美 国 药 典 在 线 点 播 课 程 USP On-Demand Webinar

USP 微粒系列课程–可见微粒：美国药典通则<1>，<790>和<1790>

All the Particulars on Particles Visible Particles: Introduction to Compendial Particulate Standard USP General Chapters <1>, <790>, and <1790>

课程时长 Course Duration: **1小时** 1 hour

课程介绍与目的 Course Description and Objectives:

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。课程着重于 USP 通则〈1〉、〈790〉和〈1790〉，内容涉及在可见范围内注射剂中可观察到的微粒。同时，也将介绍具体方法和要求，并与欧洲药典和日本药典中的相关标准进行比较。课程还将讨论 FDA 发布的题为“注射产品的可见微粒检查”的指南草案。

（本课程的现场版本录制于 2022 年 5 月 12 日）

This series will keep you informed of the latest USP developments on Particulate Matters. The series will focus on USP General Chapters <1>, <790> and <1790>, which address particles observed in injections in the visible range. Specific methods and requirements will be reviewed and compared with similar expectations found in the European and Japanese Pharmacopeias. Also included is a discussion about the released draft guidance from FDA titled Inspection of Injectable Products for Visible Particles.

(The live version of this recording took place on May 12, 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、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。他指导实验室分析人员专项于微粒调查。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调查和显微镜分析培训。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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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 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.

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 leaded 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.

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