FibonacciLab
An EFESO Group Company

# Quality CoPilot

## CASE STUDY

AI boosted Quality Management assistant

by Piero Donaggio and Laura Woznialis

CASE STUDY

# Quality CoPilot

## FibonacciLab

A background of excellence. Decades of experience in the fields of Supply Chain, Data Science and Artificial Intelligence gathered in a team of consultants, technicians and developers. The definitive fusion between the know-how and expertise of big companies and the attention to detail and tailor-made design typical of a consultancy-boutique.

FibonacciLab works at the convergence of Supply Chain and Data Science. We are one of the few boutique consulting firms bringing together decades of experience in both fields and across multiple business sectors. Our goal is to become Your Trusted Advisor in boosting your business performance through data and digital technology. All our digital solutions are tailored to your specific needs and blend with traditional consulting to facilitate change and sustain improvement in the long term.

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# 01. Identikit

Quality CoPilot is an **AI Deviation Search Tool**. In other words, it is an intelligent AI-based search engine for quality deviations that combines a straightforward and user-friendly interface with the capability for users **to find similar historical deviations to a problem statements articulated in the naturale language**. The goal is to become **the only reliable tool for exploring the deviations of the past**.

**The future of QA Management**

## What is does

Quality CoPilot can **explore and query massive pools of data in search of similar deviations**, with the aim of highlighting events of novelty and understanding reoccurrence of similar failure modes. The fact that the system combines **the simplicity of the search experience** based on the use of natural language (similar to that offered by web search engines such as Google) with the analytical power of artificial intelligence, leads the search for deviations **to a completely different level** making everything much simpler, faster and intuitive.

**The goal is to become the only reliable tool for exploring the deviations of the past.**

## When to use it

- When advanced analyses need to be conducted on databases with a large amount of historical data.
- When deviations, repetitions, and patterns need to be identified with a very high degree of precision and flexibility in formulating the problem statement.
- When the need is to automatically identify, label and cluster group of deviations and similarities from a large pool of data.
- When a clear and reasoned view of the data is needed to establish truly effective Corrective and Preventive Actions (CAPA).
- When it is necessary to optimize, simplify, and expedite the workflow of analyses for reasons of timing, costs and/or team expertise

# Challenges

## OUR CLIENT

Our client is **a global pharmaceutical company** and stands as a biopharmaceutical group leader at the forefront of various healthcare domains. With a specialized focus on reproductive medicine, maternal health, gastroenterology, and urology, our client is dedicated to advancing scientific innovation with a clear commitment to a **research-driven approach** and a profound confidence in the **transformative potential** of cutting-edge investigations.

**Today, traditional quality management software mainly focuses on recording and historicizing deviation reports and has very poor capabilities in terms of data analysis, pattern recognition and ensuring overall CAPA effectiveness.**

**Utilizing AI-boosted Quality Management assistants could be a strategic approach to solve this issue and advance dramatically in this field.**

In the contemporary landscape of quality management software, there exists a paradigm shift where the conventional approaches primarily center around the mere documentation and historical archiving of deviation reports. However, **this traditional methodology fall short** in harnessing the full potential of **data analysis, pattern recognition, and the holistic effectiveness** of Corrective and Preventive Actions (CAPA).

The evolution of quality management systems **demands a dynamic solution that transcends the limitations of antiquated practices**. Beyond the rudimentary task of recording deviations, a cutting-edge platform should empower organizations with robust capabilities for sophisticated data analysis, enabling them to glean actionable insights from their quality data. This analytical prowess **not only aids in identifying patterns** but also serves as a **proactive measure in mitigating potential issues** before they escalate.

Moreover, the essence of an effective quality management system lies not only in addressing deviations but also in optimizing CAPA processes. A progressive software solution should seamlessly integrate with a company's workflow, providing real-time visibility into CAPA activities and their overall impact on quality improvement initiatives.

For the same reason, it is crucial that these tools **employ user-friendly interfaces and straightforward systems** for conducting in-depth analyses. For instance, using plain language to formulate questions and analyze data should be a key feature. This approach not only simplifies the software usage but also democratizes access to advanced functionalities, making quality management accessible to a wide range of users within the organization.

