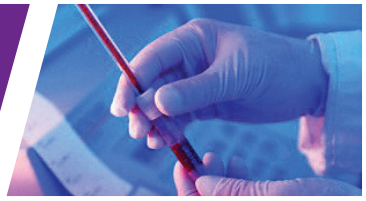
临床研究中的偏差调查和防范措施



2013年9月2 - 3日

中国 · 成都

临床研究规范(GCP)是运用于临床试验整个过程中的最佳实践和质量标准的集合体。临床研究质量的最终目标是为确保病人的安全和数据完整性。本次培训课程介绍在GCP的实践中对偏差的防范管理和如何采取有效的纠偏/防偏(CAPA)措施，这也是临床研究质量管理体系的基本核心要点之一。偏差管理和根源分析专家将介绍全球GCP环境的规范和要求。参会者将了解如何在临床研究质量体系的框架下计划和执行有效的根源调查和实施纠偏和防偏的方案。

学习内容

- 临床规范原则
- 稽查计划和策略
- 稽查的角色
- 稽查的准备
- 检查中的问题发现和处理
- 稽查报告
- 药物清点和临床数据稽查
- 申办者自查/服务商/和对第三方的检查
- FDA检查和问题处理
- 483表和警告信
- 比较药监部门在GCP检查的要求
- 欺诈行为
- 对电子临床计算机系统检查

学习目标

一旦完成本次培训，您应当能够:

- 掌握GCP的偏差管理
- 描述申办者，TPO和研究机构对偏差管理监督的要求
- 理解如何评估危急程度，和概述风险性质
- 识别如何有效解决的最佳方案和实践及其如何对企业文化产生影响
- 熟悉各种根源分析工具和如何应用这些工具
- 了解修正和纠偏/防偏(CAPA)之间的差异，及监管指南和要求
- 把握如何评估纠偏/防偏的有效性以避免问题的再次出现
- 识别被动反应和积极主动风险消减之间的差异

参会人员

- 临床研究专业人员
- 临床研究辅助人员
- 质量保障和质量监控专业人员
- 临床稽查员和检查员
- 数据管理专业人员
- 临床项目管理人员
- 临床监查人员
- 药政事物专业人员
- 临床研究者和研究协调员

组委会主席

刘川 博士
医药数据解决方案公司大中华地区发展总监

组织委员会

李庆红 医师
辉瑞医药质量保证部亚洲地区负责人

主讲人

Yolanda L. TAYLOR PhD
礼来公司全球医学质量总监

Kevin J WILSON
礼来公司全球医学质量经理

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第一天 | 9月2日 星期一

08:30 - 08:45 欢迎和介绍

- 讲员介绍
- 参会者背景
- 课程概述和目的

08:45 - 09:30 第1节: 偏差管理

本节的目的是要向与会者介绍临床试验进行中偏差管理系统的基本要素背景信息

- 原理
- 监管与期待
- 了解影响力

09:30 - 10:30 第2节: 标准操作步骤及其它偏差

- 何为偏差?
- 质量的其它来源

10:30 - 10:45 茶歇

10:45 - 12:00 第3节: DIA GCP偏差管理学术沙龙意见书

- 介绍
- 意见书的制定
- 初步结果
- 未来计划

12:00 - 13:00 午餐

13:00 - 13:30 第4节: 偏差报告和文件

- 文件的重要性是什么?
- 重要性的原因是什么?
- 定量体系
- 趋势识别

13:30 - 14:15 第5节: 影响分析和危急程度

本节的目的是要更好地理解所出现问题的严重性，哪些问题需要解决的先后顺序及其合理的解决方案

- 理解风险
- 优先顺序和程度判定
- 明确影响性
  - 病人安全性
  - 数据的适用性
  - 监管期许

14:15 - 14:30 茶歇

14:30 - 15:15 第6节: 组织机构变革管理

本节是要讨论组织机构变革管理的原则，其会对偏差管理文化的影响。

- 影响行为
- 鼓励偏差报告
- 归属权与问责制

15:15 - 16:30 第7节: 练习

本节将为参与者就如何理解影响，调查重点和程度的危急度分析提供“亲身”演练的机会

- 记录偏差
- 显著影响

第二天 | 9月3日 星期二

08:30 - 08:40 第二天日程介绍

08:40 - 09:30 第8部分: 界定问题

本节的目的是要告知参与者如何开始根源调查

- 偏差调查的质量信号
- 组织机构的目标
- 问题的范畴
- 需要确切地防范什么?

