

## 美国药典在线点播课程 *USP On-Demand Webinar*

### What's New in Biologics? 美国药典对于 COVID-19 疫情的应对

### What's New in Biologics? Focus on USP's COVID-19 Response

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

免费视频课!

#### 课程介绍 **Course Description:**

USP Biologics 很高兴启动一系列网络会议，让你了解当前趋势、USP 倡议和利益相关方影响公共卫生标准的机会。第一场网络会议于 2020 年 5 月 19 日举行，随后的会议将间隔大约 4 个月。鉴于 COVID-19 疫情大流行以及我们在支持公共卫生方面发挥的重要作用，美国药典委员会已拨出大量资源支持开发和生产，并与许多利益相关方合作，维护供应链的完整性。第一次网络研讨会将与您分享一些我们发现的需求、以及从公共服务中得到的教训。支持疫苗开发和单克隆抗体表征的 USP 标准将与支持应对 COVID-19 疫情工作的工具也将一起被回顾。

通过学习，您将了解能够支持 COVID-19 疗法、疫苗和相关生物制剂分析方法开发和验证的 USP 人员和资源；描述未来 COVID-19 创新的趋势和需求；并了解支持疫苗和单克隆抗体的开发和特性表征的 USP 标准。

USP Biologics is pleased to kick off a series of webinars to keep you up to date on current trends, USP initiatives and opportunities for stakeholders to impact public health standards. The first event was held on May 19, 2020, with subsequent events approximately 4 months apart. Due to the COVID-19 pandemic and our essential role in supporting public health, USP has assigned significant resources to supporting development, manufacturing, and to maintaining supply chain integrity in collaboration with many stakeholders. This first webinar will share some of the needs we've uncovered and the lessons we've learned as a result of our public outreach. USP standards that support vaccine development and monoclonal antibody characterization will be reviewed along with tools supporting this work. Upon completion of this course, you will be able to

- Identify USP staff and resources that can support analytical method development and validation for COVID-19 therapeutics, vaccines and related biologics
- Describe trends and needs for future COVID-19 innovation
- Identify USP standards that support development and characterization of vaccines and monoclonal antibodies

#### 参训对象 **Who Should Attend:**

从事研发、制造和生产的实验室人员；制造和 CRO 机构的科研人员和经理；QA/QC 专员和审计员；监管机构专家等。

Lab personnel in research and development, manufacturing and production, Scientists and managers of manufacturing and contract research organizations, QA/QC specialists and auditors, Regulatory professionals.

#### 授课语言 **Language:**

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

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### What's New in Biologics? 美国药典对于 COVID-19 疫情的应对

#### What's New in Biologics? Focus on USP's COVID-19 Response

#### 讲师介绍 Instructor:

**Fouad Atouf 博士**，美国药典委员会科学部门全球生物制品副总裁

**Fouad Atouf, Ph.D., Vice President, Science – Global Biologics, U.S. Pharmacopeia**

Fouad Atouf 博士领导 USP 在生物制品方面的科学活动和战略，并与全球利益相关方合作，调整生物标准以满足他们的需求。他在 USP 工作的 15 年期间担任过各种科学领导职务。在加入 USP 之前，Atouf 博士任职于美国国立卫生研究院，负责研究集中于糖尿病体外细胞治疗方法的开发。Atouf 博士是同行评审期刊上众多出版物的作者，并经常在国外科学会议上发表演讲。

Dr. Atouf leads USP's scientific activities and strategy for biologics, collaborating with global stakeholders to adapt biologic standards to meet their needs. He served in a variety of scientific leadership roles across his nearly 15 years of experience at USP. Prior to USP, his research at the U.S. National Institutes of Health focused on methods development for in vitro generation of cell-based therapies for diabetes. Dr. Atouf is the author of numerous peer-reviewed publications and a frequent speaker at national and international scientific conferences.

#### 报名方式 Register Procedures:

本课程免费！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。

#### 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.