

## 美国药典在线点播课程 USP On-Demand Webinar

# 分析桥接试验：如何在两种生物活性检测方法之间建立联系 Analytical Bridging: How to Cross on the Wire Stretched Between Two Bioassay Methods?

课程时长 **Course Duration:** 30分钟 30 minutes

### 课程介绍 **Course Description:**

生物制品依赖于广泛的分析方法进行批量放行和稳定性测试。方法改进是生物药生命周期管理中不断努力的结果，因此桥接试验是证明新旧方法之间可比性的关键。通过案例研究，将设法排除障碍，允许在两个效价方法和关键参数之间建立连接，在桥接练习中加以考虑。

*(本次录播课内容来自 2019 年 9 月 18-19 日举行的第八届 USP 生物活性检测研讨会)*

Biological products rely on a wide range of analytical methods for lot release and stability testing. As method improvement is a continued effort during lifecycle management of biopharmaceuticals, bridging studies are key to demonstrate comparability between old and new methods. Through a case study, we will attempt to clear the way, sometimes complex, allowing to establish the link between two potency methods and the key parameters to be considered in a bridging exercise.

*(This on-demand recording is from the 8th USP Bioassay Workshop, held September 18-19, 2019.)*

### 参课对象 **Who Should Attend:**

生物制药和疫苗行业的专业人员、细胞和基因治疗产品开发人员、生物活性检测监管审核人员、生物类似药生产商、生物活性检测软件开发人员、统计学工作者、生物活性检测 QA/QC 专员。

Biopharmaceutical and vaccines industry professionals, Cell and gene therapy product developers, Regulatory reviewers of bioassays, Biosimilar manufacturers, Bioassay software developers, Statisticians, QA/QC specialists for bioassays

### 讲师介绍 **Instructor:**

**Gaël Debaue** 博士，比利时UCB公司

**Gaël Debaue, PhD, UCB**

### 授课语言 **Language:**

英语（含中文文字幕）

English (with Chinese subtitles)

## 美国药典在线点播课程 *USP On-Demand Webinar*

### 分析桥接试验：如何在两种生物活性检测方法之间建立联系 Analytical Bridging: How to Cross on the Wire Stretched Between Two Bioassay Methods?

#### 课程有效期 **Access Duration:**

课程在线观看有效期：自在线报名成功日起，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)

Access to this course expires 14 days from the date of registration or until you mark it 'Complete' in your transcript—whichever occurs first.

**培训费用 Fee:** 150 元人民币/人 RMB 150/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 by express after successful registration.