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IFS HPC Companion

Guidelines for the Implementation of the IFS HPC Standard

ENGLISH

You might face many challenges as the person responsible for implementing the IFS HPC in your company. IFS HPC version 2 was published in April 2016. Being audited against IFS HPC requires precise knowledge as well as good interpretations and backgrounds of the individual requirements.

Do you to want to guarantee the highest possible safety of the products manufactured in your company in order to ultimately ensure the stability and success of your company? You should achieve a certificate based on the IFS HPC standard due to customer requests and/or your own internal company goals? You have time and resources for developing complete concepts and planning appropriate measures?

Your IFS HPC Companion will provide all the support you need in managing these tasks.

Enjoy your reading!

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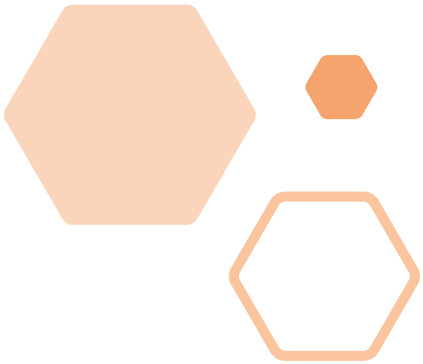
Standard Manager IFS HPC



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How do you optimally benefit from your IFS HPC Companion?

This handbook contains both an overview and specific information about individual topics and is divided into 2 main sections.

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This section will provide you information on the fundamental goals of IFS HPC, how and where to start the process for a successful implementation and how to secure a long-term certification.

2

KEY ASPECTS AND REQUIREMENTS OF IFS HPC

The requirements of IFS HPC shouldn't be excessively burdensome for a company that manufactures household and personal care products. However, the detailed understanding and implementation can sometimes cause few worries. This section will provide tips and explanations on key requirements.

1

CERTIFICATION ACCORDING TO IFS HPC

1. Certification according to IFS HPC certification

1.1 What's the story of the IFS HPC standard?

First thing before starting is to understand where the IFS HPC comes from.

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

The first version of 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.). Version 2 was published in April 2016 and was written by a number of impressive experts from different countries (e.g. France, Germany, Italy, Spain, The Netherlands, UK) and from organizations with 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 this standard, which makes it widely accepted and used as a reference on the market.

The IFS HPC certification will not only allow you to drive continuous improvement but is also a key factor to set up trust with customers and, at the end, with consumers.

1.2 How and where to start?

First step is to get and 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 requires that the company appoints an IFS representative. Main role of the IFS representative is to be the point of contact for 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 have a regular look on new and very added value documents that are available on the IFS website, such as table explaining the different scopes and associated products, guidelines on how to implement product defense requirements, generic guidelines, etc.

The IFS HPC standard is divided into 4 mains sections:

1

AUDITOR PROTOCOL – PART 1

This part explains everything related to how the audit is performed and defines the audit duration, the scoring system, the timelines between audit and certificate issuance, etc.

2

AUDIT CHECKLIST – PART 2

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

3

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

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

4

REPORTING – PART 4

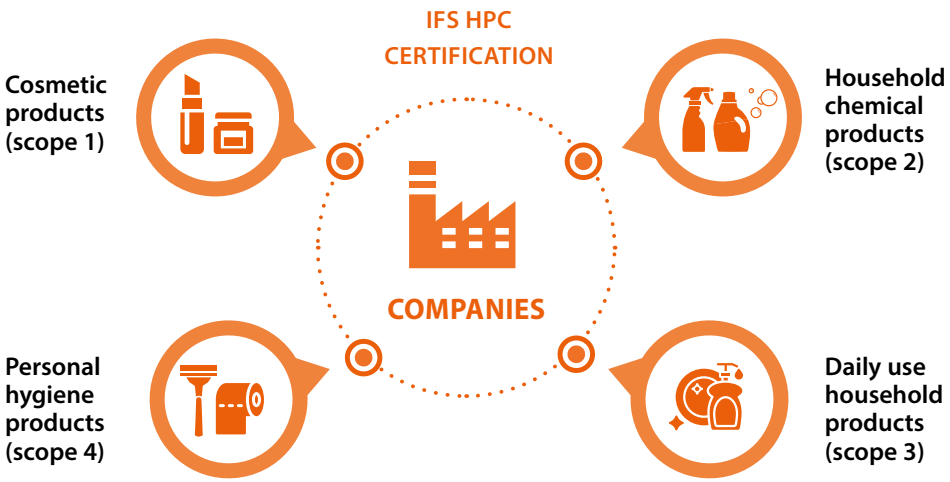
This part explains how the IFS HPC audit report, action plan and certificate shall look like, as this is totally uniformed across certification bodies and countries, for a better reading and recognition.

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 to be implemented within the company and how to get prepared for the audit.

Is your company in the scope of IFS HPC certification?

IFS HPC standard applies to companies having ***manufacturing*** activities or activities where there is a hazard for product contamination during the primary packing.

It applies to the following products (retail brands and industry brands, etc.)



Some medical devices class 1 (e.g. gauze/bandages, compresses, physiological serum without the sterile condition, etc.) are also included in the scope of the standard, either in scope 1 or 4.

If you have a doubt about the correct product scope(s) where your products belong, you can check on IFS website a detailed table ("Product Examples") listing many product examples for each scope.

The standard also provides a list of products which are excluded from the audit scope, such as toys, textiles, OTC and medicines under medical prescription, etc.

