The monthly European Industrial Pharmacists' newsletter April 2022

Technology & Research

Trends in the development of new dosage forms

The work plan defines the priorities of action to prepare for the entry into force of the new regulation (EU) 2021/228 on Heath Technology Assessment, including the setting up of the methodological and operative framework needed to support joint scientific consultations

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Regulatory Affairs

A new joint work plan to 2023 for EMA and EUnetHTA 21

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Business & Policies

IPI, a new international procurement instrument at the EU level

The European Council and Parliament reached in March 2022 an agreement on the draft International Procurement Instrument (IPI). The new regulation is expected to favour the expansion of European companies in third countries' public procurement markets, on the basis of a reciprocity of access. **>>**

EU Focus

EDQM, the RTEMIS scheme for remote inspections

After the closure of the pilot phase, the EDQM confirmed the Real-Time Remote Inspections (RTEMIS) programme as its third pillar to run inspective activities relative to GMP compliance and CEP certificates for API suppliers. The Directorate also released updated application forms for CEP and will soon launch its completely re-designed website. **>>**

News from EIPG

Revision of the PIC/S GMP Guide: Annex 13 and Annex 16

The Pharmaceutical Inspection Co-operation Scheme has updated its PIC/S GMP Guide. The revised Annex 13 reflects the new EU "Clinical Trials" regulation, while Annex 16 is completely new and addresses the certification and batch release processes which fall under the responsibility of the Authorised Persons. **>>**