IFS HPC

IFS HPC Companion

Guideline for the implementation of the IFS HPC Standard

Version 2

ENGLISH

INTRODUCTION

Welcome to the IFS HPC Companion, which has been updated to IFS HPC version 3. This document will help with gaining a better understanding of the intent of the HPC standard requirements and provide practical advice on how to implement them effectively.

Managers responsible for product safety and quality of household and personal care products will find the IFS HPC Companion a helpful resource for daily tasks. Whether you are starting your journey towards IFS HPC Certification or looking to optimise your current processes, this guide will help you achieve compliance, increase efficiency, and drive continuous improvement.

We want to point out that the implementation of the IFS HPC Requirements depends on the company's specifics and its risk assessment. Therefore, this document only has an explanatory and supportive character and is not normative nor legally binding.

Join us as we explore the best practices and actionable steps to meet and exceed the requirements of the standard with the help of the IFS HPC Companion.

Further IFS Support for suppliers of HPC products

To support suppliers of household and personal care products, IFS offers these **complementary tools** and resources:

- The **IFS Database** is a resource that helps you find IFS certified suppliers and enables potential customers to find you.
- The **IFS Software, auditXpress Neo**, that you can download from your IFS Database login area simplifies reporting on internal audits.
- The **IFS Pathway** is a source of knowledge offering technical resources to enhance quality management skills.
- The **IFS Guidelines** help with practical information about specific technical topics such as product defence or pest control.
- **IFS Representatives** located worldwide are your local contact persons, who will advise you on all matters concerning IFS Certification.

IFS also works with several **experienced training providers and consultants** around the globe. They offer industry training courses that provide skills for implementing the HPC requirements based on official IFS Training Materials. Also, they can support your company with customised solutions.

Visit the **IFS HPC Standard webpage** for more information, relevant documents, and details regarding our tools and partners: ***https://www.ifs-certification.com/en/hpc-standard***

Should you have any questions, you can email standardmanagement@ifs-certification.com

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1

CERTIFICATION ACCORDING TO IFS HPC

1 CERTIFICATION ACCORDING TO IFS HPC

1.1 What is the IFS HPC Standard all about?

The first thing to understand before starting is where the IFS HPC Standard comes from.

The creation of the IFS HPC Standard originated from the wish of different stakeholders to have one standard covering key aspects of the Quality and Product Safety Management System, Good Manufacturing Practices (GMPs), Good Hygiene Practices and also Risk Management principles, for manufacturers of household and personal care products in one document. One important objective was to harmonize audit requirements into one single standard, recognised by the market.

The first version of the IFS HPC Standard was developed in 2006 by IFS (co-owned company by FCD and HDE, French and German retail federations) and international stakeholders (from industry, retail, certification bodies, etc.). The latest version was published in December 2022 and was drawn up by a number of experts from different countries (e.g. France, Germany, Italy, Spain, The Netherlands, UK) and from organizations with a global footprint. In the "Acknowledgements" section of the standard, you will see that many retailers and well-known manufacturers from the HPC market were involved in the creation of the standard, which makes it widely accepted and used as a reference on the market.

The IFS HPC Certification not only enables you to drive continuous improvement but is also a key factor in building trust with customers and ultimately consumers.

1.2 How and where to start?

The first step is to read the IFS HPC Standard to make sure that your company:

- Fits in the scope of the standard,
- Has enough time and resources to implement the requirements of the standard. Be aware that the standard requests the company to appoint an IFS Representative. The main role of the IFS Representative is to be the person in charge of all topics related to IFS (internally and externally, for example for the certification body). This person can be the Quality/ Safety Manager, but this is not a must.

You can download the IFS HPC Standard for free on the IFS Website: ***www.ifs-certification.com***.

IFS also provides some supporting documents and often updates them, so take a regular look at the new and added value documents that are available on the IFS Website, such as a table explaining the different scopes and associated products, guidelines on how to implement product defence requirements, generic guidelines, etc.

The IFS HPC Standard is divided into 4 main sections:

1

PART 1: CERTIFICATION PROTOCOL

This part provides a detailed description of procedures to be followed before, during and after an IFS HPC Audit. It explains everything related to how the audit is performed and defines the audit duration, scoring system, timelines between audit and certificate issuance, etc.

2

PART 2: LIST OF HPC AUDIT REQUIREMENTS

This part lists all audit requirements which will be checked and assessed by the auditor during your certification audit.

3

PART 3: REQUIREMENTS FOR ACCREDITATION BODIES, CERTIFICATION BODIES AND AUDITORS

This part addresses requirements of competencies and processes for accreditation bodies, certification bodies and auditors.

4

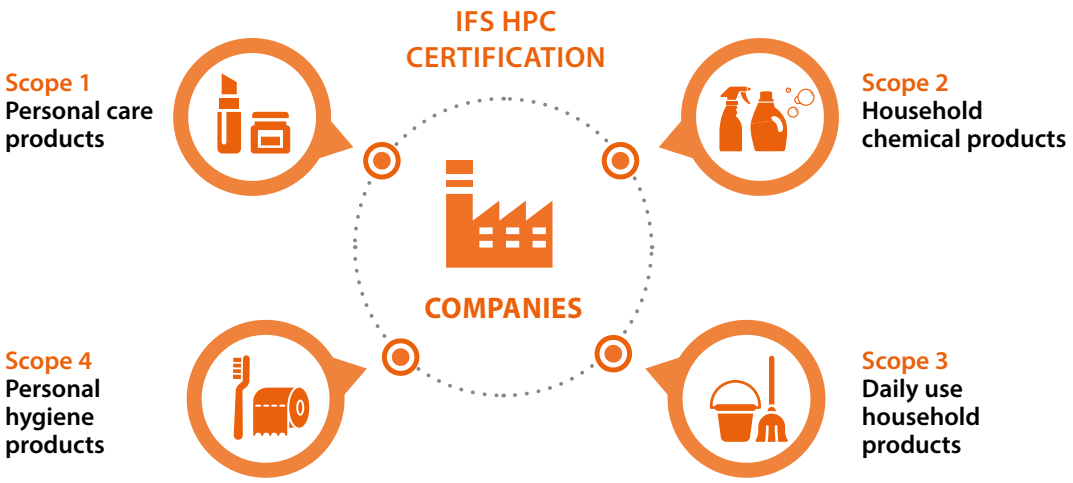
PART 4: REPORTING, SOFTWARE AND DATABASE

This part explains what the IFS HPC Audit Report, Action Plan and Certificate shall look like, as this can be totally uniform for a better reading and recognition across certification bodies and countries.

Although Part 3 and 4 are very important, Part 1 and Part 2 should be reviewed as a priority for you to understand how the IFS HPC Certification Audit will occur, what is to be implemented within the company and how to prepare for the audit.

Is your company in the scope of IFS HPC Certification?

The IFS HPC Standard applies to companies with **processing** activities or activities where there is a hazard for product contamination during the primary packing stage.
It applies to the following products (customer branded and own branded):



Some medical devices class I (e. g. gauze/ bandages, compresses, classic plasters, incontinence product etc.) are included in scope 4 of the standard.

If you have doubts about the correct product scope(s), you can check a detailed table ("IFS HPC v3 product examples chart") listing many product examples for each scope on the IFS Website.

The standard also provides a list of products which are excluded from the audit scope, such as toys, electronic devices, OTC and medical devices higher than class I, etc. (see Annex 3 of the IFS HPC Standard).

