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Chinese-Language Podcast: 中国生物制药行业 关键政策和临床指导

Key Policies And Clinical Guidance To Watch

by Brian Yang

China's once-in-five-years Communist Party National Congress and new leadership, as well as new guidelines on therapeutic cancer vaccines, are the main topics for this new China Biotech Hot Topic podcast. Brian Yang and Dexter Yan discuss key points to watch and the implications for major players and the wider pharma sector.

China's Center for Drug Evaluation (CDE), the country's top drug regulatory body, has revealed its considerations on how sponsors should design clinical trials for therapeutic vaccines for use in oncology, as biotechs in the country increasingly pursue innovation in this and other sectors.

On 9 October, the CDE published a draft version of the proposed new *Technical Guidelines for Clinical Trials of Therapeutic Cancer Vaccines*, on which it will collect public comments until 9 November.

The podcast discussion looks at the key differences between the planned Chinese guidance and that of the US Food and Drug Administration issued in 2011, along with other key points to watch and the major domestic players in the development of therapeutic cancer vaccines.

In the second part of the podcast, we take a look at the Communist Party's just concluded, once-in-five-years National Congress, which elected a new senior leadership group and which gave President Xi Jinping an unprecedented third term. Major themes including the ideas of "common prosperity" and "dual circulation" and the implications for the pharma and health sector are discussed.

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