3 Hrs. Virtual Seminar : China: Compliance Processes for Life Science Products: Company Establishment, Clinical Trials, Registrations, Renewals and Supply Chain Considerations - Recorded Webinar

Description: The Chinese government's establishment of a single drug regulatory authority in 2003 (The State Food and Drug Administration) was an important step toward foreign access, because it eliminated the conflicting standards that prevailed among provincial government agencies, centralized the Chinese healthcare regulatory system, and made it more transparent to industry partners. The SFDA now oversees all medications. Other former functions of the ministry have been assigned to different government bodies. The most important of these was the transfer of medical insurance responsibilities to the new Ministry of Labor and Social Security. The Ministry of Health retains its other main functions: regulatory development and oversight, healthcare resource allocation, and medical research and education.

Along with it in 2010, China has amended GMP, GLP, GCP, GSP and other regulations, China's aim is to further align the country with international standards of practice. For manufacturers and distributors and importers of drugs and medical devices in China, it is imperative to pay close attention to the pace at which SFDA implements these changes. They have to make changes accordingly to their standard operating procedures so that they can ensure compliance quickly and effectively with the evolving regime.

Course Objective: China has been improving its regulatory regime governing the food and pharmaceutical industry in recent years. In 2010, by promulgating the amended GMP and amending GLP, GCP, GSP and other regulations, China will further align the country with international standards of practice. For manufacturers and distributors of drugs and medical devices in China, it is important to pay close attention to the pace at which SFDA implements these changes and to make changes to their

This 90-minute session specifically focuses on the overall regulatory compliance requirements and procedures for Pharmaceuticals, Medical Devices, Biologics and Combination Products in China. The course will cover topics relating to pre-clinical and clinical requirements, as well as, addressing the structure of the regulatory agencies in China. Content will also include descriptions of the methods by which regulators in the SFDA process filings and registrations and what is expected in the authorization and dossier maintenance of licensed products.

Target Audience:

This course will be beneficial to:

- Regulatory, Quality, Manufacturing, Global Business Development and General Management personnel whose responsibilities require knowledge of China's regulatory, quality and import / export requirements
- Administrative staff responsible for ensuring compliance with regulatory filings and overall GCP, GMP and GLP compliance requirements will also find this training highly relevant
- Global business development and general management requiring an understanding of how regulations and compliance issues are culturally handled along with how best to consider China into one's Global Business Strategy will profit from attending

Contents: Course Outline:

- Country Profile / Healthcare System.
- Key Country Information.
- Governmental & Regulatory Authorities / Agencies / Structure.
- Company Establishment; Licenses & Key Personnel.
- Partner Companies / Local Relationship Options.
- In-Country Operational Considerations; Importance of Local Distributors
- Requirements to Conduct Clinical trials / Approvals / GCP
- Licensing Products (Innovative Drugs, Generics/Similars, Orphan Drugs, Biologics/Vaccines, Medical Devices).
- Variations and Amendments to Licenses.
- GMP and Inspections.
- Packaging and Labeling.
- Price Establishment.
- Reimbursement.
- Import / Export / Customs Clearance.
- Taxes / Duties.
- Advertising & Promotion.
- Vigilance Reporting / Post-Marketing Requirements.
- Patents & Trademarks.
- Working with Local Agencies / Authorities.
- Conclusions.

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