CTD格式申报——要求与实践

2012年3月14-16日
中国 · 北京

授课专家

Fritz Erni 博士
欧盟CMC专家，瑞士

Christa Wirthumer-Hoche 博士
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上海强生制药有限公司亚太区 OTC R&D 分析研发副总监

本课程人数有限，请尽早注册!

Fritz Erni 博士
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本课程由来自欧盟及中国专家讲授。 内容涵盖欧盟和中国对注册和申报资料模板1和3的要求及实践。 课程也结合ICH Q8和Q9的指南，通过案例分析，课堂讨论，对CTD和ICH要求进行详细的指导和论述。
DIA此课程被公认为是针对制药的研发，审评及申报有指导作用的培训。此课程已在欧盟，亚洲及中东地区分别开设并广受欢迎。

课程内容

- CTD，eCTD
- 模板 1
  - 随函
  - 申请表
  - 产品信息
  - 环境风险评估
  - 孤儿药市场独占权
  - 风险管理
  - 儿童用药方面的信息
- 模板3
  - 药品开发和质量风险管理
  - 活性成分的质量，纯度
  - 杂质检测
  - 稳定性试验
  - 质量标准制定
  - 上市许可程序
  - 变更程序及管理

专业目标

本课程结束时,参加人员应当能够:
- 了解对药品原料药和制剂的最新规定要求并能够准备高质量的注册资料
- 了解对药品开发的注册和审评标准及流程
- 讨论资料规定要求的法律依据及相关的指导原则

参加人员

- 药品审评机构及相关单位
- 制药业专业人员
- 法规部,研发部门负责人
- 质量保证体系和生产部门负责人

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第1天 –2012年3月14日

8:00 – 8:30 AM 注册

8:30 – 8:40 AM 欢迎及介绍

8:40 – 10:00 AM 第1部分

讲者: Christa Wirthumer-Hoche 博士

通用技术文件（CTD）框架的概述

- CTD的框架 (模块 1 – 5)
  - 相关的指导原则
- eCTD
  - 现行的指导原则
  - 准备和受理 eCTD
  - eCTD的未来

10:00 – 10:15 AM 茶歇

10:15 - 12:00 AM 第2A部分

讲者: 黄晓龙 副部长

中国国家食品药品监督管理局药品审评中心

CTD 在中国的实践

12:00 – 1:15 PM 午餐

1:15 – 2:00 PM 第2B部分

讲者: Christa Wirthumer-Hoche 博士

欧盟模块1的内容讨论:

- 申请表
- 产品信息
  - 法律规定及指导原则
  - 可读性测试
  - 盲文
- 专家信息
- 与孤儿药市场独占权相关的信息
  - 相似性 / 市场独占权
- 药物警戒相关信息
  - 药物警戒主文件
  - 风险管理体系
- 临床试验相关信息
- 儿童用药信息

2:00 – 3:15 PM 第3部分

讲者: Fritz Erni 博士

CTD – 模块3 质量 – 重要章节的讨论– 第1部分

- CTD文件中质量部分必须执行的内容
- 选择的可能性和机会
- 药学开发和质量风险管理
- 新的ICH Q8（药学开发）指导原则及应用

3:15 – 3:30 PM 茶歇

3:30 – 4:30 PM 第3部分

讲者: Fritz Erni 博士

质量 – 重要章节的讨论– 第2部分

- 与ICH Q8（药学开发 ）的相互作用
- 在资料中如何落实质量风险管理
- ICH Q9指导原则（质量风险管理）
- 质量风险管理的要素
- 质量风险管理的申请

4:30 – 5:15 PM 第4部分

讲者: Fritz Erni 博士

质量风险管理案例分析的介绍

分组讨论

5:15 PM 第1天培训结束

第2天 –2012年3月15日

8:30 – 10:00 AM 第5部分

全体讲者

质量风险管理案例分析及讨论

10:00 – 10:15 AM 茶歇

10:15 – 12:00 AM 第6部分

讲者: Christa Wirthumer-Hoche 博士

各类申请的具体要求

- 文献式申请的信息
  - 关于已普遍认可使用的申请的法律规定
- 仿制药、“混合”或生物相似申请
  - 仿制药的法律规定
  - 数据保护期
- 知情同意申请的信息
- 集中程序的具体规定
  - 例外情况
  - 有条件的上市许可
  - 加快审评

