

美国药典在线点播课程 *USP On-Demand Webinar*

USP 微粒系列课程 – 硅油液滴

All the Particulars on Particles: Silicone Oil Droplets

课程时长 Course Duration: 1.5小时 1.5 hours

课程介绍与目的 Course Description and Objectives:

USP 微粒系列网络课程介绍美国药典微粒标准的最新进展。作为润滑剂，硅油存在于药品生产和管理的许多材料中，并且硅油可能从这些来源（包括瓶塞、注射器、管材等工艺设备）渗入药品中。本课程将通过案例分析讨论来自分析和检验方面的挑战以及安全顾虑，还将介绍一项跨组织合作项目成果，该项目旨在研究商业产品中硅油的影响。

This webinar series will update you on the latest USP developments in Particulate Matter. Silicone oil is present as a lubricant on many materials used during drug manufacturing and administration and can leach into drug product from these sources (including stoppers, syringes, tubing other processing equipment). This webinar will discuss the analytical and inspection challenges as well as the safety concerns they present. Results from a cross-organization collaboration looking at the effects of Si oil in commercial products will be presented.

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:

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。

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讲师介绍 **Instructor (cont.):**

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.

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.

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

Miguel Saggi博士, Genentech公司药物发展部门资深首席科学家

Dr. Miguel Saggi, Sr. Principal Scientist, Pharmaceutical Development, Genentech

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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：电子发票通过电子邮件发送 e-Invoice is available by email after successful registration.