. 病理学:组织病理学
主讲人：**Johnnie J. EIGHMY**

12:00 –13:00 午餐

午餐会：12:00-13:00 讨论致癌性试验
Kevin S. McDORMAN，**Johnnie J. EIGHMY**

13:00 –17:00（茶歇：15:00 -15:15）

J. 毒物代谢动力学
主讲人：**Anthony L. KIORPES**

K. 暴露和影响的生物标记
主讲人：**Kevin S. McDORMAN**

L. 生物药毒性研究的特别考虑
主讲人：**Suzanne WOLFORD**

第三天　星期二 10月20日

8:30 –13:00 （茶歇：10:00 -10:15）

M. 研究报告的撰写与归档
主讲人：**Suzanne WOLFORD**

N. 规范检查
主讲人：**Byungja MARCIANTE**

O. 课题的外包与研究监督
主讲人：**Carol AULETTA**

12:00–13:00 午餐

13:00 –17:00（茶歇：15:00 -15:15）

P. 案例研究
1. 出现不可控制因素引起的问题时怎么办?
2. 参照物的污染控制
3. 隔开处理参照物–是否好的科学手段?
4. 动物的意外死亡
5. 灌饲之误
6. 剂量的制备和采样
7. 我在中国的个人经验

与专家进行现场讨论
主持人：付立杰

讲者简介

Carol **AULETTA**

卡罗尔•奥列塔女士从事毒理学研究已30多年。她拥有罗切斯特大学道格拉斯学院生物学学士学位及莱德大学MBA学位。奥列塔女士持有美国毒理学的资格(DABT)认证，并通过了医药法规(RAC)认证。

奥列塔女士在合同研究机构(CRO)任职多年，目前她在新泽西州的亨廷顿生命科学研究中心担任项目管理主任，此前她在该中心担任过多年的安全评价资深主管和研究主管。奥列塔女士发表过多部、多篇有关毒理学实验方法和实验毒理学的专著、文章。

她目前是美国毒理学院院长，她担任了2009年毒理学年会组委会主席及2005-2007年毒理学协会会员委员会会长.

奥列塔女士是中大西洋地区毒理学会前会长，也曾在毒理学会(SOT)的法规、安全性评估、皮肤科毒理学部门和妇女毒理学兴趣小组任职。同时她还是毒理学与药理学立法研究的国际学会会员。

奥列塔女士在ACT研究指导者培训讲座中担任过多年的讲师。奥列塔女士参与并主持了非传统实验动物毒理学讲座(ACT主办)，皮肤毒性讲座(SOT主办)以及ACT和SOT举办的多个学术和职业发展讲座。奥列塔女士在SOT多个委员会任过职，并热心于大众传播、科普和教育事业。

Johnnie J. **EIGHMY**

约翰•艾米博士分别于1977和1981年分别获得密苏里大学的硕士和兽医学学位。自兽医学校毕业之后，他曾在美国加利福尼亚州，华盛顿DC、及菲律宾服了10年兵役。服役期间，艾米博士接受了华盛顿区国防病理学院的兽医病理学培训。并于1989年获得了由美国病理学家学会颁发的证书。1995年，他又获得了美国毒理学会授予的证书。艾米博士拥有二十多年有关毒理学和病理学方面的研究经验，其大部分职业生涯致力于非临床研发。自1998年起，他担任全球非临床研发服务机构和研究组织——科文斯实验室的病理学家。他最近从美国乔迁至中国的上海科文斯实验室，同时担任毒理学和病理学家二职。从1991到1998年，在加入科文斯之前，艾米博士在密歇根Mattawan国际研发公司和毒理学研究服务中心担任毒理学、病理学主任等职务。

付立杰

付立杰博士是中国毒理学会副理事长，中国毒理学会资格认证委员会副主任兼秘书长，。曾先后担任Medicilon/MPI执行副总裁，药明康德新药开发有限公司(WuXi PharmaTech. NYSE:WX)运营副总裁，美国博际新药开发有限公司(Bridge Pharmaceuticals Inc.) 的全球一体化副总裁美国跨世纪公司股份有限公司总裁。

付博士在毒理学领域有30余年的丰富经验，在新产品开发、临床前研究和毒理学的不同领域中都有建树，并且在新药研究与开发、实验动物福利、GLP 规范和临床前合同研究机构的创建与运营等方面有着广泛全面的了解和直接经验，是世界卫生组织(WHO) GLP和化学物安全评价专家，国际实验动物评估认证管理委员会(AAALAC)咨询专家(*ad hoc* Specialist)，在如何建立和运营GLP合同研究实验室方面积累了丰富的经验。

付立杰博士编著(译)出版了《现代毒理学及其应用》《畸胎学》《生物技术世纪》等四本中文书，发表了大约70多篇中英文文章和书籍章节，其中《生物技术世纪》影响广泛，被列为中国人必读的100本书之一。他还担任“中国药理学与毒理学杂志”编委会顾问，中国毒理学会二届、三届和第四届理事，曾任中国旅美毒理学家首届理事长和美中毒理学会(AACT)理事，美中药协(SAPA)终身会员，中国济南海外学人联谊会名誉主席。

Anthony L. **KIORPES**

安东尼•吉奥尔佩斯博士是无锡AppTec（苏州）有限公司的执行董事和首席毒理学家。此前他曾担任过MGI制药公司的毒理学主任，Primedica公司的毒理学和病理学主任，也曾在位于威斯康辛麦迪逊的康文思公司担任资深研究员。在进入企业任职前，吉奥尔佩斯博士曾分别在堪萨斯州立大学和威斯康辛－麦迪逊大学担任过生理学和兽医内科学教授。 吉奥尔佩斯博士获哥伦比亚大学学士学位，威斯康辛麦迪逊大学的硕士和博士学位，堪萨斯州立大学兽医学博士学位，及阿肯色大学的MBA学位。他撰写了50多篇学术论文、摘要、专著章节，学科涉及兽医学、生理学和毒理学。他目前是明尼苏达大学毒理学兼职教授。