If your company doesn't have any processing activities but does have trading or storing (of packed products) activities, for instance, then the IFS HPC Standard does not apply but IFS has implemented other standards to cover those steps of the supply chain (e. g. IFS Logistics, IFS Broker). Annex 1 explains the differentiation between the IFS Standards.

Once you have checked whether the activity of your company fits in the frame of the IFS HPC Standard, you can go on with the next steps.

How to define audit scope?

The IFS HPC Audit is site-specific and it is a product and process certification audit; therefore, the audit shall cover the full activities of your company and cannot exclude any parts, premises or production lines.

Exclusion of products (not of processes) may be allowed under the risk-based approval of the certification body you'll have to choose to perform your audit. If the excluded product has no impact on product safety and quality, the CB need to complete the "IFS HPC Questionnaire for certification bodies, to define, under exceptional circumstances, product exclusions in the audit scope" (see Annex 4, of the IFS HPC Standard). The result of this questionnaire will be verified, approved and validated each year by the auditor in your audit.

An exclusion of products is among others not possible when the product is a retail branded product or when the product is not differentiable from the rest of the products.

How to select an auditor?

You will not select an auditor, but your certification body will appoint the right auditor for your company.

Certification bodies which are approved to perform IFS HPC Audits are listed on our IFS Website.

Approved certification bodies have signed a contract with IFS and are accredited to ISO/IEC 17065:2012 norm for the IFS HPC Certification, which is evidence of competence, independence and impartiality.

When selecting the certification body, the following should be considered:

- Available auditor competencies for the product scopes related to your activity (auditors are approved per product scope(s))
- Proximity of location (to reduce auditor travel fee)

- Language of the auditor. The audit shall preferably be carried out in the language of your company (to facilitate employee interviews and understanding of company documents by the auditor). If this is not possible, the audit shall be performed in English Please note, that depending on each situation, an interpreter may be consulted.
- Available dates. The audit shall take place when all production lines are operating, to enable the evaluation of all audit requirements of the audit scope. This is very important! If some lines are not operating during the audit and products are different from those operating, the auditor will not have the full picture of your company and will not be able to assess all requirements of the standard. In this case an extension audit needs to be performed.
- Available competences for a combined audit in case your company would like to leverage the IFS HPC Certification Audit to perform another certification audit in parallel.

Describe the activity of your company in as much detail as possible, to give the certification body a good overview of the audit scope. Specific company organisations such as outsourced activities, multi-location production sites with central management shall be notified to your certification body as this impacts the certification process.

Provide all relevant information, so that your certification body can define the audit scope and the appropriate audit duration.

NOTE: **You need to ensure to inform your certification body whenever your management and organisation have changed, your products or production methods have been modified and addresses have changed. In case of officially ordered product recalls with authorities involved and which results in notification and/or penalties related to product safety and/or legality you need to inform the CB within 3 working days (see requirement 1.2.5 in part 2 of the checklist).**

What is the duration of an IFS HPC Audit?

The certification body will define a customised audit duration, based on the information provided on company size, organisation, type and number of products, number of employees, etc.

Be aware that the minimum duration of an IFS HPC Audit is **2 working days** (=16 hours) and may be extended based on your company parameters. This duration allows sufficient time for all requirements of the audit checklist to be audited. For some specific situations, the audit duration can be reduced by 0,5 days (IFS combined, multi-location etc.).

Apart from the audit itself, the certification body will add 2 hours for preparation of the audit and a further 6 hours to write the audit report.

Once you have selected a certification body and agreed on all details together, you should record this in a contract.

What is the IFS Integrity Program (IP)?

You may have seen a reference to the IFS Integrity Program in Part 1 of the standard and in the contract with your certification body and are wondering what this is all about? IFS Integrity Program is a Compliance Program that IFS has developed to ensure that all certification bodies, auditors and IFS certified companies are operating in line with IFS Requirements.

This program includes IFS Integrity Certification Body Offices Audits, observations of IFS Auditors during IFS Audits and Integrity On-site Checks (IOCs) of IFS certified companies by independent IFS Integrity Program Auditors.

Your certification body has included a reference to the IFS Integrity Program in your contract, as it may happen that:

- the IFS Auditor, who is commissioned to audit your company is observed by an IFS IP Auditor, or
- an IFS IP Auditor performs an unannounced on-site check of your company. Your company may be selected on a risk-based foundation by the IFS Integrity Program team (for example your company is producing lipsticks and there was recently a major recall on lipsticks on the market) or based on a complaint e. g. by a retailer or other interested parties. You shall give access and support the IP auditor, as this is part of the requirements of all IFS Standards and may result in the withdrawal of the current certificate if the contract is not honoured.

This should not be a cause for concern as the objective is to verify and ensure that IFS Requirements and good manufacturing practices are always met and implemented consistently.

What can you do to help prepare for your IFS HPC Audit?

Your company can decide to perform a voluntary pre-audit, to evaluate the level of implementation of IFS HPC Requirements before performing the certification audit. This pre-audit cannot be uploaded in the IFS Database and has to be performed by a different auditor to the one who performs the IFS Audit.

If you already have a quality/product safety management system in place, and/or if the outcome of your customer audits is usually positive, your company is in a good position to fulfil the IFS HPC Requirements. Nevertheless, a full review of audit requirements is necessary to ensure that your company is ready for the certification audit.

Based on company testimonies, it may take from 3 to 6 months to get prepared for an IFS HPC Certification Audit, depending on what is already implemented on-site.

Announced or Unannounced audit?

With the new IFS HPC version 3, you can decide on an unannounced audit, which is carried out within a specific time window without prior notice. Registration for this option is voluntary for HPC.

Evaluated through extensive experience in the food industry, an unannounced audit rewards and supports you in "living" your product and safety culture. This helps to strengthen trust between business partners. To make this achievement widely visible, you will receive the new IFS Star Status on your certificate and in the IFS Database until another announced audit has taken place.

The audit will be performed within a specific time window, which is 16 weeks before and 2 weeks after the audit due date. Together with your CB, you can define a so-called blackout period during which no audit will take place when lines are not operating.

Make sure that auditor access is always guaranteed during the audit window, otherwise the current certificate will have to be withdrawn. Section 2 of this document will support you to understand and implement IFS HPC Audit Requirements (checklist of requirements in part 2 of the standard), but before this step, let's check how the certification audit will be carried out.

1.3 The certification audit

Several days before the audit, you will receive an audit time schedule from your certification body, which defines the steps of the audit including a provisional time plan and the topics to be covered. Make sure that the relevant personnel from the company are available at the corresponding times (e.g. senior management for opening and closing meeting, maintenance manager during the assessment of maintenance related requirements, etc.).

The first audit performed in your company is called an "Initial audit". To maintain certification, the production site shall be certified each year. This is known as a "Recertification audit". Regardless of the audit type and the final audit results, all audit requirements are evaluated each year.

The audit takes place in the following steps:

- **Opening meeting:** Introduction of auditor and company personnel and review of the audit scope, to ensure the accuracy and that no activity is missing.
- **Evaluation of existing product safety and quality management system:** This step is usually performed by checking documentation (e.g. hazard analysis and risk assessment, quality management documentation, etc.).
- **On-site evaluation:** Observation of all production lines and production processes within the production area. This shall take at least 50% of the total audit time. Working personnel may be interviewed by the auditor, CCPs will be monitored, and control measures crosschecked to understand your company processes and assess whether the personnel are aware of their responsibilities.

