



Technology & Research

EMA's Industry stakeholders' group (ISG)

The ISG will act a specific reference point to support the dialogue of EMA with the industrial counterparts, under the new extended mandate. The three key areas of interest during the pilot phase are the Emergency Task Force, the shortages of critical medicines and medical devices and the experts' groups on medical devices.

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Regulatory Affairs

ICMRA, two pilot programmes to optimise regulatory assessment and inspections

Collaborative assessments of CMC and post-approval change submissions and hybrid inspections are the focus of the two one-year pilot projects launched by ICRMA in order to better harmonise procedures and expectations at the global level.

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Business & Policies

The new European Innovation Agenda

The five areas of intervention of the new European Innovation Agenda announced by the EU Commission include investments to support startups, development of regulatory sandboxes, initiatives to attract talents and to standardise the terminology used to draft policies and the creation of a network of regional innovation valleys.

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EU Focus

Current inspection trends and new approaches

Collaboration, reliance and delegation are among the suggestions to improve inspection practices in the future. MHRA launched a pilot programme focused on the new figure of Compliance Monitor consultants and the Compliance Protocol agreed with the regulator following an inspection.

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News from EIPG

Trends in Drug delivery and Formulation

The 2021 Global Drug Delivery & Formulation Report highlights the recent trends in approvals of new drug formulations and drug delivery technologies. Injectable and oral products maintain the leading positions, but new approaches are emerging, for the example in the case of nasal delivery to treat ocular conditions.

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