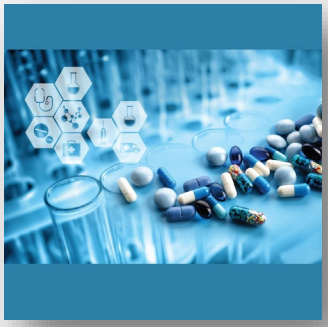
The monthly European Industrial Pharmacists' newsletter January 2022



Technology & Research

EU Medicines Regulatory Network Data Standardisation Strategy

The document issued by EMA and the HMA discusses the principles and recommendations identified as requirements to achieve the harmonised adoption, adaptation and implementation, by regulatory authorities members of the EMRN, of common standards to manage data for regulatory purposes >>

Regulatory Affairs

EMA's Q&A on the integration of EudraGMDP and OMS

The guideline resumes the questions posed in October 2021 during a live webinar organised by EMA to support interested parties with the transition to the new system, that will become fully operative since 28 January 2022, together with the new Veterinary Medicinal Products Regulation. >>

Business & Policies

ACT EU: the EU's vision for the future of clinical trials

The strategic document "Accelerating Clinical Trials in the EU" released by the EU Commission, EMA and HMA indicates six objectives and ten specific actions for years 2022-2023 to improve the European framework for clinical trials and the attractiveness of Europe to host larger, multinational studies. >>

EU Focus

ICMRA published a Reflection paper on remote inspections

The experience gathered by regulatory authorities at the international level during the pandemic was analysed by ICRMA's working group to highlight critical issues and cases where this type of approach proved unfeasible. On-site inspections shall continue to be run also in future, suggests the regulators' association. >>

News from EIPG

Draft guideline on the acceptability of names for human medicines

This update of the guideline further clarifies specific aspects of the criteria applied to address safety and public health concerns, international non-proprietary names issues and product-specific concerns in proposed (invented) names.

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