

# G 23 IZOGOOD® 22716

## DECRYPTING ISO 22716 WHILE HAVING FUN



### **GAMER'S BOOKLET**

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## 1. Rules of the game

The game is intended for one person, but nothing prevents playing in a small group, it will be much more fun.

The game is compatible with recent versions of web browsers. Otherwise the game can be slow.

A game session typically lasts between half an hour to 2 – 3 hours. You can play as many times as you like during your 60-day access and learn a lot about the ISO 22716 standard.

The goal of the game is to reach the final space (Finish) as quickly as possible.



The standard's requirements and comments are on this [page](#). A free quiz on the ISO 22716 requirements is provided at the beginning. This allows you to discover, decrypt and become familiar with the requirements of the standard.

Having a copy of the ISO 22716 standard at hand (not provided with the game) is a prerequisite.

The board of the game is a city with a car's journey.

In the top left, there is a clock showing elapsed time. In the top right, you have a help button and option to exit the game.

At the bottom left, there's a button to mute the sound. In the bottom center, you can see the total stars you've earned. ★ At the bottom right, there's a button linking to the ISO 22716 standard requirements page.

At the beginning, the car is parked at the Start space. 

Click on the "START GAME" button to begin.

The sequence of spaces (types of cards) is as follows:

- RISK - threat or opportunity - silver
- MCT - multiple choice test - green
- PRACTICE - good or bad practice - orange
- CASE – situation, challenge and solutions - blue

You also have special Maintenance





and Pandora's box spaces



Each type of case includes 50 questions (cards), and each answer is linked to a paragraph of the ISO 22716 standard version 2007.

Each card is presented in the following steps:

- step 1: The back of the card showing the card type, number (from 1 to 50) and the number of stars (from one to three) in blue, white and red ★☆☆☆☆

- step 2: The card type, its number, the question (e.g., “Is the following statement more of a threat or an opportunity?”), the statement (e.g., “The scope of the GMP describes the company’s main activities”) and the star(s)
- step 3: The answers (one or more correct answers are possible) with a green emoji  and a red emoji  (for **all** correct answers) and a red emoji (for a wrong answer)
- step 4: The paragraph from the standard and a comment for the correct or incorrect answer





The car starts and arrives at the Risk space.

The card number is random. Depending on the question’s difficulty, the stars are one, two or three.

If you guess the correct answer, the car moves forward as many spaces as there are stars on the question.

If you don’t guess the correct answer (or answer partially) the car stalls on the same space, and the next card will be of the same type.



If you land on a Maintenance  or Pandora's box space , you may get lucky or unlucky. From the car’s trunk or Pandora's box comes a random luck or misfortune card. If



luck is on your side, you get Joker card , and your car moves forward 3 spaces. If



misfortune strikes , your car moves back 3 spaces.

If a second person is with you and has printed this booklet, they can increase the game’s difficulty by asking questions like:




- What is the clause and sub-clause (paragraph) of the standard related to the question?
- Can you provide an example from your department related to this question?

When you reach the Finish space for the first time, you can download your IZOGOOD®

22716 game participation Certificate.



You can also view your game results:

- number of stars earned 
- date and time each time you played 
- time spent 

The educational objectives of the game are to allow each player to:

- identify whether a risk is more of a threat or an opportunity

- enhance their knowledge of the standard's requirements through MCTs
- guess whether a statement is a good or a bad practice
- study each proposed case's situation, challenge, and to find the right solution (one or more correct solutions are possible)
- decrypt the clauses and paragraphs of the standard and assimilate the requirements

Some questions have a touch of humor (even if the boss forgot to say it).

Relax, it's just a game.



A bias is inevitable regarding the "correct answers" to retain, especially for RISK or PRACTICE cards.

Here's an example:

RISK 01. Is the following statement more of a threat or an opportunity? **"The most important thing is that the company's strategy was established in the past"**

One might answer that it's a threat or an opportunity, but it depends on when the strategy was defined.

If you answer that it's a threat, you're right because it's not specified when the previous strategy was developed (a year ago, 10 years ago). There's missing information. But you could answer that it's an opportunity because you think "in the past" means 2 to 3 years ago.

Thus, the presented answers and the relevance of the comments are debatable; in the end, the truth is sometimes relative.

The IZOGOOD games are created and developed with great care. Thank you in advance for communicating any potential improvement points you've identified via the link: <https://www.pqbweb.eu/contact.php>

## 2. Glossary

**The beginning of wisdom is the definition of terms. Socrates**

Some specific quality terms:

**Acceptance criteria:** *everything that is compared to the requirements to assess compliance*

**ANSM:** *National Agency for the Safety of Medicines and Health Products*

**Audit evidence:** *demonstrably true data related to audit criteria*

**Audit:** *a systematic and independent survey to determine whether activities and results comply with pre-established measures and are capable of achieving the objectives*

**Batch:** *quantity of a cosmetic product manufactured in a homogeneous operation cycle*

**Bulk product (semi-finished):** *any intermediate product of a process or activity*

**Calibration:** *the set of operations for establishing the relationship between the values indicated by the instrument and the known values of a reference standard*

**Cleaning:** *any operation to separate and remove dirt by means of chemical, mechanical or temperature action*

**Concession (after production):** *written authorization to deliver a nonconforming product*

**Conformity:** *fulfillment of a specified requirement*

**Contamination:** *presence of undesirable substances in the product*

**Continual improvement:** *permanent process allowing the improvement of the global performance of the company*

**Control (inspection):** *actions of measuring, testing, and examining a product, service, process or material to determine compliance with requirements*

**Corrective action:** *action to eliminate the causes of nonconformity or any other undesirable event and to prevent their recurrence*