12:00 – 1:15 PM 午餐

1:15 – 3:00 PM 第7部分

讲者: Christa Wirthumer-Hoche 博士

原料药的质量

- 原料药
  - 原料药主文件
  - 适用性证书

讲者: Fritz Erni 博士

杂质检测：经验和新趋势

- 原料药中的杂质
- 制剂中的降解产物
- 残留溶剂
- 残留金属
- 遗传毒性杂质

3:00 – 3:15 PM 茶歇

3:15 – 5:00 PM 第8部分

讲者: Fritz Erni 博士

稳定性试验

- 相关指南的讨论
- 实例

质量标准制定

5:00 – 5:30 PM

案例分析演讲， 分组讨论

5:30 PM 第2天培训结束

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第3天 – 2012年3月16日

8:30 – 10:00 AM　　第9部分

全体讲者

案例分析讨论

10:00 – 10:15 AM　　茶歇

10:15 - 12:00 AM　　第10部分

讲者: Christa Wirthumer-Hoche 博士

上市许可程序

- 欧洲网络
- 集中程序
- 相互认可程序
- 分散式程序

12:00 – 1:15 PM　　午餐

1:15 – 2:15 PM　　第11部分

全体讲者

案例分析

- 计划并组织与药品监管当局的会议
    - 科学咨询、递交前的会议、申报过程中的口头听证会

2:15 – 3:30 PM　　第12部分

讲者: Christa Wirthumer-Hoche 博士

上市许可持有

- 变更/批准后变更
    - 新的欧洲法律框架
        - 变更的定义
        - 程序及分类的指导原则
    - 批准后的管理方案

3:30 – 3:45 PM　　茶歇

3:45 – 4:45 PM　　专家讨论

全体讲者

对中国实例的互动讨论（问答部分）

4:45 – 5:00 PM　　总结

5:00 PM　　培训课程结束

Fritz Erni 博士
欧盟CMC专家，瑞士

Fritz Erni博士毕业于瑞士苏黎世联邦理工学院并获得博士学位。 他在制药业的研发及质量认证上有30多年的工作经验。

他的职业生涯起于日本的日立公司研发工作。1974年在瑞士巴塞尔的Sandoz公司从事化学分析研发。他负责多项分析研究、新型药品的开发工作，并于1986年晋升为分析研究及开发部门的领导。

1995年他调至技术运营部门，从事管理及负责Sandoz的质量保证、监管以及该公司与诺华合并后的部门管理。

自2000年至2002年，他担任诺华制药SA在瑞士洛迦诺的公司总监，此为一家专为诺华制药集团从事药品稳定性测试的公司。

2002年11月，他担任诺华技术合作全球质量运营，巴塞尔地区的主要领导人。在此期间，他也负责诺华全球关于流程分析技术(PAT)以及质量源于设计（QbD）的项目。 Erni博士同时也在苏黎世瑞士联邦理工学院教授分析化学。他已出版50多篇论文。

1992年，他担任ICH欧洲工业（EFPIA）杂质项目的负责人，参与ICH有关原料药杂质，药剂制品杂质以及残余溶剂指南的制定。 他也是ICH专家工作组Q8医药发展及ICH Q8/Q9/Q10执行工作组成员。

2009年，他从工作了35年的诺华制药公司退休，目前从事于医药咨询工作。

Christa Wirthumer-Hoche 博士
奥地利药品局

Christa Wirthumer-Hoche博士，生物化学专业，1981年毕业于维也纳科技大学，于1983年获医学生理学博士。1983年至1998年5月，她任职于奥地利国家研究所药品质量控制管理局，主要从事质量资料的审评。1998年6月至2005年12月，她负责许可药品部门，其单位隶属于奥地利妇女健康联邦部门。