By embracing a forward-thinking approach, **organizations can leverage technology that goes beyond the historical context**, actively contributing to a culture of continuous improvement. In essence, the next generation of quality management software **transcends the role of a mere recorder, evolving into a strategic partner** that empowers businesses to proactively enhance their quality standards and drive sustained excellence.

## Benefits

- **Facilitate problem investigation process**
- **Boost compliance to problem management standards**
- **Streamline deviation search, generation and analysis**
- **Generate information rich data for broader analysis**
- **Make analysis and researches easier, user friendly and more intuitive**

# Performances

One of the main advantages that an AI-based approach can provide to deviation analysis for QA management lies in **optimizing the search processes** and, consequently, making subsequent analyses conducted on that data faster and simpler as well. Having to dedicate less time and energy to the deviation research phase means **having more time to analyze information and structure potential strategies** or solutions, and this, in turn, translates to greater control and the ability to minimize the risk of future deviations.

**"The goal is to take similarity search to a whole new level."**

# +50%

## Improvement in Analysis Accuracy

This is closely related to the previous two, especially to the Search Accuracy one. The combination of increased Search Accuracy and reduced Search Time (thus allowing more time for analysis) leads to an enhancement in the accuracy of the analyses, which, although lower than before, remains nevertheless high.

# +75%

## Improvement in Search Accuracy

For the same reason, the use of this approach facilitates advanced searching of pertinent, similar deviations using natural language. As a result, the accuracy of the obtained results will be much higher compared to traditional search methods.

# -30%

## Reduction in Search Time

Compared to keyword-based searches, which require numerous attempts, the AI-based approach understands the contextual relationships within information and can comprehend the meaning of user requests formulated in natural language. Consequently, the number of searches required to achieve the desired result is minimized.

## Increased Awareness of the Production Environment

Not precisely measurable, but nonetheless a significant advantage. An increased awareness of deviations also enables greater control over the main problems and critical issues around the company, consequently allowing for the development of more effective strategies.

# Applicability

We designed Quality CoPilot with a **primary focus** on analyzing quality deviations in the pharmaceutical industry. However, the system proves to be **highly scalable**, offering numerous potential applications. Essentially, it can be employed in any scenario where extensive data is available, **providing quick and precise answers** with minimal effort. This is particularly beneficial in situations requiring advanced and highly customizable analyses, enabling the search for specific statements within the data.

**The system is highly scalable**

Some possible alternative use cases could be:

## Sales Trend Analysis for an Online Retailer

An online retailer could use the AI-based search engine to analyze historical transaction data and identify sales trends. For example, pinpointing the most purchased products during specific times of the year, categories with the highest sales, or recurring customer reviews. This information could guide inventory strategies, marketing efforts, and service improvement.

## Security Monitoring in a Technological Environment

A technology company could employ the search engine to analyze security logs or tickets and identify potential threats or anomalies. Detecting patterns of suspicious activity, identifying recurring behaviors associated with security breaches, or analyzing access data to enhance the protection of sensitive information.

