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

液体中微粒物的测定：肠外和眼科产品
Determining Particulate Matter in Liquids: Parenteral & Ophthalmic Products

课程时长 Course Duration: 3.5小时 3.5 hours

课程介绍与目的 Course Description and Objectives:

对无菌注射药品进行微粒物测定的要求已有 30 多年的历史，然而，最近敏感蛋白药品标准方法的改进为药典标准带来了变化和其他背景信息。本课程将讨论现行通则<788>注射剂中的微粒物和通则<1788>注射剂和眼用溶液中微粒物的测定方法，亚可见微粒测定的要求。还将介绍通则<787>治疗性蛋白质注射液中亚可见微粒物的微粒测定，以及通则<1787>治疗性蛋白质注射液中超细微粒物的测量，为亚-10μm 微粒物表征提供了背景和原理。同时，也将介绍可见微粒的测定和两个相关通则 – <790>注射剂中的可见微粒、<1790>注射剂的目视检查。

通过学习，您将能够：

- 了解微粒物与注射剂概述
- 了解亚可见和可见的微粒测定方法
- 应用实验室配置和样品制备方法
- 了解 USP 通则<1>注射剂相关主题与通则<788>和<790>之间的关联
- 了解更多关于评估微粒鉴别方法相关信息和建议

Particle determination for sterile injectable products has been required for more than 30 years; however, recent improvements in standard methods for sensitive protein products have brought changes and additional background information to the Compendial guidance. This course will discuss the current <788> Particulate Matter in Injections and <1788> Methods for the Determination of Particulate Matter in Injections and Ophthalmic Solutions, requirements for sub-visible particle determination. In addition, a discussion on the new General Chapter <787>Subvisible Particulate Matter in Therapeutic Protein Injections for particle determination in protein formulations and the informational Chapter <1787> Measurement of Subvisible Particulate Matter in Therapeutic Protein Injections which provides background and rationale for sub-10μm characterization. A portion of the course will focus on visible particle determination and the two new Compendial chapters on the topic, <790> Visible Particulates in Injections and <1790> Visual Inspection of Injections.

Upon completion of this course, you will be able to:

- Outline Perspectives Regarding Particulate Matter and Injectable Products
- Outline Particulate Matter Determination Methods, both subvisible and visible
- Apply lab configuration and sample preparation methodologies
- Relate *USP* Chapter <1> Injections' topics relevant to <788> and <790>
- Find more discussion and advise for evaluating the particle identity from the related informational chapters

授课语言 Language:

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

报名请登录 USP 会议与培训中文平台，点击这里（课程报名）进行在线报名。

美国药典委员会中华区总部 USP-China
中国（上海）浦东新区洲海路 999 号森兰国际大厦 B 栋 801-804 室（200137）
Tel: (86) 21-68619800, Fax: (86) 21-68619810
E-mail: uspcn@usp.org, Website: www.usp.org

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参课对象 Who Should Attend:

从事注射剂产品检查的生产/操作人员，从事对被检产品进行抽样检验或审核检验数据的质量和监管人员，以及从事符合 cGMP 要求和与注射剂相关的监管申报人员。

Manufacturing/Operations Personnel who are responsible for the inspection of injectable products, Quality and Regulatory Personnel who are responsible for the sampling inspection of inspected products or the review of inspection data, and those responsible for compliance with cGMP and regulatory filings associated with injectable products.

讲师介绍 Instructor:

Scott Aldrich，USP制剂专家委员会成员，USP通则<788>和<790>专家小组成员

Scott Aldrich, Dosage Forms Expert Committee, <788>and <790>Expert Panels

Scott Aldrich 是公认的药品微粒物控制专家，他将固态分析方法用于各种上市药品和药品开发。在他的职业生涯中，Scott 解决了影响注射液、混悬液和冻干产品、眼用液体和混悬液、胶囊、压缩片剂、包衣和聚合物输送系统中的微粒问题。

除了具备微粒识别专业知识外，他也是药物检测方法和系统方面的专家。Scott 是一位经验丰富的微分析学科讲师，在光学显微镜、粒度测定、电子显微镜、红外光谱，并且在光学晶体学、物理特性测定、X 射线衍射和热分析方面知识渊博。他曾担任 USP 和 PDA 的专家志愿者。

Scott Aldrich is a recognized expert in pharmaceutical particulate matter control using solid-state analytical approaches for a broad array of commercial pharmaceutical products and in pharmaceutical product development. In his career, Scott has solved particulate matter problems affecting parenteral liquids, suspensions, and lyophilized products, in ophthalmic liquids and suspensions, in capsules, compressed tablets, for coating and for polymeric delivery systems.
In conjunction with particulate matter identification expertise, he has expertise in pharmaceutical inspection methods and systems. Scott is an experienced teacher and lecturer in microanalytical disciplines, primarily optical microscopy, particle size determination, electron microscopy, infrared spectroscopy, and knowledgeable in optical crystallography, physical character determination, X-ray diffraction, and thermal analysis. He has served as expert volunteer for both USP and PDA.

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： 1200 元人民币/人　RMB 1,200/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.

美国药典委员会中华区总部 USP-China
中国（上海）浦东新区洲海路 999 号森兰国际大厦 B 栋 801-804 室（200137）
Tel: (86) 21-68619800, Fax: (86) 21-68619810
E-mail: uspcn@usp.org, Website: www.usp.org