



Technology & Research

Key issues in technical due diligences

The acquisition of a pharmaceutical product requires the careful assessment of regulatory, quality and manufacturing elements and documentation as a part of the due diligence process. An exercise that may become highly complex in the case of an entire facility or a multi-site acquisition. >>



Regulatory Affairs

Joint implementation plan for the IVDR regulation

The Medical Devices Coordination Group updated the priorities of its Joint implementation and preparedness plan in view of the entry into force of the IVDR regulation in May 2022. Two distinct sets of actions presented, those to ensure the presence of IVDs on the market and those to support the smoother transition to the new legislation. >>



Business & Policies

Draft topics for the first IHI calls for proposals

The IHI initiative published the draft of two calls. Innovative technologies with a particular attention to digital health technologies and the possible contribution to prevention, diagnosis and treatment arising from AI. Cancer, neurodegenerative and cardiovascular diseases are the main therapeutic areas tackled by the announced topics. >>



EU Focus

The PIC/S Annual Report 2021

The Brazilian regulatory authority ANVISA is the 54th member of PIC/S. China's FDA is among the regulatory authorities that filed a pre-accession procedure. In 2021 many new guidances were issued, and others are undergoing the process of revision. >>



News from EIPG

Implications and Opportunities of ICHQ2(R2) and ICHQ14

In EIPG's and PIER's next webinar, to be held on 15th June 2022 (17.00 CEST), Phil Borman, director and senior fellow at GSK, pioneered the adaptation of Quality by Design principles to analytical procedures, will explain why these guidelines are being developed and will highlight their implications and opportunities. >>