

美国药典在线点播课程 USP On-Demand Webinar

USP 微粒系列课程 —

亚可见微粒：美国药典通则 <787>, <788>, <1787>和<1788>

All the Particulars on Particles –

Subvisible Particles: USP General Chapters <787>, <788>, <1787> and <1788>

课程时长 Course Duration: 1.5 小时 1.5 hour

课程介绍 Course Description:

USP 微粒系列网络课程向您介绍美国药典微粒标准的最新进展。本课程着重讨论 USP 通则 <787>, <788>, <1787>和<1788>, 内容包括在注射中观察到的亚可见微粒。课程还将讨论相关通则的演变、方法与要求、方法确认的概念及其他技术考量。

(本课程的现场版本录制于 2022 年 9 月 20 日)

This series will keep you informed of the latest USP developments on Particulate Matters. The series will focus on USP General Chapters <787>, <788>, <1787>, and <1788>, which address particles observed in injections in the subvisible range. Discussions will cover the evolution of USP chapters, methods and requirements, concepts of method qualification, and other technical considerations.

(The live version of this recording took place on September 20, 2022.)

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、法规监管人员、以及对微粒感兴趣的科研人员。

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:

D. Scott Aldrich, 美国药典委员会制剂专家委员会委员 USP Dosage Forms Expert Committee

Scott Aldrich 是美国药典委员会制剂专家委员会委员。他曾就职于 Upjohn、Pharmacia、Pharmacia & Upjohn 和 Pfizer 公司，拥有超过 35 年的行业经验。他指导实验室分析员专注于微粒研究工作。微粒大小、分布和表征是各种剂型实验室分析人员的首要工作。Scott 曾在过去 11 年中担任 Ultramikro LLC 的首席顾问，为制药、仪器和食品行业的人员提供微粒控制研究和微量分析培训。Scott 热衷于应用显微镜方法来鉴定微粒。他的研究领域涉及目视检测、显微镜分析和光谱分析领域。

Scott is a member of the USP Dosage Forms expert committee. With pharmaceutical positions at Upjohn, Pharmacia, Pharmacia & Upjohn and Pfizer over 35 years, Scott directed analytical personnel in labs specializing in particulate matter investigation. Particle size, distribution and characterization were the primary efforts in these organizational units, for a wide array of dose forms. As the principal consultant for Ultramikro LLC for the last 11 years, he provides particulate matter control investigation and microanalytical training for personnel in the pharmaceutical, instrument and food industries. His passion is the application of microscopical methods for the identification of particulate matter. Scott has published and presented his work in the field of visual inspection, microanalysis and spectroscopic analyses.

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All the Particulars on Particles – Subvisible Particles: USP General Chapters <787>, <788>, <1787> and <1788>

讲师介绍 **Instructor (cont.):**

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。Hunt博士是USP药典专业培训讲师，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 Pharmacopoeial 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.

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.

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讲师介绍 Instructor (cont.):

Dean Ripple博士，美国药典委员会制剂专家委员会委员
Dr. Dean Ripple, USP Dosage Forms Expert Committee

Dan Berdovich，美国药典委员会制剂专家委员会委员
Dan Berdovich, USP Dosage Forms Expert Committee

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**: 300 元人民币/人 RMB 300/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.