AS5-3

Progresses on regulatory science and risk assessment in China

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China has recognized the importance of establishment of a legal framework for chemical safety management and made remarkable progress in recent years. SFDA, the state drug authority, has took necessary steps to meet its goal of globalization and promulgated regulations, standards procedures and guidance in safety evaluation and administration of pharmaceutical and medical devices. The Ministry of Environmental Protection has promulgated the amended Measures on Environmental Management of New Chemical Substances (MEP Order No 7) which came into force from October 15th, 2010. Other guidance has been issued since in supporting of the execution of this regulation. Pesticide safety evaluation and registration system has also been further standardized including certify toxicology/environmental testing laboratories under new rules. The Decree 591, another regulation on safety management of dangerous chemicals had been promulgated by the state council and took effect on the 1 December 2011. This keystone regulation opens a new era for chemicals control in China to convergence with REACH, GHS on dangerous chemical control. In general, these are China's efforts to the format of US, OECD and other international standards. However, there are indeed some philosophical, technical and practical differences between China and rest of the world, giving the considerations of current situation in China.

This presentation will give an introductory overview of the Chinese regulatory framework of safety evaluation, risk assessment and management in comparison with US and other international standards in regulations, procedures and guidelines. In addition, the presentation will also discuss the new changes and trends in regulatory field in China. Finally, the talk will discuss the challenges and opportunities with personal experience both in the US and China.

AS5-4

Current and future aspects of regulatory sciences in Taiwan

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Taiwan Food and Drug Administration (TFDA) was inaugurated on January 1st, 2010 and superseded four bureaus which are Bureau of Food Safety and Sanitation, Bureau of Pharmaceutical Affairs, Bureau of Food and Drug Analysis, Bureau of Controlled Drug. Since then, TFDA has promoted new strategies to improve the review process for new drug application and a complete life cycle management system was set up to ensure the safety of drug release to market.

In this presentation, we will introduce our new policy and strategies to facilitate the new drug and unmet medical need medication, such as orphan drug, into Taiwan market. Quality enhancement as well as post market risk management system, including a well established ADR reporting system, drug relief foundation, will also be discussed.

New biotechnology development has bring a new era for fighting disease, however, it also bring a great challenge to the regulatory system. An effort to bring the outside experience through international collaboration has also been our top priority goal. Actively involved in APEC activity and establishing the bilateral collaboration agreement, such as Austria and China, has set a good example for future bilateral interaction with other countries.