

European Regulations for Medical Devices and Comparison with FDA Requirements

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Medical device development in Europe must comply with the Medical Device Directives. European regulatory bodies recognize both ISO 14155 and the ICH Good Clinical Practices (GCP's). FDA in the United States harmonizes with ISO 14155 and ICH GCP to the extent possible under the FDA regulations, but distinct differences remain in the two regulatory processes. Implementation of a clinical quality system that is a hybrid of European and U.S. FDA requirements may be the best solution for conducting clinical trials in the U.S. and internationally that will generate data that is used in support of marketing applications in both regulatory systems. This session will compare and contrast the requirements of the Medical Device Directives, FDA, ISO 14155, ICH GCP's and FDA GCP's for conducting multi-national clinical trials and the evaluation of clinical data in support of CE mark in Europe and 510(k) clearance or PMA approval in the United States.