美 国 药 典 在 线 点 播 课 程 USP On-Demand Webinar

制药用水系统的验证：USP 通则<1231>

Validation of Pharmaceutical Water System: USP General Chapter <1231>

课程时长 Course Duration: 90分钟 **90 minutes**

课程介绍 Course Description:

为生产高质量的水，必须对制药用水系统进行合理设计、运营和维护。“USP 通则<1231>制药用水”提供了关于维护、验证和监控制药用水系统的详细信息。验证是证明制药用水系统的设计和运行始终如一地产生符合USP要求的水的过程。USP通则<1231>广泛讨论了生命周期元素，用于维护已验证的控制状态。本课程对制药用水系统的验证和确认方法进行了专门讨论，包括设计和操作、水采样的目的和方法、与测试结果相关的“触发警戒”、以及微生物鉴定。*（USP 通则<1231>的其余内容将在其他课程中进行讨论。）*

通过学习本课程，您将了解验证水系统的要素，验证的法规要求（包括 FDA 和欧盟 GMP 指南附录 15）；学习制药用水系统的确认和验证方法，制定验证、过程控制和质量控制的样本方案；对正在开展的维护已验证的控制状态所需的活动进行识别。

Pharmaceutical water systems must be appropriately designed, operated, and maintained in order to produce high quality water. USP General Chapter <1231> Water for Pharmaceutical Purposes provides detailed information about nearly every aspect of maintaining, validating, and monitoring a pharmaceutical water system. Validation is the process to demonstrate that the design and operation of a pharmaceutical water system consistently produces water that meets USP requirements. General Chapter <1231> provides extensive discussion of the life cycle elements to maintain a validated state of control. This webinar specifically addresses validation and qualification approaches, including design and operation, water sampling purposes and procedures, the “trigger levels” associated with test results, and microbial identification. Other elements of USP Chapter <1231> will be discussed in future webinars.
By taking this course, you will

- Understand the elements to validate water systems
- Compare the regulatory requirements for validation including FDA and the new EU GMP Guidelines Annex 15
- Qualification and Validation
- Develop a sample plan for validation, process control, and quality control
- Identify the ongoing activities needed to maintain a validated state of control

参课对象 Who Should Attend:

水系统工程师/所有者/用户、生产经理、化学和微生物分析员、化学和微生物实验室经理、验证经理、QA/QC 经理、合规经理、法规事务专员等。

Water system engineers, owners, and users; Production managers; Analytical chemists and microbiologists; Chemistry and microbiology lab managers; Validation managers; QA/QC managers; Compliance managers; Regulatory affairs specialists

授课语言 Language:

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

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制药用水系统的验证：USP 通则<1231>

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讲师介绍 Instructor:

Rosty Slabicky，美国药典专家委员会委员

Rosty Slabicky, BS Ch E., USP Expert Committee Member

Rosty Slabicky 先生是 USP 通则-化学分析专家委员会委员，并且是多个 USP 专家顾问组成员。他作为顾问参与 USP 的工作长达 25 年，参与制定了现代制药用水标准，并连续三届担任 USP 制药用水的专家志愿者。他还曾任 PhRMA 水质量委员会主席，该委员会提出了当代水标准。

Slabicky 先生自 1986 年以来一直担任 Boehringer Ingelheim Pharmaceuticals Inc.的地区质量、合规和审计总监。他在美国纽约理工学院（Polytechnic Institute of New York，现以归属于 New York University）获得了化学工程学士学位。

Rosty Slabicky is a member of the USP General Chapters - Chemical Analysis Expert Committee and serves on several Expert Panels, including Combined Pharmaceutical Waters. He has been involved in developing the contemporary pharmaceutical water standards and associated with USP for over 25 years as an advisor, and USP Pharmaceutical Waters expert during three consecutive cycles as a volunteer. He also served as Chairman of the PhRMA Water Quality Committee that proposed the contemporary water standards.
Mr. Slabicky is Director of Regional Quality, Compliance and Audits with Boehringer Ingelheim Pharmaceuticals Inc. since 1986. He earned the degree of Bachelor of Science in Chemical Engineering from the Polytechnic Institute of New York, now part of New York University

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: 350 元人民币/人　RMB 350/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.

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