

## 美国药典在线点播课程 *USP On-Demand Webinar*

### 化学定义的细胞培养基和水解物中微量金属定量分析标准和最佳实践 Standards and Best Practices to Support Trace Metal Quantification in Cell Culture Chemically Defined Media and Hydrolysate

课程时长 **Course Duration:** 65分钟 65 minutes

#### 课程介绍 **Course Description:**

许多元素如铜、锰、锌和铁具有重要的生物学意义，并被认为是影响生物制品生产的糖蛋白合成和糖基化的关键因素。在化学定义的培养基和水解物配方的全球原料供应链中，对假定的高纯级单一成分中微量元素杂质的鉴别和控制至关重要。细胞培养基中微量元素的研究重点将确立：使用 ICP-MS 和 ICP-OES 仪器测量每十亿次测量的百分比为个位数的最佳实践指南、讨论样品制备与样品消解的方法、以及基质干扰去除和多原子干扰的注意事项。通过学习本课程，您将了解：

- 微量元素对生物制品至关重要，并能影响产品质量
- 生物制品的测量技术与小分子方法有很大的不同
- 媒介生产商和生物制药行业之间的合作对于识别污染物和建立控制至关重要
- 用于支持上游生物工艺的最佳实践和标准的 USP 和 Bioforum 活动

Many elements such as copper, manganese, zinc, and iron have significant biological relevance, and are well established as key contributors to glycoprotein synthesis and glycosylation that can impact biologics manufacturing. The identification and controls of trace element impurities in a presumed highly pure compendium grade individual components are essential in a global supply chain of raw materials for chemically defined media and hydrolysate formulations. This focus of trace elements in cell-culture media will establish: Best practices guide for measurement of single digit low parts-per-billion measurement using ICP-MS and ICP-OES instruments, Discussion on approach to sample preparations and sample digestions, Matrix interference removal and polyatomic interferences-Do's and Don'ts.

By taking this course, you will:

- Awareness within the industry for recognizing that trace elements are critical for biologics and can impact product quality
- Measurement of techniques for biologics is very different from small molecule approach
- Collaboration essential between media manufacturer and biopharma industry to identify contaminants and establish control
- Awareness of USP and Bioforum activities to support best practices and standards in support of upstream bioprocessing.

#### 参课对象 **Who Should Attend:**

生物制品行业培养基供应商，从事上游生物加工制造和开发的工程、科学工作者。

Anyone in the biologics industry- media vendors or suppliers, supply chain or engineer or scientist working on upstream bioprocessing manufacturing and development.

#### 授课语言 **Language:**

英语（含英文字幕） English (with English subtitles)

## 美国药典在线点播课程 USP On-Demand Webinar

# 化学定义的细胞培养基和水解物中微量金属定量分析标准和最佳实践 Standards and Best Practices to Support Trace Metal Quantification in Cell Culture Chemically Defined Media and Hydrolysate

### 讲师介绍 Instructor:

**Julian Goy 博士，美国Biophorum公司 项目经理**

**Julian Goy, Ph.D., Facilitator/Account Manager, Biophorum**

Julian Goy 博士是 Biophorum 公司协调员和项目经理，负责促进药物原料的工作流程，包括领导生物制药公司的同行团队进行创新和最佳实践开发活动，以实现解决方案。工作流程主要集中在细胞培养基和水解物中的微量金属，包括电感耦合等离子体-质谱分析技术的相关使用。他的工作团队还制定了生物制药工艺中原材料风险评估的行业最佳实践指南。Goy 博士在制药、汽车电池和石油行业积累了 20 年的工作经验，帮助团队实现目标。他获得爱丁堡大学植物细胞组织培养博士学位和华威商学院工商管理硕士学位。

Dr. Julian Goy, Facilitator/Account Manager at Biophorum, facilitates the Raw Materials workstream within the Drug Substance Phorum of BioPhorum. The role involves leading peer to peer teams of biopharmaceutical companies in innovation and best practice development activities, towards solution implementation. To date, the workstream has focused on trace metals in cell culture media and hydrolysates including the associated use of 'inductively coupled plasma - mass spectroscopy' as an analytical technique. The team has also developed industry best practice guidance for the assessment of raw material risks in biopharmaceutical processes. Julian uses 20 years of experience from the pharmaceutical, automotive battery and oil industries to help the team achieve its goals; as well as a Ph.D. in plant cell tissue culture from The University of Edinburgh and an MBA from Warwick Business School.

**Diane McCarthy 博士，美国药典委员会全球生物部门科学与标准高级经理**

**Diane McCarthy, Ph.D., Senior Manager, Science & Standards, Global Biologics, USP**

McCarthy 博士是 USP 美国药典委员会全球生物部门科学与标准高级经理。她与利益相关者们通力合作确定哪些领域需要标准，并定义和开发新的标准。在加入 USP 之前，McCarthy 博士担任 Caprion Biosciences 公司高级科学总监，从事用质谱来表征生物制品和宿主细胞蛋白方面的工作。此外，她还曾担任 Ezose Sciences 公司科学事务部总监，负责多糖的质谱法鉴别和定量工作，以及 Bio-Rad 公司生物标志物研究中心全球经理，负责指导转化和生物标记研究合同，以及与行业、协会、学术和政府团体之间的合作。

Dr. McCarthy is a senior manager of science and standards within USP's Global Biologics department. She works with stakeholders to identify areas where standards are needed and defined and develop new standards. Prior to joining USP, Dr. McCarthy was senior scientific director at Caprion Biosciences, where she focused on the use of mass spectrometry for characterization of biologics and host cell proteins. Her previous roles also included Director of Scientific Affairs at Ezose Sciences, where she focused on identification and quantification of glycans by mass spectrometry, and Global Manager of Biomarker Research Center at Bio-Rad Laboratories, where directed translational and biomarker research contracts and collaborations with industry, key consortia, academic and government groups.

**Bala Ramanathan 博士，强生公司生物治疗药物材料科学部门高级研究员**

**Bala Ramanathan, Ph.D., Senior Scientist, Biotherapeutics Material Sciences, Janssen**

Bala Ramanathan 博士是强生公司生物治疗药物材料科学部门高级研究员，从事生物制品的培养基特性、上游细胞培养过程、下游原料特性和填充处理的工作，负责为原料问题找到解决方案，为小分子和大分子原料和辅料开发分析方法。他还积极参与单克隆抗体、疫苗、细胞和基因模式商业化生产的调查工作。

Ramanathan 博士是密歇根州立大学化学博士。

## 美国药典在线点播课程 USP On-Demand Webinar

# 化学定义的细胞培养基和水解物中微量金属定量分析标准和最佳实践 Standards and Best Practices to Support Trace Metal Quantification in Cell Culture Chemically Defined Media and Hydrolysate

### 讲师介绍 Instructor (continued)

Dr. Bala Ramanathan, Senior Scientist in the Biotherapeutics Material Sciences department at Janssen, is an analytical chemist working on media characterization, upstream cell culture processes, and raw materials characterization for downstream and fill finish for biologics. His primary role is to identify solutions for raw material issues, analytical method development for both small and large molecule raw material, excipients. He actively participates in investigations of commercial manufacturing of monoclonal antibodies, vaccines, cell and gene modalities. He has worked as small molecule analytical development chemist in his previous job and is a PhD graduate in chemistry from Michigan State University. His post-doctoral research includes stints at both Michigan State university and University of Michigan.

### 课程有效期 Access Duration:

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)

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:** 600 元人民币/人 RMB 600/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.