

## 美国药典在线点播课程 *USP On-Demand Webinar*

### 分析仪器和系统确认：全生命周期方法 Enhancement of General Chapter 1058 Analytical Instruments and Systems Qualification: A Full Lifecycle Approach

课程时长 **Course Duration:** 60分钟 60 minutes

免费视频课!

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

美国药典有两个通则对生命周期的方法和要求进行了概述，通过证明计量(通则<1058>)和方法(通则<1220>)的完整性来确保数据质量。USP 通则<1058>“分析仪器的确认”正在进行修订，旨在将现行版本更新为全生命周期方法并支持 USP 通则<1220>“分析方法生命周期”。USP 通则<1058>旨在提供一个框架，确定仪器和系统“适合预期用途”，用于根据 USP 通则<1220>在分析方法中生成“适合预期用途”的结果，以确定是否符合 USP 各论标准。

United States Pharmacopoeia (USP) has two General Chapters summarizing the lifecycle approaches and requirements to ensure data quality by demonstrating metrological (<1058>) and procedural integrity (<1220>). United States Pharmacopoeia (USP) General Chapter <1058> on Analytical Instrument Qualification (AIQ) is undergoing a revision process which intends to enhance the current version to a fully lifecycle approach and support General Chapter <1220> on Analytical Procedure Lifecycle. General Chapter <1058> is intended to provide a framework establishing 'fitness for intended use' of instruments and systems for use within analytical procedures generating results which are 'fit for intended purpose' in accordance with General Chapter <1220> for establishing compliance with the standard monographs of the USP.

#### 参课对象 **Who Should Attend:**

仪器和系统生产商，行业最终用户（如制药行业研发实验室人员、质量控制实验室人员、实验室计量小组人员），CRO 和 CDMO 实验室人员及相关职能部门工作人员，行业协会以及监管机构，分析化学和制药科学研究生和博士后，分析化学和制药科学专业教职人员，验证和计量工程师、员工和管理人员，咨询顾问。

Instrument and system manufacturers, industry end users (such as pharmaceutical industry research and development laboratory staff, QC laboratory staff, metrology groups staff in centralized laboratories), contract research and development and contract pharmaceutical manufacturers laboratory staff and related functions staff, industry associations and groups as well as regulators, Analytical Chemistry and Pharmaceutical Science graduate students and postdocs. Analytical Chemistry and Pharmaceutical Sciences faculty, Validation and metrology engineers, staff and managers, independent consultants.

#### 授课语言 **Language:**

英语（含英文字幕） English (with English subtitles)

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### 分析仪器 and 系统确认：全生命周期方法

### Enhancement of General Chapter 1058 Analytical Instruments and Systems Qualification: a Full Lifecycle Approach

#### 讲师介绍 Instructor:

**Christopher Burgess** 博士，美国药典委员会通则-化学分析专业委员会成员  
**Christopher Burgess, Ph.D., USP GCCA Expert Committee Member**

Burgess 博士在分析化学和分析科学领域发表了 100 多篇论文、文章和书籍。他是一名特许化学家，在制药行业拥有超过 50 年的经验。Burgess 博士最初在葛兰素公司从事分析研发、质量控制和质量保证工作，之后又在国际咨询公司工作了 30 年。2010 年至 2025 年，他担任美国药典委员会专业委员会成员，负责修订和审查光谱通则<85x>和<185x>系列，他还是斯特拉斯克莱德大学药学和生物医学院 (SIPBS) 的客座教授。Burgess 博士是 USP 负责开发通则<1220>的专业委员会成员，也是负责修订通则<1058>的 JSC 主席。

Dr. Burgess has published over 100 papers, articles and books in analytical chemistry and analytical science. He is a Chartered Chemist and has more than 50 years' experience in the pharmaceutical industry initially with Glaxo in Analytical R&D, Quality Control and Quality Assurance followed by 30 years in international consultancy. He was appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2025 revising and reviewing spectroscopic general chapters <85x> and <185x> series and is a visiting professor at the University of Strathclyde's School of Pharmacy and Biomedical Sciences (SIPBS). He was a member of the USP Expert Panel which developed General Chapter <1220> and is chairman of the JSC tasked with revising General Chapter <1058>.

#### 报名方式 Register Procedures:

本课程免费！请登录 USP 会议与培训中文平台，[点击这里（课程报名）](#) 进行在线报名。

#### 课程有效期 Access Duration:

课程在线观看有效期：自在线报名成功日起，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.