NOTE: **Make sure that your staff is available for the audit period and that they are aware of possible interviews.**

- **Documentation and record review and inspection:** During this step, the auditor evaluates and documents procedures by crosschecking investigations and findings from the on-site observation.
- **Final conclusion:** This moment is usually for the auditor to wrap up audit findings and set up an overview of the company audit result.
- **Closing meeting:** This is the last step of the audit. The auditor will share the most significant non-conformities and/ or deviations with you. A final result (certified/not certified) cannot be provided at this stage. Other steps of the certification process need to be realised before making this final decision. Those steps are the implementation of a corrective action plan by your company, its validation by the auditor and finally, the certification decision made by the certification body based on the action plan and the final audit score.

IMPORTANT: **During the audit, the auditor will review company records and documents. This is part of the normal audit process and you should agree to make those documents available to the auditor, as the certification body and the auditor are committed to maintaining confidentiality (this is usually regulated in the contract you sign with the certification body).**

1.4 After the audit, until certificate delivery

The auditor and/or the certification body will send an action plan with the list of findings to you. A provisional audit report can be made available upon request.

You should receive the action plan within 2 weeks and complete it as follows:

- Provide evidence for implementation of corrections and proposed corrective actions for all deviations (B, C, D scoring), for KO B scoring, KO D scoring and for Major non-conformities.
- Provide responsibilities and a timeline for the implementation of corrections and corrective actions for all of the above.

You need to send the completed action plan back to the certification body within 4 weeks of receiving the plan. The certification body or the auditor will validate and assess the relevance and the evidence you have proposed. If the evidence is inadequate, the action plan must be revised and sent back for review.

NOTE: **To ensure that the action plan can be validated in due time, make sure, that you provide it to the CB early enough within the 4 weeks to have time for a possible revision.**

Implementation of corrective actions can take longer but need to be provided in the action plan within 4 weeks also.

Based on the validation of the action plan and the technical review of the report the certification body will take the final certification decision **within a further 2 weeks**. In total the upload of report, action plan and certificate to the IFS Database shall **not take longer than 8 weeks** after the last audit day.

The report will contain an individual evaluation of all IFS HPC Audit Requirements, with the following scores:

RESULT	EXPLANATION	
A	Full compliance of the requirement	**20 POINTS**
B	Almost full compliance of the requirement but a small deviation was found	**15 POINTS**
C	Part of the requirement has not been implemented	**5 POINTS**
D	The requirement has not been implemented	**– 20 POINTS**
N/A	The requirement is not applicable (with an explanation by the auditor)	**NO SCORE**
MAJOR (non-conformity)	Substantial failure to meet requirement related to product safety and/or legislation, internal dysfunctions, customer issues. *(subtract 15% of the possible total amount; the certificate cannot be issued)*	**– 15%**

Total audit score is calculated in percentage (number of points gained by the company/ maximum number of possible points).

Here are examples of deviations, to give you an idea of how the scoring system is used:

B deviation*:

- One of 50 employees in the production area wore a wristwatch, even though this is prohibited in the internal regulations (in a low-risk production area).
- The recall procedure is almost complete; only one phone number of the five-person crisis team is not available in the contact list.

C deviation*:

- 10 out of 50 employees wore a wristwatch in the production area despite internal regulations prohibiting this (in a low-risk production area).
- One out of 50 employees wore a wristwatch in the production area despite internal regulations prohibiting this (in a high-risk production area).

D deviation*:

- A large number of employees do not comply with the ban on jewellery (in a low-risk production area).
- Windows without pest screens are open in the packaging area.

Major non-conformities*:

- In a company producing face lotion: several requirements from the applicable legislation are missing from one product the labelling of one product.
- In a company producing detergents in pods under private labels: the product labelling doesn't mention a specific warning against child consumption and this was requested in the customer specification and contract.
- In a company producing diapers: some moulds were repeatedly found on conveyor belts where the unpacked diapers are running.
- In a company producing coffee filters: several packs are found with only 40 units whereas customer specification requires 50 units per pack.

** These are only examples to illustrate the deviations and non-conformities and shall not be taken as a common rule. In practice, situations have to be assessed taking into account the full picture, the context and the specific risks of your company.*

The scoring described above applies to all IFS HPC Audit Requirements, except for 6 of them, which are considered as essential and address key topics to be ensured by the production site to reach compliance. They are known as **"KO requirements"**:

1.2.1 Governance & Commitment
2.2.3.8 Monitoring system of each CCP
4.2.2.2 Finished product specifications
4.16.1 Traceability
5.9.1 Procedure for product recall, withdrawal and incidents
5.11.2 Corrective actions

For those 6 pre-defined requirements, specific scoring applies:

SCORING	EXPLANATION	
A	Full compliance of the requirement	20 POINTS
B	Small part of the requirement is not implemented, with no impact on product safety, legality and customer requirements.	0 POINTS
C	Not possible for a KO requirement	—
D	The requirement has not been implemented *(Subtract 50% of the possible total amount; the certificate cannot be issued.)*	– 50%
N/A	Not possible for a KO requirement (except for 2.2.3.8, e.g. if there is no critical control point)	—

More explanations on KO requirements are described in section 2 of the companion.

What are the conditions to get finally certified?

The final certification decision depends on both the completion of corrections and corrective action and the overall audit score.

A company can pass the certification audit if the final score is above 75%, with a distinction between certification in foundation level (score between 75% and 95%) and in higher level (score above 95%).

In case of a Major or KO non-conformity, certification will not be possible. In specific cases where only one Major is given and the overall score is above 75%, there is still a chance for certification, but a Follow-up audit will have to be performed.

More scenarios on scoring and the impact on certification are described in part 1, chapter 4.2.1, chart 6 of the standard.

A nominated reviewer from the certification body (different from the auditor who performed your audit) will check all documents related to your certification audit file (e. g. contract, audit report, action plan, auditor notes, etc.) and will recommend issuing a certificate or not. After that, the certification body can issue the IFS HPC Certificate.

1.5 Information to share with your customers/business partners

Congratulations! You are now IFS HPC certified.

You should know that your IFS HPC Certificate is valid for 1 year starting from the date of issuance.
To facilitate time management, you can book the audit dates for the following year with your certification body. This audit date can be scheduled for the following year, between 8 weeks before and 2 weeks after the audit due date (for an announced audit) and for a voluntary unannounced audit between 16 weeks before and 2 weeks after the last day of audit due date.

Which documents are provided to you as evidence of certification and how to share them easily?

The certification body will provide you with your IFS HPC Certificate, your final audit report and your validated corrective action plan, through the IFS Database. If you would like to get an overview of those documents, you can check the templates in Annex 8-10 of the IFS HPC Standard.

The IFS Database hosts all audit data of all certified companies, with specific confidentiality and security measures. Your certification body will create a log in for you and you will have access to all your audit data.

By being IFS HPC certified, your login also allows you to have access to the list of all other IFS HPC certified companies. This gives you an opportunity to benchmark your market!
By default, your audit report and action plan are not visible to any third party. Only if you decide grant access to one or more other companies they will get access to them.

Information visible to other IFS certified companies and registered retailers	Information visible only if you grant access
• Company's name and address • Certification body's name and address • Name of auditor • Scope of the audit • Audit date and duration • Certificate (pdf) • Validity and issue date of the certificate	• Action plan (pdf) • Audit report (pdf)

Information sharing is easy to manage and secures data communication between you and your customers/business partners.

1.6 What happens after certification? How to maintain it until the next audit?

The first audit is over. You and your employees are relieved that all your hard work has paid off and that you now have a certificate. When you think about it, it wasn't as challenging as you thought it would be. But beware: the hard part is yet to come, because now you have to maintain certification.