If your company doesn't have any processing activities but has, for instance, trade or storage (of packed products) activities, then IFS HPC standard doesn't apply but IFS has implemented other standards to cover those steps of the supply chain (e.g. IFS Logistics, IFS Broker). Annex 1 in Part 1 explains the demarcation between the different IFS standards.

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

How to define audit scope?

IFS HPC audit is site specific and is a product and process certification audit; therefore, the audit shall cover the full activity of your company and can not exclude any parts, premises, production lines. Exclusion of products (but not processes) may be allowed in very exceptional cases and under the risk-based approval of the certification body you'll have chosen to perform your audit.

How to select an auditor?

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

Certification bodies which are approved to perform IFS HPC audits are listed on IFS website.

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

Selection of the right certification body should take into account, for example:

- Available auditor competencies in the product scope related to your activity (as 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 the 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 language. Please notice, that depending on each situation a translator may be needed.
- Available dates. The audit shall take place when all production lines (or production lines involving all risk assessment studies) are operating, to enable the assessment of all auditing requirements of the audit scope. This is extremely important! If not all lines (or lines involving different risk assessment studies) are not operating during the audit, 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, she/he would have to come back to your facilities to perform an extension audit.

- Available competences for a combined audit, in case your company would like to leverage the IFS HPC certification audit to perform in parallel another certification audit.

You should describe to the certification body the exact and detailed activity of your company, in order to give them a good overview of the audit scope. Specific company organization such as use of outsourced activities, multi-sites with central management shall be notified to your certification body as this impacts the certification process.

NOTE: **It´s key to provide to the certification body as much information as possible on your company activity, for the certification body to be able to define best described audit scope and most suitable audit duration.**

What's the duration of an IFS HPC audit?

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

Be aware that the minimum duration of an IFS HPC audit is 2 days (of 8 to 10 hours each) and may be extended based on your company parameters. This duration allows auditing all requirements of the audit checklist in a suitable way.

In addition to calculated audit duration, the certification body will add further 0,5 day to write audit report.

Once you selected the right certification body and that you agreed on all settings, you should sign a contract with the certification body.

What is IFS Integrity Program?

You have seen a reference to IFS Integrity Program both in Part 1 of the standard and in the contract with your certification body but are wondering what this is 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 uniformly and in line with IFS requirements.

This program outlines, among other means to check compliance, audits of certification body offices, observations of IFS auditors during IFS audits and on-site checks of IFS certified companies by independent IP auditors.

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

- the IFS auditor who is missioned to audit your company is observed by an IFS Integrity Program auditor, or
- an IFS Integrity Program auditor performs a one-day on-site audit of your company, in a different timeslot than the IFS certification audit. Your company may be selected by the IFS Integrity Program team risk-based (for example your company is producing lipsticks and there was recently a major recall on lipsticks on the market), or based on a complaint from an IFS user.

This should not worry you, as the objective is to verify and ensure that IFS requirements and good auditing practices are always fulfilled and uniformly implemented.

What can help you to prepare your IFS HPC audit?

Your company can decide to perform a pre-audit, to get an in-house picture of the level of implementation of IFS HPC requirements before performing the certification audit. This pre-audit cannot include any recommendations.

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

Based on the testimonies of companies, 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.

Section 2 will support you to understand and implement IFS HPC auditing requirements (Part 2 of the standard), but before this step, let's explain how the certification audit will be carried out.

1.3 The certification audit

Several days before the audit, you will receive from your certification body an audit time schedule, defining the steps of the audit (including tentative timing and topics to be covered). Make sure that relevant personnel of 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 which will be performed in your company is named "initial audit". The following year, and all years later, this will be named "renewal audit". Regardless of the audit type and audit final score, all auditing requirements are assessed each year. Therefore an IFS HPC audit will be performed every year, without any modification of audit duration (unless some changes occurred in your organization).

The audit takes place with the following sequences:

- Opening meeting: this is where auditor and company personnel get introduced and where the auditor reviews the audit scope, to ensure that it's still accurate and that no activity is missing.
- Evaluation of existing quality and safety management systems: this step is usually performed by checking documentation (e.g. risk assessment, quality manual, etc.).
- On-site audit and interviews of personnel: this step is performed within the different areas of the site and shall take at least 1/3 of the total audit time. Different people from the personnel may be interviewed by the auditor, as this is a good audit technique to understand the company processes and assess whether personnel is aware of their responsibilities.

  NOTE: **Make sure that employees are made available for this period and that they've been explained before the audit that they may be interviewed for the purpose of the audit.**
- Final conclusions drawn from the audit: this moment is usually dedicated for the auditor to wrap up audit findings and set up an overview of the company assessment.

- Closing meeting: during this last step of the audit, the auditor will share with the company the most significant identified non-conformities and/or deviations. At this stage, the status of the company (certified/not certified) can not be provided, as there are later other steps in the certification process before making this final decision. Those steps are the implementation of a corrective action plan by the 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 grade.

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 maintain confidentiality (this is usually regulated in the contract you sign with the certification body).

1.4 After the audit, until certificate delivery

After the audit, the auditor will send you a pre-audit report and an outline of action plan, usually within 2 weeks after the audit.

NOTE: **the outline of the action plan and pre-audit report are edited via the software auditXpressX™ and will always have the same format, regardless of the certification body/ auditor you will work with. Such harmonized formats facilitate very much the reading of documents by your customers.**

The pre-audit report will contain an individual assessment of all IFS HPC audit requirements, with the following grading:

GRADE	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	Only a small part of the requirement has been implemented	5 POINTS
D	The requirement has not been implemented	– 20 POINTS
N/A	Substantial failure to meet requirement related to legislation, internal dysfunctions, customer issues or lead to a serious health hazard	NO SCORE
MAJOR	Substantial failure to meet requirement related to legislation, internal dysfunctions, customer issues or lead to a serious health hazard *(- 15% on the total score, no certificate awarding possible)*	– 15 %

Here are some examples of deviations, to give you some hints on how this scoring system is used*:

B deviation:

- One out of 50 employees in production wore a wrist watch despite internal rules forbid it (in a low risk production area).
- The recall procedure is almost complete; only one phone number of the crisis team – composed of 5 members – is not available in the contact list.

