Evolving Regulatory Environment in China

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Starting from 2015, the State Council of China and the China Food & Drug Administration (CFDA) have collaborated on a series of multifaceted regulatory reforms with significant goals, including improving the quality of drug review and approval, safeguarding the quality of generic drugs, enhancing regulatory transparency, and encouraging new drug research and development. In the last 1.5 years, CFDA has issued an unprecedented series of new regulations and taken several important measures, intending to improve the efficiency of the agency and transform the pharmaceutical industry in China to focus on quality and innovation. Globally, these initiatives support the conduct of multiregional clinical trials, both inside and outside of China, and use of the data for product registration in China, thus creating a clinical, industry, and regulatory framework for quality and innovation for patients in China and around the world.

The biopharmaceutical industry, as one of the key development areas in China’s 13th five-year planning cycle, has gone through rapid growth in recent years and brought many new challenges to the regulatory system. In this session, you will get to know the regulatory reform measures that will benefit the biopharmaceutical industry development. The following topics will be extensively discussed:

- CFDA’s priorities in the next 3-5 years
- CFDA’s policy to encourage biopharmaceutical innovation
- Key considerations on regulatory reform on biopharmaceuticals related policies
- China’s policy on biosimilars, and considerations on biosimilar review from a CMC perspective
- Regulatory requirements on post approval CMC change and how that will evolve considering recent international development (e.g. WHO guideline on post-approval changes for biotherapeutics).