讲者简介 续

无照片

Byung-Ja MARCIANTE

马碧佳女士1989年就任美国食品药品管理局新泽西州地区办公室，后升任该地区办公室生物研究监控专家一职。她负责对医疗器械生产企业、临床和非临床检验机构进行检查，在美国国内及国外已经拥有超过15年的相关检查工作的经验。

马碧佳女士是多个课程顾问小组的成员，这些课程顾问小组负责为FDA的员工开发和开展培训课程。同时她也是几个专业组织的成员并在多个企业界专业会议上代表FDA发言。

2009年10月，马碧佳女士加入美国食品药品管理局局长办公室的国际项目，成为美国食品药品管理局在境外开设的办公室—驻华办公室8位美籍员工中的一员。作为高级助理主任及上海办公室的主要负责人，马碧佳女士负责驻上海办公室的相关事务。马碧佳女士目前不仅负责对企业进行检查，同时也参与相关教育培训活动，包括为中国政府监管部门及所监管的企业提供培训。

Kevin S. McDORMAN

凯文•麦东曼博士于2008年加入了位于美国内华达州的查士睿华临床前服务事务所并任病理学主管。目前他担任查士睿华病理学事务所总经理，其事务所总部位于美国马里兰州的弗雷德里克。在加入查士睿华事务所之前，他在Amgen药厂从事将近四年的病理学兽医工作，并在基因科技公司做过两年的科研人员兼病理学家，主要负责研发工作。参与过研发领域的各项工作，在期刊上发表过科学报告和监管评议等文章。凯文拥有兽医学博士学位及解剖学和毒性病理学等方面的专业训练，并荣膺北卡罗莱纳州立大学高级毒理学博士学位。他与环境保护局的环境致癌部门一道研究化学物的致癌作用。1999年他获得美国兽医病理工作者学会的专业医师资格。凯文活跃在联合专业协会，在美国兽医病理学及毒理病理学的众多委员会和工作组会上担任主席或委员职务。自2006年起他活跃在美国毒理学学会的研究培训课程班上并担任培训者。

Suzanne WOLFORD

苏姗•沃尔芙德博士是具有三十多年经验的毒理学者和药物发展顾问。自伊利诺斯州大学获得博士学位之后，她在美国氰胺公司(现在的辉瑞公司)荣膺科学家、组长和主管经理等职务。她并在美国依阿华州立大学的兽医医药学院从事过光毒性学的研究工作。她目前在位于威斯康辛州麦迪逊的科文斯实验室担任高级主管并在此从事研究咨询管理达十五年之久，她主持了两百多场有关毒理学的研究会以致力人类药物产品的研究。她编著了有关实验室动物临床病理学等相关论文。她是美国毒理学学会、社会毒理学以及美国毒理学学院成员。同时她也是美国毒理学学院奖学金委员会委员以及毒理学培训课程的讲师。

关于DIA（药物信息协会，以下简称DIA）

DIA是全球知名的涉及药物发现、药物开发、药事法规、监管及药品或相关药物产品市场开拓等领域的专业协会，在全球拥有超过1.8万人的会员。DIA致力于向其会员广泛传播最新的药物知识和信息并以推进专业实践与职业训练为目标。DIA作为一个经济独立的非营利性组织，通过举办会议培训和收取会员费自筹资金，并为其会员在全球提供一个不受任何组织或权力影响的中立的学习环境。DIA举办相关会议和培训时，只向会员收取一定的合理的会议费用，所有向会员提供的会议内容和专业文章均源于DIA会员及讲者的志愿服务。

DIA的使命

DIA推动创新以提高全人类的健康和幸福水平的途径包括：

- 召开重要论坛，交流重要信息并讨论与保健产品、技术和服务有关的最新问题；
- 分享专门性学习经验；
- 建立、维持和推动致力于实现DIA价值观和要求的个人、机构之间的信任关系；以及创造一个因诚信和相关性而在全球广受赞誉的跨学科中立环境。

DIA的愿景

DIA是一个全球性的知识交流论坛，旨在推动创新，以提高全人类的健康和幸福水平。

DIA 中国其他会议：

- **理解药物临床研究中的统计学思维第二期培训讲习班**
  2010年11月4-5日 中国 北京
- **临床项目管理培训讲习班**
  2011年初 中国 上海

欲了解更多DIA在中国地区的信息，敬请关注DIA China官方网站：www.diachina.org

www.diahome.org

关于ACT

美国毒理学院（ACT）是一个专业性学会，旨在加强毒理学领域科学信息交流促进毒理学学科的发展。

ACT的使命

ACT的使命是对行业、政府和学术界的专业人士进行教育、组织并为其提供服务，通过促进安全评价信息和观点的交流以及毒理学相关新研发成果的应用

ACT约有1,000名成员，他们积极投身于毒理学实践，代表了多个行业和领域（包括学术界、监管机构、制药业、环保、消费品、化工、CRO和咨询业等）。ACT以毒理学实践作为工作重点。ACT通过召开会议、开设培训课程和开展其他活动促进成员与受邀演讲人之间的交流，并为成员提供了与新研发成果、最新监管动态和各种学术观点接触的机会。