自2006年1月1日新的奥地利药监局成立，她的职位是奥地利卫生和食品安全局（AGES PharmMed）负责市场授权、医药产品周期管理部负责人，也是AGES PharmMed的副局长。

自1994年起，Christa Wirthumer-Hoche博士参与许多欧洲委员会及工作组/协会， 包括CPMP/CVMP质量工作组，医药专利产品议会（CPMP），MRFG，等。

1999年12月，欧盟委员会任命她为欧盟CTD的执行协调员。

2010年6月，她作为EMA-CMD联盟工作组的领导者，主持原料药主文件档案(Active Substance Master File, ASMF)的工作。之后她成为ERMS(欧洲风险管理机构)的成员，参与药物警戒立法的执行。

作为演讲者，Christa Wirthumer-Hoche博士多次参加国际以及欧洲的多项会议，并且是维也纳、波恩、丹麦哥本哈根等大学药品监督管理研究生课程的讲师。

黄晓龙 副部长
国家食品药品监督管理局药品审评中心

1984.9-1989.7就读于华西医科大学药学院，1992年毕业于中国医学科学院药物研究所，获理学硕士学位。2004年晋升为主任药师。

1992.8-1997.1在中国医学科学院药物研究所合成室工作。1997年2月至今在国家食品药品监督管理局药品审评中心历任药学审评员、药学组组长、副部长，现负责注册分类四、五、六类药的技术复核工作。1999年起牵头组织和起草了《原料药制备工艺》、《结构确证》、《化学药物杂质研究技术指导原则》、《 手性药物药学研究技术指导原则》， 2011年组织本部开展了以仿制药的审评为主的CTD资料审评试点工作。

CTD Dossier-Modules, Requirements and Practices

March 14-16, 2012
Beijing, China

Course Faculty

Fritz Erni, PhD
Consultant
Switzerland

Christa Wirthumer-Hoche, PhD
AGES PharmMed
Austria

HUANG Xiaolong
Deputy Director, CMC Review Office, CDE, SFDA, China

Program Committee

REN Yi PhD, MBA
Senior Director, Head of Chemistry, Manufacturing and Control, Roche R&D Center(China) Ltd.

YE Ling PhD
Associate Director, R&D Analytical, Asia Pacific OTC R&D, Shanghai Johnson & Johnson Pharmaceuticals, Ltd.

LIMITED CLASS SIZE, REGISTER EARLY!

Fritz Erni, PhD
Consultant
Switzerland

Christa Wirthumer-Hoche, PhD
AGES PharmMed
Austria

HUANG Xiaolong
Deputy Director,
CMC Review Office,
CDE, SFDA, China

The course is designed to introduce requirements, process, and techniques for preparing successful and high quality registration dossiers for regulatory submissions.

The Modules provide a comprehensive description on the Common Technical Dossier structure — completely updated to reflect the latest changes in pharmaceutical regulatory affairs. The course will focus on the specific regional requirements for Module 1 including discussion of the relevant legislation in EU and China. The requirements for the Quality documentation (Module 3) will be presented in detail based on the recent ICH-Q guidelines.

The course is for new developments as well as for generics.

Featured Topics

- CTD, eCTD
- Module 1
  - Cover Letter
  - Application Forms
  - Product Information
  - Environmental Risk Assessment
  - Information Relating to Orphan Market Exclusivity
  - Risk-management System
  - Paediatric Information
- Module 3
  - Pharmaceutical Development and Quality Risk Management
  - Quality of Active Substance Including Purity Issues
  - Impurity Testing
  - Stability Testing
  - Setting Specifications
  - Marketing Authorisation Procedures
  - Variation Procedures

Learning Objectives

At the conclusion of this course, participants should be able to:

- Identify the recent requirements for developing drug substance and drug products and setting up a registration dossier
- Define the requirements for developing a product and discuss how to prepare the regional Module 1 and the Quality documentation
- Discuss the legal background of the dossier requirements and identify the relevant guidelines
- Demonstrate optimal presentation of information and justifications

Who Should Attend

- Regulatory agencies
- Pharmaceutical industry professionals
- Regulatory Affairs, and R&D professionals
- Quality Assurance and manufacturing professionals