This means:

- Implement the corrective actions, at latest by the next audit
- Working in line with the described processes
- Maintaining up-to-date documentation
- Monitoring the full system regularly

Your certificate is valid for one year, which means that everything you have implemented and presented to the auditor during the certification audit shall be current and be maintained at the same level until the next certification audit.

If your company is facing any changes that may affect one or several IFS HPC Requirements (such as product recalls, alerts, modifications on the products or production methods, change of address, legal names or locations, etc.), make sure to inform your certification body.

Product recalls by official order and/or visits from authorities which result in notifications or penalties require the certification body to be informed within three (3) working days. Based on the information provided, your certification body will evaluate if an additional visit is necessary to maintain the existing IFS HPC Certification.

So back to work but keep in mind that routine is dangerous!

2

KEY ASPECTS AND REQUIREMENTS OF IFS HPC

2 KEY ASPECTS AND REQUIREMENTS OF IFS HPC

First of all, you need to understand that all IFS HPC Requirements are written to answer the following questions:

- Are your products safe?
- Do your products fulfil customer specifications?

A safe product (according to the General Product Safety Directive (Directive 2001/95/EC), European law on product safety), is a product which, **under normal or reasonably foreseeable conditions and duration of use** does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a **high level of protection for the safety and health of persons**, taking into account:

- the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance,
- the effect on other products,
- the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product,
- the categories of consumers at risk, when using the product (esp. children and the elderly).

The requirements of the IFS HPC Standard, divided in 5 chapters, were all defined to demonstrate that your company manufactures safe products in accordance with the Safety Directive and also has a strong focus on meeting customer requirements:

2.1 The 6 KO requirements

A key point is to ensure that the 6 KO requirements are implemented correctly, as non-fulfilment jeopardizes the IFS HPC Certification.

KO N°1 – Corporate structure (requirement 1.2.1)

The senior management shall ensure that **employees are aware of their responsibilities** related to product requirements and that **mechanisms are implemented to monitor the effectiveness** of their operation. Such mechanisms shall be clearly **identified and documented.**

Key word	How to demonstrate compliance?	Examples of common deviations
Senior management commitment	• Organigram • Evidence of responsibilities for organisation, implementation, control, supervision	• Personnel does not know quality/ safety management procedures • Top management delegated all responsibilities related to quality and safety management system to the quality/ safety team, with no further understanding of the tasks • Employees do not apply internal procedures
Awareness of employees of their responsibilities	• Documented assignment of tasks • Job descriptions • Trainings and retraining	
Effectiveness monitoring	• Employee interviews • Internal audits • Factory inspections	
Documented	• "Only what is written can be assessed" • Everything shall be recorded and documented	

KO N°2 – Conduct a hazard analysis and risk assessment for each step (requirement 2.2.3.8)

Establish a monitoring system for each critical control point

Specific **monitoring procedures** in terms of method, frequency of measurement or observation and recording of results shall be **documented, implemented and maintained** for each CCP to detect any loss of control at that CCP. Each defined CCP shall be **under control**. Monitoring and control of each CCP shall be demonstrated by records.

Key word	How to demonstrate compliance?	Examples of common deviations
Monitoring procedures	• Written procedures including what to do, how, by whom, as well as what to do in case of non-compliance/ deviation	• CCPs are not well defined and therefore not monitored properly • CCPs are not under control • Records are missing or incomplete • Person in charge of controlling the CCPs did not receive adequate training
Each critical control point	• Risk assessment (see following chapter)	
Documented, implemented and maintained	• Shall be written, shall be done and shall be kept up to date and regularly reviewed	
Under control	• Monitoring shall be based on a well-defined risk management system (see following chapter)	

KO N°3 – Finished product specifications (requirement 4.2.2.2)

Current and approved finished product specifications shall be the **basis for the composition** of products. They shall also be the **basis for the control of the production process** and to **monitor the finished products´ compliance**.

Key word	How to demonstrate compliance?	Examples of common deviations
Basis for composition of products	• Full alignment between specification and instructions • Evidence that formulation is carefully followed	• A raw material is changed which affects finished product formulation • One important parameter of the product is its colour, but this is only checked once per year, during the internal audit • Formulation as described in the product specification is not applied
Basis for control of production process	• Product specification needs properly translated into GMPs and work instructions	
Basis to monitor finished product compliance	• Product specification parameters well translated in product testing/control plan	

KO N°4 – Traceability (requirement 4.16.1)

A traceability system shall be **documented, implemented and maintained** that enables **the identification of product lots** and their relation to **batches of raw materials and packaging** in direct contact with product and intended or expected to be in direct contact with product.

The traceability system shall **incorporate all relevant records** of:

- receipt,
- processing at all steps,
- use of rework,
- distribution.

Traceability shall be ensured at all stages and documented **until delivery to the customer**.

Key word	How to demonstrate compliance?	Examples of common deviations
Identification of product lots	• Labels/lot numbers on each product	• Products in storage area without possibility to identify them • Packaging not included in the traceability system • No link possible to identify raw materials and finished products • Traceability stops at the warehouse
Relation with raw materials and packaging	• Traceable link/relation between finished products and raw materials and packaging • List of suppliers • Result of traceability test	
Incorporate all relevant records	• Full documented system related to receipts, processing steps, use of rework and distribution	
Until delivery to customer	• Capacity to track the products until delivery to customer	

NOTE: **4.16.3 […] The test records shall demonstrate upstream and downstream traceability (from delivered products to raw materials and vice versa). The traceability of the finished products shall be performed within four (4) hours maximum.**

Clarification according to IFS HPC Doctrine: If your customer requires a full traceability system test in less than four (4) hours this needs to be followed.

KO N°5 – Management of product recall, product withdrawal and incidents (requirement 5.9.1)

An **effective procedure** shall be documented, implemented and maintained for the management of recalls, withdrawals, incidents and potential emergency situations with an impact on product safety, quality, and legality. It shall include at a minimum:

- the assignment of responsibilities,
- the training of the responsible persons,
- the decision-making process,
- the nomination of a person authorized by the company and permanently available to initiate the necessary process in a timely manner,

- an up-to-date alert contact list including customer information, sources of legal advice (if necessary), and contacts availability,
- a communication plan including **customers, authorities, and where applicable consumers**.

Key word	How to demonstrate compliance?	Examples of common deviations
Effective	• Test of the procedure	• Missing or incomplete procedure • Partial list of contacts • No assigned employee in case a withdrawal/recall occurs • Missing or not documented training
Procedure	• Documented, including, what to do, how, by whom, as well as what to do in case of non-compliance/ deviation, assignment of responsibilities	
Information of customers, authorities and consumers	• List of contacts and communication plan up to date	

KO N°6 – Management of deviations, non-conformities, corrections and corrective actions (requirement 5.11.2)

Corrective actions shall **be formulated, documented and implemented** as soon as possible to **avoid further occurrence** of deviations and non-conformity. The **responsibilities and the timescales** for corrective actions shall be defined. The documentation shall be securely stored and easily accessible.

Key word	How to demonstrate compliance?	Examples of common deviations
Formulated, documented and implemented	• Documented corrective actions with non-conformity, responsible person and timeline	• Corrective actions from last audit not implemented • Timescale and/or responsibility missing • Deviations identified but no corrective actions initiated
Avoid further occurrence	• Relevance of corrective action (unlike a correction, the corrective action must prevent the problem from recurring and the solution offered must be sustainable)	
Securely stored	• See chapter on record keeping	

By the way, do you know the difference between a correction and a corrective action?