ACT是一家财务上独立的非营利性机构，资金来源包括会议、培训课程和会费。我们的演讲人、培训讲师和工作委员会成员来自致力于实现本学会使命的广大志愿者。演讲人和课程组织者由我们的成员担任，他们通过免费共享自己的专业知识使ACT以最低的支出实现优质服务。

每一届ACT年会都会吸引700位以上与会者，成为与同业人士会晤、交流信息和观点并探讨毒理学领域新研发成果的重要场合。ACT开辟了继续教育课程的概念，并有在年会上开设专题负责人培训课程的悠久历史。这项课程现已与DIA和合作在中国开设。今年，这项课程已扩展为一周课程，即“工业与管理毒理学课程”。ACT与美国毒理病理学会（STP）长期合作并开设一系列针对毒理学家的病理学课程。ACT也是国际毒理学联合会（IUTOX）的成员之一。近年来，ACT组织了关于毒理学最新课题的一系列网络研讨会。ACT主办的《国际毒理学杂志》是一本广受欢迎的权威性综合性杂志。

如需进一步了解ACT，请访问我们的网站：
www.actox.org。

关于CST

中国毒理学会(CST)是隶属于中国科学技术协会的国家一级学会，成立于1993年，旨在满足毒理学各领域专业人士相互交流，促进毒理学在中国的发展，为中国经济与社会的可持续发展，保护人类健康和生态环境发挥应有的作用。

过去15年来，本学会得以迅速发展，目前已有21个专业委员会、5个地方学会，4,500多位会员遍布于高等院校和科院院所、与健康有关产品的企业、以及政府管理部门，已成为中国主要科学学会之一。

学会的领导机构是理事会，常务理事会作为本学会的领导机构，均定期选举产生；学会办公室设在北京，负责本协会的日常事务。理事会现任理事长为庄志雄博士、副理事长兼秘书长为周平坤博士。

详情请见：www.chntox.org 或致电学会办公室：01068183899

Joint DIA-ACT-CST Toxicology Study Director Workshop

18-20 October, 2010

Crowne Plaza Sun Palace Beijing | Beijing, China

PROGRAM COMMITTEE

William J. BROCK, PhD, DABT, Fellow ATS
Program Chair and Organizer,
Brock Scientific Consulting

Li-jie FU, PhD
On-Site Program Chair, Chinese Society of Toxicology

Mary Ellen COSENZA, PhD, DABT
Executive Director, Amgen

Kenneth A. HASTINGS, DrPH, DABT, Fellow ATS
Associate Vice-President, Regulatory Affairs
sanofi-aventis

Barbara MOUNHO, PhD, PhD, DABT
Toxicologist Research Scientist, Amgen

FACULTY

Carol AULETTA, DABT
President, American College of Toxicology;
Director of Program Management,
Huntingdon Life Sciences

Li-jie Fu, PhD
Vice President, Chinese Society of Toxicology

Byungja MARCIANTE
Investigator / Assistant Director
US - FDA Shanghai Office

Johnnie J. EIGHMY, DVM, MS, DACVP, DABT
Director, Pathology, Covance Pharmaceutical R & D
(Shanghai) Co., Ltd.

Anthony L. KIORPES, PhD, DVM, DABT
Executive Director and Head of Toxicology,
WuXi AppTec (Suzhou) Co., Ltd

Kevin S. McDORMAN, DVM, PhD, DACVP
General Manager, Charles River Pathology Associates

Suzanne WOLFORD, PhD, DABT
Study Director - Toxicology, Covance Inc.

DIA-CHINA ADVISORY COUNCIL MEMBER

Kewen JIN, PhD
General Manager, Charles River Preclinical Services, China

Worldwide Headquarters
Drug Information Association, Inc.
800 Enterprise Road, Suite 200
Horsham, PA 19044, USA

Regional Offices
Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China

There has been rapid growth in outsourcing and the contract research organization (CRO) industry over the last several years with much of that growth occurring in China. There is an increasing demand for trained professional and technical staffs in China to conduct of toxicology and safety studies necessary to meet the regulatory requirements for pharmaceuticals, food additives, pesticides, industrial and environmental chemicals, etc. Therefore, the industrial sectors have been hesitant to place studies in China in spite of the generally lower costs for conducting studies in China. This workshop will provide attendees with the details of conducting, supervising and monitoring toxicology studies in an ever-increasing stringent regulatory environment. The content of this workshop is provided in the tentative outline but the course will include topics on Good Laboratory Practice regulations, study protocol development, species selection, in-life study evaluations, pathology and clinical pathology evaluations, study monitoring, report writing etc.

Although this workshop is directed towards toxicologists and related professional in toxicological testing laboratories, this course would be valuable to a broad range of nonclinical, clinical, management and regulatory personnel in pharmaceutical, medical device, biotechnology, food additives, agricultural, commodity chemical and other industrial sector companies. Regulatory and managerial personnel will gain a thorough working knowledge of preclinical development to facilitate planning, project management and creation of efficient development and regulatory strategies.

Simultaneous translation will be available.

Participants will receive a Certificate of Attendance, issued by DIA, ACT, and CST, upon completion of this workshop.

