

## Bridging the gaps of China GCP regulation compared to ICHGCP to effectively conduct multinational clinical trials (MCTs)

Libin Zhao<sup>1</sup>, Henry Sun<sup>1,2</sup> and Zhixin Guo<sup>1</sup>

<sup>1</sup>TaslyGroup, Co. Ltd., China, and Tasly Pharmaceuticals, Inc., USA

<sup>2</sup>Tianjin University, China

Currently, with the regulatory harmonization of the US, EU, JP, CN and the related countries/regions internationally, the discovery, development, authorization and marketing of the new drugs is also moving toward the globalization, this trend results in the evolution of clinical strategies that more and more clinical trials could be conducted in multiple countries simultaneously to prevent unnecessarily duplicated studies and make drug development more efficient and cost-effective, therefore, the establishment of the mutual standardization, understanding and implementation of the GCP principle are now extremely concerned and driven by the regulators, sponsors and the investigators worldwide considering the ethnic and race factors with a large of world populations.

Chinese GCP regulation was firstly introduced by the Ministry of Health (MOH) in March 1998 with reference to WHO, ICH 4 ICH and EC guideline, and then the practice was revised again by the new competent authority (SFDA) in 2003 to apply to China's actual pharmaceutical environment. In the recent 5 years, a large number of the international (ICH, FDA and EU) guidelines are being adopted as well to pace up with the evolution of the international GCP. Chinese GCP includes 13 chapters with the total 70 articles, whose general aspects of the principles and contents are compatible with ICHGCP, however, in details the special situation was considered to better implement China GCP, e.g. clinical regulatory review/approval, qualification of the investigators/clinical sites, IEC/IR Band, etc.

Compared to the current clinical development in the USA, EU and some other western countries, the conduct of the clinical trials in China is merging because of the highly accessible subject, comparable expense, increased well-educated staffs, improved regulatory environment and flexible regulations to encourage innovation, China's clinical data is being more credible, reliable and internationally recognized, the escalated number of the global clinical trials has stated that this regulatory gap is bridging between in China and ICH countries. T89, one of the pioneer botanical products exploring the FDA approval, also will be employed as the case story to show this evolution.

### Biography

Libin Zhao is the Associate Director of Tasly Global Regulatory Affairs Department of Tianjin Tasly Group Co. Ltd, one of the leading pharmaceutical & botanical product enterprises in China. He has more than 15 years of industrial experience and published more than 20 papers in China's scientific journals/publications.

zhaolb73@gmail.com