美国药典在线点播课程 USP On-Demand Webinar

2024 USP/US FDA 膳食补充剂研讨会

2024 USP/US FDA Dietary Supplements Workshop

课程时长 Course Duration:

4小时11分钟　　4 hour 11 mins

免费视频课！

课程介绍 Course Description and Objectives:

美国药典委员会于 2024 年 9 月在中国深圳和北京举行了“ 2024 膳食补充剂研讨会-US FDA 法规和 cGMP 要求、USP 公共标准及其他”。本课程的视频来源于研讨会中美国 FDA 和 USP 专家演讲的现场录频，涵盖美国膳食补充剂的法规（DSHEA 和 21 CFR 111）、cGMP 要求、质量标准、合规与执行等中国膳食补充剂出口相关企业关注的热点话题，同时也介绍了植物提取物、咀嚼凝胶(软糖)、益生菌的相关法规和标准。

演讲主题如下：

- 美国膳食补充剂法规
- 美国膳食补充剂 cGMP 要求
- cGMP 要求：膳食成分的鉴别测试
- 美国膳食补充剂法规：合规与处罚
- 膳食补充剂中的活微生物
- USP 膳食补充剂标准 – 质量的综合方法
- USP 植物提取物标准
- USP 咀嚼凝胶（软糖）各论概览
- USP 益生菌标准

This recorded video brings together experts from US FDA and USP on dietary supplement regulations (DSHEA and 21CFR111), US cGMP requirements for dietary supplements, quality standards, compliance, and enforcement. Botanical extracts, chewable gels (gummies) and probiotics are also included in the workshop. These presentations were abstracted from a workshop in China in September 2024 for dietary supplement exporters. Accordingly, a few references to China may be observed in these presentations.

Speech topics include:

- U.S. Regulations for Dietary Supplements
- U.S. CGMP Requirements for Dietary Supplements
- U.S. CGMP Requirements: Identity Testing of Dietary Ingredient
- U.S. Regulation of Dietary Supplements: Compliance and Detention
- Live Microbials in Dietary Supplements
- USP Dietary Supplement Standards – A Comprehensive Approach for Quality
- USP Standards for Botanical Extracts
- Overview of USP Monographs for Chewable Gels (Marketed as Gummies)
- USP Standards for Probiotics

授课语言 Language: 英文（带中文字幕） English (with Chinese subtitles)

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参课对象 Who Should Attend:

膳食补充剂及保健食品行业的生产企业/品牌方/出口商、国内监管机构、科研院所、合同外包实验室等单位；战略规划、市场及销售、质量管理、研发、法规注册及合规、采购等人员；以及其他对研讨会主题感兴趣的人员。

Strategic Planning, Sales & Marketing, Quality Assurance/Quality Control, Regulatory Affairs, Purchasing staff from dietary supplements and health food manufacturers, brand parties, exporters, regulators, academic institutions, contract labs, etc.

讲师 Instructor:

Haijing Hu 博士，美国食品药品管理局食品安全和应用营养中心膳食补充剂项目办公室政策与法规执行部门法规执行处处长

Haijing Hu, Ph.D., Chief, Regulations Implementation Branch, Division of Policy and Regulations Implementation, ODSP, CFSAN, US FDA

Haijing Hu博士于2010年加入美国食品药品管理局，曾担任过多个职务，目前是FDA食品安全和应用营养中心 (CFSAN)膳食补充剂项目办公室 (ODSP) 政策与法规执行部门法规执行处处长。她领导一个多学科团队，负责审查行业提交的材料以及有关标签和 CGMP 合规性的检查结果。同时还与FDA其他办公室合作制定合规政策和执法行动。在加入膳食补充剂项目办公室 (ODSP) 之前，Hu博士曾是FDA 药品审评和研究中心 (CDER) 合规办公室、制造质量办公室的高级微生物学家，还曾在 CDER 药品质量办公室对无菌药品生产进行微生物评估。在加入CDER之前，她在FDA医疗器械和辐射健康中心(CDRH)担任无菌和非无菌医疗器械的评估工作。Hu博士于2003 年获得博士学位。在加入FDA之前，她有超过10年的微生物研究经验。

Haijing Hu joined the FDA in 2010 and has served in several roles and positions. Her current role is as the Chief ofthe Regulations Implementation Branch in the Division of Policy and Regulations Implementation within the Office of Dietary Supplement Programs (ODSP) at FDA's Center for Food Safety and Applied Nutrition (CFSAN). She leads a multi-disciplinary team to review industry submissions and inspectional findings on labeling and CGMP compliance. She also collaborates with other FDA offices in the development of compliance policies and enforcement actions. Prior to joining ODSP, she was a senior microbiologist in FDA's Center for Drug Evaluation and Research (Office of Compliance, Office of Manufacturing Quality). She also conducted microbiological assessments for sterile drug manufacturing in CDER's Office of Pharmaceutical Quality. Before joining CDER, she evaluated medical devices at FDA's Center for Devices and Radiological Health (CDRH). Haijing Hu obtained her Ph.D. in 2003. She attained more than 10 years of experience in microbiological research prior to joining the FDA.

Nandakumara Sarma 博士，美国药典委员会科学部门膳食补充剂标准总监

Nandakumara Sarma, Ph.D., Director, DS Standards, Science-DS & Herbal Meds, USP

Nandakumara (Nandu) Sarma 博士是美国药典委员会膳食补充剂和草药科学部门膳食补充剂标准总监，负责新项目和创新项目的战略和外部利益相关方的参与，与全球利益相关方和专家志愿者合作制定膳食补充剂和草药的质量标准（各论和通则），这些标准在《USP 膳食补充剂法典》和《草药法典》中发布。Sarma 博士于 2006 年加入 USP 。在此之前，他曾在贝塞斯达国家癌症研究所和费城托马斯杰斐逊大学从事博士后研究员工作，并在印度喜马拉雅制药公司担任高级科学官。Sarma 博士的研究经验包括分离和分析植物药的活性成分及其生物活性。Sarma 博士在同行评议期刊上发表了 30 多篇科学论文。他是美国植物委员会（American Botanical Council）的顾问委员会成员和美国生药学学会（American Society of Pharmacognosy）的官员。Sarma 博士拥有班纳拉斯印度大学药剂师学位和药学（生药学）博士学位。

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讲师 Instructor*(cont.)*:

Dr. Nandakumara (Nandu) Sarma is Director, Dietary Supplements and Herbal Medicines at US Pharmacopeia (USP) responsible for strategy and external stakeholder engagement for new and innovative projects, working with global stakeholders and expert volunteers in the development of quality standards (monographs and general chapters) for dietary supplements and herbal medicines that are published in the USP Dietary Supplements Compendium and the Herbal Medicine Compendium. Before joining USP 2006, he was a post-doctoral fellow at National Cancer Institute, Bethesda, and Thomas Jefferson University, Philadelphia and was a Senior Scientific Officer at The Himalaya Drug Company, India. His research experience includes isolation and analysis of active components of botanicals and their biologic activity. He published more than 30 scientific articles in peer -reviewed journals. He is an advisory board member of the American Botanical Council and an officer of the American Society of Pharmacognosy. Dr. Sarma holds a Pharmacist degree and a Ph.D. in pharmaceutical sciences (pharmacognosy) from Banaras Hindu University, India.

报名方式 Register Procedures:

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（报名成功后您会收到课程登录信息通知邮件）

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