Jointly organized by:

www.diahome.org

DAY 1 | MONDAY, OCTOBER 18

7:30 – 8:30 REGISTRATION

8:30 – 12:00 SESSION 1 (BREAK: 10:00 – 10:15)

A. Introduction to Course/Basics of Study Director Role (i.e. What is the Definition of a Study Director per GLP Regulations)

Li-jie FU
Chinese Society of Toxicology

B. History of GLP Regulations as they Apply to the Study Director Role, Management, and QA

Li-jie FU
Chinese Society of Toxicology

C. The Protocol - Development, Amendments, Deviations and Maintenance

Carol AULETTA
American College of Toxicology

12:00 – 13:00 LUNCH BREAK

13:00 – 17:00 SESSION 2 (BREAK: 15:00 – 15:15)

D. Pre-Study Preparation – Study Requirements, Technical Considerations

Carol AULETTA
American College of Toxicology

E. Study Conduct – Study Director Oversight and Study Management

Carol AULETTA
American College of Toxicology

F. Sub-Contracting – Multi-site Studies – Special Considerations

Suzanne WOLFORD
Covance Inc.

17:30 – 19:00 NETWORKING RECEPTION

DAY 2 | TUESDAY, OCTOBER 19

8:30 – 12:00 SESSION 1 (BREAK: 10:00 – 10:15)

G. Clinical Pathology – Endpoints and Measurement

Kevin S. McDORMAN
Charles River Pathology Associates

H. Pathology: Necropsy and Gross Pathology

Johnnie J. EIGHMY
Covance Pharmaceutical R&D (Shanghai) Co., Ltd

I. Pathology: Histopathology

Johnnie J. EIGHMY
Covance Pharmaceutical R&D (Shanghai) Co., Ltd

12:00 – 13:00 LUNCH BREAK

Lunch Talk on Carcinogenicity

Kevin S. McDORMAN
Johnnie J. EIGHMY

13:00 – 17:00 SESSION 2 (BREAK: 15:00 – 15:15)

J. Toxicokinetics

Anthony L. KIORPES
WuXi AppTec (Suzhou) Co., Ltd

K. Biomarkers of Exposure and Effect

Kevin S. McDORMAN
Charles River Pathology Associates

L. Special Considerations for Biopharmaceuticals

Suzanne WOLFORD
Covance Inc.

DAY 3 | WEDNESDAY, OCTOBER 20

8:30 – 12:00 SESSION 1 (BREAK: 10:00 – 10:15)

M. Report Writing/Archiving

Suzanne WOLFORD
Covance Inc.

N. Regulatory Inspections

Byungja MARCIANTE
US FDA

O. Study Monitoring

Carol AULETTA
American College of Toxicology

12:00 – 13:00 LUNCH BREAK

13:00 – 17:00 SESSION 2 (BREAK: 15:00 – 15:15)

P. Case Studies

a. What to do when things go wrong! Acts of God
b. Contamination of Control samples
c. Controls in a separate room – is this good science?
d. Unexpected mortality
e. Gavage errors
f. Dose preparation and sampling
g. Pathology background incidence
h. Personal experience in China

Panel Discussion with All Speakers

Panel Chair:
Li-jie FU
Chinese Society of Toxicology

17:00 ADJOURN

ABOUT THE SPEAKERS

Carol AULETTA

Carol Auletta has worked in toxicology research in the CRO industry for over 30 years and is currently Director of Program Management at Huntingdon Life Sciences in the US. She received a BA in Biological Sciences from Douglass College (Rutgers University) and an MBA degree from Rider University. She is board certified by the American Board of Toxicology (DABT) and is also certified in Regulatory Affairs (RAC).

She is currently President of the American College of Toxicology and chaired the Program Committee for the 2009 annual meeting and the Membership Committee from 2005 to 2007. She is a past president of the Mid-Atlantic Society of Toxicology, the Regulatory and Safety Evaluation and Dermal Toxicology Specialty Sections and the Women in Toxicology Special Interest Group of the Society of Toxicology (SOT). She is also a board member of the International Society of Regulatory Pharmacology and Toxicology.

Carol has been a speaker for the ACT Study Director Training course for several years. She has co-chaired continuing education courses on non traditional animal models in toxicology (ACT) and in cutaneous toxicity (SOT) and has participated in other scientific and career-development courses and symposia at both ACT and SOT meetings. She has served on several SOT committees and has a strong interest in public communication, mentoring and education.

Johnnie J. EIGHMY

Dr. John Eighmy received his MS (1977) and DVM (1981) degrees from the University of Missouri. After graduating from veterinary school, he completed over 10 years of military service with assignments in California, the Republic of the Philippines, and the Washington, D.C. area. While on active duty, Dr. Eighmy received his veterinary pathology training at the Armed Forces Institute of Pathology in Washington, D.C., and he became board-certified in anatomic pathology by the American College of Veterinary Pathologists in 1989. In 1995, he was also awarded Diplomate status by the American Board of Toxicology.

Dr. Eighmy has over 20 years of experience in toxicology and pathology and has spent most of his career working in the contract research industry. He has been a pathologist at Covance Laboratories, a global contract research organization, since 1998. He recently relocated from the US to an assignment at Covance China's laboratory facility in Shanghai where he is employed as both a toxicologist and pathologist. Prior to joining Covance, from 1991-1998, Dr. Eighmy was a toxicologic pathologist and department director at International Research and Development Corporation and MPI Research in Mattawan, Michigan.

