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Charles Schmidt

Faculdade de Ciencias Médicas da Santa Casa de Sao Paulo, Brazil

Recent developments for regulatory clinical trial approvals in Brazil

In the last 2 years Brazil has taken some actions to improve the timeline and quality for regulatory approvals in clinical trials. The Local Health Authority–ANVISA issue 2 new regulations for this process that also involves bio-similar and medical devices. The efforts has been showing some results, nevertheless adjusts has to be taken to increase transparence and reliable process for those procedures and also include better training of the ANVISA resources. At the same time the association- Brazil Alliance for Clinical Research (Aliança Pesquisa Clinica Brasil Clinica Brasil) worked with the Brazilian Senators to issue a new law for Clinical Research that is still in analyses by the government but it will be a landmark for the country and Latin America in this field. We intend to discuss those new initiatives and clarifying the audience that Brazil is moving to the right direction regarding regulation for clinical trials following better GCP, Bioethics and Human Rights

Biography

Charles Schmidt is a Pediatrician with Master and Doctorate degree. He has been practicing and teaching while working in the Bio-pharma for the past 25 years. He had developed and managed successfully big and medium size CROs in Latin America and at their global level for more than 15 years. His experience also includes leadership roles in medical affairs, pharmacovigilance and medical monitoring in pharmaceutical companies. He has an extensive background in clinical development efforts in many therapeutic areas in LatAm. He is an attending physician in coordinating the post-graduation program in clinical research at Santa Casa Medical School in Sao Paulo - Brazil since 2007. Also, he is the medical manager of the Central Institute of Clinical Research at Hospital de Clínicas - Sao Paulo. He was the founder and ex-President of the Brazilian Association of CROs and Director of Brazilian Association of Pharmaceutical Physicians - SBMF.

csmdt@terra.com.br