

Gain US market access with the right US FDA drug approval strategies!

USA alone accounts for 55% of the world drug expenditure. The unreasonable high price of biologic drugs on the US market has been the driving force behind the US congress evaluating new laws to pave the way for affordable versions of biologic drugs through biogenerics and the development of alternate drug sources.

Are you a Chinese pharmaceutical looking to penetrate the lucrative US biologics market? This Masterclass is designed to provide you with a rational strategy and a clear understanding of US FDA regulations to help you take advantage of this golden opportunity for Chinese biomanufacturers to fill the great demand for affordable and high quality biologic drugs. An ex-FDA suit will show you how!

Key topics:

- 1) US FDA requirements and processes for approval for biologic drugs
- 2) Strategies for developing the right biologic drugs for the US market
- 3) In depth coverage of technical issues for the manufacturing of monoclonal antibodies (which account for 65% of all biologic drugs in US)
- 4) Understanding ICH S6 guide for preclinical studies for biologics
- 5) Basics of cGMP, GLP and preparation for US FDA inspection
- 6) Immunogenicity issues in biologic drug development
- 7) Qualification and validation of assays
- 8) Strategically plan for manufacturing biologic drug for each phase of clinical trials (discussion of scale up, comparability issues)

About your Pre-conference Masterclass Leader:



Lei Zhang
Head of China Office
Biologics Consulting Group, China
Dr Lei Zhang has spent the last 7 years working at the US FDA, holding positions at the Division of Monoclonal Antibodies and the Division of Biological

Oncology Products at the Center for Drug Evaluation and Research (CDER). He has extensive expertise and direct experience in the development of biological therapeutic protein drugs including intimate knowledge of the complex regulatory issues associated with biological therapeutic protein drug development. Dr Zhang is now based in Beijing as the new Head of China Office at the Biologics Consulting Group, USA.

生物药品获得美国药物管理局批准

进入美国医药市场的最佳战略

美国药品市场约占世界的55%，因此美国药品市场是世界制药厂的必争之地。美国国内的非理性的高居不下的生物药品价格正在给美国的疾病患者造成极大的困难以至于美国国会不得不立新法律以促发展制造价格合理同类生物药品。美国国内对于合理价格生物药品的巨大的需求正向全世界制药界提供无限的商机..

中国的生物制药界有着得天独厚的发展生物药品的条件和进军美国市场的潜力。前美国药管局生物药品审批官员特别设计的课程将使您对美国药管局生物药的审批过程和相关法律法规有深入的了解，并且本课程将对美国和欧洲的生物药发展的现状，中国制药界进军美国生物市场的策略以及相关的技术问题进行深入 浅出的探讨和讲解。课程以中英双语讲授。

课程内容:

- 1) 美国药管局生物药审批的要求和过程
- 2) 选择适合进入美国生物药市场的生物药的策略
- 3) 研发和生产抗体类药物的现状和相关的技术问题 (抗体类药物约占生物药市场的65%)
- 4) 美国药管局对临床前期药理, 毒理实验的相关要求
- 5) 了解美国药管局对药厂审计过程和相关的潜在问题
- 6) 处理生物药品免疫原性的策略
- 7) 实验方法验证的策略
- 8) 相对应于每一临床实验生物药品的生产策略

关于课程讲座者:



张磊
中国区首席代表
美国生物制药咨询集团
张磊博士曾在美国药管局单克隆抗体部和肿瘤生物药品部工作七年。在获得佐治亚州大学免疫学博士前为广州总医院医生。张磊对于生物药品的研发, 制造, 临床前和临床试验以及相关的美国药管局药物审批法规有着丰富的经验和独到的见解。张博士现为美国生物制药咨询集团中国部的主任并常驻中国北京。