Li-jie FU

Dr. Li-jie Fu was the Executive Vice President Medicilon/MPI Pre-Clinical Research, Vice President of Operations at WuXi PharmaTech and Head of the SuZhou PharmaTech Operations. Dr. Fu has been active in the field of toxicology for more than twenty-nine (29) years, has a wealth of experience in the operations of a CRO, and possesses a sound knowledge of GLP regulations and practices. Prior to joining WuXi PharmaTech, Dr. Fu was a Vice President of Global Integration of Bridge Pharmaceuticals, a US based CRO with operations in China. Before Bridge Pharmaceuticals, Dr. Fu was President and CEO of Next Century Incorporated, a fully compliant GLP laboratory he founded in 1994. Dr. Fu received his GLP and animal welfare training and experience in the late 1980's at the DuPont Companies' Industrial Toxicology Laboratory (Haskell Laboratories) where he was a Visiting Scientist and Study Director. In addition, Dr. Fu has given presentations on GLPs and animal welfare to the scientific community in China as early as 1996. He was also hired by WHO as an expert to train regulators and professionals in China on Safety Evaluation and GLP Regulations, and Dr. Fu was appointed by AAALAC as an ad hoc specialist. During this period, he also provided advice to several Chinese National Centers on US GLP and AAALAC accreditation, and learned the setup of Chinese GLP and its practice in the process.

Dr. Fu is a former President and member of the Board of Directors of the American Chinese Society of Toxicology (ACST), a current Vice President of the Chinese Society of Toxicology (CST, 2009-2013) in charge of International Affairs, and Vice-Chair and Secretary General of CST Certification Committee for Toxicologist (2010-2012).

Anthony L. KIORPES

Anthony L. (Andy) Kiorpes is the Executive Director and Head of Toxicology at WuXi AppTec (Suzhou) Co., Ltd.

Former Industry positions included Director of Toxicology at MGI Pharma, Inc., Director of Toxicology and Pathology at Primedica Inc, and senior study director at Hazleton (Covance) in Madison, WI. He is a 1994 diplomate of the American Board of Toxicology and holds current veterinary licenses in two states (Wisconsin and Arkansas).

Prior to his career in industry, Andy was a professor at Kansas State University (physiology) and the University of Wisconsin-Madison (veterinary internal medicine). He holds degrees from Columbia University (BA), the University of Wisconsin-Madison (MS, PhD), Kansas State University (DVM), and the University of Arkansas at Little Rock (MBA). He is the author of over 50 scientific articles, abstracts, and book chapters in veterinary medicine, physiology, and toxicology. He is currently an Adjunct Professor of Toxicology at the University of Minnesota.

ABOUT THE SPEAKERS *(continued)*

No Picture Available

Byung-Ja MARCIANTE

Miss. Marciante joined the US FDA's New Jersey District in 1989, and was promoted to the position of the District BioResearch Monitoring Specialist. Miss. Marciante's responsibilities included conducting inspections of medical device manufacturers, clinical and non-clinical testing facilities. Miss. Marciante has conducted these inspections domestically and internationally for over 15 years.

Miss. Marciante is member of several course advisory groups responsible for developing and executing training curriculum for FDA employees, member of several professional organizations and has spoken to many industry conferences.

October 2009, Miss. Marciante joined the Office of the Commissioner's Office of International Programs, becoming a team of eight FDA employees who opened the first FDA office outside of the United States, in China. Miss. Marciante, as the Senior Assistant Director and Section Chief for this Shanghai Post is the primary contact person for the Department of State. Miss. Marciante's responsibility includes not only conducting inspections, but she is also involved with outreach activities, providing training to Chinese regulatory authorities, and the regulated industries in China.

Kevin S. McDORMAN

Kevin McDorman joined Charles River Preclinical Services, NV, USA as Director of Pathology in 2008. He is currently the General Manager of Charles River Pathology Associates headquartered in Frederick, MD, USA. Prior to joining Charles River, Kevin spent nearly 4 years as a Veterinary Pathologist at Amgen and 2 years as a Scientist/Pathologist at Genentech where he held various positions in both research and development sciences. While at Amgen and Genentech, Kevin was active in drug development team activities and contributed to several journal publications, scientific presentations and regulatory submissions. Kevin is a DVM, has specialty training in Anatomic and Toxicologic Pathology, and earned an advanced degree in Toxicology (PhD) at the University of North Carolina at Chapel Hill, where he studied chemical carcinogenesis with the Environmental Carcinogenesis Division of the Environmental Protection Agency. He has been a Diplomate of the American College of Veterinary Pathologists (ACVP) since 1999. He is active in allied professional societies and has served as chair and/or member on numerous committees and working groups for the ACVP and the Society of Toxicologic Pathology (STP). He has also been an active speaker participant for several American College of Toxicology (ACT) Study Director Training courses since 2006.

Suzanne WOLFORD

Dr. Wolford has 30 years of experience as a Toxicologist and Drug Development Consultant. After receiving her PhD from the University of Illinois, she worked as a Scientist, Group Leader, Study Director and Manager at the American Cyanamid Company (now Wyeth/Pfizer). She also conducted research in phototoxicity at the School of Veterinary Medicine at Iowa State University. Currently she is a Senior Study Director at Covance Laboratories in Madison, Wisconsin where she has worked for 15 years in study direction and consulting. She has served as Study Director on over 200 toxicology studies in support of human pharmaceutical products. She has authored nine papers, including several articles on normal ranges for clinical pathology of laboratory animals. She is a Diplomate of the American Board of Toxicology and a member of the Society of Toxicology and the American College of Toxicology (ACT). She has served ACT as a member of the Awards and Finance Committees, as a Councilor, and as a lecturer at the Study Director training course.

ABOUT DIA

DIA is a professional association of more than 18,000 members worldwide who are involved in the discovery, development, regulation, surveillance, or marketing of pharmaceuticals or related products.

DIA is committed to the broad dissemination of information among its members, with continuously improved professional practice as the goal. DIA serves its members in a neutral, global environment that operates independent of the influence of any one organization or authority.

DIA operates as a financially independent nonprofit organization that funds itself from meeting and membership fees. The voluntary efforts of DIA members and speakers allow DIA to provide programs and publications to members at a reasonable, competitive cost.