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DAY 1 (WEDNESDAY, MARCH 14, 2012)

8:00 – 8:30 AM REGISTRATION

8:30 – 8:40 AM WELCOME AND INTRODUCTIONS

8:40 – 10:00 AM SESSION 1

Speaker: Christa Wirthumer-Hoche, PhD

INTRODUCTION TO THE COMMON TECHNICAL DOCUMENT STRUCTURE OF THE LICENSING DOSSIER – IN GENERAL

- Structure of the CTD (Module 1 – 5)
  - Relevant guidance documents
- eCTD
  - Current guidance documents
  - Readiness to prepare and accept eCTD
  - Future of the eCTD

10:00 – 10:15 AM COFFEE BREAK

10:15 - 12:00 AM SESSION 2A

Speaker: HUANG Xiaolong
Deputy Director, CMC Review Office, CDE, SFDA, China

CTD PRACTICES IN CHINA

12:00 – 1:15 PM LUNCH

1:15 – 2:00 PM SESSION 2B

Speaker: Christa Wirthumer-Hoche, PhD

DISCUSSION OF THE CONTENT OF MODULE 1 IN EUROPE:

- Application Forms
- Product Information
  - Legal provisions and guidance documents
  - Readability Testing
  - Braille
- Information about the Expert
- Information relating to Orphan Market Exclusivity
  - Similarity / Market Exclusivity
- Information relating to Pharmacovigilance
  - Pharmacovigilance Master File
  - Risk-management system
- Information Relating to Clinical Trials
- Pediatric Information

2:00 – 3:15 PM SESSION 3

Speaker: Fritz Erni, PhD

CTD – MODULE 3 QUALITY – DISCUSSION OF IMPORTANT CHAPTERS – 1st PART

- What is Necessary in the Quality Section of the CTD
- What are the Optional Possibilities and Opportunities
- Pharmaceutical Development and Quality Risk Management
- Possibilities of the New ICH 8 Guideline on Pharmaceutical Development

3:15 – 3:30 PM COFFEE BREAK

3:30 – 4:30 PM SESSION 3

Speaker: Fritz Erni, PhD

CTD – MODULE 3 QUALITY – DISCUSSION OF IMPORTANT CHAPTERS – 2nd PART

- Interaction with ICH Q8 Pharmaceutical Development
- How to Implement Quality Risk Management in a Dossier
- The ICH Q9 Guideline on Quality Risk Management
- Elements of Quality Risk Management
- Application of Quality Risk Management

4:30 – 5:15 PM SESSION 4

Speaker: Fritz Erni, PhD

INTRODUCTION TO THE QUALITY RISK MANAGEMENT CASE STUDY
(Working in Groups)

5:15 PM END OF DAY 1

DAY 2 (THURSDAY, MARCH 15, 2012)

8:30 – 10:00 AM SESSION 5

All Speakers

DISCUSSION OF THE QUALITY RISK MANAGEMENT CASE STUDY

10:00 – 10:15 AM COFFEE BREAK

10:15 – 12:00 AM SESSION 6

Speaker: Christa Wirthumer-Hoche, PhD

SPECIFIC REQUIREMENTS FOR DIFFERENT TYPES OF APPLICATIONS

- Information for Bibliographical Applications
  - Legal Provisions Concerning well Established use Applications
- Information for Generic, "Hybrid" or Bio-similar Applications
  - Legal Provisions Concerning Generics
  - Data Protection Period
- Information for Informed Consent Applications
- Specific Provisions Concerning the Centralised Procedure
  - Exceptional Circumstances
  - Conditional Marketing Authorisation
  - Accelerated Review

12:00 – 1:15 PM LUNCH

1:15 – 3:00 PM SESSION 7

Speaker: Christa Wirthumer-Hoche, PhD

QUALITY OF ACTIVE SUBSTANCE

- Active Substance
  - Active Substance Master File
  - Certificate of Suitability

Speaker: Fritz Erni, PhD

IMPURITY TESTING : EXPERIENCE AND NEW TRENDS

- Impurities in Drug Substance
- Degradation Products in Drug Products
- Residual Solvents
- Residual Metals
- Genotoxic Impurities

