

Good Manufacturing Practices (GMP), GMP Inspection reports and product sample results available to the EMEA or the European Commission.

6. Good Clinical Practices (GCP) inspections for specific products and GCP Inspection reports available to the EMEA or the European Commission.

7. Information Technology systems supporting regulatory processes.

At the EMEA, the information may be shared with national experts on secondment from the EU Member States, EEA countries, or EU candidate countries. These individuals will be required to sign a confidentiality undertaking with the EMEA (form to be annexed). This form will also be completed by each FDA staff member visiting the EMEA.

The Participants reserve the right to limit the scope of the above information should its dissemination or exchange undermine specific interests, including commercial, industrial or professional secrecy, the protection of the individual and of privacy, the public interests of the EU or the protection of the EMEA or the European Commission's interests in the confidentiality of its proceedings. In some cases, exchange of information under this arrangement may be subject to prior authorisation from the companies concerned.

Participants note that it is an essential element of this international arrangement on regulatory cooperation that confidential information emanating from the other Participant will be treated as such.

On each occasion where there is a request for disclosure to third parties of non-public information received from EMEA or the European Commission, FDA shall consult with the EMEA or the European Commission. Likewise, on each occasion where there is a request for disclosure of non-public information received from FDA, the EMEA or the European Commission shall consult with the FDA.

The EMEA and the European Commission affirm that they have the authority to protect non-public information, including confidential commercial information, provided to their officials or representatives by the FDA, and will protect such information as information not to be disclosed under Article 4.1(a) of Regulation (EC) No 1049/2001. The EMEA and the European Commission understand that the FDA considers it crucial that this non-public information be protected from disclosure; otherwise, it could endanger the international relations between the Participants. The EMEA and the European Commission agree that "confidential commercial information" includes information referred to in the US Freedom of Information Act, 5 U.S.C. § 552(b)(4), and in Regulation (EC) No. 1049/2001

Similarly, the FDA affirms that it has the authority to protect non-public information, including confidential commercial information, provided to its officials or representatives by the EMEA or the European Commission, and will protect such information as information not to be disclosed under the US Freedom of Information Act. The FDA understands that the EMEA and the European Commission consider it crucial that this non-public information be protected from disclosure; otherwise, it could endanger the international relations between the Participants. The FDA agrees that "confidential commercial information" includes information referred to in the US Freedom of Information Act, 5 U.S.C. § 552(b)(4), and in Regulation (EC) No. 1049/2001.