A **correction** only allows the issue to be corrected at the time the issue occurs, without acting on the cause, whereas a **corrective action** includes a root cause analysis of the issue and therefore not only corrects the issue but also ensures that it does not occur again.
Let's take a look at an example:

A **correction** would be: You remove the raw material so that it does not go into production.

A **corrective action** would be: You remove the raw material and you also get in contact with the supplier to understand why the raw material is damaged. You work with the supplier to ensure that the raw material arrives in good condition next time.

2.2 Product safety management

This chapter (2.2) is a core chapter of the IFS HPC Standard and it is divided into 3 steps:

- Establish the frame,
- Assemble a team and
- Identify hazards and assess the risks.

This is where the difference lies between this standard and any other "classic" audit checklist, as the methodology that your company needs to use to identify hazards and assess risks is defined here.

Let's go through the chapter and follow the sequences of the IFS HPC Standard in this chapter. You will see that the first requirement is not directly dealing with product safety management but is strongly connected to it.

Risk assessment framework

Req. 2.2.1.1

Before developing the hazard analysis and risk assessment, the company shall have implemented all necessary good manufacturing practices/best practices which are commonly used in its scope of activity.

This shall be the first step before setting up the hazard analysis and risk assessment.

"GMPs" stands for "Good Manufacturing Practices" and include (but may not be limited to):

Personnel hygiene	**Equipment**
Personnel training	**Pest control**
Transport	**Utensils**
Basic sanitation operations	**Waste management**
Water supply	**Raw materials management (receipt and storage)**
Sanitary facilities	**Plant and construction design**

GMP guidelines may exist for your types of products (for example, you can check with your industry federation or with the authorities of your country), but this may differ significantly depending on the industry.

The main purpose of GMPs is always to prevent harm to the end consumer. One specific GMP is for example the GMPs for cosmetics products, the ISO 22716 norm. If there are no specific GMPs available, you can surely take examples from existing ones and create your own GMP guidelines. You can find more GMP guideline references in Annex 1 of this document.

Many requirements in the IFS HPC Standard already address common GMPs. Check them to assess whether your company fulfils the common level of GMPs that IFS HPC requires. The following chart provides some examples:

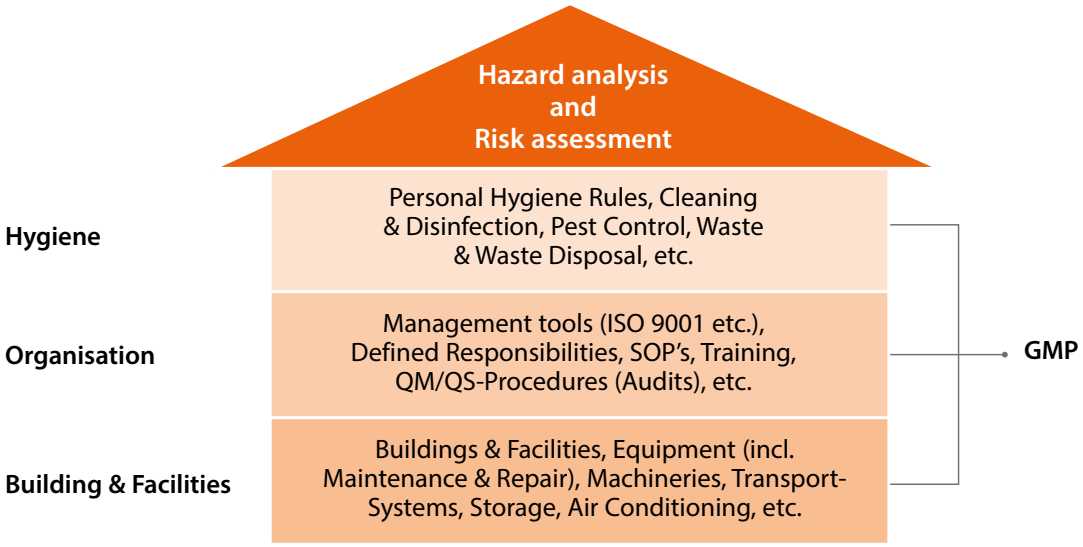
GMP type	IFS HPC Requirement related to this GMP
Construction, layout and facilities of premises	4.5, 4.6, etc.
Supplies of water, power and other utilities	4.7.10 Water, 4.7.11 Utilities, etc.
Waste control	4.9 Waste management
Equipment suitability – cleaning and maintenance	4.8 Cleaning, 4.14 Maintenance, 4.15, etc.
Prevention of cross contamination	2.2.2.3, 4.7.1, 4.10, etc.
Supplier control	4.4.4, 4.4.5, etc.
Management of purchased materials	4.4.1, 4.4.2, 4.4.3, etc.
Cleaning and sanitizing	4.8, 3.4, etc.
Pest control	4.11 Pest monitoring/Pest control
Personnel hygiene	3.2 Personal hygiene management
Training	3.5 Training and instruction
Transportation	4.13 Transport
Traceability systems	4.16 Traceability
Recall procedure	5.9 Management of incidents, product withdrawal, product recall

You can find a comparison between specific Cosmetics GMPs – ISO 22716 and IFS HPC Requirements in Annex 13 of the standard.

The main differences between GMPs and specific steps defined as "control measures" or "critical control points" rely on the level of monitoring and control, and on the evaluation of the impact on product safety hazards, on health effects for the consumer and the environment.

Both will need to be monitored, updated and recorded but GMPs will not be subject to additional specific control measures (more details to come in the next chapter).

Therefore, GMP's are considered as the basis before performing the hazard analysis and risk assessment:



Req. 2.2.2 Risk assessment team

The second step is to assemble a risk assessment team which is multidisciplinary and includes staff from operational areas as well. If you cannot find enough personnel with specific knowledge of hazards and risks to products and processes, you should obtain an external expert. Make sure that the risk assessment team is well established in your company and that the senior management provides enough resources to support the team.

Req. 2.2.3 Hazard analysis and risk assessment

Before diving into the methodology of the third step of your product safety management, let's start with some basic definitions:

- **Hazard:** A biological, chemical or physical agent with the potential to cause an adverse health effect.
- **Hazard analysis:** The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for product safety and therefore shall be addressed in the risk assessment.
- **Risk:** A function of the probability of an adverse health effect and the severity of that effect, consequential to (a) hazard(s) in products.

The hazard analysis and risk assessment is site-specific and cannot be "copy and pasted", neither from your head office nor from any other company, as it will be based on your site-specific hazards, GMPs, processes, etc. They shall include all processes (from good receipt to good dispatch) and all products.

This system shall be based upon scientific literature or technical verified specifications relating to the manufactured products and procedures. For example, if you identify 'pieces of metal' as a hazard and are convinced that they may lead to a risk before you pack your product, you will probably decide to use a metal detector to control this risk. To do this, you will either need scientific data or technical specifications for the metal detector to confirm/prove that the metal detector effectively controls and reduces the risk to an acceptable level.

In addition, the system shall take into account any legal requirements of the production and destination countries. For example, a raw material may be banned in one country but permitted in another and vice versa. This must be considered when performing the hazard analysis and risk assessment.

What is the difference between "risk-based/based on risks" and "based on hazard analysis and risk assessment"?

In the IFS HPC Standard, some requirements are described in this way whereas others are completed with the sentence "based on hazard analysis and assessment". What does this mean?

