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Information sheet
Medical devices – content requirements for CAPA plan

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1 Objectives and scope of this information sheet

When deviations from legal requirements (non-conformities[1,2]) are identified at an economic operator in the course of market surveillance by authorities [3] (e.g. an inspection), Swissmedic requests submission of a written corrective and preventive action plan ("CAPA plan") for their rectification.

This information sheet is intended to support economic operators of medical devices in the development of a CAPA plan and summarises basic content requirements.

2 Abbreviations used in the information sheet

Abbreviation	Explanation
CAPA	Compound term for corrective actions (CAs) and preventive actions (PAs) [4]
EO	Economic operators for medical devices in the Swiss market (e.g. manufacturers, authorised representatives, importers), legal addressees vis-à-vis Swissmedic
EU IVDR	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (*In-vitro Diagnostic Medical Device Regulation "IVDR"*)
EU MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (*Medical Device Regulation "MDR"*)
IvDO	Ordinance on In Vitro Diagnostic Medical Devices of 4 May 2022, SR 812.219
MedDO	Medical Devices Ordinance of 1 July 2020, SR 812.213
NC / NCs	Nonconformity, deviation from the legal requirements
PDCA	Plan, Do, Check, Act phases in the Deming cycle; a process model for continuous improvement

3 Corrective and preventive actions

Non-conformities (NCs) are deviations from or failure to fulfil a specific requirement. A single NC may have several **causes**.
Corrective actions (CAs) eliminate these causes. A CA is taken to prevent the recurrence of an NC that has already been identified.
Preventive actions (PAs) eliminate a cause of a potential NC or another possible undesirable situation. A PA is taken to prevent the future occurrence of a potential NC.

4 Objectives of the CAPA plan

In a CAPA plan, the economic operator (EO) communicates to Swissmedic its binding strategies to rectify (CA) and preventively address (PA) each identified non-conformity (NC) along with its underlying causes.

[1] Art. 95 para. 1 and Art. 97 para. 1 EU-MDR
[2] Art. 90 para. 1 and Art. 92 para. 1 EU-IVDR
[3] Chapter 9 MedDO
[4] Terms based on Art. 57 para. 1 MedDO and Art. 50 para. 1 IvDO

An appropriate CAPA plan is:

- clear and complete, i.e. all NCs are **individually referenced and addressed**
- set out in writing with details of those responsible, actions, methods and timelines
- traceable and suitable to eliminate all NCs sustainably and completely (restoration of conformity of devices, processes and/or systems)
- effective in eliminating the root causes of NCs and with an overall view of all devices / processes / interfaces
- binding and has proven effectiveness (efficacy)
- submitted on time (CAPA plan usually drawn up within 30 days; however, this deadline does not include implementation of the actions)

5 Possible CAPA plan approach model

The following table explains a possible process-oriented approach model for drawing up a CAPA plan based on the Deming cycle (PDCA cycle) known from quality management:

PLAN Analysis Planning CAPA objectives	• Description of the NCs incl. context • Cause and risk analysis, other devices / processes / interfaces if necessary • Development / definition of corrective (CA) and preventive (PA) actions as well as any immediate actions • Planning of the subsequent process phases (Do, Check, Act) and necessary resources
DO Implement CAPA	• Scheduling and implementation of the defined action(s) • Management of interactions between the actions
CHECK Verify CAPA effectiveness	• Check the effectiveness of the implemented action(s) (target/actual comparison)
ACT Assess CAPA effectiveness	• Check and document the effectiveness of the CAPA actions implemented to completely eliminate the NCs • Derive any need for improvement and, if necessary, return to the planning phase (continuous improvement)

Note: Swissmedic reviews the CAPA plans submitted by the EO as well as their evidence of implementation. If Swissmedic deems the analyses, objectives and corrective actions described by the EO's CAPA to be insufficient, the EO will be requested to define and implement further actions, or Swissmedic may order measures as part of the administrative procedure.

6 Notes on the use of the information sheet (disclaimer)

In accordance with the regulations, the EO must proactively identify deviations from legal requirements (NCs) at all times, independently of the market surveillance by authorities, and, if necessary, rectify them by means of a CAPA plan[5,6].

[5] Art. 10 para. 9 let. l EU-MDR and Art. 10 para. 8 let. l EU-IVDR
[6] Art. 50 MedDO and Art. 43 IvDO

This information sheet summarises the requirements for CAPA plans in a highly simplified form in order to set out the minimum requirements for CAPA plans to be submitted, particularly for EO's without a quality management system, and to ensure that the process runs efficiently.

Further guidance on the creation of CAPA plans can be found, for example, in chapter 8.5 of ISO 13845:2016[7] in conjunction with chapter 8.5 of ISO 13485:2 016 Medical Devices – A Practical Guide[8] and in the document GHTF/SG3/N18:2010 – Quality Management System – Medical Devices – Guidance on corrective action and preventive action and related QMS processes (Global Harmonization Task Force).

While the information sheet outlines one possible approach to drawing up a CAPA plan, alternative methods can be employed Utilizing this information sheet does not imply general conformity of devices, processes or systems and should therefore not be interpreted and communicated as such, regardless of the respective role of the EO.

As the supervisory authority for medical devices, Swissmedic does not provide specific advice regarding the development, qualification, classification, registration, certification, conformity or placing on the market of medical devices. Swissmedic can also not comment on contractual and liability issues. For such concerns please contact a private consulting company directly.

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Further information on medical devices can be found at www.swissmedic.ch → Medical devices

[7] ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes
[8] ISO 13485:2016 – A Practical Guide, advice from ISO/TC 210, © ISO 2017, ISBN 978-92-67-10774-5

Change history

Version	Change	sig
2.1	Minor changes to content (document title, references and footers in chapter 6)	hut
2.0	Thorough revision of sections 1-6 after completion and evaluation of the test phase	hut
1.0	First version of information sheet for test phase	hut