On-site verification of Good Manufacturing Practice

0 Objective

Ensuring that IFS requirements relating to Good Manufacturing Practices (GMP) in general and in particular with requirements for implementing HACCP as well as pest control processes are maintained and are in compliance under the current extraordinary circumstances. The IFS GMP Check is an independent tool to achieve a quick GMP status check conducted unannounced by a third party as soon as travel restrictions are lifted and on-site checks are possible again.

Note: This document generally refers to GMP. In the sense of GMP, however, Good Distribution Practices (GDP) are also covered.

1 Scope

The GMP check is only applicable for companies which are already IFS certified and where a scheduled IFS Renewal audit was still not possible to organise due to the Covid-19 crisis and less auditor capacity. For IFS Global Markets this check does not apply.

Within the IFS Database, there is a new section where certification bodies are able to select or tick a check-box to indicate the above situation and save all of the documentation associated to the GMP check (for further details see point 9).

The GMP check is an overview how companies are operating while getting out of the Covid 19 crisis as well as a verification of the IFS Requirements relating to GMP in general and in particular with requirements for implementing HACCP as well as pest control processes. Due to the fact that this is just a “spot check”, the result of the GMP check cannot be taken into account for future IFS Certification Audits according to ISO/IEC 17065:2012.

The GMP check can never be used to replace the renewal audit and cannot be used to reduce the duration of the renewal audit in any way.

Note 1: A GMP Check is always site specific (COID).

Note 2: The certification body who issued the last certificate should preferably conduct the GMP Check, as the company and operations / processes are already known. However, in the case of a CB change by the company, the check can also be conducted by the new certification body.
Note 3: This GMP check should preferably be conducted by the same auditor who performed the last initial/renewal audit.

Note 4: In case a company has seasonal production, the CB is obliged to ensure that there is ongoing production during the GMP Check. It is not possible to conduct a GMP Check when the facility is not operating.

2 Duration

Depending on the company’s size and complexity in regards to products, processes and/or technologies, the duration for the GMP Check can vary, but shall be as a minimum five (5) hours and shall not exceed eight (8) hours.

Note 1: The certification body needs to consider that in certain cases more time is needed e.g. high number of employees, large production area, several floors, high number of production lines, etc.

Note 2: Two (2) auditors shall be assigned if the company has 500 ≥ FTEs or a minimal calculated audit time of thirty-six (36) hours as per IFS Calculation Tool.

3 Auditor Competency

Applicable product scopes, as required in the relevant IFS Standard.

Note: We expect that certification bodies train the IFS auditors in a way that they can do the GMP check in line with IFS principles, to provide a high professional standard.

4 Scheduling / Framework / Trail

The IFS GMP Check shall be conducted UNANNOUNCED.

To ensure the UNANNOUNCED character, the GMP Check shall be conducted within a timeframe of maximum eighteen (18) weeks after the company has registered itself for the GMP Check with its responsible CB (see 1. Note 2).

Blackout days
When registering for an unannounced GMP Check with its certification body, the company has the opportunity to identify maximum ten (10) operational days, plus not operating periods, when the site is not available for the audit. These dates shall be notified to the certification body at the same time as the company is registered for the unannounced GMP Check by its certification body and reasons shall be
provided. Reasons may be challenged by the certification body or by the auditor during the GMP Check.

**Note 1:** the company may only split the ten (10) operational days into a maximum of 3 periods (e.g. planned customer visit, holidays of Quality manager, etc.).

The auditor shall start the production tour at the latest 30 mins after arrival on-site. Within these first 30 minutes, the auditor shall briefly explain the objective of the GMP Check and, where necessary, have a brief review of:

- Organizational chart including deputation of responsibilities
- Site map describing internal flows of personnel, raw materials, semi-finished goods and final products
- Current production schedule of the day/ week
- Flow chart of the processes identifying each CCP and a list of CCPs and CPs
- Pest monitoring/ monitoring documents

Only records and documents presented to the auditor during the ongoing GMP check can be considered as evidence.

- HACCP / changes and day-by-day implementation
- Implementation and maintenance of prerequisite programs (personnel hygiene, cleaning, pest control, temperature control)
- Prevention of (cross) contamination (foreign materials, allergens, any other unwanted substances), goods receiving, storage, dispatch and transport where applicable
- Protection from adulteration
- Requirements as listed in the designated GMP checklist as per Standard

**Note 2:** The review of documents and records shall be limited to daily operation records (e.g. CCP and CP records of the production day; quantity checks of the day, etc.). Only in case of severe findings during the production tour shall the auditor investigate deeper into related records and documents.

