

## 美国药典在线点播课程 USP On-Demand Webinar

### What's New in Biologics? 猪、牛肝素钠分析 What's New in Biologics? Analysis of Heparin Sodium Porcine and Bovine

#### 课程时长 Course Duration:

50分钟 50 minutes

#### 课程介绍 Course Description:

肝素钠是一种重要的抗凝血药物，有许多适应症，用于输血、透析流程、治疗栓塞。除了作为药物的功能外，肝素钠原料药也是用于治疗深静脉血栓的低分子量肝素的起始物料，如依诺肝素和达肝素。用于制造肝素钠的起始物料主要来自于猪，因此容易受到与牲畜有关的供应问题和潜在的掺假问题的影响。USP 有许多工具可用于肝素钠药物原料和低分子量肝素的质量评估，包括杂质检测方法、效价测定和 NMR 方法进行鉴定。USP 正在利用这些工具来制定肝素替代来源的标准，包括牛源性物料。本次网络研讨会将介绍其中的一些方法，它们如何应用于牛肝素，以及未来替代品种的肝素标准。这是“*What's New in Biologics?*”系列网络研讨会的第五次会议，旨在分享 USP 科学人员和全球专家的知识与专长，这些主题将塑造生物制品的未来。

*(该课程的现场版本录制于 2022 年 6 月 29 日)*

Heparin sodium is an important anticoagulant with many indications, use in blood transfusions and dialysis procedures and the treatment of embolisms. In addition to its function as a drug product, the heparin sodium drug substance is the starting material for low-molecular-weight heparins used in the treatment of deep vein thrombosis, such as enoxaparin and dalteparin. The raw material used to make heparin sodium is most notably derived from porcine, making it susceptible to livestock-related supply issues and potential adulteration. USP has many tools available for the quality assessment of heparin sodium drug substance and low-molecular-weight heparins, including impurity methods, potency assays, and NMR methods for identification. USP is leveraging these tools in approaching standards for alternative sources of heparin, including bovine derived material. This webinar will describe some of these methods and how they can be applied to bovine heparin and future standards for heparin from alternative species. This “*What's New in Biologics?*” webinar is fifth in a series that shares the knowledge and expertise from USP staff and global experts on topics that will shape the future of biologics.

*(The live version of this recording took place on June 29, 2022)*

#### 参课对象 Who Should Attend:

猪和牛的肝素产品制造商、从事肝素产品研发、制造和生产的实验室人员、监管机构人员、QA/QC 专员和审计人员

Manufacturers of Heparin products, Porcine and Bovine, Lab personnel in research and development, manufacturing and production of Heparin products, Regulatory professionals, Quality assurance and quality control specialists and auditors

#### 授课语言 Language:

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

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### What's New in Biologics? 猪、牛肝素钠分析

#### What's New in Biologics? Analysis of Heparin Sodium Porcine and Bovine

##### 讲师 Instructor:

**Kevin Carrick 博士，美国药典委员会全球生物部门科学与标准总监**

**Dr. Kevin Carrick, Director of Science & Standards, Global Biologics Department, USP**

Kevin Carrick 博士是美国药典委员会全球生物部门科学与标准总监。Carrick 博士和他的团队与生物制品领域的五个 USP 专家委员会和多个专家顾问组共同协作，制定支持生物药质量评估的标准。这些标准包括从多肽到细胞疗法等各种药物的书面标准（各论和通则）与标准物质。在加入 USP 之前，他曾在 ProMetic BioTherapeutics 公司担任产品表征副总监，负责临床前开发中的多种药物的表征工作。Carrick 博士还曾任美国红十字会蛋白质表征小组组长和美国北卡罗来纳大学教堂山分校蛋白质小组的副总监。

Dr. Kevin Carrick is a Director of Science & Standards in USP's Global Biologics Department. Kevin and his team work with the five USP Expert Committees and multiple Expert Panels in the area of biologics to develop standards that support biopharmaceutical quality assessment. These standards include documentary (monographs and general chapters) and physical reference standards for varied products from peptides to cell therapies. Prior to joining the USP he worked at ProMetic BioTherapeutics as the Associate Director of Product Characterization where he directed the characterization of several drug substances in preclinical development. Dr. Carrick has also held positions, as group leader for protein characterization at the American Red Cross and as an Associate Director at the University of North Carolina at Chapel Hill Proteomics facility.

##### 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 only be 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. 请点击这里 ([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.