09:30 - 10:15 第9部分：角色和职责

本节将描述在进行根源分析和解决问题过程中不同的角色及其责任

- 根源调查员与根源促进者
- 商务的角色
- 制定期望值
- 制定时间表

10:15 - 10:30 茶歇

10:30 - 12:00 第10部分: 调查工具

本节将介绍若干可用于确定根源的各种调查工具

- 因果关系属性
- 工具
  - 5个为什么
  - 鱼骨法
  - 故障树
- 流程图解

12:00 - 13:00 午餐

13:00 - 14:00 第11部分: 纠正和预防措施 (CAPA)

本节的目的是要对CAPA系统条款的合理使用作出阐述，并概述为达到CAPA系统目标而发展解决方案的最佳规范。

- 定义
  - 纠正
  - 纠正措施
  - 预防措施
- 避免“CAPA致死”
- 制订可持续性的CAPA
- 效益和效力
- 理解回报与后果

14:00 - 14:45 第12部分: 评估效力

本节将概述评估每个所完成的有效力的CAPA最佳实践，这种效力体现在问题不需要被多次调查

- 评估所发现有问题的数据
- 原因消除与消减
- 再现和出现

14:45 - 15:00 茶歇

15:00 - 15:45 第13部分: 风险消减

本节的目的是要让参与者理解如何来描述风险，和如何运用纠正与预防措施回应和主动积极地消减风险。

- 失效模式效应分析
- 优化CAPA实施

15:45 - 17:00 第14部分: 练习和问答

本节将向参与者就根源调查，消除问题再现的相应解决方案方面提供“亲手”练习的机会。

- 发展CAPA
- 问答

17:00 培训结束

Root Cause Investigations and Corrective Actions for GCP Compliance

September 2-3, 2013
Chengdu, China

Good Clinical Practice (GCP) is a compilation of best practices and quality standards to be applied to the overall process of a clinical trial. The ultimate goals of quality in clinical research are to ensure patient safety and data integrity. This is a class-setting training on how to implement Deviation Management and an effective CAPA program in a GCP organization, which constructs one of the basic core elements in the QMS of clinical studies. Deviation Management and Root Cause Analysis experts will give attendees the fundamental knowledge of practices and expectations in a global GCP environment. The trainees will also learn how to plan and conduct effective root cause investigation and implement corrective and preventive actions in the architecture of QMS of clinical studies.

FEATURED TOPICS

- Principles of Good Clinical Practices
- Audit Programs and Strategies
- The Role of the Audit
- Preparation for the Audit
- CFDA Inspection and Finding
- The Audit Report
- Drug Accountability and Clinical Data Audit
- Audit Issues for Sponsor Self/Vendors/ Support Functions and Third Party
- FDA Audits and Findings & Follow-up
- Review of Inspection Observations
- Comparison of CFDA/ FDA/EMA Auditing and Inspection
- Fraud and Misconduct
- Inspection of E-clinical Computer Systems

LEARNING OBJECTIVES

At the conclusion of this training, you should be able to:

- Understand deviation management for GCP
- Describe the expectations for deviation management oversight at the sponsor, TPO, and investigator site
- Understand how criticality is measured, and describe the nature of Risk
- Recognize the best practices for implementing an effective solution and how to influence the culture of the organization
- Be familiar various root cause analysis tools and understand when to apply these tools
- Describe the differences between corrections, and CAPA to meet the regulatory guidelines for the use of these terms
- Know well how to measure effectiveness to prevent recurrence of problems
- Identify the differences between reactive and proactive risk mitigation

WHO SHOULD ATTEND

- Clinical Study Professionals
- Clinical Research Associates
- Quality Assurance and Quality Control Professionals
- Clinical Auditors and Inspectors
- Data Management Professionals
- Clinical Project Management
- Clinical Monitors
- Regulatory Affairs Professionals
- Clinical Researchers and Study Coordinators

PROGRAM CHAIRPERSON

Daniel LIU, PhD
Director, China Development
Medidata Solutions Worldwide, China

PROGRAM COMMITTEE

Helen Q. LI, MD
QA Asia Lead, Emerging Market/PCO QA, Pfizer Medical Quality Assurance

INSTRUCTORS

Yolanda L. TAYLOR, PhD
Director, Global Medical Quality
Eli Lilly and Company, USA

Kevin J WILSON
Manager, Global Medical Quality Systems, Eli Lilly and Company, USA

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DAY 1 | MONDAY, SEPTEMBER 2

08:30 - 08:45 WELCOME AND INTRODUCTION

Daniel Liu or Jane Cai

- Introduction of Faculty
- Background of Participants
- Course Outline and Objectives

08:45 - 09:30 SESSION 1: DEVIATION MANAGEMENT

Yolanda Taylor

The purpose of this session is to provide the participants with background information on the basics of a Deviation Management System for the conduct of clinical trials.

