

G 22 IZOGOOD® 13485

DECRYPTING ISO 13485 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 13485 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 13485 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 13485 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 13485 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 13485 standard version 2016.

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 QMS 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®

13485 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:

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

Audit evidence: demonstrably true data related to audit criteria

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

Conformity: fulfillment of a specified requirement

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

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

Customer: anyone who receives a product

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

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

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

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

Process: activities which transform inputs into outputs

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

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

Quality: aptitude to fulfill requirements

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

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

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: probability of occurrence of a threat or an opportunity

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

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

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

Remark 1: the use of ISO 9000 and ISO 13485 definitions is recommended. The most important thing is to determine a common and unequivocal vocabulary for everyone in the company.

Remark 2: a document can be presented as documented information that must be maintained (procedure ) or retained (record ).

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 § 4.2 ★

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 QMS processes are efficient, i.e. carried out with minimum effort (even when the boss isn't around)

Threat § 4.1 ★★★

By implementing the necessary actions to achieve the planned results, see § 4.1.3

RISK 03 In-house promotion of process mapping (because the boss said to manage on our own)

Opportunity § 4.1 ★

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

RISK 04 Compliance with applicable regulatory requirements does not require the retention of process-related records (if the manager agrees)

Threat § 4.1 ☆☆☆

On the contrary! The standard requires each QMS process to establish and maintain the necessary records, cf. § 4.1.3

RISK 05 An external process, even if it has an impact on product conformity, is the responsibility of the external provider (if the boss says so)

Threat § 4.1 ★

Responsibility cannot be outsourced. The company shall monitor and control the external process. Control elements are proportionate to the associated risk and include written quality provisions, cf. § 4.1.5

RISK 06 Records of software application validation are retained (even if the boss forgot to mention it)

Opportunity § 4.1 ★

The validation of software applications used in the QMS is documented in the form of procedures, see § 4.1.6

RISK 07 QMS documentation includes a quality manual, documented procedures, records and other documents specified by applicable regulatory requirements

Opportunity § 4.2 ☆☆☆

The quality manual is mandatory, the required procedures are 27, but several procedures can be merged into one, see § 4.2.1

RISK 08 The scope of the QMS is included in the quality manual

Opportunity § 4.2 ★

The quality manual also includes details and justification of exclusions (non-applicability), see § 4.2.1