C deviation:

- 10 out of 50 employees in production wore a wrist watch despite internal rules forbid it (in a low risk production area).
- One out of 50 employees in production wore a wrist watch despite internal rules forbid it (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 are open, without pest screens in the packaging area.

Examples of Major non-conformities*:

- In a company producing face lotion: one product labelling misses several requirements from the applicable legislation.
- In a company producing detergents in pods under private labels, product labelling doesn't mention a specific warning against kid consumption, whereas this was requested in the customer specification and contract.
- In a company producing diapers: some molds were repeatedly found on conveyor belts where the unpackaged diapers are running.
- In a company producing coffee filters: several packs are found with 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 above described grading applies to all IFS HPC auditing requirements, except for 6 of them, which are considered as fundamental and named "KO requirements". Those are:

1.2.3 Responsibility of the senior management
2.2.3.8 Establish a monitoring system for each critical control point
4.2.2.2 Product specifications
4.14.1 Traceability
5.9.4 Withdrawal/recall procedure
5.11.2 Corrective actions

For those 6 KO requirements, specific grading applies:

GRADE	EXPLANATION	
A	Full compliance of the requirement	20 POINTS
B	Almost full compliance of the requirement	15 POINTS
C	Not possible for a KO requirement	NOT POSSIBLE
D	The requirement has not been implemented *(– 50% on the total score – no certificate awarding possible)*	– 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 this document.

Total audit score is calculated in percentage (number of points gained by the company/maximum number of possible points * 100).

The outline action plan will include the list of all IFS HPC auditing requirements which were not evaluated with A or NA by the auditor.

When received, you should complete the action plan as following:

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

This action plan shall be sent back to the auditor within 2 weeks, for her/him to validate the relevance of corrective actions. The auditor will review and assess the measures you have proposed. If she/he rejects them, they must be revised and sent back for review.

NOTE: **the 2 weeks deadline is for providing corrective action plan but not necessarily for implementing them! You should provide, for each deviation/non-conformity, a reasonable and feasible timeline for implementation. During the renewal audit (of the following year), the auditor will check if all corrective actions from the previous audit are implemented.**

What are the conditions to get certified?

Final certification decision depends on both relevance of corrective action and overall audit score.

A company can pass the certification audit if 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 Major or KO score with D, the certification is not possible. In specific cases where only one Major is given and that the overall score is above 75%, there is still a chance to get certified, but a follow up audit will have to be performed.

More scenarios on scoring and impact on certification are described in Part 1, chapter 6.8 of the standard.

Once/if the corrective action plan is validated by the auditor/certification body, and if the overall score allows certification, competent personnel from the certification body (different from the auditor who performed your audit) will review all documents related to your certification audit file (e.g. contract, audit report, action plan, auditor notes, etc.) and will make the certification decision. After this step, certification body can issue the final audit report, the agreed corrective action plan and certificate.

What is the timeline between the audit and the certificate/final audit report issuance?

Timeline is maximum 8 weeks, which are split as following:

- 2 weeks for the auditor to write the pre-audit report and outline of action plan
- 2 weeks for you to complete corrective action plan and send it back to the auditor
- 2 to 4 weeks for the auditor to validate your corrective action plan and for the certification body to make the final certification decision.

1.5 Information sharing 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 at this stage book the audit dates for the following year audit with your certification body. This audit date can be scheduled the following year, between 8 weeks of and 2 weeks after the audit due date (anniversary date of your first audit). This gives you a lot of flexibility, without compromising the validity of your IFS HPC certificate.

Which documents are provided to you as an 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 action plan, through the IFS portal. If you would like to get an overview of those documents, you can check some examples/templates in Part 4 of the IFS HPC standard.

The IFS portal is a database which hosts all audit data of all certified companies, with specific measures of confidentiality and security.

Your certification body will create a log in for you and you will access to all your audit data.

By being IFS HPC certified, your login also allows you having 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, action plan and certificate are not visible by any third party. Only if you decide to release the access of those documents to one or more other companies, they will get access to them. For this, you only have to log in and tick the boxes related to the companies to whom you would like to grant the access to your data.

Information which are visible by other IFS certified companies and registered retailers	Information which are visible only if you grant access (through individual tick boxes for each customer)
Company's name and address	**Certificate (pdf)**
Certification body's name and address	**Action plan (pdf)**
Auditor's name	**Audit report (pdf)**
Scope of the audit	
Audit date and duration	
Certificate's date of issue and validity	

This 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 next audit?

The first audit is over. You and your employees are relieved that all of your hard work has paid off and now you have a certificate. When you think about it, it wasn't as challenging as you had anticipated. But watch out: the hard part is still to come, because the challenge now is to maintain your certification.

This means:

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

Your certificate is valid for one year, meaning that everything you have implemented and presented to the auditor during the certification audit shall be living and be maintained at the same level until next certification audit. If your company is facing any changes that may affect one or several IFS HPC requirements (such as product recall, major modifications on the products, works in your facilities, etc.), you shall inform your certification body within 3 working days. Based on the information provided, your certification body will assess if an additional visit is necessary or not to maintain the existing IFS HPC certification.

