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1485-10-2025
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17 October 2025

Confirmation of Equivalence of Regulatory Inspections for Good Manufacturing Practice (GMP)

To whom it may concern

This declaration confirms the harmonized inspection standard for the Principality of Liechtenstein and Switzerland, ensuring adherence to a singular, internationally MRA-recognized framework.

Inspections carried out by the Regional Medicines Inspectorate of Eastern and Central Switzerland (Regionale Fachstelle der Ost- und Zentralschweiz) are conducted in accordance with the regulatory requirements and standards for Good Manufacturing Practice (GMP) as defined under Swiss law and supervised by Swissmedic, the Swiss Agency for Therapeutic Products.

The equivalence of these standards is formally recognized by the United States Food and Drug Administration (US-FDA) through the existing Mutual Recognition Agreement (MRA) between the Swiss Confederation and the United States of America concerning pharmaceutical GMP. This agreement confirms that the inspection practices and regulatory oversight of Swiss authorities, including the Cantonal Inspectorates, are considered equivalent to those of the US-FDA. As a result, both parties mutually rely on each other's inspection outcomes for the relevant products.

Additionally, inspections conducted in the Principality of Liechtenstein are governed by an agreement with the Regional Medicines Inspectorate of Eastern and Central Switzerland, ensuring that the same Swiss regulatory requirements and GMP standards are applied. Compliance with European Union (EU) GMP guidelines is also ensured, as Switzerland maintains a separate MRA with the EU for mutual recognition of GMP certificates and batch release. The EU, in turn, has an MRA with the US-FDA, establishing mutual reliance on GMP inspections among all three parties.

The Regional Medicines Inspectorate of Eastern and Central Switzerland has been accredited according to ISO/IEC 17020:2012 since the year 2000. This accreditation is subject to regular surveillance by the Swiss Accreditation Service (SAS), ensuring continued compliance with international standards for inspection activities.

All GMP inspections conducted by Swiss authorities in Switzerland and Liechtenstein follow a standardized procedure defined by the official Swissmedic guidance document "Conduct of inspections of establishments manufacturing or distributing medicinal products or collecting blood" (I SMI.RL.01). This document provides the mandatory framework for a consistent, risk-based inspection approach, ensuring that the same standards are applied across all inspected sites.

Cantonal Office for the Control of Medicines
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