- Principles
- Regulations vs. Expectations
- Understanding Impact

9:30 – 10:30 SESSION 2: STANDARD OPERATING PROCEDURE AND OTHER DEVIATIONS

Kevin Wilson

- What is a Deviation?
- Other sources for Quality

10:30 – 10:45 REFRESHMENT BREAK

10:45 – 12:00 SESSION 3: DIA GCP COMMUNITY POSITION PAPER ON PROTOCOL DEVIATION

Yolanda Taylor

- Introduction
- Development of the Position Paper
- Preliminary results
- Next steps

12:00 - 13:00 LUNCHEON

13:00 - 13:30 SESSION 4: DEVIATION REPORTING AND DOCUMENTATION

Kevin Wilson

- What is important to document?
- Why is this important?
- Systems for Metrics
- Identification of Trends

13:30 - 14:15 SESSION 5: IMPACT ANALYSIS AND CRITICALITY

Kevin Wilson

The purpose of this session is to better understand the severity of each issue, and prioritize which issues need to be resolved with sustainable solutions.

- Understanding Risk
- Prioritization and Leveling
- Articulating Impact
  - Patient Safety
  - Data Fit for Purpose
  - Regulatory Expectations

14:15 – 14:30 REFRESHMENT BREAK

14:30 - 15:15 SESSION 6: ORGANIZATIONAL CHANGE MANAGEMENT

Yolanda Taylor

This session will discuss the principles of organizational change management which are needed to influence the right culture for Deviation Management.

- Influencing Behaviors
- Encouraging Deviation Reporting
- Accountability vs. Blame

15:15 – 16:30 SESSION 7: WORKSHOP

This workshop will provide a “hands-on” exercise on how to understand impact, prioritize the investigation and level criticality

- Documenting the Deviation
- Articulating Impact

DAY 2 | TUESDAY, SEPTEMBER 3

08:30 – 08:40 INTRODUCTION

08:40 - 09:30 SESSION 8: DEFINING THE PROBLEM

Kevin Wilson

The purpose of this session is to provide the participants with an understanding of the starting point of a root cause investigation.

- Quality Signals for Root Cause Investigation
- Goals of the Organization
- Scope of the Problem
- What Exactly Needs to be Prevented?

09:30 – 10:15 SESSION 9: ROLES AND RESPONSIBILITIES

Yolanda Taylor

This session will describe the different roles and responsibilities involved in the conduct of a root cause analysis and problem solving project.

- Root Cause Investigator vs. Root Cause Facilitator
- Goals of the Organization
- Setting Expectations
- Setting Timelines

10:15 - 10:30 REFRESHMENT BREAK

10:30 - 12:00 SESSION 10: INVESTIGATION TOOLS

Kevin Wilson

This present several different root cause investigation tools that can be used to determine cause.

- The Nature of Cause and Effect
- Tools
  - 5 Whys
  - Fishbone
  - Fault Tree
- Process Mapping

12:00 - 13:00 LUNCHEON

13:00 - 14:00 SESSION 11: CORRECTIVE AND PREVENTIVE ACTIONS (CAPA)

Yolanda Taylor

The purpose of this session is to educate on the proper use of the terms of a CAPA system, as well as describe the best practice for developing solutions that accomplish the goals of the CAPA system.

- Definitions
  - Corrections
  - Corrective Action
  - Preventive Action
- Avoiding “Death by CAPA”
- Formulating Sustainable CAPA
- Efficiency and Effectiveness
- Understanding Rewards vs. Consequences

14:00 – 14:45 SESSION 12: MEASURING EFFECTIVENESS

Kevin Wilson

This session will describe the best practice of measuring each completed CAPA for effectiveness, so that problems do not need to be investigated multiple times.

- Finding Data for Measurement
- Cause Elimination vs. Mitigation
- Recurrence and Occurrence

14:45 – 15:00 REFRESHMENT BREAK

15:00 - 15:45 SESSION 13: RISK MITIGATION

Kevin Wilson

The purpose of this session will be to provide participants with an understanding how Risk is described and mitigated with corrective and preventive actions both reactively and proactively.