Let's check two examples:

Topic	"Risk-based"	"Based on hazard analysis and risk assessment"
Water	**4.7.10.2:** A water monitoring program shall verify that the water treatment is adequate and effective on a **risk-based** sampling plan.	**4.7.10.1:** A water monitoring program shall exist covering all process waters (...). The **risk assessment** shall address this topic.
Product development	**4.3.2.10: Based on risks**, the company shall check and verify the suitability and interaction between the product and packaging in direct contact and intended or expected to be in direct contact (…)	**4.3.2.9:** The finished product shall be designed and labelled to prevent non intended use to protect the safety of the potential user. The **risk assessment** shall address this topic.

In this way, the IFS HPC Standard gives your company more flexibility to adapt the risk assessment to the individual conditions. In many cases where it says "based on a risk assessment", it is up to your company to define what level of risk is appropriate for them, as long as you can provide justification and documentation. A thorough hazard analysis and risk assessment may identify the steps in your production process where controls need to be implemented (control measures and/or critical control points).

REMINDER: A risk management system shall be site specific, based on scientific/technical literature, consider applicable legal requirements, cover the full activity of your company and be reviewed regularly.

You can find many methodologies to set up your risk management system. For example, the ISO/IEC 31010 norm provides information on risk management and risk assessment techniques.

The IFS HPC Standard is also a very good tool and guides you in the risk assessment methodology by listing the different required steps:

- Describe the product
- Identify intended use and foreseeable use
- Construct flow diagram
- On-site confirmation of the flow diagram
- **Conduct a hazard analysis and risk assessment for each step**
- **Determine critical control points and other control measures**
- Establish validated critical limits for each critical control point
- Establish a monitoring system for each critical control point (KO requirement)
- Establish corrective actions
- Establish verification procedures

Although all steps are very important when it comes to setting up an effective risk management system, this guideline places the focus on the following two steps.

Conduct a hazard analysis and risk assessment for each step

The hazard analysis shall only be performed for hazards **that may be possible and are reasonably expected**. It's not worth listing all existing hazards and including those with no chance of occurring in your company: this would be a waste of time and may lead to an ineffective hazard analysis.

Here we can link the hazard analysis with the previously described GMPs. Already implemented GMPs will help to determine if the hazard could lead to a risk or not. That's why GMPs have to be implemented ***before*** the hazard analysis is conducted.

For example, a company is producing detergents. Hazard analysis is performed for the step "reception of raw materials". One potential hazard is the chemical hazard from one of the raw materials.

The company has implemented the following GMPs:

> Training of personnel on how to segregate raw materials in the storage area, clear labelling and colour coding of "dangerous" raw material.

Based on those GMPs, this hazard does not seem to lead to a risk and should not be managed through a critical control point.

While you perform your hazard analysis, check the associated GMPs to assess if they support the control of relevant hazards so that no risk can occur.

When listing the hazards (physical, chemical, biological), always associate them with the source/root cause (e. g. physical hazard, due to metal blade of knife).

There are different existing methodologies to define if a hazard could lead to a risk (= risk assessment) and the IFS HPC Standard does not require you to choose a specific method as long the goal of having an effective risk assessment system is achieved. Don't forget to document all the hazard analysis, to be able to present it to the auditor and also to facilitate review, when necessary.

An example of a template to set up the hazard analysis could be:

Step	Hazards which may reasonably occur and root cause of the hazard	Hazard probability	Hazard severity	Risk score
Step 1 (e.g. raw materials receipt)	Biological: Physical: Chemical:			
Step 2…				

Each company can use its own template and methodology, as long as the methodology used to conclude whether a hazard could lead to a risk is documented and comprehensive for the company's entire operations.

To determine if a hazard could lead to a risk, and especially if a critical control point needs to be implemented, you can use different tools.

Before that, let's check one thing: Do you understand what is a hazard and what is a risk?

- A pathogenic microorganism is a biological hazard, while the likelihood of a consumer becoming ill is a risk
- A shard of glass is a physical hazard, while the likelihood of a consumer injuring themselves is a risk

Risk shall always be assessed based on the impact on the consumer and also based on the probability of an adverse health effect and the severity of that effect on (a) hazard(s) in products.

You can either use a decision tree (for example, the one from Codex Alimentarius, which is used in the food industry, or the FDA one) or a risk matrix (see example below) to assess the risks:

Frequency	**1**	**5**	**10**	**15**	**20**	**25**
	2	**4**	**8**	**12**	**16**	**20**
	4	**3**	**6**	**9**	**12**	**15**
	4	**2**	**4**	**6**	**8**	**10**
	5	**1**	**2**	**3**	**4**	**5**
		1 small incovenience	**2 less serious**	**3 serious**	**4 very serious**	**5 disastrous**
		Severity				

Risk is calculated by multiplying the severity by the frequency.

Grading should be determined with the support of scientific and/or technically validated literature. For example, in Europe, the European Commission has implemented the "Safety Gate" – Rapid information system, which provides an updated list of all alerts and recalls on non-food products on the European market with an explanation of the product defect and the associated risk to consumers. This is a very interesting source of information for assessing and weighing the risks.

Historical data of the company (number of recalls, customer complaints, etc.) can also be taken into account.

For example, frequency grading could be the following:

Term	Frequency on incident base
5 Probably	Equal or more than once a day
4 Reasonable	Equal or more than once per week
3 Possible	Equal or more than once per month
2 Unlikely	Equal or more than once per trimester
1 Very unlikely	Less than 1 case per year

And severity grading:

Term	Severity
5 Disastrous	• Severe health injury or death because of explosion • Large amount of people seriously ill/ injured because of explosion
4 Very serious	• Serious illness or hospitalised • Large number of persons ill
3 Serious	• Several illnesses or allergic people • Large number of unsatisfied customers
2 Less serious	• A person is ill or lightly allergic • Several unsatisfied customers
1 Small inconvenience	• Noticeable, but no harmful on the health of persons • One single incident

The scale shall be as detailed as possible to allow a clear distinction between the different grades. Keep in mind that a "grey zone" will not help to identify risks.

You should also define when/where the risk falls into the "unacceptable" zone.

In the example above, the red zone means an unacceptable risk and these situations need to be controlled by implementing specific measures.

Determine critical control points

Once the hazard analysis has been carried out and the risk is assessed, you need to determine what should be implemented for your "red zone" to control the risk and reduce it to an acceptable level. This is done by introducing critical control points.

Critical control point (CCP):

A step within the production process identified by the hazard analysis and risk assessment at which control shall be applied and which is essential to prevent, eliminate or reduce a hazard/risk in the product and/or the environment to an acceptable level. Loss of control at this step may increase the likelihood of an adverse health effect of the consumer (e.g., illness, injury, etc.).

A possible example of a template to determine the critical control points:

Step	Hazards which may occur and the root cause of the hazard	Hazard probability	Hazard severity	Risk score	Is a CCP necessary to control the risk?	CCP type
Step 1 (e.g. raw materials receipt)	Biological: Physical: Chemical:					
Step 2…						

Examples of CCPs may be*:

- To control risks related to physical hazards (e.g. foreign materials): metal detection, X-ray
- To control risks related to biological hazards (e.g. pathogens): process parameters such as time + temperature
- To control risks related to chemical hazards (e.g. allergens): specific validated cleaning and sanitation program

* *These are only examples to illustrate the CCPs and shall not be taken as a common rule. In practice, CCPs have to be determined taking into account the full picture, the context and the specific risks of your company.*

A relevant CCP will be:

- **A process step**
- **Monitored through specific parameters (method, critical limits, frequency)**
- **If possible: continuously monitored**
- **If possible: results of monitoring should be available before products are dispatched from the factory**

Although the next steps of the risk management system are not detailed further in this guideline, it is crucial to implement the next steps of the system:

- Establish validated critical limits for each critical control point
- Establish a monitoring system for each critical control point
- Establish corrective actions
- Establish verification procedures

Keep in mind that the step "Establish a monitoring system for each critical control point" is a KO requirement (KO N°2) and that the monitoring and control of each CCP shall always be recorded!