DIA Mission
DIA fosters innovation to improve health and well being worldwide by:

- Providing invaluable forums to exchange vital information and discuss current issues related to health products, technologies, and services;
- Delivering customized learning experiences;
- Building, maintaining, and facilitating trusted relationships with and among individuals and organizations that drive and share DIA values and mandates; and
- Offering a multidisciplinary neutral environment, respected globally for integrity and relevancy.

DIA Vision
DIA is the global forum for knowledge exchange that fosters innovation to raise the level of health and well-being worldwide.

UPCOMING DIA MEETINGS

- **2nd Training Workshop in China – Understanding the Statistical Thinking in Clinical Research for Drug Development**
  4-5 November 2010, Beijing, China
- **Clinical Project Management Workshop**
  Early 2011, Shanghai, China

www.diahome.org

For more information about DIA activities in China, Please visit our regional website: www.diachina.org

ABOUT ACT

The American College of Toxicology (ACT) is a professional society dedicated to providing an interactive forum for the advancement and exchange of scientific information in the field of toxicology.

ACT Mission: The mission of the ACT is to educate, lead and serve professionals in industry, government and academia by promoting the exchange of information and perspectives on safety assessment and the application of new developments related to toxicology.

ACT has approximately 1000 members who are actively involved in the practice of toxicology and represent a wide variety of interests and industries (academic, regulatory, pharmaceutical, environmental, consumer product, chemical, CRO, consulting). ACT focuses on the practice of toxicology. ACT presents meetings, courses and other events designed to facilitate interaction among members and invited speakers and to provide access to new developments, regulatory updates and a diversity of view points.

ACT operates as a financially independent, and financially stable, nonprofit organization funded by meeting, course and membership fees. A large base of volunteers provides speakers, instructors and working Board members committed to achieving the mission of the College. Our members serve as speakers and course organizers and freely share their expertise to provide high-quality offerings at minimal expense to ACT.

ACT's Annual Meeting attracts more than 700 participants and serves as a place to meet colleagues, exchange information and ideas and explore new developments in the field of toxicology. ACT pioneered the concept of continuing education courses and has a long history of presenting a Study Director Training course at its annual meeting. This course is now being presented in China in collaboration with DIA and CST. It was also expanded this year to a highly successful week-long course, Toxicology for Industrial and Regulatory Scientists. ACT collaborates regularly with the Society for Toxicologic Pathology (STP) and has presented a series of courses on Pathology for Toxicologists. ACT is also active in IUTOX. It has recently inaugurated a series of webinars on current topics in toxicology, The ACT journal, International Journal of Toxicology, is comprehensive, well-respected and widely read.

For more information about ACT, please visit our website: www.actox.org.

ABOUT CST

The Chinese Society of Toxicology (CST) was established in 1993 in response to the need of communication and sharing ideas among professionals from different areas of toxicology. The mission of the Society is to play a leading role in the advancement of toxicological science in China, and to promote the study and application of toxicology in all aspects.

During the past 15 years, the CST, with 21 Speciality Sections, 5 Regional Chapters, and more than 4500 members from academia, industries, and governmental sectors, has become one of the major scientific societies in China.

The CST is governed by elected Council which representing diverse professionals and scientific disciplines of toxicology, and managed by an administrative office in Beijing. The Council is currently led by Dr. Zhixiong Zhuang, the President of the Society and the Secretary General, Dr. Pingkun Zhou.

The CST has grown rapidly in recent years and will continue to make great contributions to the toxicology society in China and the world.

For more Information about CST, please visit our website at www.chntox.org.

Block Code X39
Oct. 18 – 21, 2010 Beijing, China

CROWNE PLAZA
SUN PALACE BEIJING
北京新云南皇冠假日酒店

PLEASE REGISTER ONLINE HERE

Reservation/Confirmation 预订确认

Confirmation No 确认号: _____

公司名称/Company: _____ 日期/Date: _____

联系人/Booker: _____ 传真/Fax: _____ 电话/Tel: _____

MR/MS 先生/女士	Surname 姓	First Name 名			PC NO 优悦会卡号.	
Date of Arrival 到店日期		Date of Departure 离店日期			Nationality 国籍	
Room type	King 大床	Twin 双床	Smoke 吸烟	Non - Smoke 不吸烟	Rate (Per room night) 价格(每间夜)	Remark 备注
Superior Room 高级间					RMB800.00net 人民币 800 元净价	
Deluxe Room 豪华间						
Executive Room 行政间					RMB1200.00net 人民币 1200 元净价	
Executive Suite 行政套间					RMB1800.00net 人民币 1800 元净价	
Arrival Time 到店时间		Flights Details 航班号			Extra Bed ☐ 加床 RMB350.00 净价	Baby Cot ☐ 婴儿床

备注 Notices:
- All above room rates are based on per room per night and include in 15% service charge.
以上房价均包含 15%服务费。
- Cut off date for booking is Oct. 15, 2010.
请于 10 月 15 日前预定
- All above room rates are including 1 or 2 American Buffet breakfast at designated venue. RMB98net will be charged as extra breakfast fee.
以上价格均包含 1 份或 2 份自助早餐，如需额外早餐，酒店将加收人民币 98.00 净价/位.
- Rate for in-room high speed internet access at RMB120 net or 24 hours or at RMB3.00 net per minute.
房间内高速上网费用为人民币 3.00 元净价/分钟，人民币 120.00 元净价/天。
- The offer rate only use for the period of this event.
上述房价只适用于本次活动内的时间。