3:00 – 3:15 PM COFFEE BREAK

3:15 – 5:00 PM SESSION 8

Speaker: Fritz Erni, PhD

STABILITY TESTING

- Discussion of the Relevant Guidelines
- Practical Examples

SETTING OF SPECIFICATIONS

5:00 – 5:30 PM

CASE STUDY PRESENTATION AND START WORKING IN GROUPS

5:30 PM END OF DAY 2

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DAY 3 (FRIDAY, MARCH 16, 2012)

8:30 – 10:00 AM SESSION 9

ALL SPEAKERS

DISCUSSION OF THE CASE STUDY

10:00 – 10:15 AM COFFEE BREAK

10:15 - 12:00 AM SESSION 10

SPEAKER: Christa Wirthumer-Hoche, PhD

MARKETING AUTHORISATION PROCEDURES

- The European Network
- Centralised Procedure
- Mutual recognition Procedure
- Decentralised Procedure

12:00 – 1:15 PM LUNCH

1:15 – 2:15 PM SESSION 11

ALL SPEAKERS

CASE STUDY

Planning and Organising a Meeting with Authority

- Scientific Advice, Pre-submission Meeting, Oral Hearing During a Procedure

2:15 – 3:30 PM SESSION 12

SPEAKER: Christa Wirthumer-Hoche, PhD

MAINTENANCE OF MARKETING AUTHORISATIONS

- Variations / Post approval changes
  - New EU legal framework
    - Definition of Variations
    - Procedural & Classification Guideline
  - Post Approval Management Protocol

3:30 – 3:45 PM COFFEE BREAK

3:45 – 4:45 PM

ALL SPEAKERS

INTERACTIVE DISCUSSION ON CHINESE PRACTICES

Question & Answer Session

4:45 – 5:00 PM CLOSING REMARKS

5:00 PM END OF TRAINING COURSE

Fritz Erni, PhD
Consultant
Switzerland

Dr. Fritz Erni has a Ph.D. from the Swiss Federal Institute of Technology (Dr. sc.nat. ETH) in Zurich and more than 30 years experience in research, development and quality assurance in the pharmaceutical industry. He started his career in Japan in research at Hitachi Ltd. and moved 1974 to Sandoz in Basel to take up a position in Analytical Research and Development. He had several positions in the analytical research and development of new drug substances and products and was promoted to Head of Analytical Research and Development in 1986. In 1995 he moved to Technical Operations, where he had several management positions in Quality Assurance/Control at Sandoz and later after the merger within Novartis. From 2000 to 2002 he was Director of Novartis Pharmanalytica SA in Locarno, Switzerland, a company specialized in stability testing for the Novartis group. Since November 2002 he is head of Technical Liaison, Global Quality Operations of Novartis in Basel. In this function he was also responsible for the establishing of Novartis Global activities on Process Analytical Technologies (PAT) and Quality by Design. Dr. Erni was also teaching Analytical Chemistry for advanced students in Chemistry at the Swiss Federal Institute of Technology in Zurich. He has published more than 50 papers.

Since 1992 he is topic leader of the European Industry (EFPIA) for impurity topics for the International Conference on Harmonization (ICH) and was involved in the elaboration of the impurity ICH guidelines for impurities in drug substances, impurity in drug products and residual solvents. He is also member of the ICH Expert Working Group Q8 on Pharmaceutical Development and the ICH Q8/Q9/Q10 Implementation Working Group.

Since 2009 he retired from Novartis after 35 years in the pharmaceutical Industry and is working as a consultant.

Christa Wirthumer-Hoche, PhD
AGES PharmMed
Austria

DI Dr. Christa Wirthumer-Hoche studied biochemistry and graduated at the Technical University, Vienna in 1981, she did her doctoral thesis at the Institute for Medical Physiology, graduating in 1983. She joined the Austrian National Institute for Quality Control of Drugs in 1983 until May 1998, focusing on the assessment of quality documentation. From June 1998 until December 2005 she was the Head of the Licensing Division for medicinal products, in the Unit for Pharmaceutical Affairs in the Austrian Federal Ministry of Health and Women.