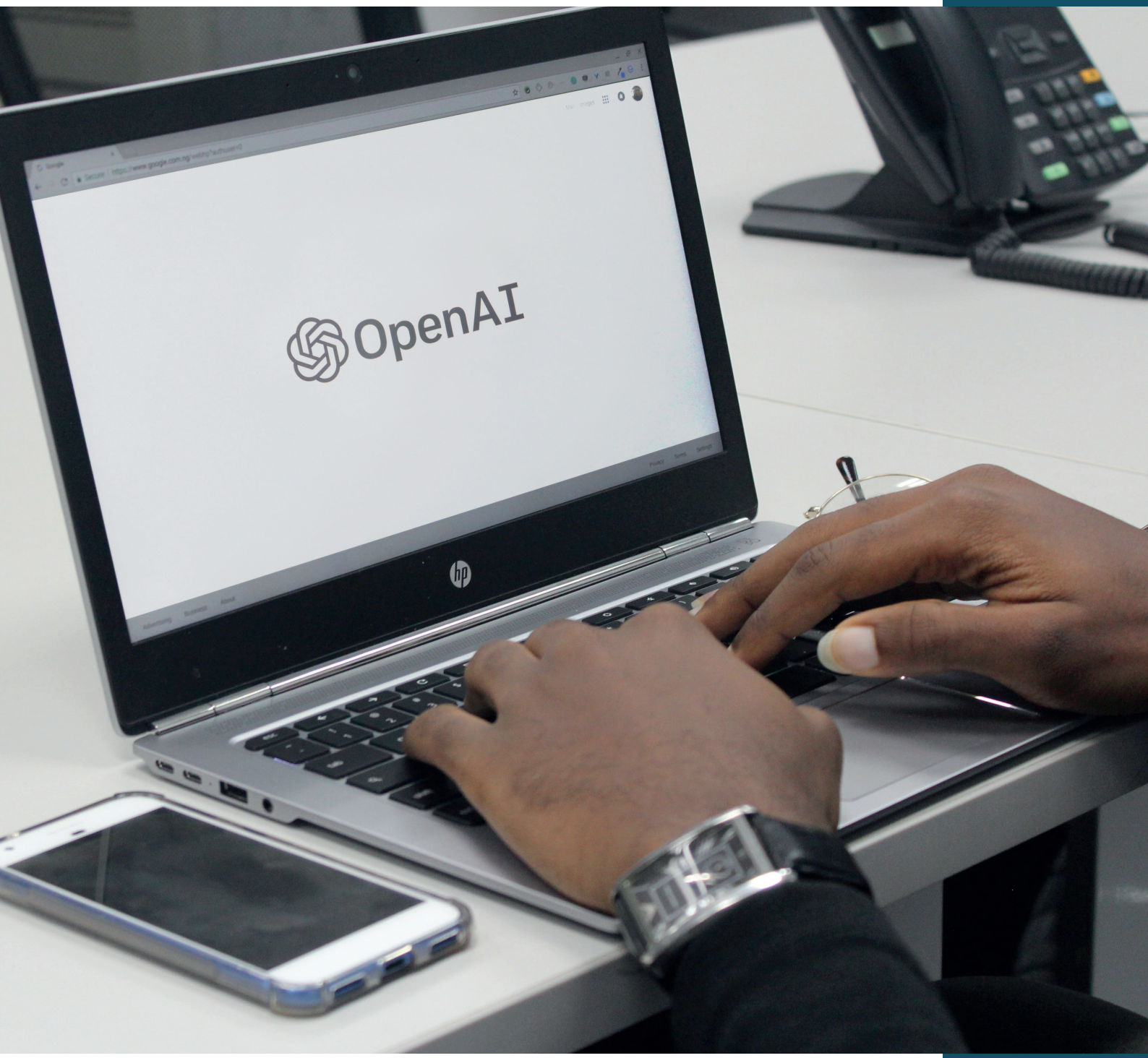
## Human Resource Management in an Organization

A company could use the search engine to analyze historical employee data, including feedback, performance, and professional development. This would enable the identification of patterns of excellence, pinpoint areas requiring additional training, or predict potential employee turnover risks. Applying this analysis could improve human resource management and overall business productivity.

## Analysis of Customer Responses in a Customer Support Center

A company with a customer support center (eg a telecommunications company or a flight company) could use the search engine to analyze past interactions, highlighting the most common issues reported by customers, successful solutions, and any patterns that could enhance customer support efficiency. This would allow for resource optimization and ensure better customer satisfaction.

# 02. AI-Boosted Search Engine and Why



## Why an AI-Boosted Search Engine?

As previously indicated, the main purpose of the tool was intended to function as an **accessible and intuitive similarity search engine**, offering the ability to conduct searches for similar deviations based on either problem statement inputs or keywords expressed in the native language. Additionally, the tool was also supposed to **adhere to specific constraints** outlined within the project scope and tied to the client's specific requirements.

**To summarize, the objectives of the solution were:**

- **Capability to handle multi-site deviations.**
- **Ability to search through both the title and full problem statement.**
- **Integration within the client's Azure environment.**
- **Development of a standalone application with the possibility of integration with the main QA Management tools.**
- **Implementation of a user interface that is both simple and comprehensive.**
- **Provision of a flexible structure for adding modules for additional languages.**

As it is easy to imagine, faced with such a set of prerequisites we had to **immediately discard many of the more conventional and traditional solutions**, as they were neither powerful nor flexible enough, or did not meet one or more of the prerequisites. What we needed was **an intelligent and robust solution**, yet at the same time, **extremely user-friendly and easy to use**, capable of navigating quickly and accurately within a vast pool of data, identifying differences, and responding to user requests in the best possible manner. **Hence, the choice to use a tool enhanced with AI**.