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

2

KEY ASPECTS AND REQUIREMENTS OF IFS HPC

2. Key aspects and requirements of IFS HPC

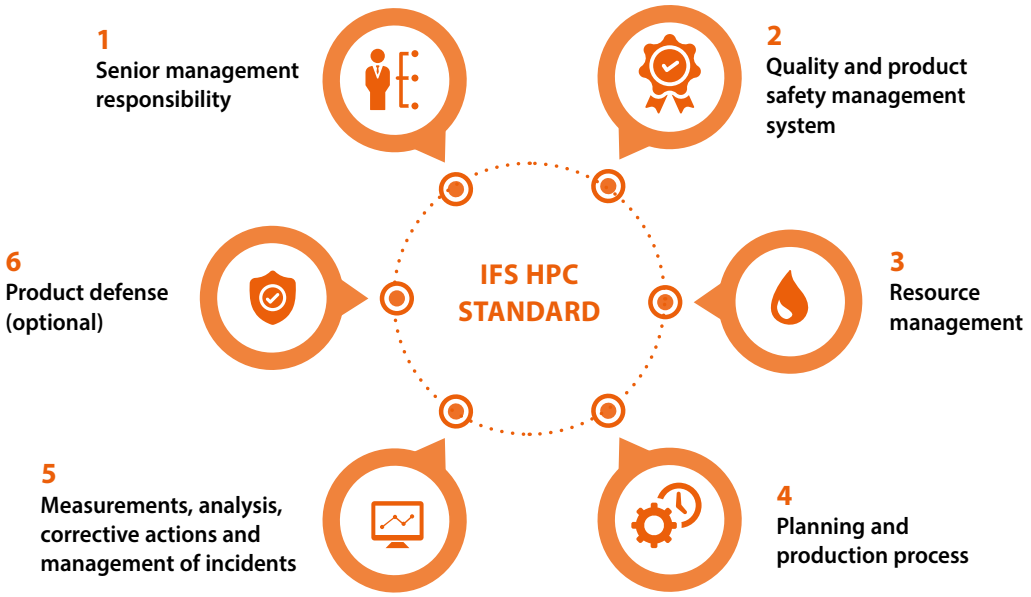
First thing you need to understand is that all IFS HPC requirements were written to answer to the 2 following questions:

- Are your products safe?
- Does your product fulfill customer specifications?

A safe product (according to GPSD – General Product Safety Directive, European law on product safety), is a product which, ***under normal or reasonably foreseeable conditions of use*** including duration 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 requirements of the IFS HPC standard, divided in 6 chapters, were all defined to be able to demonstrate that your company is processing safe products and that they fulfill customer specifications:



2.1 The 6 KO requirements

One first tip is to "secure" the correct implementation of the 6 KO requirements, as the impact when they're not fulfilled is compromising the IFS HPC certification.

KO n°1 – Senior management responsibility (requirement 1.2.3)

The Senior Management shall ensure that **employees are aware of their responsibilities** relating to product safety and quality. Senior management shall also ensure that **mechanisms are in place to monitor the effectiveness** of the operation of the employees. Such mechanisms shall be clearly **identified and documented**.

Key word	How to demonstrate compliance?	Examples of common deviations
Senior management commitment	• Organigram • Evidences of responsibilities for organization, implementation, control, supervision	• Personnel other than Quality/ safety team does not know Quality/safety management procedures • Top management deputized all responsibilities related to quality and safety management system to the Quality/ safety team, with no clue of what it is • 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 – Monitoring system of each critical control point (requirement 2.2.3.8)

Specific **monitoring procedures** shall be stablished for **each critical control point (CCP)** to detect any loss of control. Records of monitoring shall be maintained for a **relevant period**. Each defined critical control point shall be under control at all times. Monitoring and control of each critical control point shall be **demonstrated by records**. The records shall specify the **person responsible**, as well as the **date and result** of the monitoring activities.

Key word	How to demonstrate compliance?	Examples of common deviations
Monitoring procedures	• Written procedure including what to do, how, by whom, as well as what to do in case of non-compliance/deviation	• CCPs not well defined, therefore not monitored properly • Records with missing information (e.g. name, date, result)
Each critical point	• Risk assessment (see following chapter)	
Relevant period	• Minimum one year after the end of product shelf life (see 2.1.2.3)	
Under control at all times	• Frequency of monitoring shall be based on a well-defined risk management system (see following chapter)	
Records, with responsible person, date and result	• Records, with responsible person, date and result	

KO n°3 – 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 online • Evidence that formulation is carefully followed	• A raw material is changed and this affects finished product formulation • One important parameter of the product is its color but this is checked only once per year, during internal audit • Formulation as described in the product specification is not applied
Basis for control of production process	• Product specification needs well translated into GMPs and work instructions	
Basis to monitor finished products' compliance	• Product specification parameters well translated in product testing/control plan	

KO n°4 – Traceability (requirement 4.14.1)

A traceability system shall be in place which enables the **identification of product lots** and their relation to **batches of raw materials, packaging** in direct contact with product and packaging intended or expected to be in direct contact with product. The traceability system shall incorporate **all relevant processing and distribution records**. Traceability shall be assured and documented until delivery to the customer.

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

KO n°5 – Withdrawal/recall procedure (requirement 5.9.4)

There shall be an **effective procedure** for the withdrawal and recall of all products, which **ensures that involved customers are informed** as soon as possible. This procedure shall include a clear assignment of responsibilities.

