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Strengthening EU-US cooperation in medicine inspections

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New commitment allows FDA to share full inspection reports with European Commission and EMA

The European Commission (EC), the United States (US) Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have signed a new confidentiality commitment that allows the US regulator to share non-public and commercially confidential information, including trade secret information relating to medicine inspections with EU regulators. This confidentiality commitment is a milestone in the ongoing implementation of the mutual recognition of inspections of medicine manufacturers and it aims to strengthen the EU-US relationship. Ultimately it will contribute to a more efficient use of inspection resources by regulators for the protection of human and animal health.

The EU and the US have had confidentiality arrangements in place since 2003, allowing for the exchange of confidential information as part of their regulatory and scientific processes. However, complete exchange of information was not possible under these arrangements.

The new confidentiality commitment formally recognises that FDA's EU counterparts have the authority and demonstrated ability to protect the relevant information. This step now allows the sharing of full inspection reports, allowing regulators to make decisions based on findings in each other's inspection reports and to make better use of their inspection resources to focus on manufacturing sites of higher risk.

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