

Title: Harmonization of regulatory requirements for approval of medicines: a Brazilian perspective.

In: Global harmonisation of quality standards for medicines: Improving patient care and safety on Thursday, 6 September 2018, 14:30-17:30

Type: Presentation

By: SANTOS, Gustavo (ANVISA, Brazil)

Co-author(s): Gustavo Mendes Lima Santos:Safety and Efficacy Manager,Anvisa,Brasilia,Brazil, ()

Abstract:

Challenge associated with harmonization is the need to consider diverse regional realities in order to define requirements, which may result in different approaches based in economics, politics or technological contexts. Anvisa, which is the Brazilian regulatory agency has been playing a leading role in regional harmonization forums and taking part of important discussions of definition of common technical requirements. This presentation will cover Brazilian perspective regarding harmonization and bring some of the current regulatory and pharmaceutical industry practices in Brazil.