

## 美国药典在线点播课程 USP On-Demand Webinar

# 制药用水的微生物分析：USP 通则<1231> Microbiological Analysis of Pharmaceutical Water: USP General Chapter <1231>

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

### 课程介绍 **Course Description:**

为了生产高质量的水，必须对制药用水系统进行适当维护。“USP 通则<1231>制药用水”提供了关于维护、鉴定和监控制药用水系统的详细信息。微生物控制无疑是制药用水系统中最具挑战的工作，因此通则<1231>大量介绍了如何对其进行监控。本课程针对性地对微生物监控问题进行了介绍，包含生物膜开发、微生物检测方法、水采样的目的和方法、与测试结果关联的“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：水系统生物膜生长的基础知识、用于确定系统中微生物组的可用的测试方法选项；学习使用微数据进行过程控制和质量控制，包括警报限/行动限及其标准；了解正确、一致的采样技术和位置的重要性；学习何时以及为何需要识别微生物。

Pharmaceutical Water Systems must be appropriately 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, qualifying, and monitoring a pharmaceutical water system. Microbial control is unarguably the most challenging aspect of operating a pharmaceutical water system, which is why it is discussed extensively in <1231> along with how to monitor it. This webinar specifically addresses microbial monitoring issues, including biofilm development, microbial test methods, water sampling purposes and procedures, the “trigger levels” associated with the test results, and microbial identification. Other elements of the USP Chapter <1231> will be discussed in future webinars.

By taking this course, you will

- Understand the basics of water system biofilm growth
- Understand the available test method options for determining the microbiome in your system
- Learn the process control and quality control uses of the micro data, including Alert and Action Levels and Specifications
- Understand the importance of proper and consistent sampling technique and locations
- Learn when and why microbial identification is needed

### 参课对象 **Who Should Attend:**

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

Analytical microbiologists, Microbiology lab managers, QA/QC managers, Water system engineers, owners, and users, Production managers, Compliance managers, Regulatory affairs specialists

### 授课语言 **Language:**

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

美国药典在线点播课程 *USP On-Demand Webinar*

## 制药用水的微生物分析：USP 通则&lt;1231&gt;

## Microbiological Analysis of Pharmaceutical Water: USP General Chapter &lt;1231&gt;

讲师介绍 **Instructor:**

**Teri C. Soli 博士，美国药典专家委员会委员 Teri C. Soli, Ph.D., USP Consultant & Expert Committee Member**

T. C. Soli 博士是微生物学家，Soli Pharma Solutions 公司总裁，在涉及水系统、灭菌、无菌和非无菌制造、微生物实验室以及微生物和 β-内酰胺污染控制领域提供故障排除和培训的专业知识。他有 40 年的医药顾问经验，曾在 DSM Pharmaceuticals、Glaxo Wellcome、Burroughs Wellcome 和 Pfizer 等公司任职。

Soli 博士在 USP 制药用水专家委员会服务的 18 年中，参与共同编著了 USP 中与水有关的所有章节。他曾在美国药品研究和制造商协会（PhRMA）水质量委员会任职 18 年，其成就包括制定了 USP 纯净水和注射用水的水电导率和总有机碳规范，并在全球范围内被采用。

Soli 博士是生物制药、医疗设备和个人护理产品行业中涉及污染和生物膜控制方面公认的全球专家，他在 USP 药典论坛、制药工程和制药技术以及其他出版物中发表了多篇文章，并为 PDA 和 ISPE 出版的许多书籍和行业指南撰写章节。他毕业于美国亚利桑那大学，微生物学和免疫学博士。

T.C. Soli is a Ph.D. Microbiologist and President of Soli Pharma Solutions, Inc. offering troubleshooting and training expertise covering water systems, sterilization, sterile and non-sterile manufacturing, microbiological laboratories, and microbial and beta-lactam contamination control. He has 39 years of pharmaceutical experience as a consultant and with operating companies including DSM Pharmaceuticals, Glaxo Wellcome, Burroughs Wellcome, and Pfizer. He is in his 18th year on USP Expert Committees responsible for Pharmaceutical Water and has co-authored everything related to water in USP. He previously served for 18 years on the PhRMA Water Quality Committee whose achievements included creating the Water Conductivity and TOC specifications used in USP Purified Water and Water for Injection and adopted world-wide.

Dr. Soli is a recognized global expert in contamination and biofilm control in the Biopharmaceutical, Medical Device, and Personal Care Product Industries and has authored numerous articles in Pharmacopeial Forum, Pharmaceutical Engineering, and Pharmaceutical Technology, as well as other publications and has authored chapters in many books and industry guides published by PDA and ISPE. He's Ph.D., Microbiology and Immunology, graduated from University of Arizona.

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.