



## **U.S.–Swiss Mutual Recognition Agreement on Good Manufacturing Practices**

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“Reliance” is a buzzword in the world of national competent authorities (NCAs) for enforcing pharmaceutical regulations. The more NCAs work together and are able to rely on one another’s assessments, evaluations, and inspections, the more they can streamline procedures and decisions and lessen the burden on their resources. The willingness to rely on work results produced by foreign NCAs has increased in the past 10 years. The U.S. Food and Drug Administration (FDA) already has a mutual recognition agreement (MRA) in place with the European Union (EU) and one with the United Kingdom, while Switzerland has already concluded MRAs on good manufacturing practices (GMPs) with the EU, the UK, and South Korea. There also has been collaboration in non-GMP spaces such as the [ACCESS consortium](#) and the U.S. FDA-led [Project Orbis](#).

As a result of globalization, facilities manufacturing products for multiple markets are in place and need regulatory oversight by each jurisdiction. A seamless partnership that enables such regulatory authorities, as trusted partners, to rely on, coordinate with, and leverage one another’s work, data, and actions to meet their public health goals benefits both the regulators and industry. NCAs benefit by efficiently and proactively learning about a manufacturer’s current state, while manufacturers benefit by not having multiple inspections.

Additionally, bilateral agreements such as memoranda of understanding (MoUs) and confidentiality commitments (CCs) allow for cooperation between NCAs.

### **The U.S.–Swiss MRA on GMP**

On January 12, 2023, the United States and the Swiss Federation signed a bilateral treaty on GMP inspections that, once implemented, would allow the FDA and the Swiss Agency for Therapeutic Products (Swissmedic) to rely on each other’s GMP inspections of pharmaceutical manufacturing facilities for human and veterinary drugs (for detailed information about the MRA, please consult our article of January 30, 2023, [here](#)).

According to the MRA’s transitional provisions (MRA, Annex 3), the two concerned agencies had to mutually assess and align their respective criteria and procedures before the MRA could enter into force. In the months after the signing of the MRA, the two partner authorities audited

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each other's processes for monitoring medicinal product manufacturers in their respective jurisdictions and agreed that they were equivalent.

The entering into force of the MRA guarantees that safe, effective and high-quality medicinal products will continue to be available to patients in both countries while avoiding that manufacturers of such products have to undergo dual inspections by the FDA and Swissmedic at the same locations.

In essence, the MRA requires that before an inspection is conducted by the FDA in Switzerland or by Swissmedic in the USA, the agency requiring an inspection will check whether the production site in question has already been inspected by the other agency. If so, GMP documents will be made available to the partner authority. This transfer of information, however, is not done automatically but is conditional to an explicit consent provided by the manufacturer. These documents can then be used to evaluate the manufacturer instead of conducting an on-site inspection.

For Swissmedic the MRA is not only a proof of the quality of its inspectorates, and an important step toward making GMP inspections more efficient, but also represents a further milestone in its longstanding cooperation with the FDA that started with the [FDA/Swissmedic MoU](#) on the Exchange of Information about Pharmaceutical Products for Human and Animal Use, and Medical Devices, signed in September 2003.

Swissmedic [announced](#) that it will optimize the implementation of the MRA together with FDA and will work with FDA toward expanding the MRA's scope to vaccines.