付款方式 Payment 公司 Company A/C: ☐ 客人自付 Guest(s) A/C: ☐ 付款备注 Payment Remark

Guarantee ☐ 不需要 No ☐ 公司担保 By Company:
担保方式 ☐ 信用卡/卡号 Yes: By Credit Card No: / /

用车服务 Limousine Service: ☐ 接机 Pick Up ☐ 送机 Drop Off ☐ 接送机 Two Way
航班号 / Flight Number: _____ 人数 / PAX: _____
☐ Audi A6 (RMB480.00 per one way) ☐ Mercedes Benz (RMB900.00 per one way)
☐ Buick GL8 (RMB600.00 per one way)

特殊需要 Special Request:

备注 Notices:
- Bookings will be released after 6pm on arrival day if not guaranteed. The AMEX, Visa, Master, Diners Club and JCB card can be accepted for guarantee.
除非信用卡或公司担保，否则预订将保留至当晚 6 点，6 点以后不予保留. 如担保预订取消需当晚 6 点之前通知酒店，否则将收取一晚房费. 酒店接受美国运通卡/维萨卡/万事达卡/大来卡/日本 JCB 卡

Please kindly fill out the form and send it back to the hotel. We will confirm the room according to the availability of the hotel.
请填写完此表格后，根据以下联系方式返回酒店. 根据酒店的可用房间数量进行预定房间的确认。

Reservation Center
预定中心

Crowne Plaza Sun Palace Beijing
北京新云南皇冠假日酒店
No. 12 Qisheng Middle Street North-East 3rd Ring Road.
东北三环七圣中街 12 号
Chaoyang District, Beijing 朝阳区,北京 100028

Tel 电话 (86 10) 6429 8888
Fax 传真 (86 10) 6452 1889
E-mail邮件 reservation@cpsunpalace.cn

DIA-ACT-CST毒理专题负责人研修班

会议编码：#10980， 2010年10月18–20日

会议举办场所：

新云南皇冠假日酒店
北京市朝阳区东北三环七圣中街12号云南大厦
Tel: (86) 10 62398888
Fax: (86) 10 64521889

联系方式：

会议咨询：请与刘丹女士联系

DIA China
北京市朝阳区东三环北路霞光里18号佳程广场A座11层1177室，100027
电话：+86 10 5923 1109 传真：+86 10 5923 1090
E-mail: dia@diachina.org

取消注册： 须在2010年10月8日前（含10月8日）

取消注册必须进行书面确认，并确保DIA中国联络处于2010年10月8日之前收到确认。参会注册者如逾期未取消或未参加培训，则注册费不予退还 ，并应自行取消住宿预订及差旅订票等。
如取消注册，将扣除手续费如下：
会员/非会员：RMB500

▸ 同意取消注册条款，请在下方横线处签名

参会代表签名 _____

在线注册截止至2010年10月13日
可登录www.diachina.org，或 点击此处

会议注册费

含茶歇、午餐及会议资料

培训班注册费	非会员价	会员价
提前注册(7月5日– 9月17日)	RMB2780 ☐	RMB2500 ☐
标准价格(9月18日–10月13日)	RMB3080 ☐	RMB2800 ☐
现场注册(10月14日–10月20日)	RMB3380 ☐	RMB3100 ☐

* 提前注册价格优惠截止9月17日。

现在就加入DIA只需880元， 即享受会员优惠	会员费
立即加入DIA吧！	RMB880 ☐

同时提交会议注册表及会员申请表并付款，即可享受会员优惠。

其他优惠	非会员价	会员价
政府机构(全职人员)	RMB2080 ☐	RMB1800 ☐
非营利组织/学术机构(全职人员)	RMB2580 ☐	RMB2300 ☐

* 2010年10月13日后只接受现场注册。

☐ 索取发票
请发送电子邮件至qi.tan@diachina.org或传真至
+86 10 5923 1090
收件人：谭祺 先生
在收到您的全部款项后，我们会将发票邮寄给您。

* 汇率以中国人民银行当日外汇牌价为准.

付款方式 请注明您的付款方式。

☐ 银行汇款

请即付人民币_____ 会议编码 #10981
银行帐号： 803020296408091001
开 户 行： 中国银行北京建国门外支行
银行地址： 北京市朝阳区建国门外大街24号
收 款 人： 科伦管理咨询（北京）有限公司
SWIFT ： BKCH CN BJ 110
(请确保全额注册费到帐)

☐ 信用卡支付：

持卡人姓名_____
发卡行_____ 信用卡到期日_____
卡号_____ 安全码_____
☐ 维萨卡 ☐ 万事达卡 ☐ 其它卡 持卡人签名_____

* 目前不接受招商银行卡、美国运通卡和大莱卡支付。

团体注册优惠：同一家企业四人同时报名，其中一个人可以享受免费优惠。**所有四人必须同时注册并同时提前付费，均无例外**。DIA将给予第四人最优惠的待遇，但是其他项目及会员费不在享受优惠。如需更换参会人员，则替代人员与被更换人员属于同一注册类型。**团体注册不可在线登记，同时不适用于政府、非盈利组织/学术机构的全职人员等**。