Key word	How to demonstrate compliance?	Examples of common deviations
Effective	• Test of the procedure	• Missing or incomplete procedure • Partial list of customer contacts • No assigned employee in case a withdrawal/recall occurs
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	• List of contacts up to date	

KO n°6 – Corrective actions (requirement 5.11.2)

Corrective actions shall be clearly formulated, documented and undertaken as soon as possible to avoid further occurrence of non-conformity. The responsibilities and the time scales for corrective actions shall be clearly defined. The documentation shall be securely stored and easily accessible.

Key word	How to demonstrate compliance?	Examples of common deviations
Formulated, documented **Responsibilities and timescales**	• Documented corrective actions, with non-conformity, actions, responsible person and timeline	• Corrective actions from last audit not implemented • Timeline and/or responsibility missing • Deviations identified but no corrective actions initiated
Avoid further occurrence	• Corrective action relevance (in opposite to a correction, the corrective action shall prevent the issue to happen again and the solution provided shall 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 will only allow correcting the issue at the time the issue occurs, without acting on the cause, whereas a corrective action includes a cause analysis of the issue and will therefore not only correct the issue but also ensure this will not happen again.

Always easier with an example: at the reception area, you received 2 times in a row a damaged raw material.

A correction would be: you remove the raw material so that it doesn't 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 raw material is damaged; you're working with the supplier to ensure that next time the raw material will be received in good shape.

2.2 Risk management system

This chapter (2.2) is a core chapter of the IFS HPC standard and really makes the difference between this standard and any other "classic" audit checklists, as this defines the methodology that your company uses to identify hazards and assess risks within your company.

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 risk management but is strongly connected to it.

2.2.1 Good Manufacturing Practices (GMPs)

2.2.1.1 ***Before*** developing a risk management system, the company shall have implemented all necessary Good Manufacturing Practices (GMPs) which are commonly used in its scope of activity.

Obviously, this shall be the first step before building the risk management system.

Indeed: why should your company implement many "hot spots" or "critical points" (= steps identified as risky by your risk management system, implying strong monitoring, records, implementation of critical limits, specific actions to control and correct them), whereas those could be treated as "basic" practices of the company and of the sector of your industry?

"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). This is for example the case for cosmetics products, with ISO 22716 norm. If not, you can surely get tips from existing ones and create your own GMP guidelines. You can find more GMP guideline references in Annex 1.

Many requirements in the IFS HPC standard are addressing GMPs. Check on them to assess whether your company fulfils the level of GMPs that IFS HPC requires:

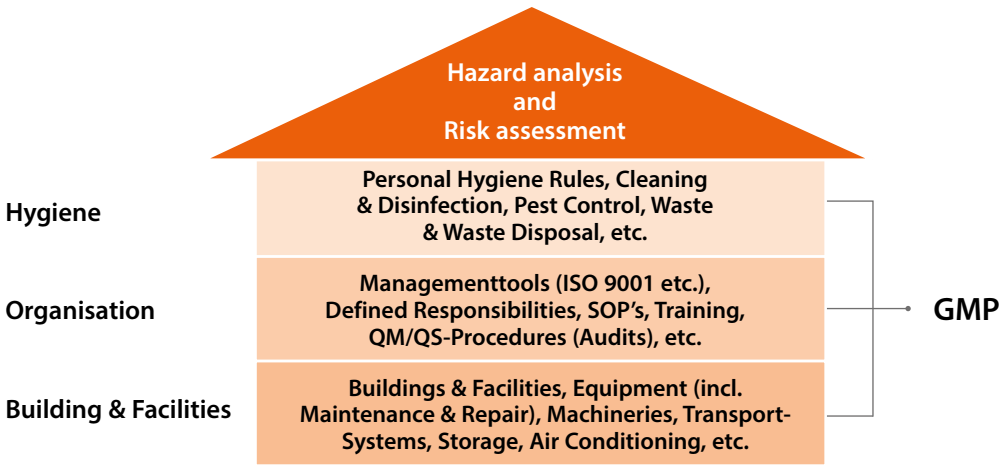
GMP type	IFS HPC requirement related to this GMP
Construction, layout and facilities of premises	4.5.2 4.5.3 4.5.4 4.13
Supplies of water, power and other utilities	4.5.4.3 4.5.4.1.6 – 4.5.4.1.7
Waste management	4.7
Equipment suitability – cleaning and maintenance	4.6 4.12
Prevention of cross contamination Raw materials control	4.7.1 4.10.2
Management of purchased materials	4.4
Cleaning and sanitising	4.6
Pest control	4.9
Personnel hygiene	3.2
Training	3.3
Transport	4.11
Traceability system	4.14
Recall procedure	5.9

NOTE: you can also find a comparison between specific Cosmetics GMPs – ISO 22716 and IFS HPC requirements in Annex 2, Part 2 of the standard.

Main differences between GMPs and specific steps defined as "hot spot" or "critical control points" rely on the level of monitoring and control and on the impact on product safety.

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.

Good Manufacturing Practices (GMPs) and hazard analysis



What's the difference between "regular" GMPs and GMPs which are "based on hazard analysis and assessment of associated risks"?

In the IFS HPC standard, some GMPs are described as such whereas some others are completed with the sentence "based on hazard analysis and assessment of associated risks in relation to product and process". What does it mean?

