

## INSTRUCTIONS FOR THE SUBMISSION OF A CAPA PLAN FOLLOWING A GDP INSPECTION

---

**The applicant for a GDP certificate shall submit, within 30 days of receipt of the *GDP inspection report*, a proposed CAPA Plan addressing the identified non-conformities.**

The applicant for a GDP certificate shall use [Annex 1 – Agreed CAPA Plan](#), available on CInMED website ([www.cinmed.me](http://www.cinmed.me) > *Inspectorate* > *Wholesale/Good Distribution Practice* > *Instructions and Forms*).

Annex 1 shall be completed in such a manner as to ensure that:

1. all relevant information concerning the wholesaler and conducted inspection is provided, including the name of the wholesaler, the address of the wholesale distribution site, the file reference number, the date of the GDP inspection, the CAPA Plan version number, and the date on which the respective version was submitted to CInMED);
2. the field “*Observed Non-Conformities*” contains all non-conformities identified in the *GDP Inspection Report*, with each non-conformity entered as a separate row in the table (e.g. *1a* = one row in the table);
3. proposed response to the non-conformity, i.e. corrective and/or preventive measure(s) is provided in the *Response / CAPA Measure*” field;
4. the deadline for the implementation of the corrective and/or preventive action(s) is specified in the “*Implementation Deadline*” field. Proposed date shall be indicated in the format dd.mm.yyyy.

Once completed, proposed CAPA Plan shall be submitted to the Institute in Word format by e-mail to [pisarnica@cinmed.me](mailto:pisarnica@cinmed.me), with reference to the relevant file number. The e-mail shall be copied to all members of the inspection team who conducted the inspection.

Following receipt of CInMED’s comments (**highlighted in red**) on the proposed CAPA Plan, the applicant shall:

1. **below CInMED’s comment** (for traceability purposes), provide a revised or supplemented corrective and/or preventive action proposal, where a response is considered unacceptable or incomplete;
2. **below CInMED’s comment**, propose a new deadline for the implementation of the corrective and/or preventive action(s), where proposed implementation deadline is not acceptable.

Following agreement on all proposed CAPA actions and implementation deadlines, the Lead Inspector shall forward the *Agreed CAPA Plan* to the applicant. The applicant shall print the *Agreed CAPA Plan* in two copies (in colour) and submit both signed and dated copies to the CInMED Registry Office, with reference to the relevant file number.

**Note:** Information entered in previously submitted versions of the CAPA Plan **shall not be deleted**.

The date of the *Agreed CAPA Plan* shall be inserted by CInMED in the document header.

Only the *Agreed CAPA Plan* shall be signed and dated by the Responsible Person of the wholesaler, or their deputy, and by the Lead Inspector. Previous versions of the CAPA Plan shall be submitted in Word format as described above.