

美国药典在线点播课程 USP On-Demand Webinar

美国药典制药用水要求

USP Perspectives on Pharmaceutical Waters

课程时长 Course Duration: 11小时 11 hours

课程介绍与目的 Course Description and Objectives:

课程全面、详尽地介绍源水、纯化水、注射用水、无菌注射水和其他无菌水各论、血液透析用水和纯蒸汽的美国药典和法规要求，检查产生这些水的系统，以及确保保持化学和微生物特性所需的化学和微生物控制要求。同时，还将介绍与水相关的 USP 通则<643>总有机碳、<645>水电导率、<1231>制药用水的修订提议。

通过学习，您将能够解释源水质量和预处理问题的重要性；总结对纯化水、注射用水和其他 US 水各论的要求（包括标准、测试和设备）；根据 USP 通则<232>解释元素杂质要求的影响；了解生物膜如何在制药用水系统中繁殖；解释生物膜如何影响净化单元操作和水质；讨论如何控制水的化学和微生物质量；确定制药用水系统中微生物控制的现实和误解；总结将要进行和正在进行的制药用水相关计划。

该课程的现场版本录制于 2021 年 4 月 21-22 日。

This two-day course explains compendial and regulatory requirements for source waters, purified water, water for injection(s), sterile water for injection and other sterile water monographs, water for hemodialysis and pure steam. The course examines the systems that produce these waters as well as the chemical and microbiological controls that are required to ensure chemical and microbiological attributes are maintained. The course will also address proposed changes for the water related USP General Chapters Total Organic Carbon <643>, Water Conductivity <645> and Water for Pharmaceutical Purposes <1231>. (The live version of this recording took place on April 21 - 22, 2021.)

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

- Explain the importance of source water quality and pre-treatment concerns.
- Summarize the requirements for purified water, water for injection and other USP water monographs, including specifications, testing, and instrumentation.
- Explain the impact of elemental impurities requirements according to USP General Chapter <232>.
- Describe how biofilm propagates in pharmaceutical water systems.
- Explain how biofilm impacts purification unit operations and water quality.
- Discuss how to control the chemical and microbial quality of the water.
- Identify the realities and myths for microbial control in pharmaceutical water systems.
- Summarize the pending and ongoing pharmaceutical water initiatives.

参课对象 Who Should Attend:

化学分析员、水系统设计师、监管机构人员、制药工程师、工艺工程师、QA 和 QC 经理/专员、设施维护人员等。

Analytical chemists, Water system designers, Regulatory Authorities, Pharmaceutical Engineers, Process Engineers, QA & QC Managers/Scientists, Maintenance Personnel, etc.

授课语言 Language:

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

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课程纲要 **Course Outline**

- USP 和化学分析专家委员会介绍 Introduction to USP and the Chemical Analysis Expert Committee
- 水、水系统与水化学 101 Water, Water Systems and Water Chemistry 101
- 纯化水和注射用水的各论要求 Overview of Purified Water and Water for Injection Monograph Requirements
- 无菌用水的各论要求 Overview of Sterile Water Monograph Requirements
- 纯蒸汽以及透析用水概览 Overview of Pure Steam and Water for Hemodialysis
- 生物膜及其对水系统纯化运作的影响 Biofilm and Its Effect on Water System Purification Operations
- 水系统微生物控制和消毒方法 Water System Microbial Control and Sanitization Methods
- 水的微生物检测方法 Microbial Test Methods for Water
- 电导率 Conductivity
- USP 通则<645> 水电导率 USP <645> Conductivity
- 总有机碳 Total Organic Carbon
- USP 通则<643>总有机碳 USP <643> Total Organic Carbon
- 水的内毒素检测和控制 Testing and Controlling Endotoxins in Water
- 制药用水和蒸汽系统验证 Validation of Pharmaceutical Water and Steam Systems
- USP 通则<1231>制药用水 Overview of USP Chapter<1231> Water for Pharmaceutical Proposes

讲师介绍 **Instructor:**

Anthony C. Bevilacqua 博士，美国药典专家委员会委员 USP Chemical Analysis Expert Committee Member

Anthony Bevilacqua 博士是美国梅特勒-托利多·桑顿 (Mettler-Toledo Thornton) 公司的研发负责人。他在美国塔夫茨大学 (Tufts University) 获得了分析化学和物理化学博士学位。自 1994 年以来，Bevilacqua 博士一直任职于桑顿公司，在仪器仪表开发的多个研发领域取得进展，包括优化高温电导率测量，研究二氧化碳对纯水的影响，使用超纯水 (UPW) 作为电导率标准溶液，开发数字化传感器，以及拓展用于分析和控制高纯水系统（包括制药用水系统）的实时分析参数（电导率、总有机碳、微生物检测、臭氧、钠和二氧化硅）。

在 90 年代中期，Bevilacqua 博士在 USP 通则<645>水电导率和<643>总有机碳的实施期间担任 USP 的电导率顾问，他开发了用于纯净水和注射用水的电导率测试的理论、方法和实践。Bevilacqua 博士在 2000-2005 年和 2005-2010 年期间曾担任 USP 制药用水专家委员会主席，在 2010-2015、2015-2020、2022-2025 期间担任 USP 化学分析专家委员会委员。在过去的 20 年中，Bevilacqua 博士一直与欧洲药典、日本药典及其他药典机构一起致力于制药用水质量标准和分析测试方法的国际协调工作。

Dr. Anthony Bevilacqua is the Head of Research and Development at Mettler-Toledo Thornton. He earned a doctorate in Analytical and Physical Chemistry from Tufts University. He has been at Thornton since 1994, leading the instrumentation development for Thornton in several areas of R&D including improved high temperature conductivity measurements, the impact of CO₂ on pure water, use of ultrapure water (UPW) as a conductivity solution standard, development of digital sensors, and the expansion of real-time analytical parameters (conductivity, TOC, microbial detection, ozone, sodium, and silica) for measurement and control of high purity water systems, including pharmaceutical water systems.

Anthony was the conductivity consultant to the USP during the implementation period for the <645> Water Conductivity and <643> Total Organic Carbon USP chapters in the mid-1990's, and he developed the theory, methods, and practices used for conductivity testing for Purified Water and WFI. Anthony was Chair of the USP Pharmaceutical Water Expert Committee from 2000-2005 and 2005-2010. In addition, Anthony's role continued in the 2010-2015 and 2015-2020 USP Chemical Analysis Expert Committee (CA EC), and he is serving on the current CA EC for 2020-2025. For the last 20 years, he has been working with EP, JP and other Pharmacopeias for international harmonization of pharmaceutical water quality standards and analytical test methods.

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讲师介绍 (续) Instructor (cont.):

Lucia Clontz 博士, 美国药典委员会顾问, 制药用水专家小组成员。

Lucia Clontz, Ph.D., USP Consultant, Pharmaceutical Waters Expert Panel

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: 2000 元人民币/人 RMB 2000/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 after registration.