

## 美国药典在线点播课程 *USP On-Demand Webinar*

### USP 微粒系列课程 - 药典微粒标准介绍

### All the Particulars on Particles: Introduction to Compendial Particulate Standards

**课程时长 Course Duration:** 1小时 1hours

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

USP 微粒系列网络课程将向您介绍美国药典微粒标准的最新进展。在本次课程中，我们将概述 USP 微粒现行标准，并与欧洲药典和日本药典的相关标准进行比较。

This series will keep you informed of the latest USP developments on Particulate Matters. For this introductory session, we will provide an overview of current USP standards on particulate matter and compare and contrast to what is published in the European and Japanese Pharmacopoeia.

#### **授课语言 Language:**

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

#### **参课对象 Who Should Attend:**

实验室科学人员、实验室经理、制药和相关行业的 QA/QC 人员、监管人员、以及对微粒感兴趣的科学人员。

Laboratory scientists, Lab managers, QA/QC staff in the pharmaceutical and allied industries, Regulatory professionals, Scientists with interest in Particulate Matter.

#### **讲师介绍 Instructor:**

**Desmond Hunt 博士，美国药典委员会科学部门通则标准资深首席科学家**

**Dr. Desmond Hunt, Senior Principal Scientific Liaison, Science - General Chapters, USP**

作为美国药典委员会科学部门通则标准资深首席科学家，Hunt博士负责协助USP“包装、储存与分销专家委员会”、“制剂专家委员会”建立公共标准。他与工业界、学术界、监管机构和其他科学组织紧密联系，致力于药典通则的制定和修订工作。他有超过20年的丰富科研经验。在加入USP之前，Hunt博士是美国马里兰毕士大国家卫生研究院研究员。他领导了多项开发和建立用于药物包装系统材料公共标准的研究。Hunt博士同时也是产品质量研究所包装和可提取物和浸出物工作组成员。

作为USP药典专业培训讲师，Hunt博士开发并讲授药物包装课程和注射剂微粒检测课程。他在众多国内外会议上经常受邀发表专题演讲。Hunt博士在美国德州大学奥斯汀分校获得理学硕士和博士学位。

Dr. Desmond G. Hunt is a Senior Principal Scientific Liaison in the General Chapters Science division at the United States Pharmacopoeia. He is responsible for assisting USP Expert Committees, Packaging, Storage and Distribution and Dosage Forms, in the development and revision of USP Standards. Dr. Hunt has over 20 years of research experience and prior to joining USP, he was a Research Fellow at the National Institutes of Health, Bethesda, MD, USA. Dr. Hunt has conducted a number of studies relating to the development and establishment of public standards for materials used for pharmaceutical packaging and has developed Pharmacopeial Education Courses on pharmaceutical packaging, the determination of particulate matter in parenterals and ophthalmic products and good storage and shipping practices. He is a member the Product Quality Research Institute Container-Closure and Extractable and Leachable Working Groups. He obtained his Master of Science and Doctoral Degree from the University of Texas at Austin, USA.

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##### 讲师介绍 Instructor (cont.):

**Linda Narhi 博士, 美国药典委员会制剂专家委员会委员**

**Dr. Linda Narhi, USP Dosage Forms Expert Committee**

Narhi博士是USP制剂专家委员会委员、目视检查专家顾问组成员、并领导亚可见微粒分析专家顾问组。同时, 她也是USP利益相关者论坛的副主席。

Linda Narhi博士2019年从Amgen公司工艺开发科学组科学执行董事的职位上退休, 目前是Genentech和其他公司的兼职顾问。她于30多年前加入安进公司, 一直致力于生物医药工艺和产品开发工作, 包括蛋白质候选物的选择、蛋白质高阶结构的表征、蛋白质聚合物和微粒, 以及研究蛋白质属性特别是聚合物对分子潜在免疫原性的影响。她在这些领域发表过大量文章。

Narhi博士在美国密歇根大学获得化学学士学位, 在加州大学洛杉矶分校获得生物化学博士学位。她是加州大学圣巴巴拉分校的兼职教授, 也是加州大学洛杉矶分校生物工程项目的工业咨询委员会的联合主席。

Linda Narhi is a member of the USP Dosage Form expert committee, and of the expert panels for visible inspection, devices, and leads the expert panel on subvisible particle analysis. She is also the vice-chair for the USP stakeholders Forum. She recently retired as scientific executive director in the attributes science group in process development at Amgen. She is currently consulting part time for Genentech and others. She joined Amgen more than 30 years ago and has been involved in the process and product development of Bio therapeutics throughout her career. It includes protein candidate selection, characterization of protein higher-order structure and protein aggregate and particles, and studying the impact of protein attributes, especially aggregates, on the potential immunogenicity of molecules. She's published extensively on these topics. She received her bachelor's in chemistry degree from the University of Michigan and her doctorate in Biology Chemistry from UCLA. She's also an adjunct professor at the University of California Santa Barbara. She is the co-chair of the Industrial Advisory Board for the UCLA Bioengineering program.

**John G. Shabushnig 博士, 美国药典委员会制剂专家委员会委员**

**Dr. John G. Shabushnig, USP Dosage Forms Expert Committee**

Shabushnig博士是美国药典委员会制剂专家委员会委员, 并领导注射剂目视检测专家顾问组。他是Insight Pharma咨询公司的创始人, 提供目视检测和微粒控制领域的专业咨询指导。他在Upjohn公司担任科学家, 开始了他的医药职业生涯, 之后在Pharmacia公司的运营部工作, 随后在辉瑞公司的企业QA部门中担任经理。

Shabushnig博士在美国卡罗尔学院获得化学学士学位, 在美国印第安纳大学获得分析化学博士学位。他是美国注射剂协会(PDA)成员, 曾担任董事会主席和科学顾问委员会主席, 组织并领导目视检测小组。他还负责PDA的培训和研究机构的指导工作。他发表了许多关于光谱分析、PAT、快速微生物测试和药品目视检测的论文。Shabushnig博士与他人合著出版了《目视检测和微粒控制》。

John serves on the USP Dosage Forms Expert Committee and chairs the Visual Inspection of Parenterals Expert Panel. He is the founder of Insight Pharma Consulting, providing expert guidance in visual inspection and particle control. He began his pharmaceutical career as a scientist with The Upjohn Company and subsequently worked in Operations with Pharmacia and finally as a manager in Pfizer's Corporate Quality Assurance organization. John holds a B.S. in Chemistry from Carroll College and a Ph.D. in Analytical Chemistry from Indiana University. He is an active member of the Parenteral Drug Association, having served as chair of the Board of Directors and chair of the Science Advisory Board. He organized and led the Visual Inspection Interest Group. He also instructs at PDA's Training and Research Institute. He has published and presented numerous papers on spectroscopic analysis, PAT, rapid microbiological testing and visual inspection of pharmaceutical products. He co-authored the recently published book Visual Inspection and Particulate Control.

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##### 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:** 200 元人民币/人 RMB 200/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.