- Failure Modes Effect Analysis
- Prioritizing the Implementation of CAPA

15:45 – 17:00 SESSION 14: WORKSHOP AND Q & A

Yolanda Taylor and Kevin Wilson

This workshop will provide a “hands-on” exercise on conduct the root cause investigation, and propose solutions to eliminate recurrence.

- Developing CAPA
- Q & A

17:00 SUMMARY/WRAP UP

ABOUT THE SPEAKERS

C. Daniel LIU, PhD
Director, China Development
Medidata Solutions Worldwide, China

C. Daniel LIU received his B.Sc. in pharmacy and M. Sc in pharmaceutical chemistry from China Pharmaceutical University, Nanjing, P. R. China and his PhD degree in pharmacology from University of Illinois, USA. Prior to joining pharmaceutical industry, he had more than 10 years of researching experiences in academic environment for drug research and development. He had hands-on experiences in the designing, management and execution of global clinical trials, pharmacovigilance and assembly of regulatory files for the FDA NDA/IND submissions at Novartis, Pfizer, Sanofi-Synthelabo, Schering-Plough and Johnson&Johnson, respectively. Currently, he works as Director of China Development at Medidata Solutions Worldwide. He was the member of the Advisory Council of China DIA and co-Chair of Training Committee of ACC DIA China, the member of global training committee of DIA. He has more than 20 researching papers published in professional journals related to pharmaceutical area. Moreover, he is the one of co-authors for several global GCP guidance books "Good Clinical Practice: A question and answer reference guide" in 2008 – 2012, and "New Drug Approval Process (5th edition), 2009" and so on. He participated to develop the new global GCP guidance "Computerized Systems in Clinical Research: Current Quality and Data Integrity Concepts" published in 2011. His monographic works "Clinical Trial Methodology of Medicinal Products" was published 2011.

Helen Q. LI, MD
QA Asia Lead, Emerging Market/PCO QA,
Pfizer Medical Quality Assurance

Helen LI joined Pfizer global R&D (PGRD) in April 2008 and currently holds the position of QA Asia Lead at Pfizer Medical Quality Assurance. Helen's primary responsibilities are to assure high quality clinical trials and regulatory compliance in Asia Pacific region by implementing Medical QA global strategy and delivering audit activities and other priorities in the region.

Helen began her clinical research career at AstraZeneca Canada in Jan 1997, and has had increased responsibilities within Clinical Operations at AstraZeneca Canada and Asia/China. She advanced to global Clinical Quality Assurance (GCP focused) at AstraZeneca in the US since 2001 and has extensive clinical quality assurance auditing experiences in GCP audits at investigator sites, sponsor systems & processes and documents.

Helen has presented at several international conferences in the healthcare industry, including:
- Drug Information Association, DIA conferences in China and Korea
- ExL Pharma, GCP Conference in the US

Helen graduated from Fudan University, Medical School, in Shanghai majoring in Clinical Medicine. She has also studied RA/QA Master Degree program at Temple University, School of Pharmacy, Fort Washington PA, in the US. In 2012, Helen completed MBA at Fudan University, School of Management.

Yolanda L. TAYLOR, PhD
Director, Global Medical Quality
Eli Lilly and Company, United States

Yolanda L Taylor is the Director of Global Medical Quality at Eli Lilly and Company. During her 18 year career at Eli Lilly she has held various leadership positions in Global Medical Communications, Global Clinical Development, Clinical Project Management, and Global Medical Quality. Yolanda is a trained Lean Six Sigma Black Belt and in 2005 was the recipient of the Six Sigma Rising Star Award. In 2008 she received the Lilly Research Labs President's Award for outstanding scientific achievements in Oncology Clinical Development. Yolanda has been recognized as an honorary member of Worldwide Who's Who for Executives and Professionals and she is a member of the Indiana Healthcare Business Women's Association. She received her undergraduate degree in Biology from the University of Kansas in 1991 and a Doctor of Pharmacy degree from the University of Kansas in 1995. When she is not bringing Quality to the workplace, Yolanda enjoys attending her sons' various activities, playing volleyball, and running with her dog, Henry. She resides in Carmel, Indiana with her sons, Jonathan and Adam.