Let's take two examples on GMPs related to personnel hygiene and pest control chapters:

Topic	"Regular" GMP	GMP with "based on hazard analysis and assessment of associated risks"
Personnel hygiene	3.2.1.3 Visible jewellery (incl. piercing) and watches shall not be worn.	3.2.1.1 There shall be documented requirements relating to personnel hygiene. These includes, as a minimum the following criteria: • protective clothing […] • smoking […] The requirements shall be based on hazard analysis and assessment of associated risks in relation to product and process.
Pest control	4.9.5 Incoming deliveries shall be checked on receipt for the presence of pests	4.9.1 The company shall have a pest control system in place […] and shall cover the following criteria: • factory environment […] • identification of baits on-site • frequency of inspections […] the pest control system shall be based on hazard analysis and assessment of associated risks.

We can see through both examples that IFS HPC makes the difference between:

- GMPs which need to be implemented by any company, regardless of the products they produce, their production environment, company history, etc. Possible reasons to require the same level of GMP implementation to all companies are that this may be a regulatory requirement, or a "must" in the industry.

and

- GMPs which need to be adapted and related to the company's own parameters, history and environment. If we take the example of pest control: why would a company schedule a pest control inspection every quarter if they rarely have pest issues? Would this frequency be the same for a company having regular issues with mice and flies, as well as customer complaints on flies found in the products?

In this way, IFS HPC standard gives more flexibility to companies and doesn't not impose means for all GMPs. For many of them, when it's written "based on hazard analysis and assessment of associated risks), it's up to the company to define which level of GMP is suitable to them, as long as they're able to justify and document it.

2.2.2 Risk management system

Before diving into the methodology, let's start with basic definitions:

- Hazard: a biological, chemical or physical agent with the potential to cause an adverse health effect.
- Hazard analysis: 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, consequently to hazard(s).
- Risk assessment: overall process of risk identification, risk analysis and risk evaluation. Risk evaluation involves comparing estimated levels of risk with risk criteria defined when the context was established, in order to determine the significance of the level and type of risk.
- Risk management: process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options.

IN A NUTSHELL: risk management = hazard analysis + risk assessment

The risk management system is site specific and cannot be "copy and paste", neither from your head office nor from any other company, as it will be based on your site-specific hazards, GMPs, processes, etc. It shall include all processes (from good receipt to good dispatch) and all products. Keep in mind that the system shall also include potential outsourced activities which may have an impact on your products (see also chapter 2.3).

This system shall be based on scientific or technical validated data. For example, if you identify "metal pieces" as a hazard and if you consider this can lead to a risk before packing your product: you will probably decide to implement a metal detector to control this risk; but you will need either scientific data or metal detector technical specifications to confirm/prove that the metal detection will effectively control the risk and reduce it to an acceptable level.

Finally, the system shall take into account any legal requirements, both from production and destination countries. For example: a raw material may be forbidden in one geography but allowed in another geography and conversely, so this needs to be considered when performing the hazard analysis and risk assessment.

IN A NUTSHELL: a risk management system shall be site specific, based on scientific/technical literature, take into account 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.

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

- **Assemble a risk management team**
- **Describe the products**
- **Identify their intended use**
- **Construct flow diagram**
- **Confirm on-site flow diagram**
- **Conduct a hazard analysis and risk assessment for each step**
- **Determine critical control points**
- **Establish critical limits for each critical control point**
- **Establish a monitoring system for each critical control point**
- **Establish corrective actions**
- **Establish verification procedures**

Although all steps are very important to set up an effective risk management system, this guideline places the focus on the 2 steps **in green**.

Conduct a hazard analysis and risk assessment for each step

The hazard analysis shall only be performed for hazards ***that may be reasonably expected***. It's not worth listing all existing hazards where those have no chance to occur 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 GMPs previously described. Already implemented GMPs will help to determine if hazard could lead to a risk or not, that's why GMPs have to be implemented ***before*** 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.

Company has implemented the following GMPs: training on personnel on how to segregate raw materials in the storage area, clear labelling and colour code on the "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 to control the relevant hazards so that no risk can occur.

When listing the hazards (physical, chemical, biological), always associate it 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 IFS HPC standard doesn't request you to choose a specific one, as long as your methodology is reaching the end goal to have an effective risk assessment system. 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 template to set up the hazard analysis could be:

Step	Hazards which may reasonably occur and root cause of the hazard	Hazards' probability	Hazards' 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 which lead to the conclusion whether a hazard could lead to a risk is documented and comprehensive for the full activity of the company.

To determine if the 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: are you clear on what is a hazard and what is a risk?

- A pathogenic microorganism is a biological hazard, whereas the probability for a consumer to be ill is a risk
- A piece of glass is a physical hazard, whereas the probability for a consumer to get injured is a risk

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

You can use either 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					
5	5	10	15	20	25
4	4	8	12	16	20
3	3	6	9	12	15
2	2	4	6	8	10
1	1	2	3	4	5
	1 small inconvenience	2 less serious	3 serious	4 very serious	5 disatrous

SEVERITY

Risk is obtained by multiplying the severity by the frequency.

Grading should be defined, for example with the support of scientific and/or technical validated literature. For example, in Europe, European Commission has implemented RAPEX – Rapid Alert System, which provides an updated list of all alerts and recalls on non-food products on European market, with an explanation on the product defect and the associated risk on consumers. This is a very interested source of information to assess and weight the risks.

It can also take into account historical data from the company (number of recalls, customer complaints, etc.)

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 hospitalized 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 facilitate a clear demarcation between the different gradings. 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 above example: red zone is related to unacceptable risk and those situations need to be controlled through the implementation of specific measures.

Determine critical control points

Once the hazard analysis is performed and the risk assessed, you need to define for your "red zone" what should be implemented to control the risk and reduce it to an acceptable level. This will go through the implementation of 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 have it under control, in order to limit or to reduce the harm to the consumer and/or the potential severity of damage to an acceptable level and/or to guarantee a compliant product. Loss of control at this step may increase the likelihood of a health damage of the consumer.