**Cosmetic product:** *any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors (Article 2, 1a of Cosmetic Regulation)*

**CPNP:** *Cosmetic Products Notification Portal*

**Customer satisfaction:** *top priority objective of every quality management system related to the satisfaction of customer requirements*

**Customer:** *anyone who receives a product*

**Document:** *any support allowing the treatment of information*

**Effectiveness:** *capacity to realize planned activities with minimum effort*

**Efficiency:** *financial relationship between achieved results and used resources*

**External provider (supplier):** *an entity that provides a product*

**Finished product:** *any end result of a process or activity*

**GMP:** *Good Manufacturing Practices*

**Indicator:** *value of a parameter, associated with an objective, allowing the objective measure of its effectiveness*

**Inspection:** *the actions of measuring, testing and examining a process, product or material to establish whether requirements are met*

**Maintenance (preventive):** *a set of planned preventive actions to maintain equipment in perfect condition and ensure the specified service*

**Making available on the market:** *any supply of a cosmetic product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge (Article 2, 1g of Cosmetic Regulation)*

**Management review:** *a periodic survey carried out by top management of the management system for its continual improvement*

**Management system:** *set of processes allowing objectives to be achieved*

**Nonconformity:** *non-fulfillment of a specified requirement*

**Organization (company):** a structure that satisfies a need

**Performance:** measurable and expected results of the management system

**PEST:** Political, Economic, Sociological, Technological. Analysis to identify the influence of external factors

**PIF:** product information file

**Process approach:** management by the processes to better satisfy customers, improve the effectiveness of all processes and increase the global efficiency

**Process:** activities that transform inputs into outputs

**Product (or service):** every result of a process or activity

**Quality management:** activities allowing the control of a company with regard to quality

**Quality objective:** quality related, measurable goal that must be achieved

**Quality:** aptitude to fulfill requirements

**Recall:** any measure aimed at achieving the return of a cosmetic product that has already been made available to the end user (Article 2, 1r of Cosmetic Regulation)

**Requirement:** explicit or implicit need or expectation

**Review:** a survey of a file, product, process so as to verify if pre-set objectives are achieved

**Risk:** likelihood of occurrence of a threat or an opportunity

**Sanitization:** any operation to reduce undesirable invisible contaminants

**SCCS:** Scientific Committee on Consumer Safety

**Stakeholder:** person, group or company affected by the impacts of an organization

**Subcontractor (supplier):** an entity that provides a product

**SUE (serious undesirable effect):** an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalization, congenital anomalies or an immediate vital risk or death (article 2, 1p of the Cosmetic Regulation)

**SWOT:** Strengths, Weaknesses, Opportunities, Threats. Tool for structuring a risk analysis

**Top management:** group or persons in charge of the company's control at the highest level

**Traceability:** the aptitude to memorize or restore all or part of a trace of executed functions

**Undesirable effect:** an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product (article 2, 1o of the Cosmetic Regulation)

**Validation:** notice that the application of any process, product or material allows expected results to be achieved

**Verification:** the periodic inspection survey of compliance of a process, product or material

**Waste:** anything that is destined for disposal

**Withdrawal:** any measure aimed at preventing the making available on the market of a cosmetic product in the supply chain (Article 2, 1q of Cosmetic Regulation)

*Remark 1: ISO 22716 is entitled Cosmetics - Guidelines on Good Manufacturing Practices. In the content, the verb used is: should and not shall. This is a recommendation, not a requirement, but to simplify understanding we use recommendation and requirement together*

*Remark 2: the use of ISO 22716 and ISO 9000 definitions is recommended. The most important thing is to determine a common and unequivocal vocabulary for everyone in the company*

### 3. RISKS



Recurring question: Is the following statement more of a threat or an opportunity?

**RISK 01** The most important thing is that the company's strategy was established in the past

**Threat** § 3.3 ★★★

*Every three years on average, it's advisable to verify the strategy's adequacy with the company's context and the expectations and needs of stakeholders. It's a threat because the date when the strategy was developed isn't specified*

**RISK 02** The company's context is an element that can be considered (even if the boss forgot to mention it)

**Threat** § 14.1 ☆☆☆

*This is a requirement of the standard and is unavoidable. It's one of the first tasks to carry out since the validation of the company's strategy depends on it*

**RISK 03** Trying to anticipate the evolution of customer expectations is a waste of time (if the boss says so)

**Threat** § 14.1 ★

*Since the company's goal is to sustainably satisfy its customers, knowing the evolution of expectations is a key success factor for the future*

**RISK 04** We can try to comply with legal requirements (if the boss agrees)

**Threat** § 8.1 ★

*We must strictly comply with legal requirements and the Cosmetics Regulation (EC 1223/2009)*

**RISK 05** The good manufacturing practices scope describes the company's main activities

**Opportunity** Clause 1 ★

*Describing the scope of good manufacturing practices is delimiting the entities and activities concerned. Exclusions must be specified*

**RISK 06** In-house promotion of process mapping (the boss said to manage on our own)

**Opportunity** § 3.2 ★

*This is an opportunity to let everyone know about process mapping. This allows everyone to situate themselves in the overall operation of the organization and in supplier customer relationships with other processes, cf. 3.2.1*

**RISK 07** In a service company, to check if top management is showing leadership, it is necessary to audit top management

**Opportunity** § 16.1 ☆☆☆

*It is an opportunity when the director leads by example  
But it can be a threat when the director is insincere*

**RISK 08** Involve staff in the day-to-day application of good manufacturing practices approach (even when the boss is not around)

**Opportunity** § 3.1 ★

*When staff is involved on a daily basis, operational efficiency is enhanced and continual improvement is possible*