The monthly European Industrial Pharmacists' newsletter June 2022

Technology & Research

IVD regulation in force & new MDCG guidelines (CTR – UDI)

The IVD regulation (EU) 2017/746 entered into force on 26 May 2022. The Medical Devices Coordination Group issued some new guidelines to clarify its interface with the Clinical Trial regulation and the implementation of the Unique Device Identification (UDI) system.

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Regulatory Affairs

The Digital Application Dataset Integration (DADI) user interface

EMA has published an updated timeline for the implementation of the new Digital Application Dataset Integration (DADI) user interface. The DADI project aims to improve interoperability of data and compliance to ISO IDMP standards for the identification of medicinal products, and to reduce the administrative burden for regulators and industry. **>>**

Business & Policies

EIC: challenges for the governance & opportunities for innovation

While delays are still experienced with the availability of funding for companies entitled to access the EIC Accelerator programme, the EU Parliament launched an investigation on the current governance. The Pilot Expert Group proposed two dedicated deep-training programmes to better support the development of entrepreneurial skills. **>>**

EU Focus

The Data Governance Act & the protection of personal data (CTIS)

The DGA will regulate the sharing and reuse of public-sector data. It describes the rules applying to data intermediation services, digital platforms for the sharing of data and data altruism. EMA has published a draft guideline on how to approach the protection of personal data within CTIS. A public consultation on the document is open. **>>**

News from EIPG

Consultation on draft Q&As on remote certification of batches

The public consultation of the Q&As' draft guideline was open up to 13 June 2022. The document discusses how to address the routine remote certification and confirmation of batches, including requirements for the Qualified Persons (QP) and MIA holders.

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