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

## USP 微粒系列课程 — 眼用制剂：美国药典通则<771>和<789>

## All the Particulars on Particles: Ophthalmic Products - USP<771>, and <789>

**课程时长 Course Duration:** **1.5 小时** 1.5 hour

**课程介绍 Course Description:**

USP 微粒系列网络会议将向您介绍美国药典微粒物标准的最新进展。本次课程将着重于 USP 通则<771>、可见微粒(通则<790>)和亚可见微粒(通则<788>和<789>)标准对眼用制剂的适用性，内容将涵盖 USP 通则的演变、方法和要求、方法认证的概念以及其他技术考量。

This webinar series will update you on the latest USP developments in Particulate Matters. This webinar will focus on USP General Chapter <771> and the applicability of USP's visible (<790>) and subvisible (<788> and <789>) standards to ophthalmic drug products. Discussions will cover the evolution of USP chapters, methods and requirements, concepts of method qualification, and other technical considerations.

**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、制药及相关行业的 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 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、储存与流通专家委员会”、“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.

**Margareth Marques博士，美国药典委员会资深首席科学家**
**Dr. Margareth Marques, Senior Principal Scientist, USP**

Margareth Marques博士是USP资深首席科学家，她负责管理有关溶出度、崩解度、药物释放、眼用制剂和皮肤应用产品的书面标准。此外，她还负责管理关于试剂、色谱柱和溶出/崩解测试的数据库。Margareth Marques博士是《溶出技术》杂志的编辑和撰稿人。Margareth Marques博士在巴西圣保罗大学获得药学学士学位和药学硕士学位，以及在巴西坎皮纳斯州立大学获得分析化学博士学位。Margareth Marques博士在活性药物成分和药物制剂的质量控制和质量保证领域有超过20年的经验。

Dr. Margareth Marques is currently Senior Principal Scientist at USP, where she manages several documentary standards on dissolution, disintegration, drug release, ophthalmic products and products applied to the skin. In addition, she manages the databases on reagents, chromatographic columns and dissolution/disintegration tests. She is an editor and contributor to the Dissolution Technologies journal. She has a Bachelor degree in Pharmacy, a M.Sc. in Pharmacy, both by the University of Sao Paulo, Brazil, and a Ph.D. in Analytical Chemistry by the State University of Campinas, Brazil. She has more than 20 years of experience in Quality Control and Quality Assurance both for active pharmaceutical ingredients as well as for pharmaceutical dosage forms.

**Dr. Mary Lee Ciolkowski, 美国药典委员会通则<1790>&<788>专家顾问组顾问**
**Dr. Mary Lee Ciolkowski, USP <1790> & <788> Expert Panels**

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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：** 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.

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