Since the founding of the new Austrian Agency 1 January 2006 her current position is Head of the Unit for Marketing Authorisation and Lifecycle Management of Medicinal Products at AGES PharmMed, and Deputy Head of AGES PharmMed.

Since 1994 she has been involved in different European committees and working groups (CPMP/CVMP Quality Working Party, the Committee for Proprietary Medicinal Products (CPMP), MRFG, Notice to Applicants Group, in the PERF project and CMD).

In Dec.1999 she was appointed by the European Commission as Co-ordinator for the CTD Implementation in Europe (ICH-IWG).

Since June 2010 she is the chair of the Joint EMA-CMD working party for ASMF procedures. Further she is a member of the ERMS (European Risk Management Group), involved in the implementation of the Pharmacovigilance legislation.

She is a frequent speaker at numerous international and European meetings and a lecturer at Universities in Vienna, Bonn and Copenhagen for the post-graduate courses “Master of Drug regulatory Affairs”.

HUANG Xiaolong
Deputy Director,
CMC Review Office,
CDE, SFDA, China

Mr. Huang studied in West China School of Pharmacy, Sichuan University during Sept. 1984 – July 1989. He graduated from Institute of Materia Medica (IMM), Chinese Academy of Medical Sciences & Peking Union Medical College with a Master Degree in science (MS) in 1992. In 2004, he was promoted to Chief Pharmacist.

Mr. Huang worked in the Medicinal Chemistry Department of IMM from Aug. 1992 to Jan.1997. Since 1997, he has been working in Center for Drug Evaluation (CDE), State Food and Drug Administration (SFDA) of China. He has served as a CMC reviewer, leader of CMC review office and the deputy director of the CMC review office. Currently, he is responsible for technical inspections of chemical drugs classes 4, 5 and 6. From 1999, Mr. Huang has led the organization and development of several guidelines including《Technical Guideline for Preparation Process and Structure Confirmation Research of Chemical Drug Substances》,《Technical Guideline on Impurity Studies for Chemical Drugs》and 《Technical Guideline on Pharmaceutical Research of Chiral Drugs》. In 2011, Mr. Huang led and organized the project for the CTD review focusing on generic drugs.

CTD格式申报——要求与实践

会议编码：#12983 • 2012年3月14-16日

中国 • 北京

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联系人：任彦　　Email: rsvn.hithbj@ihg.com

DIA 中国办公室：

北京市朝阳区东三环北路霞光里18号佳程广场A座11层1155室，邮编：100027

电话: +86 10 5923 1222/1288　　传真: +86 10 5923 1180

Email: dia@diachina.org

取消注册*：须在2012年3月9日前（含3月9日）

- 如需取消注册，须于规定日期前（含）以书面方式告知DIA中国办公室，并得到DIA中国办公室的书面确认，方可视为取消成功。
- 凡已注册并付款者，若于规定之日前（含）取消注册，DIA中国办公室可办理退款手续，但须扣除手续费人民币500元。
- 凡已注册并付款者，若逾期未办理取消手续，将不予退款。
- 参会者应自行负责住宿、交通等有关预订及取消。

预了解更多DIA会议信息
可登录 www.diachina.org

会议注册费（含茶歇、午餐及会议资料）

企业	会员	推荐 新会员（会员费+会议费）	非会员
提前注册 (01月04日-03月02日)	RMB3500☐	RMB4380☐	RMB4380☐
标准价格 (03月03日-03月09日)	RMB4000 ☐	RMB4880☐	RMB4880☐
现场注册 (03月10日-03月16日)	RMB4500☐	RMB5380☐	RMB5380☐
政府机构/学术机构(全职人员)	RMB 2600 ☐	RMB3480☐	RMB3480☐

