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Q&A on impact of EU-USA Mutual Recognition Agreement on marketing authorisation applications and relevant variations - *Revised 1st October 2025*

Q1: How does the EU-USA Mutual Recognition Agreement (MRA) affect marketing authorisation applications or variations?

A1: The following guidance is relevant for medicinal products covered by the EU-USA MRA; please see here for further details about the scope of the agreement. In order to facilitate the verification of GMP compliance, applicants should submit **all available** documents as proof of GMP compliance for manufacturing sites that have been previously inspected by US FDA, as follows:

- Proof of FDA Drug Establishment Registration *(always required)*
- Certificate to Foreign Government for products authorised in the USA
- Current Good Manufacturing Practice (CGMP) Certificate
- The 90-day facility classification decisional letter issued by FDA
- A screenshot from the FDA Inspection Classification Database (*FDA Data Dashboard*)
- The most recent FDA Establishment Inspection Reports (EIRs) covering activities and facilities relevant to the application (including for non-US sites that were inspected by FDA);
- For products that are authorised by US FDA, a Certificate of Pharmaceutical Products (CPP) should be submitted if the manufacturing site is also registered in the US dossier. These export certificates are valid for 2 years once issued and conform to the format recommended by the World Health Organization's (WHO), Certificate of Pharmaceutical Product scheme. The applicant should ensure that the submitted CPP refers to GMP compliance of the manufacturing site(s) referenced in the EU application.

The relevant documentation should be submitted in Annex 5.9 of the Application Form.
The applicants are advised to ensure before submitting an application for a variation or marketing authorisation that the sites listed in the application are registered with and supervised by US FDA for the proposed activities and products and the outcome of the last inspection was not Official Action Indicated (OAI). If this information cannot be verified during the assessment it may lead to delays in the procedure.

If valid GMP certificates issued by an EEA authority are available, these can also be provided.
The absence of information in relation to GMP as described above will normally trigger a GMP pre-approval inspection to confirm GMP compliance (see also Q3).

Following an evaluation through a pilot programme the EU GMP/GDP Inspectors Working Group agreed to enable the voluntary provision of the EU-US MRA foreseen in Article 3(1) of the agreement to rely on the outcome of US FDA inspections conducted outside the US as of 1 October 2025. Following a case-by-case assessment and the application of a risk-based approach EU national competent authorities may decide to apply reliance and to postpone the conduct of an EU inspection that would normally be required during the assessment timelines of a Marketing Authorisation Application or variation. A proactive provision of FDA inspection reports by applicants in the pre-submission phase or with the filing of the MAA or variation will facilitate the application of this provision..

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Q2: Where can I find more information on the MRA?

A2: Further information can be found here and will be updated as major developments occur. In addition, submission guidance impacted by the MRA will be identified and updated as soon as possible.

Q3: Shall I discuss with the regulatory authorities the possibility of inspections when planning to file an EU marketing authorisation or variation?

A3: Yes. Although the US-EU MRA foresees mutual recognition of inspections there may be situations where an inspection will be needed in the context of an EU marketing authorisation or variation procedure. Such situations may for instance arise in connection with product dossier specific issues that require an on-site verification or because no pertinent inspection report is available.

In order to facilitate a timely and resource efficient organisation of inspections, applicants are advised to proactively contact the relevant regulatory authorities to discuss the need and timing of any potential inspections.

This proactive approach will be particularly useful in case of parallel filing or close-in-time filing in both regions as it may allow the inspectorates to appropriately manage the necessary inspection activities, e.g., through delegation of inspections under MRA Article 11 or through organisation of joint inspections.