药用辅料专场

Pharmaceutical excipient Forum

9/3 8:30 – 12:00

会议室M2

主持人：王粟明

时间 **Time**	**演讲主题** **Topic**	**演讲嘉宾** **Speaker**	**演讲者简介** **Speaker biograph**
8:30-9:20	The cooeration and Win-Win of makers and users under the excipients management of bundling review and aproval with drugs in China 关联审评审批法规政策下生产者与使用者的合作共赢要点解析	王粟明/Cissy Wang	Cissy Suming Wang , Chair of International Pharmaceutical Excipients Council（IPEC China), Program Professor of Yeehong Business School, is working as a product regulatory professional in Ashland (China) Holding Co., Ltd. and taking in charge of the compliance management, regulatory affairs, compliance system standards establishment, and regulatory coordination& communication on pharmaceutical excipients, food additives and personal care / home care products. Specially focus on regulatory policies and strategy, standards development, and compliance applications and risk assessment for excipients used in pharmaceuticals. 王粟明，现任职于亚什兰（中国）投资有限公司特种化学品部任产品法规专家，国际药用辅料协会（IPEC 中国）主席，亦弘商学院授课教授。负责亚太区药用辅料、食品添加剂及个人护理/家居护理产品的产品注册、法规事务、合规体系标准建立和管理及监管协调沟通等。专注于药品所使用的辅料的法规政策和策略、标准制定，合规应用及风险评价。

9:20-10:10	The Impact of Excipients on Generic Quality Consistency Evaluation - The Assessment of BE Waiver for BCS III Drug Products 药用辅料对一致性评价的影响-BCS III 类药物免 BE 评估	胡嘉伟/Jiawei, Hu	Jiawei Hu, Senior Regulatory Affairs Manager is working Fresenius Medical Care R&D (Shanghai) Co., Ltd and is responsible for Chemistry, Manufacturing and Control (China and Asia Pacific) with 10-year experience in regulatory affairs. He worked as the regulatory CMC person in AstraZeneca, Baxter and Merck, was responsible for CMC documents drafting and review for IND, NDA and variation. Meanwhile the reference listed drugs application, generic quality consistency evaluation and imported drugs tech transfer were in the working scope. He was also responsible to support FDA and EMA regulatory CMC tasks. Additionally, he worked with R&D and manufacturing functions to provide CMC support, suggestion, regulatory strategy and risk assessment. 费森尤斯医药研发（上海）有限公司 高级法规事务经理，中国及亚太区法规事务（化学、生产和控制 - CMC）负责人。从事法规注册工作 10 年，目前就职于费森尤斯医药研发（上海）有限公司，负责中国以及亚太区法规事务化学、生产和控制（CMC）相关工作。 在加入费森尤斯之前，胡嘉伟曾就职于阿斯利康，百特和默克雪兰诺，负责新产品申报以及已上市产品法规 CMC 资料撰写、核准，公司进口药品参比制剂遴选、仿制药一致性评价以及进口产品地产化技术转移等工作，也负责国际注册包括 FDA、EMA 以及亚太区法规申报资料 CMC 部分的撰写核准；同时，配合研发和生产各技术部门日常工作，提供 CMC 部分法规的建议和意见，为产品在中国市场上是提供国内法规注册策略制定和风险评估。
10:10-11:00			吴丽（Lilly Wu） 罗氏（中国）投资有限公司

	Challenges faced by pharmaceutical companies under the joint review policy 关联审评政策下制药企业面临的挑战	吴丽 /Lilly Wu	吴丽女士，2012 年加入罗氏（中国）投资有限公司，现任药学法规事务经理。主要工作参与制定中国 CMC 药政政策策略，组织参与全球跨部门团队开展的与中国药品监管和行业协会之间的沟通合作，支持制定在中国的注册申报策略。她积极参与行业协会、学术组织以及非营利组织的各种学术交流活动。她是 RDPAC 稳定性研究和关联审评工组共同负责人，并带领参与协会成员就药学领域的相关问题与相关利益方进行积极的沟通并开展学术交流活动。在加入罗氏之前，曾在上海（诺华）贸易有限公司从事药品注册申报工作。
11:00-11:50	Value added third party certification scheme and data integrity requirements for excipients 《第三方 GMP 认证价值和药用辅料的数据可靠性要求》	程宁 /Nevin Cheng	Nevin Cheng：Ph.D. and MBA, more than 20 years of work experiences in pharmaceutical industry, Nevin has taken various commercial roles of technical services, quality, marketing, sales and general management in Colorcon and Gattefosse. As the founder of IPEC China, he was elected as the first chair in 2008. He founded Shanghai PHEXPACT Consulting Co., Ltd. in 2015 to continue promoting initiatives of excipients in China. As the local consultant of EXCiPACT, he has been working with multiple stakeholders to promote excipient GMP&GDP 3rd party certification in order to help local pharmaceutical industry to reduce quality auditing burden and improve supply chain security. 程宁，博士/MBA 有超过 20 年制药行业经验，曾就职于卡乐康、嘉法狮公司，从事过技术服务，质量和法规管理，以及商务运营等多个职位。作为 IPEC 中国成立的发起人之一，于 2008 年被当选为第一任主席，2015 年创立了上海欧范企业管理咨询有限公司。作为 EXCiPACT 在中国的顾问以及合作机构，程宁博士一直致力与其它相关方一起推广药用辅料第三方认证项目，向本地制药行业介绍能降低质量审核负担、提升供应链安全的合规新模式。

11:50-12:00	答疑		