* DIA推荐非会员参会者以 新会员价格 注册。加入DIA，将在一年有效期内享受DIA会员服务及会议优惠

☐ 领取发票（如需发票，请填写以下信息）

发票抬头 _____

发票金额　人民币 _____

服务项目　☐会议费　☐会务费　☐培训费

*注意：

1. 请详细填写以上内容。款项入账并确认无误后，开具发票
2. 发票可于会议现场到注册台领取

付款方式（本次会议仅接受银行汇款，汇率以中国人民银行当日外汇牌价为准）

人民币_____　会议编码 #12983

收 款 人：迪亚恩（北京）医药信息咨询有限公司

开 户 行：中国银行北京市朝阳支行营业部

银行帐号：333757195112

SWIFT Code: BKCH CN BJ 110

银行地址：北京市朝阳区东三环北路霞光里18号佳程广场A座一层

*注意：

早期优惠价格注册：2012年3月3日前付款

标准注册：2012年3月10日前付款

单位类别　☐ 药企　☐ 政府部门　☐ 科研院校　☐ 实验室/CRO　☐ 医疗机构（医院/诊所）　☐ 咨询公司　☐ 其它

请填写下表并保持字迹清晰

姓 _____　名 _____　职位 _____　性别：☐ 先生　☐ 女士

单位名称（英文）_____

中文地址（请注明地址以便今后能正确邮寄DIA资料）_____

英文地址 _____

省份及城市_____　国家 _____　邮政编码 _____　☐ 公司地址　☐ 家庭地址

电话 _____　传真 _____　手机 _____

电子邮件（必填，以便通过电子邮件发送确认）_____

CTD Dossier-Modules, Requirements and Practices

Event I.D. # 12983 – March 14 - 16, 2012

Beijing, CHINA

TRAVEL AND HOTEL

Holiday Inn Temple of Heaven Beijing
No.1 Ding An Dong Li, South 3rd Ring Rd., Fengtai Dist., Beijing, 100075
Tel: +86 10 67626688 – 5269 Fax: + 86 10 6761 1616
Contact: Annie REN Email: rsvn.hithbj@ihg.com

DIA CHINA OFFICE

Gateway Plaza, Tower A, Room 1155, 18 XiaGuangLi, North Road, East Third Ring, Chaoyang District, Beijing, 100027, China
Tel: +86 10 5923 1222/1288 Fax: +86 10 5923 1180
Email: dia@diachina.org

CANCELLATION POLICY*: ON OR BEFORE March 9, 2012

1. Cancellations must be made in writing and received by May 10, 2012, in order to receive the refund.
2. A cancellation processing fee of RMB 500.00 will be deducted from the refund for each paid registrant.
3. No refund if the written cancellation is not received after March 9, 2012.
4. Registrants must be responsible for their own travel, hotel registration and cancellation expenses.

For more meeting details
Please visit www.diachina.org

REGISTRATION FEES FOR CONFERENCE (*Registration fee includes Coffee Breaks, luncheons*)

INDUSTRY		MEMBER	NEW MEMBER PACKAGE	NONMEMBER
Industry Early-bird*	(Jan 04 - Mar 02)	RMB3500☐	RMB4380☐	RMB4380☐
Industry Standard	(Mar 03 - Mar 09)	RMB4000☐	RMB4880☐	RMB4880☐
Industry Onsite	(Mar 10 - Mar 16)	RMB4500☐	RMB5380☐	RMB5380☐
NONPROFIT/ACADEMIA/GOVERNMENT (Full-time)		RMB2600 ☐	RMB3480☐	RMB3480☐

* It is highly recommended nonmember attendees register the event with ***New Member Package*** (Meeting Fee + 1 Year Membership Fee)
Join DIA to receive more DIA benefits!

☐ REQUEST CHINESE OFFICIAL INVOICE (FA PIAO)

If you need a chinese official invoice, Please complete following question

Invoice Title _____

Amount Charged RMB _____

Service Item ☐ Meeting Fee ☐ Training Fee

PAYMENT (Bank Transfer Only)

Payment in the amount of RMB_____ Meeting I.D. #12983

Payee: DIA (Beijing) Healthcare Information Consulting Limited

Bank Name: Bank of China, Beijing Chaoyang Sub-branch Banking Dept.