Instead of explanations, let's illustrate this with an example (from a real audit situation):

Company description and audit findings:
A company manufactures toilet wipes. These wipes are manufactured in a clean room, which has a metal detector system to prevent the presence of metallic joints in the non-woven tissue. This metal detector step has been considered as a CCP, based on the analysis of hazards and risk assessment of the company.

The CCP monitoring matrix and the work instruction indicate that detector monitoring must be carried out at the beginning and end of the production of each batch.

During the audit tour, the IFS HPC Auditor checks that the metal detector has an alarm and rejection system in the event of metal detection.

When reviewing the site's operational records from the previous day, the auditor observes that the monitoring of the correct functioning of the detector at the end of production is not recorded.

Is the situation acceptable and compliant with the IFS HPC Requirement?
As the company has defined the metal detection step as a CCP, it must be controlled and monitoring results must be recorded with the parameters/critical limits and frequencies defined in the risk assessment.

In this specific case, there are no monitoring records and therefore no evidence that the controls were performed. The process control is not guaranteed and the auditor scored the KO requirement 2.2.3.8 with a KO non-conformity (D deviation).

Finally, the entire risk management system shall be reviewed regularly. Remember to update it every time something changes in the product, the process or the environment of the product. A common deviation seen in companies is that they forget to update the system when changes occur (e. g. new production lines with new parameters, new formulation with new hazards to consider, etc.). Don't fall into this trap!

Before moving on to the next chapter, let us discuss the most typical mistakes that occur when introducing a risk assessment system:

- Mix up of "hazard" and "cause" (e. g. microbiological hazard from a raw material as opposed to contamination due to a lack of line cleaning)
- Mix up of "hazard" and "risk"
- Identify risks which are not associated with the end consumer (e. g. hazard = mixture of chemical substances in the storage area and risk = hazardous chemical reactions)
- Indication of a scale for severity and probability which is not detailed enough (e. g. frequent, rare, very serious, serious, etc.)
- No explanations of the acceptable limit between "risky" and "not risky"
- Identification of irrelevant CCPs (e. g. out of specification raw material)
- Implementation of irrelevant/unassessed critical limits (e. g. raw material specification)
- In small companies: insufficient documented risk assessment system
- In large organizations (multi sites): individual sites implement the central risk assessment guidelines, which do not reflect the current situation of the respective site.

We hope this will show you what to avoid and where to be careful!

2.3 Product specifications

Do you remember that the standard is aimed at answering 2 main questions:

Are your products safe and in compliance with the law and customer specifications?

We saw in the above section that the safety part is mostly addressed in the risk management system chapter. Now, let's check how the IFS HPC implies the assessment of compliance with customer related specification(s) as well as the legal compliance of the products.

First of all, do you know what a specification is? A specification is a detailed description of the product, often including formula/recipe, the type of packaging, the type of sales unit for the consumer if applicable, the weight, etc. It can also include more details, e. g. the type/origin of raw materials, suppliers, etc.

There are specifications for finished products, but also for raw materials.

Chapter 4.2.2 on finished product specifications

An important requirement is that all your finished products shall have specifications, which are documented and implemented. Please ensure that they are up to date, traceable, unambiguous and relevant to the personnel. Where required by customers, specifications shall be formally agreed (by you and your customers).

If the product specification is not provided by your customer, you shall create one and transfer all customer requirements to the document. Finally, you need to make sure that the specifications comply with legal requirements of both the production and destination countries.

Documentation, control and monitoring is very important when it's about specifications.

That's why specifications shall be up to date (4.2.2.1) and an accepted control procedure shall ensure that any modification related to raw materials, formulas, processes and packaging material is included. (4.2.2.4).

ADVICE: As the auditor will check if the specifications are updated, keep in mind to always include the date of creation, the date of review, the version number of the document and the reason for modification. In this way, you not only provide the auditor with clear documentation, but also prove that you have reviewed the document and amended it, if necessary.

KO N°3 (4.2.2.2) requires that the specifications of finished products shall be the basis:

- for the composition of products → the specification document is the source for the design/ manufacture of the product, as it contains all the criteria that the finished product shall fulfil.
- for the control of the production process → instructions given to operators and on the production line are based on the product specification and are intended to ensure that the criteria of the finished product are implemented
- to monitor the compliance of finished products → parameters for the product testing/ control plan are based on the criteria of the product specification

With every change in equipment (e. g. new cutting machine), formula (e. g. new supplier temporarily supplying a slightly different raw material), packaging (e. g. 3 units per pack instead of 2 or new marketing information on the product label), manufacturing conditions (e. g. a part of the process is now outsourced to another company), etc., you should always ask yourself: **Does this affect the parameters of the finished product and does the finished product still meet the specification?**

To understand the extent of compliance with product specification, let's illustrate this with an example (from a real audit situation):

Company description and audit findings:
A company manufactures make-up removal wipes for sensitive skin under a retailer brand. During the traceability exercise, the auditor asks for the specification agreed with the client and notes that the main ingredient in the formulation is Olus oil (100% vegetable). However, in the production record from the day on which the product was manufactured, the use of paraffin oil (petrolatum) was recorded. When asked about this change, the company indicates that its regular vegetable oil supplier was not able to supply them for the last 2 weeks and they had to use mineral oil on a temporary basis while they found another supplier. Product labelling remained unchanged and the customer was not informed.

Is the situation acceptable and compliant with the IFS HPC Requirement?
There is a lack of compliance with the customer specification, affecting an ingredient of the formula. No communication was made with the customer. Therefore, the auditor scored the KO requirement 4.2.2.2 with a KO non-conformity (D deviation).

Chapter 4.2.1 on raw materials, semi-finished products and rework specifications and chapter 4.4 on purchasing

As for finished products, your company shall have specifications for all raw materials and semi-finished products (where relevant). You shall be able to identify the related supplier for all of these.

IMPORTANT: **Raw materials as defined by the IFS HPC Standard include ingredients, additives, packaging materials and rework as well as semi-finished products. If reworked material is used and incorporated into production, it is considered a raw material.**

IFS HPC requires you to implement a procedure to approve and monitor your internal and external suppliers of products and services. You need to set up criteria which will help you define the level of compliance of your suppliers. These could be but are not limited to individual risks of suppliers or raw materials, performance standards, exceptional situations, as well as based on risks, audits, testing results, supplier reliability, questionnaires and number of complaints. Results of this assessment shall be reviewed at least once within a 12-month period and the actions taken and records of the review shall be documented.

Specific requirements on outsourced production:

If there is a part of the production process (and/or primary packing/labelling) that isn't performed on-site but is outsourced to another company, the first thing to do is to inform your customer and obtain their approval. If you produce retail branded products, retailers are considered as producers, even if they do not produce the products themselves. That's why they need to know if you choose to outsource a part of the production of their products. Suppliers of partly outsourced processes shall either have a HPC certification or have received a documented supplier audit, or in case of e.g. retailer brands shall be accepted by the customer on the basis of other conditions. You need to ensure that:

- partly outsourced production is included in your product safety and quality management system → when you perform your hazard analysis, don't forget to include the process step(s) that is/are managed by the subcontractor
- you shall sign a contract with the subcontractor including any arrangements according to in-process controls, testing and monitoring plans
- you shall regularly audit the subcontractor and the audit requirements shall cover at least the requirements for product safety, quality and legality; this audit shall be performed by an experienced and competent person (unless the subcontractor is already HPC certified)
- if relevant, you shall regularly check the products on receipt from the subcontractor, to check if they're compliant with specifications.

