

## 美国药典在线点播课程 *USP On-Demand Webinar*

### 美国药典对原料药和制剂中杂质的控制要求

#### Impurities in Drug Substances and Drug Products – A USP Approach

**课程时长 Course Duration:** 约5小时 about 5 hours

#### **课程介绍 Course Description:**

药物杂质因其可能对药品的质量、安全性和有效性产生影响，成为国内外药品监管机构的重点关注内容之一。了解国外法规市场的药物杂质控制要求，加强对药物杂质的分析与控制是国内药品生产企业共同关注的话题。

课程通过介绍 ICH 和 FDA 相关杂质指南、USP 杂质相关通则以及 USP 各论的杂质检测方法，详细阐述美国药典通则<476>“原料药和制剂中有机杂质的控制”和通则<1086>“原料药和制剂中的杂质”要求，以及 USP 各论开发和修订中的杂质案例分析。

通过学习，您将了解：杂质的来源和分类；全球与杂质相关的指南；美国药典对原料药和制剂中杂质的控制要求；美国药典杂质相关的通则；USP 在药典协调中的杂质相关工作；通过案例分析了解美国药典杂质相关的文件标准。

This course integrates ICH Guidance and FDA policy for impurities, relevant USP General Chapters about impurities, and USP's approach to impurities in monographs. It also provides insights to USP-NF General Chapters <476> and <1086> and include case studies for impurities in the development and revision.

Upon completion of this course, you will be able to:

- Discuss the origin and classification of impurities in pharmaceuticals.
- Explain global guidance's for impurities.
- Describe the USP approach to impurities in drug substances and drug products.
- Discuss the USP general chapters on impurities.
- Explain the USP approach to harmonization across pharmacopeia.
- Demonstrate knowledge of USP's approach for impurities in documentary standards via case studies.

#### **参课对象 Who Should Attend:**

制药和相关行业的实验室经理、主管和技术员、QA/QC 人员、制剂处方研究员、CMC 提交和审核员、法规事务人员等。

Lab scientists, supervisors and managers, QA/QC, Formulators, Manufacturing scientists, CMC submission and review scientists, Regulatory professionals

#### **授课语言 Language:**

英语（含中文字幕） English (with Chinese subtitles)

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#### Impurities in Drug Substances and Drug Products – A USP Approach

##### 讲师介绍 Instructor:

**Christian Zeine 博士**，美国药典委员会科学事务高级经理

**Christian Zeine Ph.D. Senior Manager Scientific Affairs, USP**

Christian Zeine 博士是 USP 欧洲区科学事务高级经理，专注于小分子各论、USP 通则和生物制品标准。Zeine 博士与科学专家和利益相关者合作，负责保护和提升 USP 在该区域和全球的科学声誉。在加入 USP 之前，Zeine 博士在药物杂质标准物质领域工作了 17 年，之前任职于 IVD（体外诊断）行业。他的科学专长包括杂质测试、标准物质表征和相关领域。Zeine 博士发表了多篇文章和白皮书，主题包括杂质、标准物质在方法开发和方法验证中的使用等。

Dr. Christian Zeine is Senior Manager in the Scientific Affairs Group for the EMEA region, with a focus on Small Molecules, USP's General Chapters and Biologics. Dr. Zeine collaborates with scientific experts and stakeholders and is responsible to protect and grow USP's scientific reputation in the region and globally. Before joining USP, Dr. Zeine worked for seventeen years in the field of pharmaceutical reference standards with a focus on impurities, and before that in the IVD (In Vitro Diagnostic) industry. His scientific expertise includes impurity testing, reference standards characterization and adjacent fields. Dr. Zeine has published several articles and white papers on topics such as impurities, overview about (certified) reference materials, and the use of reference standards in method development and validation.

##### 课程有效期 Access Deadline:

课程在线观看有效期：自在线报名并缴费成功日起，14 天内有效，逾期课程访问通道将自动关闭。  
(报名成功后您会收到课程登录信息通知邮件)

This course will be only available to you for 14 days from the day of successful registration or until you mark it 'Complete' in your transcript– whichever occurs first.

**培训费用 Fee:** 1,200 元人民币/人 RMB 1,200/attendee

##### 报名方式 Register Procedures:

1. 点击这里 ([课程报名](#)) 进行在线报名。

USP-China 收款账户: USP-China account

**收款人 Beneficiary:** 美药典标准研发技术服务(上海)有限公司

**账号 Account No.:** 6841 12464 120

**银行 Bank:** 美国银行有限公司上海分行

2. 发票领取: 快递/邮寄方式提供 Invoice is available by express after successful registration.