Bank Account: 333757195112

SWIFT Code: BKCH CN BJ 110

Bank Address: 1st Floor, Tower A, Gateway, No.18 Xiaguangli, North Road, East Third Ring, Chaoyang District, Beijing, 100027, P.R.China

*Notes:
Early-bird must be paid before March 03, 2012
Standard must be paid before March 10, 2012

Please check the applicable category: ❑ Industry ❑ Government ❑ University ❑ CRO ❑ Hospital/Medical Practice ❑ Independent Consultant ❑ Other

PLEASE PRINT ALL INFORMATION CLEARLY

Last Name First Name M.I. Full Name in Chinese (If applicable) Gender ❑ Male ❑ Female

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

Address City Postal Country

Address in Chinese (If applicable)

Telephone Number Fax Number Mobile Number

Email (Required for confirmation)

假日酒店
Holiday Inn
北京中成天坛
BEIJING TEMPLE OF HEAVEN

预订确认信

由:		*自:*	*北京中成天坛假日酒店*
公司名称;		*传真号码.*	*+86 10 67636199*
传真号码		*电话号码*	*+86 10 67626688-5271*
邮箱地址:		*邮箱地址*	*rsvn.hithbj@ihg.com*
页数	*1*	*日期*	

Thank you for your recent inquiry with regards to the accommodation at the Holiday Inn Beijing Temple of Heaven. We are pleased to confirm your reservation as the following:

客人姓名			
确认号		*预订情况*	
房型		*入住日期*	
价格	*550元/每晚 （含1-2人次早餐）*	*航班时间*	
房间数量		*到店时间*	
人数		*离店日期*	
接机		*航班时间*	
送机		*离店时间*	

For Club Room or Club Suite guest, you could enjoy Express check in and check out at Club InterContinental Reception on 16F.

PRIORITY CLUB REWARDS - JOIN TODAY FOR MORE POINTS, MORE REWARDS, MORE PRIVILEGES

Easier to join, easier to earn points, and easier to redeem for more rewards. Choose from more than 4,000 hotels worldwide including over 100 hotels in China. There are a variety of ways to earn and redeem points for free nights awards, airline miles, gift vouchers or various brand-name merchandise from electronics to house ware.

If you or your guests are not our member now, please provide the detail information so we can make the enrollment right now. We will provide the tentative card upon you or your guest's check in and will earn points or miles immediately.

RESERVATION STATUS

* 18:00 p.m Release
Your reservation has been held under Non Guaranteed basis. Please advise credit card number with expiry date if you wish to guarantee the above reservation. For Non-Guarantee reservation, hotel will hold room till 18:00p.m on the day of arrival.

Airport pick up/ drop off service can be arranged at RMB400.00net/per way per car. The car type is Audi A6 (Max person: 2)

If you have any enquires, please do not hesitate to contact us.

Best regards,

Andy Cheng
Tel: 13661125811
Senior Sales Manager

假日酒店
Holiday Inn
北京中成天坛
BEIJING TEMPLE OF HEAVEN

RESERVATION CONFIRMATION

To		*From*	*Holiday Inn Beijing Temple of Heaven*
Company		*Fax No.*	*+86 10 67636199*
Fax No.		*Telephone No.*	*+86 10 67626688*
Telephone No. Or E-Mail :		*Email*	*rsvn.hithbj@ihg.com*
No. of Pages	*1*	*Date*	

Thank you for your recent inquiry with regards to the accommodation at the Holiday Inn Beijing Temple of Heaven. We are pleased to confirm your reservation as the following:

Guest Name			
Confirmation No.		*Reservation Status*	
Room Type		*Arrival Date*	
Daily Rate	*CNY 550/net(with one or Two breakfast*	*Arrival Flight*	
Number of Room(s)		*Arrival Time*	
Number of People		*Departure Date*	
Arrival Transfer		*Departure Flight*	
Departure Transfer		*Departure Time*	*12:00*

For Club Room or Club Suite guest, you could enjoy Express check in and check out at Club InterContinental Reception on 16F.

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Best regards,

Andy Cheng
Tel: 13661125811
Senior Sales Manager

中成天坛假日酒店
Holiday Inn Temple of Heaven Beijing