▸ **为了能正确使用本优惠，团体注册的四人没人均需正确完整地填写一张注册表，并发送电子邮件至dia@diachina.org或邮寄/传真至我处**

请核对使用类型 ☐ 学术机构 ☐ 政府机构 ☐ 制药企业 ☐ CRO

请填写下表并保持字迹清晰

姓 _____ 名 _____ 职位 _____ 性别： ☐ 先生 ☐ 女士

单位（公司）名称 _____

中文地址（请注明地址以便今后能正确邮寄）_____

英文地址 _____ ☐ 公司地址 ☐ 家庭地址

省份及城市_____ 国家 _____ 邮政编码_____

电话 _____ 传真 _____ 手机 _____

电子邮件（以便通过电子邮件发送确认） _____

如果您传真或邮寄报名表，请提供您的名片或名片复印件。

科伦管理咨询（北京）有限公司在中国境内代表DIA， 并在中国境内为DIA会员提供服务。

Joint DIA-ACT-CST Toxicology Study Director Workshop

Meeting I.D. # 10980 – October 18-20, 2010

Crowne Plaza Sun Palace Beijing, Beijing, CHINA

LOCATION AND VENUE

Crowne Plaza Sun Palace Beijing, Beijing, China, No. 12 Qisheng Middle Street, North-East 3rd Ring Road, Yunnan Dasha, Chaoyang District, Beijing, 100028, P.R. China. The closest airport to this hotel is Beijing Capital International Airport.

CONTACT INFORMATION

For general inquiries and registration, contact Ms. Stephanie Liu at dia@diachina.org.

Drug Information Association, China office: 11F/1177, Block A, Gateway Plaza, No.18, XiaGuangLi, North Road East 3rd Ring, Chaoyang District, Beijing 100027, P. R. China, Tel: +86-10-59231109 Fax: +86-10-59231090, www.diahome.org, dia@diachina.org

CANCELLATION POLICY: On or before OCTOBER 8, 2010

Cancellations must be made in writing and received by October 8, 2010 in order to receive a full refund minus the administrative fee of **DIA Member = RMB 500 Nonmember = RMB 500,** before the cancellation date. Registrants who do not cancel in writing by the deadline date and do not attend the event will be responsible for paying the full registration fee. Registrants are also responsible for cancelling their own hotel and airline reservations. DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any air-fare, hotel or other costs incurred by registrants.

▶ **I agree with the terms of the cancellation policy.**

Signature Participant _____

Online Registration will be available from 5 July-13 October 2010, on www.diachina.org. *Click here* to register online.

REGISTRATION FEES FOR CONFERENCE

Registration fee includes refreshment breaks, luncheons, and will be accepted by mail, fax, or eMail.

	NONMEMBER	DIA MEMBER
Industry Early-bird* (5 July-17 September)	RMB 2,780 ❑	RMB 2,500 ❑
Industry Standard (18 September-13 October)	RMB 3,080 ❑	RMB 2,800 ❑
Industry Onsite (14-20 October)	RMB 3,380 ❑	RMB 3,100 ❑

** Early Bird Closes 17 September 2010*

Join DIA now to qualify for the member discount (click here)!

To qualify for the member discount, please submit both the Registration Form and Membership Application accompanied by proof of payment.

MEMBERSHIP
RMB 880 ❑

Discount Fees	NONMEMBER	DIA MEMBER
Government (Full-time)	RMB 2,080 ❑	RMB 1,800 ❑
Charitable Nonprofit/Academia (Full-time)	RMB 2,580 ❑	RMB 2,300 ❑

• AFTER 13 OCTOBER 2010, ONLY ONSITE REGISTRATION WILL BE ACCEPTED.

❑ **REQUEST CHINESE OFFICIAL INVOICE (FA PIAO)**

Please complete the invoice request form and send it to the attention of Mr. Tan to qi.tan@diachina.org or fax to +86-10 59231090. After we confirm your payment, the invoice will be mailed to you.

**** Payment in other currencies will be subject to the financial institution's exchange rate.***

PAYMENT OPTIONS Please indicate payment method.

❑ **BANK TRANSFER**

Payment in the amount of RMB _____**Meeting I.D. #10980**

Bank Account: 803020296408091001

Bank Name: Bank of China Beijing Jianguomenwai Sub-branch

Bank Address: No. 24 Jianguomenwai Street, Chaoyang District Beijing, 100004, China.

Payee: KELLEN MANAGEMENT AND CONSULTING (BEIJING) CO., LTD.

SWIFT Code: BKCH CN BJ 110

Bank commission fee should be paid by the registrant.

❑ **CREDIT CARD PAYMENTS BY:**

Cardholder Name _____

Card Issue Bank_____Exp. Date (mm/yyyy)_____

Card #_____ Security Code_____

❑ Visa ❑ Master Card ❑ Other Signature _____

* Kindly note that China Merchant Bank, AMEX and Diners cards are currently not accepted.

GROUP DISCOUNTS

Register 3 individuals from the same company and receive complimentary registration for a 4th! **All 4 individuals must register and prepay at the same time—no exceptions.** DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. **Group registration is not available online add does not apply to the already-discounted fees for government or charitable nonprofit/academia.**

***To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the name of all four group registrants on each of the forms and return them together to DIA China by email to dia@diachina.org or mail or fax to the address above.**

Please check the applicable category: ❑ Academia ❑ Government ❑ Industry ❑ CRO

PLEASE PRINT ALL INFORMATION CLEARLY

Last Name First Name M.I. Full Name in Chinese (If applicable) *Please check one:* ❑ Mr. ❑ Ms.

Job Title Affiliation (Company) ❑ Business Address ❑ Home Address

Address (Please write your address in the format required for delivery to your country.) City Postal Country

Address in Chinese (If applicable)

Telephone Number Fax Number Mobile Number

email (Required for confirmation)

IF FAXING OR MAILING THIS FORM, PLEASE PROVIDE A COPY OF REGISTRANT'S BUSINESS CARD.

Kellen Management and Consulting (Beijing) Co., Ltd. represents DIA in China and provides services.