## And why a tool based on MS Azure and OpenAI?

There were **various possibilities** to develop this tool but, among all, we opted to develop a solution leveraging **both MS Azure and OpenAI**. The reasons are the following:

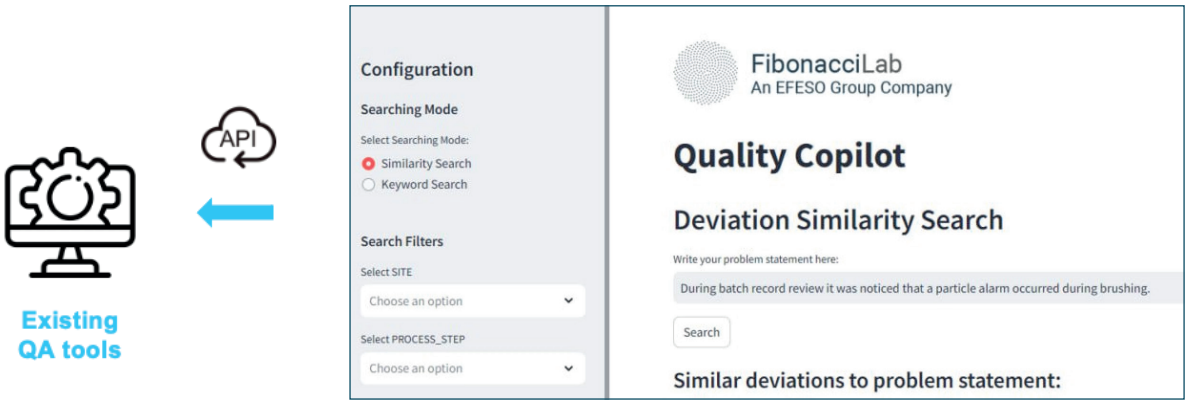
### WHY DID WE CHOOSE MS AZURE AND OPENAI?

- **Microsoft Azure ensures robust data security measures.**
- **Utilizes Azure Cognitive Search service to store transformed data and execute Similarity Search and Keyword Search functionalities.**
- **The OpenAI model learns the contextual relationships within information, converting text into numerical representations.**
- **Native multilingual support to facilitate learning from different teams worldwide.**

### WHAT ADVANTAGES DOES OUR TOOL GIVE US?

- **Provides support for selecting both Similarity Search and Keyword Search across various criteria, including Short Description, Description, Deviation category and Sub-category, Process step, and Equipment.**
- **Easy integration with any QA management tool.**
- **Facilitates advanced searching of pertinent, similar deviations using natural language.**
- **Analysis and highlight of reoccurring, trending or novel deviations, based on textual descriptions**
- **Assisted creation of high-quality, compliant problem descriptions**
- **Automatic summarization of a group of deviations**

Deviation Search CoPilot Application




API

**Existing QA tools**

Deviation text

**PARTICLE DURING BRUSHING**

OpenAI
Embedding model
`text-embedding-ada-002`

| 0.000 | 0.006 | -0.013 | ... | -0.013 |
|---|---|---|---|---|

Text as vector

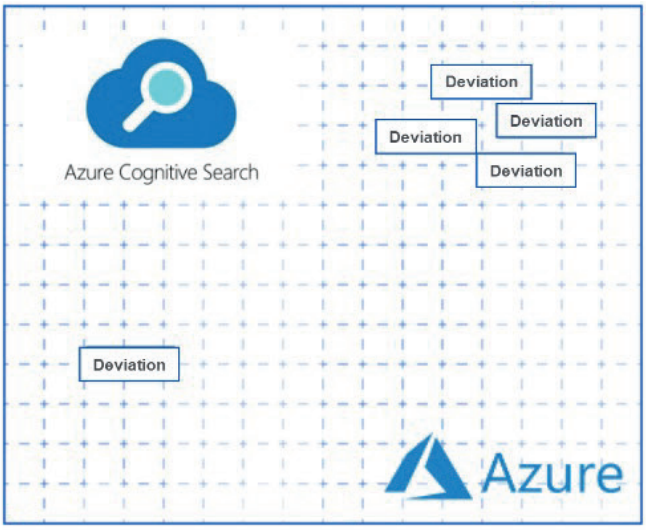
**Data indexing and storing in Azure Cognitive Search**

**Embedding the problem statement to get vector representation**

OpenAI
Embedding model
`text-embedding-ada-002`

**Searching for similar Deviations in the vector space**

**Return similar results to the application**




Example of simplified Deviation representation in a vector space

# 03. Approach

As FibonacciLab our responsibility was to gather and analyze all outcomes from the preceding phases, **formulate a new strategy**, and present a functional **Proof of Concept** to assess the actual value that a solution of this nature could bring to our client.

