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Regulatory in emerging markets

Kurt Dehaes
Medvance Clinical Research Limited, Belgium

Since a few years, we see pharma related activities moving to emerging countries, but we also see pharma companies from emerging countries trying to enter the known market, as there are Europe and US. Beside the pitfalls when entering an unknown market there are also opportunities to develop further as company, but we have to question whether we can export collected data in emerging countries into more established markets for regulatory purposes. Meaning is the quality of data collected meets the standards used like ICH-GCP, ISO14155 2011. We see that the emerging countries recently modify their legislations and try to lift up their standards to meet the standards of ICH-GCP and ISO14155 2011. But is it sufficient to transfer data between the different markets? As China is one of the biggest emerging markets, is starting to export pharma productsmainly OTC, and published his new regulations early 2013, I would like to touch base following items compared to the practice in China: Pitfalls and benefits to go to China, compare current practice and regulations in China with the standards outside emerging markets.

Biography

Kurt Dehaes holds a Master's degree in Nursing and has worked in clinical research since 1992. He started his career as a study co-ordinator and has since developed his career working on a number of device and biotech studies in and outside Europe. Besides gaining a lot of scientifically experiences, he gained also a lot of regulatory knowledge and has also involved in development of regulatory processes and the regulatory aspects of clinical trials. He is also involved in medical writing, auditing and quality assurance.

kurt.dehaes@gmail.com