OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Summit on
GMP, GCP & Quality Control
November 12-14, 2013 DoubleTree by Hilton Hotel Chicago-North Shore, IL, USA

Chinese regulatory requirements

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Overview of Presentation

- Reviewing the Chinese regulatory environment and issues around foreign medical device companies in China
- Overview of current core Chinese SFDA regulatory requirements
- Practical steps for obtaining SFDA approval for commercializing medical devices in China - Case study on Class III devices
- Understanding the clinical data evaluation process for high risk devices
- Understanding cultural differences to ensure successful business relationship

Biography

Wenkai Ma is the co-founder at ECURAC Medical Device Regulatory Consulting, former Global Regulatory Affairs director, Allergan China. She is the VP of Regulatory Affairs, where she provides technical expertise on regulatory strategy planning, regulatory agency guidance interpretation and market approval submission for medical device products in Europe, China and US. She was former director of Global Regulatory Affairs in Allergan, Santa Barbara, California. From 2010-2012, she took an assignment to Beijing, China as head of regulatory affairs, overseeing the development of regulatory plans and managing the key regulatory timelines and critical path activities. In this position, she gained firsthand experience on interacting and negotiating with SFDA scientific reviewers and administrative executives to facilitate the review and approval of regulatory submission in China. Before she joined Allergan in 2010, she worked at Johnson and Johnson for 14 years, where she accumulated extensive working experience and knowledge on pre-clinical, clinical study and regulatory submissions for class III medical devices with US FDA and other international regulatory agencies. A native of Beijing, she was educated in both China and the US. She received her bachelor's degree in Environmental Engineering from Beijing Polytechnic University and master's degree in Analytical Chemistry from University of Nevada. Currently, she is a member of China Association for Medical Devices Industry.

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