ABOUT THE SPEAKERS

Kevin J WILSON
Manager, Global Medical Quality Systems
Eli Lilly and Company, USA

Kevin Wilson has been helping to design, implement, and train on Quality systems for the past seven years. Kevin has specialized in the design and deployment of root cause analysis and corrective and preventive action (CAPA) processes. Kevin currently acts as a manager, mentor, and coach to a team of root cause investigators and quality management subject matter experts who are focused on risk mitigation and continuous improvement. Kevin's CAPA system experience has been brought to the Pharmaceutical and Device product lifecycle from Research and Development, through Clinical Development, to Manufacturing, and Post Market Surveillance. The CAPA system has been able to strategically integrate multiple signals including but not limited to Deviations, Complaints, Audits and Inspections, Changes, and Non-conformities.
Kevin has a customer focused mentality, knowing that any Quality system is only as good as the people who use the system. Kevin has been developing not just Quality systems that are easy to use, but building the support structure and tools to enable success. For any Quality system to be ultimately successful, the correct behaviors must be encouraged and rewarded.
Kevin is a graduate of DePauw University, and an ASQ certified Six Sigma Green Belt.

临床研究中的偏差调查和防范措施

会议编码：**#13984 • 2013年9月2-3日**

中国 • 成都

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Training on GCP Regulatory Audit and Inspection

Event I.D. # 13984 – September 2-3, 2013

Chengdu, CHINA

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Tel: +86.28.8292.9999 Fax: +86.28.8292.9977

DRUG INFORMATION ASSOCIATION CHINA OFFICE
7/F, Room 766, Metropolis Tower, No.2 Haidian East Third Street,
Zhongguancun Xi Zone, Haidian District, Beijing, 100080, China
Tel: +86.10.6260.2240 Fax: +86.10.6260.2201
Email: fei.xie@diachina.org or erning.ning@diachina.org
www.diachina.org

CANCELLATION POLICY: ON OR BEFORE AUGUEST 20, 2013

- Cancellation must be made in writing and received by Auguest 20, 2013, in order to receive the refund.
- A cancellation processing fee of RMB 500.00 will be deducted from the refund for each paid registrant.
- No refund if the written cancellation is received after Auguest 20, 2013
- Registrant will be responsible for his own travel, hotel reservation and cancellation expenses

For more meeting details
Please visit www.diachina.org

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

	MEMBER	NON-MEMBER
INDUSTRY	RMB1900 ❑	RMB2700 ❑
NONPROFIT/ACADEMIA/GOVERNMENT	RMB1350 ❑	RMB2150 ❑

* Join DIA now to qualify for the member service and discount!

REQUEST CHINESE OFFICIAL INVOICE (FAPIAO)

❑ Yes ❑ No

Fapiao Title _____

Amount Charged (RMB) _____

Service Item ❑ Consulting Fee

*Fapiao will be provided onsite.

Recipient Address _____

_____

Recipient _____

Phone _____

PAYMENT

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

❑ **Bank Transfer:**

Payment in the amount of RMB_____ Meeting I.D. #13984

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

❑ **POS Terminals Machine Payment (Onsite Price)**

PLEASE CHECK THE APPLICABLE CATEGORY: ❑ Industry ❑ Government ❑ Academia ❑ CSO/CRO

PLEASE PRINT ALL INFORMATION CLEARLY

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

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

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

Address in Chinese (If applicable)

Telephone Number Fax Number Mobile Number (Required)

Email (Required for confirmation)

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

宇豪罗曼大酒店
Universal House Grand Romance Hotel
★ ★ ★ ★

酒店预订函

2013年 9月 02 - 03日

请为如下来参加工作会议的客人预订房间

客人姓名： 先生 / 女士 ----------
联系方式 ： ----------
入住日期 ： ----------
离店日期 ： ----------
房间要求：（请勾选，可多选）
☐ 标间 ☐ 单早 ☐ 吸烟房
☐ 大床 ☐ 双早 ☐ 非吸烟房
房间数量 ： ----------

客房类型/房量（间）	DIA协议价格
经济商务单人间/5	259.00
商务标间/97	349.00
商务单间/51	349.00
豪华商务单人间/10	379.00
豪华单间/30	429.00
豪华标间/8	429.00

- 以上所有价格均为人民币,且均已包含服务费10%。
- 以上房价商务房型包含一份自助早餐，其它房型均包含两份自助早餐；
- 若额外增加早餐，须按净价人民币48元/人结算

联系人：王月才
预订电话：+86 13980709465
预订邮箱：370612260@qq.com

No.22, 2 Section, Ren Min Zhong Road, Chengdu, Sichuan, P.R.C. 四川省成都市人民中路二段 22 号 邮编: 610031
Tel / 电话: （86 28）8292 9999 Fax / 传真: (86 28) 8292 9977
Website / 网址:www.minyounhotels.com