An example of template to determine the critical control points could be:

Step	Hazards which may reasonably occur and root cause of the hazard	Hazards' probability	Hazards' severity	Risk score	Is a CCP neces-sary 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 shall be:

- **a process step**
- **monitored through specific parameters (critical limits)**
- **if possible: monitoring should be continuous**
- **if possible: results of monitoring should be available before products are dispatched out of the factory**

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

- Establish 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 shall always be recorded!

Instead of explanations, let's illustrate this with an example (taken 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 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 of the previous day, the auditor observes that the monitoring of the correct functioning of the detector at the end of production is not being recorded.

Is the situation acceptable and compliant with IFS HPC requirement?
As the company has defined the metal detection step as a CCP, it must be controlled and monitoring results 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 evidences that the controls were performed. Therefore, the process control is not guaranteed and the auditor scored the KO requirement 2.2.3.8 with D.

Finally, the full risk management system shall be reviewed regularly. Don't forget to update it each time something is changed in the product, the process or the environment of the product. One frequent 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 be considered, etc.), don't fall into the trap!

Before moving to the next chapter, here are the most common mistakes which are identified in the risk assessment system implementation:

- Mix "hazard" and "cause" (e.g. microbiological hazard coming from a raw material, versus contamination due to a lack of line cleaning)
- Mix hazard and risk
- Identify risk which is not linked to final consumer (e.g. hazard = mix of chemical substances in the warehouse and risk = hazardous chemical reactions)
- Provide a scale for severity and probability which is not enough detailed (e.g. frequent, seldom, very serious, serious, etc.)
- Don't provide explanations on the acceptable limit between "risky" and "not risky"
- Identify irrelevant CCP (e.g. out of specification raw material)
- Implement irrelevant/no valued critical limit (e.g. raw material specification)
- In small companies: not enough document risk assessment system

- In large organizations (multi sites): individual site implements the central risk assessment guidelines, which does not reflect the current situation of the specific 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 to answer to 2 main questions: are your products safe and do they fulfil customer specifications?

We saw in the above section that the safe part is mostly addressed in the Risk management system chapter.

Now, let's check what IFS HPC requires to control fulfilment of customer specifications (i.e. chapters 4.1, 4.2.1, 4.2.2 and 4.4).

First of all, are you clear with what a specification is? Specification means detailed description of the product, often including formula/recipe, packaging type, consumer sales unit type where relevant, weight, etc. It could also provide even more details, for example on 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 products shall have specifications. When those products are sold under retail brands or other company brands, specifications shall be agreed by both parties (you and your customers).

If the product specification is not provided by your customer, you shall create one and translate within the document all the customer requirements. Finally, you shall ensure that specifications are aligned with legal requirements, both of production and destination countries.

Documentation control and management is very important when it's about specification. That's why specifications shall be up-to-date (4.2.2.1) and their management shall be subject to a specific procedure with minimum information on when/in which case to review specifications (4.2.2.4 and 4.2.2.5).

ADVICE: as the auditor will check if the specifications are updated, keep in mind to always provide in the document, the date of creation, date of review, version number of the document and reason of modification. This will enable you, in addition to be clear on your documentation, to prove the auditor that you reviewed the document when necessary and that you modified it when necessary.

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

- for the composition of products → the specification document is the source to design/produce the product, as it will detail all criteria that the finished product shall fulfil
- for the control of the production process → instructions given to operators and on production line are all designed from product specification and to make sure that product specification is fulfilled

- to monitor finished products' compliance → parameters for product testing/control plan are based on criteria from product specification

Each time a change is introduced concerning the equipment (e.g. new cutting machine), in the formula (e.g. new supplier temporarily providing a slightly different raw material, in the packaging e.g. 3 units per pack instead of 2 or new marketing information on the product labelling), in the conditions of manufacturing (e.g. a part of the process is now outsourced to another company), etc., you should always ask: **does it affect finished product parameters and is the finished product still compliant with specification?**

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

Company description and audit findings:
company manufactures make-up removal wipes for sensitive skins, under 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 of 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 vegetable oil regular supplier was not able to supply them in the last 2 weeks and they had to use mineral oil instead, on a temporary basis while they found another supplier. Product labelling remained unchanged and customer was not informed.

Is the situation acceptable and compliant with 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 D.

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). For each, you shall be able to identify the related supplier.

IMPORTANT: **raw materials, in the meaning of IFS HPC standard, include ingredients, additives, packaging materials and rework. Indeed, when reworked material is used and included back into the production, it shall be considered as a raw material.**

Having specifications for all raw materials enables your company to set up compliance criteria and also to rely on those parameters in the contractual agreements with your suppliers.

IFS HPC requires that you implement a procedure to approve and monitor your suppliers of products and services (i.e. outsourced production, sub-process). For that, you need to set up assessment criteria which will help you to define the level of compliance of your suppliers. These could be, but are not limited to audits, certificates of analysis, questionnaires, self-assessments, number of complaints, etc. Results of this assessment shall be reviewed regularly and actions taken and recorded (e.g. what will you do if a supplier is under-performing, without any improvements, since the last 2 years?).

Specific requirements on outsourced production:

If there is a part of the production process that isn't performed on-site but outsourced to another company, ***the first thing to do is to inform your customer***. Indeed, if you're producing retail branded products, retailers are considered as producers, even if they don't produce the products themselves. That's why they need to know if you choose to outsource a part of the production of their products: they need to trust the company to which you outsource part of the production and some specific control measures need to be implemented:

- outsourced production shall be included in your risk 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
- you shall regularly audit the subcontractor and the auditing requirements shall cover at least IFS HPC auditing requirements; this audit shall be performed by a competent person
- if relevant, you shall check on receipt products coming from the subcontractor, to check if they're compliant with specifications.