All requirements that your company shall fulfil in case of partly outsourced activities are described in chapter 4.4. of the IFS HPC Audit Checklist. Please note that fully outsourced and traded products are not covered by IFS HPC Certification.

To illustrate the importance of a proper control of subcontractors, let's use an example (from a real audit situation):

Company description and audit findings:
A company manufactures personal hygiene products, including combs, hairbrushes, bath sponges and razors, both under their own brands and retailer brands.

For one of the retailers, they are producing razors in different packs and sizes.

When asked about the tri-pack reference, the company manager answers that this product is the only one that they do not manufacture on-site, but import from a Chinese supplier, as they do not have the machinery for the 3-razor pack.

When examining the contract with the retailer, the auditor found a clear indication that any type of outsourcing must always be communicated to the retailer. The manager confirms that retailer was not informed as the product is the same. The manager explains that the Chinese company is IFS HPC certified, and that he personally went to the Chinese factory to supervise workers during the first weeks of production. No complaints were received from the customer regarding this product.

Is the situation acceptable and compliant with IFS HPC Requirements?
The company outsourced the production of one product and the customer is not aware/informed of this. Despite the company implementing checks to control this supplier, the company didn't inform the customer that the production of this product was outsourced. Therefore, the auditor scored requirement 4.4.4 with a Major non-conformity.

2.4 Internal audits and site inspections

Did you know that the internal audit is a very effective tool for continuously improving your company? This is the reason why the first section of this IFS HPC Chapter deals with "Measurements, analyses, and improvements".

An internal audit is performed inhouse and is aimed at assessing all requirements related to the IFS Standard within 12 months and no later than a 15-month period to ensure that all processes and departments are working properly.

Who performs the internal audit?

To ensure objectivity, the auditor shall be independent from the audited department. The auditor must also have received appropriate training in order to be able to carry out the inspection correctly. The appointed auditor is usually the Quality Manager of the company, who cannot cover the entire audit scope as she/he cannot audit his/her own department. For this reason, other auditors should be trained, or even external auditors may be used (for internal audit purposes).

Your internal auditors shall have knowledge about processes in the company and the corresponding specifications.

What should be audited during the internal audit?

As required in the IFS HPC Standard, the scope of the internal audit shall cover at least all requirements of the standard. This applies not only to the indoor processes and areas, but also to the factory exterior and, if applicable, the off-site storage locations owned or rented by the company. Why not use the IFS HPC Audit Checklist to conduct the internal audit and go through the different chapters? This would be an easy way to ensure nothing is forgotten.

What needs to be done when preparing for an internal audit?

Once the date for the internal audit has been set, all employees shall be informed. Firstly, because they need to be available in case they are interviewed during the audit. Secondly, they should understand the objective of an internal audit before it takes place.

As the audit will indicate what is compliant and what is not, all employees shall be aware that the point of an internal audit is not to spy on the employees or blame them for identified weaknesses, but to find opportunities for improvement and to also prepare as well as possible for the certification audit! For this reason, managers play an important didactic role towards their employees.

An audit plan shall be created and reviewed to ensure that all departments are covered. Don't forget the external premises and off-site storage locations!

How often should an internal audit be performed?

The IFS HPC Standard requires the internal audit to be carried out at least once in a 12-month period, without exceeding a maximum of 15 months. The frequency can be increased, if necessary, to be determined by a risk assessment. Do you think that the laboratory and the human resource department should be audited at the same frequency with regard to product safety? List all the departments which need to be audited, weigh their impact on product safety and determine the frequency of audits. Remember that the frequency may also be updated in the event of change (e.g. if the pest control service provider has recently been changed, it is worth bringing forward the internal audit).

How does the internal audit work in practice?

The auditor shall go through the agreed audit plan and assess all requirements. To facilitate the collection of findings, the auditor should ask open questions (e.g. Explain to me how you use this? What if this doesn't work?) instead of closed questions (Do you use this tool like this?).

Transparent reporting is important → communicate non-conformities/deviations as they are identified.

The auditor draws up an audit report at the end of the audit with the list of findings and deviations/non-conformities.

As this audit is not a third-party certification audit, corrective actions and schedules can be discussed and initiated at the end of the internal audit. The results of internal audits shall be passed on to the responsible employees in order to support everyone in implementing appropriate corrective actions.

Performing internal audits and ensuring the management and implementation of corrective actions are important indicators for promoting corporate culture. In addition, this is key for continuous improvement and sustainability of the company's best practices.

Remember that IFS HPC Certification is "only" an external confirmation and that internal audits as well as other means of managing your organisation are the most important tools to ensure your success.

REMINDER: Internal audits shall be performed at least once within a 12-month period which shall not exceed a period of 15 months and shall cover all aspects of the IFS HPC Standard and be performed by a competent auditor who is independent of the audited department.

The following table summarises the key questions you should be able to answer in order to fulfil the requirements of the "Internal audit" chapter:

Key questions	Related documents
• Is there an updated internal audit plan? • Is the audit plan based on a risk assessment? • Is a checklist available? • Are the auditors competent? • Are the auditors independent? Do they have any connection to the audited activity? • How often are internal audits performed? • How are audit results communicated to those responsible/to senior management? • Are corrective actions documented? • Is there a time schedule for corrective actions?	• Internal audit plan with information on which auditor has audited which activity • Checklist for the Internal audit • List of internal auditors with details of their competences • Minutes of the internal audits • Corrective action plan from internal audits • Evidence that results of internal audits have been communicated to all relevant employees, including senior management

Internal audits versus factory inspections?

The internal audit is a holistic tool that encompasses all activities/departments of the company and aims to promote an effective company management system. Various assessment techniques can be used to conduct an internal audit: Factory inspections, staff interviews, sampling of documents, etc.

The factory inspection is one of the assessment tools of the internal audit, which relates to specific topics and is carried out to check the conformity of certain topics (e.g. hygiene, pest control, foreign body hazards). Any deviation arising from these inspections shall be addressed and corrective actions documented.

The IFS HPC Standard requires that both should be performed, as they have different objectives.

This guideline is coming to its end.
We hope you now feel more comfortable to implement the requirements
of the IFS HPC Standard and
we wish you all the best for your certification audit!

ANNEX

ANNEX
Bibliography on GMP guidelines

- Cosmetic GMP ISO EN DIN 22716 (mandatory for cosmetics)
- COMMISSION REGULATION (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food
- The Confederation of European Paper Industries (CEPI): http://www.cepi.org/#sthash.uw1EgVGV.dpuf : GMP for the Manufacture of Paper and Board for Food Contact, 2011
- Primary packaging materials for medicinal products – Particular requirements for the application of ISO 9001:2015, with reference to Good Manufacturing Practice (GMP) (ISO 15378:2015)
- EudraLex - Volume 4 "Good manufacturing practice (GMP) Guidelines" for medical devices
- Guidelines of 19 March 2015 on the formalized risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use (Text with EEA relevance)
- The quality system for FDA-regulated products (food, drugs, biologics, and devices), Current good manufacturing practices (CGMP's).
- Worldwide Overview about GMP Guidelines: http://www.ispe.org/gmp-resources/gmp-guidelines

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