To do this, it took us a process divided into **four main phases**, during which the customer was actively involved both in a constant review activity and in a field testing phase.

**“we leverage our expertise in data governance and artificial intelligence to solve any challenge.”**

## Process (what did we do so far)

The process unfolded through several key steps:

**Ignite Phase**

- Kick-off Workshops

**Elaboration Phase**

- Data Structure
- MS Azure Setup
- Solution Blueprint

**Construction Phase**

- Solution Develop
- User Testing
- Solution MVP

**Transition Phase**

- Roadmap Plan
- Sharing Workshop

1

During the initial phase, we initiated the **Ignite Phase** and established the groundwork for our solution, facilitated by a series of dedicated **Kick-off Workshops**. This phase played a pivotal role in collecting and **analyzing available data**, as well as defining expectations and creating a roadmap.

2

Following this, we transitioned to the **Elaboration Phase**. Here, we focused on both refining the data structure and configuring the **MS Azure setup** to formulate the **initial blueprint** of our solution.

3

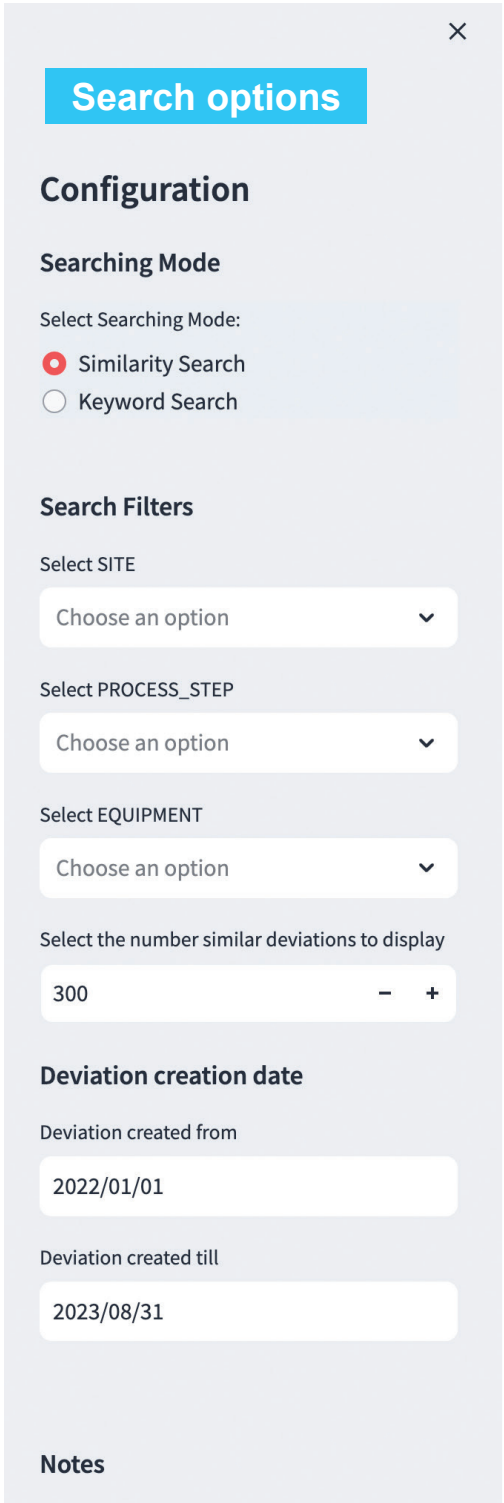
The subsequent step were dedicated to the **Construction Phase**. Here, we concurrently developed the solution while subjecting it to **constant testing** by selected users from the client. The culmination of this phase was the **Quality CoPilot MVP**, paving the way for the final phase.