**Note 3:** The GMP Check is a stand-alone tool, the diary function within IFS Database shall not be used.
5 Scoring

The scoring of the checklist requirements consists of a basic evaluation of

- “OK”
- “Not OK”
- Major (as defined in the IFS Standards)
- KO = “not OK” on KO requirements

Note: The requirement must be rated as “not OK” if the auditor determines that a corrective action is necessary, as otherwise legality or quality could be compromised.

6 Non-conformances

In case of “Not OK” and Major or KO, details of the non-conformances need to be listed in the corrective action plan. Companies have up to two (2) weeks (14 days) to respond and provide a completed corrective action plan to the certification body for review.

- If the non-conformances consist of “Not OK” only, the letter “Result of GMP Check” is issued once the certification body has accepted the completed corrective action plan clearly stating the “Passed” result.
- If the non-conformances include a Major and/or KO, the letter “Result of GMP Check” is issued clearly stating the “Failed” result. The certification body still has to review and accept the completed corrective action plan. Once the completed corrective action plan is accepted, the company can request a new date for a GMP Check. The new date shall be at the earliest four (4) weeks after the previous GMP Check.
- Corrective actions taken by the company need to be verified at the latest during the next IFS Certification Audit.
7 Results of the GMP Check

There are no percentages as a result of the GMP Check, only:

**Passed** or **Failed**

- If only “OK” evaluations are made during the check, the GMP Check is **passed**.
- If “Not OK” evaluations are raised and the certification body accepts the completed corrective action plan, the GMP check is **passed**.
- If “Not OK” evaluations are raised and the certification body does not accept the completed corrective action plan, the GMP Check is **failed**.
- If a Major and/or KO is raised, the GMP Check is **failed**. A follow-up is not possible. The company can request a new date for a full GMP Check, four (4) weeks after the previous GMP Check was failed.
- If there is a current and still valid IFS Certificate and the GMP Check is **failed**:
  - For accredited IFS Certificates, according to ISO/IEC 17065:2012 clause 7.11.1, IFS expects that in case of evaluation of a “Major” or “KO”, the certification body applies the same approach in line with IFS Standards Part 1 clause 5.8.1 and 5.8.2 (respectively 6.8.1 and 6.8.2 in the IFS HPC Standard).

8 Reporting

- The certification body shall issue a reviewed report (GMP checklist, including all evaluations) plus a corrective action plan, stating the products produced during GMP Check and the date(s) of the GMP Check.
- The template letter “Result of GMP Check” is provided by IFS.
- The certification body shall complete the template letter “Result of GMP Check” – companies are to receive the document regardless of the result (i.e. also in case of a failed GMP Check).

**Note:** additional (hand written) notes shall be taken by the auditor and be available on request.
9 Uploading of documentation to the IFS Database

- The certification body has to select the option “Due to precautionary measures and/or governmental restrictions concerning the Coronavirus (COVID-19) the renewal audit has to be postponed” in the IFS Database.
- There is one check box to select:
  - GMP Check
- The certification body has to provide the following information:
  - Name of the auditor
  - Last day of the GMP Check
- The following documents are mandatory to upload:
  - “Result of GMP Check” (visible to other users)
  - Completed corrective action plan
- The certification body is obliged to indicate the result (passed or failed) of the GMP Check by using the database field “Result”.
- The “Result of GMP Check” letter is valid for a maximum of six (6) months. As soon as a full IFS on-site Audit is possible again, the audit shall take place. At this point the “Result of GMP Check” letter expires!

10 IFS Database Notifications

- Favourites will receive a notification when the option “Due to precautionary measures and/or governmental restrictions concerning the Coronavirus (COVID-19) the renewal audit has to be postponed” is selected.
- Favourites will receive a notification that the check box “GMP Check” is selected and that the documentation is uploaded and/or in case information is modified. The notification includes also the result of the GMP Check.
11 Technical Guidance

The certification body conducting the GMP Check shall be able to ensure compliance with below essential requirements:

- The security and confidentiality of all information, records and documents obtained by the auditor during the GMP Check shall be ensured.
- The GMP Check shall be mutually agreed between the certification body and the auditee in accordance with information security and data protection measures and regulations before the GMP Check is conducted.
- The certification body is obliged to store the data (report, (hand written) auditor notes) for at least three (3) years.

12 IFS uploading Fees

IFS will charge for every uploaded GMP Check a fee of:

- 300,00€ + VAT for IFS Standards