

## 美国药典在线点播课程 *USP On-Demand Webinar*

### 总有机碳：USP 通则<643>

### Total Organic Carbon: USP General Chapter <643>

**课程时长 Course Duration:** 70分钟 70 minutes

#### **课程介绍与目的 Course Description and Objectives:**

“USP 通则<643>总有机碳”自 1996 年 USP23 版生效至今，已被其他药典采用作为测定纯化水和注射用水中有机杂质的主要方法。该测试补充了 USP 通则<645>水电导率（离子/无机杂质）。通则<643>是确定水纯化系统中有充分的化学物质控制/减少的主要的化学限度测试方法。课程将介绍测试目的、仪器要求、校准要求、在线和离线测量值、以及各种制药用水的测试限度要求。

通过学习，您将了解总有机碳方法的基本原理，总有机碳杂质的来源及如何对其进行控制；学习通则<643>的仪器设备要求；熟悉在线/离线测量和要求的区别；了解美国药典与其他药典对于各种散装水和无菌水的测试限度。

USP General Chapter <643> Total Organic Carbon has been official since USP 23 (1996), and it has been adopted by other pharmacopoeia as the primary method for the determination of organic impurities in Purified Water and WFI. This test complements USP <645> Water Conductivity (for ionic/inorganic impurities). <643> is the primary chemical limit test to determine that there is sufficient control/reduction of chemicals in the water purification system. This webinar will explain the purpose of this test, the instrumentation requirements, calibration requirements, the value of on-line and off-line measurements, and the test limit requirements for various pharmaceutical waters.

By taking this course, you will

- Understand the basic principles of the TOC method.
- where TOC impurities come from and how they are controlled.
- Learn the instrumentation requirements of <643>.
- Become more familiar with the differences between on-line and off-line measurements and requirements.
- Understand the test limits for various bulk and sterile waters for USP and other pharmacopoeia.

#### **参训对象 Who Should Attend:**

化学分析员、QA/QC 经理、合规经理、水系统工程师/所有者、实验室经理、生产经理、法规事务人员等。

Analytical chemists, QA/QC managers, Compliance managers, Water system engineers and owners, Lab managers, Production managers, Regulatory affairs specialists

#### **授课语言 Language:**

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

#### **讲师介绍 Instructor:**

**Anthony C. Bevilacqua 博士，美国药典专家委员会委员 USP Consultant & 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，

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#### 讲师介绍 Instructor: (cont.)

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 CO<sub>2</sub> 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.

#### 课程有效期 Access Duration:

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）

Access to this course expires 14 days from the date of registration or until you mark it 'Complete' in your transcript—whichever occurs first.

培训费用 **Fee:** 250 元人民币/人 RMB 250/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.