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| **Notification Form** | | |
| **GMP/GCP/GVP/Medical Devices Inspections in Switzerland** | | |
| **Identification number:** | I-308.AA.02-A04e |
| **Version:** | 3.0 |
| **Valid from:** | 27.02.2024 |

# Purpose of Notification

*The general conditions and instructions of use set out in the attachment are an integral part of this form.*

New inspection notification

Modification of prior inspection notification

Cancellation of planned inspection

# Inspecting authority

Country: ……

Name: ……

Address: ……

Contacts: Mr./Ms. Name Mr./Ms. Name

Phone: …… Phone: ……

E-Mail: …… E-Mail: ……

# Information on the planned inspection

**Company to be inspected:**

Name: …… Contacts: Mr./Ms. Name

Address: …… Phone: ……

…… E-Mail: ……

……

**Sites** to be inspected: ……

**Inspection Dates:** dd-mm-yyyy - Remote:  yes  no

**Inspection team:**

Inspector: Mr./Ms. Name

Inspector: Mr./Ms. Name

Inspector: Mr./Ms. Name

Inspector: Mr./Ms. Name

**Additional information required:**

**Type of inspection:**

GMP

GCP

GVP

Medical Devices

**Scope:**

Surveillance inspection

Pre-approval inspection

Post-approval inspection

For Cause inspection

Product(s)/Type of product(s) to be inspected: ……

*Only for pre-approval inspections:*

A/NDA Number: ……

Applicant of Marketing Authorization: ……

Remarks: ……

**On behalf of the inspecting authority, the undersigned informs Swissmedic about this inspection**

Name: …… Date: **dd-mm-yyyy**

Function: ……

Phone: ……

E-Mail: …… Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# GMP/GCP/GPV/Medical Devices Inspections in Switzerland – Notification Form – Attachment

## General Conditions

Legal aspects for inspections by foreign governmental officials in Switzerland: Article 64a Swiss Therapeutic Products Act.

An inspection in Switzerland by a foreign authority is only allowed if the inspecting authority has received prior agreement of the company to be inspected. A notification must be submitted to the Swiss Agency for Therapeutic Products (Swissmedic) at latest 30 days prior to the planned beginning of the inspection. Swissmedic will acknowledge receipt of notifications. After the inspection the inspecting authority is requested to deliver to Swissmedic a copy of the inspection report within 10 days after issuing the report, or alternatively a one-pager summary within 40 days after inspection stating the overall result, general impression/findings, conclusions. The report or summary must be in English (or possibly French, Italian or German). Swissmedic will acknowledge receipt of the report/summary.

## Instructions of use

This form serves as a template for a notification.

a) Please use one form per firm and inspection. All notifications of inspection in Switzerland must be signed by and submitted through inspecting authorities office of regulatory affairs.

b) Please transmit this form by e-mail at least 30 calendar days prior to the starting date of the planned inspection to the corresponding contacts at Swissmedic.

c) Please transmit the inspection report or the one-pager summary in a timely manner by e-mail to the responsible contacts at Swissmedic.

## Contacts at Swissmedic

In case of **Good Manufacturing Practice (GMP)** inspections related to medicinal products, including blood, blood products and immunological products (e.g. vaccines, sera), as well as transplant products/transplants, please send the documents to:

Swissmedic, Swiss Agency for Therapeutic Products

Authorisations, Certificates and Licences

3012 Bern / Switzerland

**E-mail: inspectorates@swissmedic.ch**

In case of **Good Clinical Practice (GCP)** inspections related to human medicinal products as well as in case of **pharmacovigilance inspections**, please send the documents to:

Swissmedic, Swiss Agency for Therapeutic Products

GCP/GVP Inspectorate

3012 Bern / Switzerland

**E-mail:** [**ct.medicinalproducts@swissmedic.ch**](mailto:ct.medicinalproducts@swissmedic.ch)

In case of inspections related to **medical devices** intended for human use please send the documents to:

Swissmedic, Swiss Agency for Therapeutic Products

Medical Devices Division

3012 Bern / Switzerland

**E-mail:** [**medical.devices@swissmedic.ch**](mailto:medical.devices@swissmedic.ch)