All requirements that your company shall fulfill in case of outsourced activities are described in chapter 4.4.8 of IFS HPC audit checklist.

To illustrate the importance of a proper control of subcontractors, let's use an example (taken 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-razors pack.

This outsourcing is not mentioned in the contract with the retailer and the Manager confirms that retailer was not informed, as the product is just the same. Managers explains that the Chinese company is IFS HPC certified and he went personally in the Chinese factory to supervise workers during the first production weeks. No complaints were received from the customer regarding this product.

Is the situation acceptable and compliant with IFS HPC requirement?

The company outsourced the production of one product and the customer is not aware/informed of this. Despite the company has implemented checks to control this supplier, company didn't inform the customer that the production of this product was outsourced. Therefore, the auditor scored requirement 4.4.4 with Major non-conformity.

2.4 Internal audit and factory inspections

Did you know that the internal audit is a very powerful tool to help your company continuously improving? This is probably also why this is the first section of the IFS HPC chapter related to "measurements, analyses, corrective actions and management of incidents".

An internal audit is performed in-house and is aimed to test all departments and processes of the company to ensure they're working properly. In opposite to a certification audit.

Who performs the internal audit?

To ensure objectivity, the auditor shall be independent from the department she/he will audit. Auditor shall also have received proper training to be able to perform the audit correctly. The appointed auditor is usually the Quality manager of the company, but this can not work for the full audit scope as she/he can't audit his/her own department. That's why other auditors should be trained, or even external auditor may be used (for internal audit purposes).

Your internal auditors shall be competent and trained for the job and should 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 means not only the indoor processes and areas, but also the factory exterior and, if applicable, the off-site storage locations owned or rented by the company. Why not taking the IFS HPC audit checklist to perform the internal audit and go through the different chapter? This would be an easy way to ensure nothing was forgotten.

What to do to prepare an internal audit?

When the internal audit date is scheduled, all employees shall be informed. First, because they need to be available in case they're interviewed during the audit. Secondly, they should understand the objective of an internal audit before it happens.

As, the audit will point out what is compliant and what is not, all employees shall be aware that any vulnerabilities identified during an internal audit is not a way to spy or blame them but to identify opportunities for improvement… and also to get as much prepared as possible for the certification audit! That's why Managers play an important didactic role with employees.

An audit plan shall be prepared and checked, to ensure that all departments are covered. Don't forget the outside grounds and off-site storage locations!

How often should an internal audit be performed?

IFS HPC standard requires it's performed at least once per year. But this frequency can be increased if necessary and this shall be determined by a risk assessment. Do you think that the laboratory and the human resource department be audited at the same frequency with respect to product safety? List all the departments which need to be audited, weigh their impact on product safety and determine their audit frequency. Keep in mind that frequency may also need an update in case of change (for example, if the pest control provider was recently changed, it worth preponing the internal audit).

How does the internal audit take place in practice?

Auditor shall go through the agreed audit plan and assess all requirements. To facilitate the collection of findings, she/he should ask open questions (e.g. how do you use that? explain me how you... what if this doesn't work?) instead of closed questions (am I right to think that?).

Transparent reporting is important: share the non-conformities/deviations while they're identified.

At the end of the audit, the auditor shall write an audit report with the list of findings and deviations/non-conformities.

As this audit is not a third-party certification audit, corrective actions and timelines can be discussed and initiated at the end of the internal audit. Results of internal audits shall be shared with relevant personnel, to support everyone implementing relevant corrective actions.

Performing internal audits and ensuring the management and implementation of corrective actions are important indicators to drive company culture. Moreover, it's key for continuous improvement and sustainability of company good practices. Remember that IFS HPC certification is "only" an external confirmation and that internal audit as well as other means to pilot your companies are the most important tools to ensure your success.

Internal audits versus factory inspections?

Internal audit is a holistic tool, covering all activities/department of the company and is aimed to drive an effective company management system. Different assessment techniques can be used to perform an internal audit: factory inspections, personnel interviews, document sampling, etc.

Factory inspection is one of the assessment tools of internal audit, which cover specific topics and are performed to check the conformity of specific topics (e.g. hygiene, pest control, foreign body hazards). Any deviations coming from those inspections shall be dealt with and corrective actions documented.

IFS HPC standard requires to perform both, as they have different objectives.

IN A NUTSHELL: **internal audit shall be performed at least once per year, cover all aspects of the IFS HPC standard, be performed by a competent auditor, who is independent from the department she/he's auditing.**

The following table summarizes what key questions you should be able to reply to be compliant on the Internal audit chapter:

Key questions	Related documents
• **Is there and updated internal audit plan?** • **Is audit plan based on risk assessment?** • **Is a checklist available?** • **Are the auditors competent?** • **Are the auditors independent? Do they have any connection with audited activity?** • **How often are internal audits performed?** • **How are audit results communicated to the persons in charge? To senior management?** • **Are corrective actions documented?** • **Is a time schedule in place for corrective actions?**	• Internal audit plan, with information on which auditor audited which activity • Internal audit checklist • List of internal auditors, with their competences • Minutes of internal audits • Corrective action plan from internal audits • Evidence that results of internal audits were sent to all relevant personnel, included senior management

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

ANNEX

ANNEX
Bibliography on GMP guidelines

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