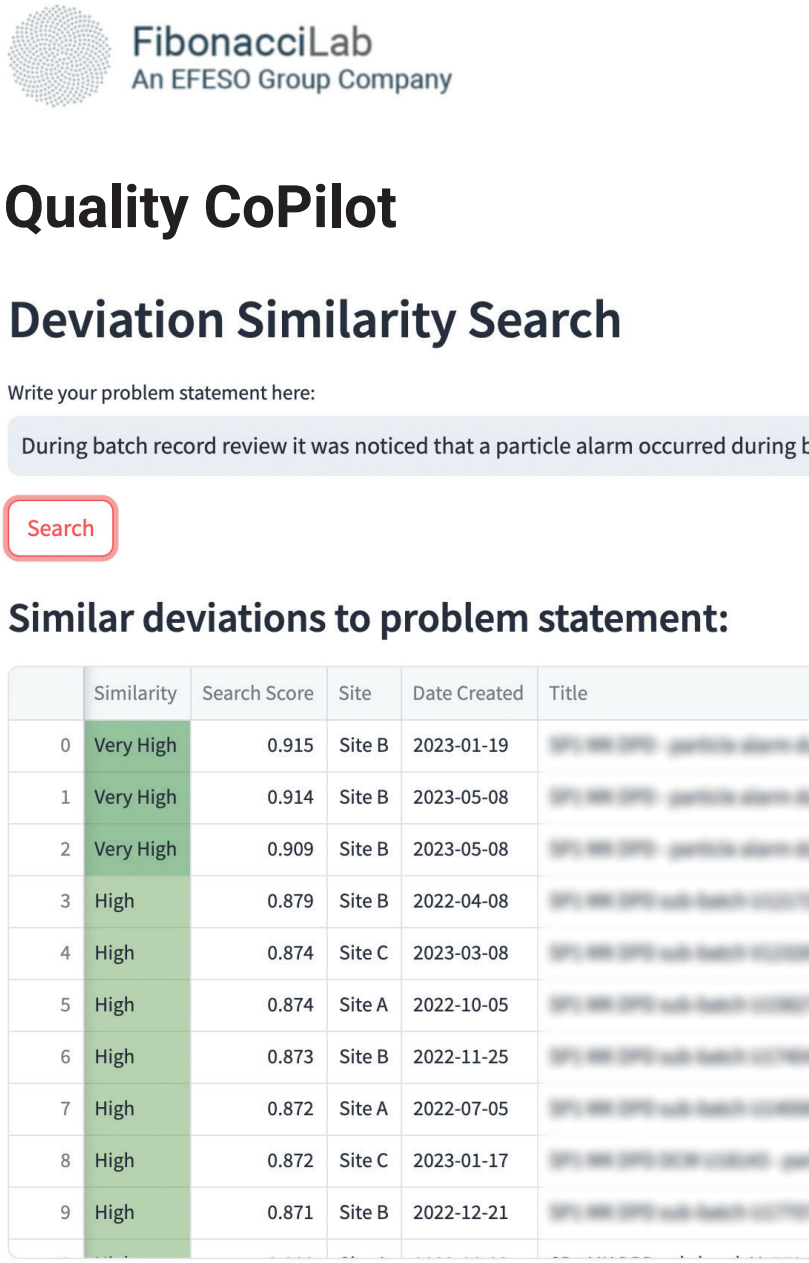
4

In the final phase, we entered the **Transition Phase**, wherein we crafted a roadmap plan and conducted the Sharing Workshop to ensure a **seamless transition** and understanding of the developed solution.

# 04. Solution Breakdown

## The Layout




| | Similarity | Search Score | Site | Date Created | Title |
|---|---|---|---|---|---|
| 0 | Very High | 0.915 | Site B | 2023-01-19 | |
| 1 | Very High | 0.914 | Site B | 2023-05-08 | |
| 2 | Very High | 0.909 | Site B | 2023-05-08 | |
| 3 | High | 0.879 | Site B | 2022-04-08 | |
| 4 | High | 0.874 | Site C | 2023-03-08 | |
| 5 | High | 0.874 | Site A | 2022-10-05 | |
| 6 | High | 0.873 | Site B | 2022-11-25 | |
| 7 | High | 0.872 | Site A | 2022-07-05 | |
| 8 | High | 0.872 | Site C | 2023-01-17 | |
| 9 | High | 0.871 | Site B | 2022-12-21 | |

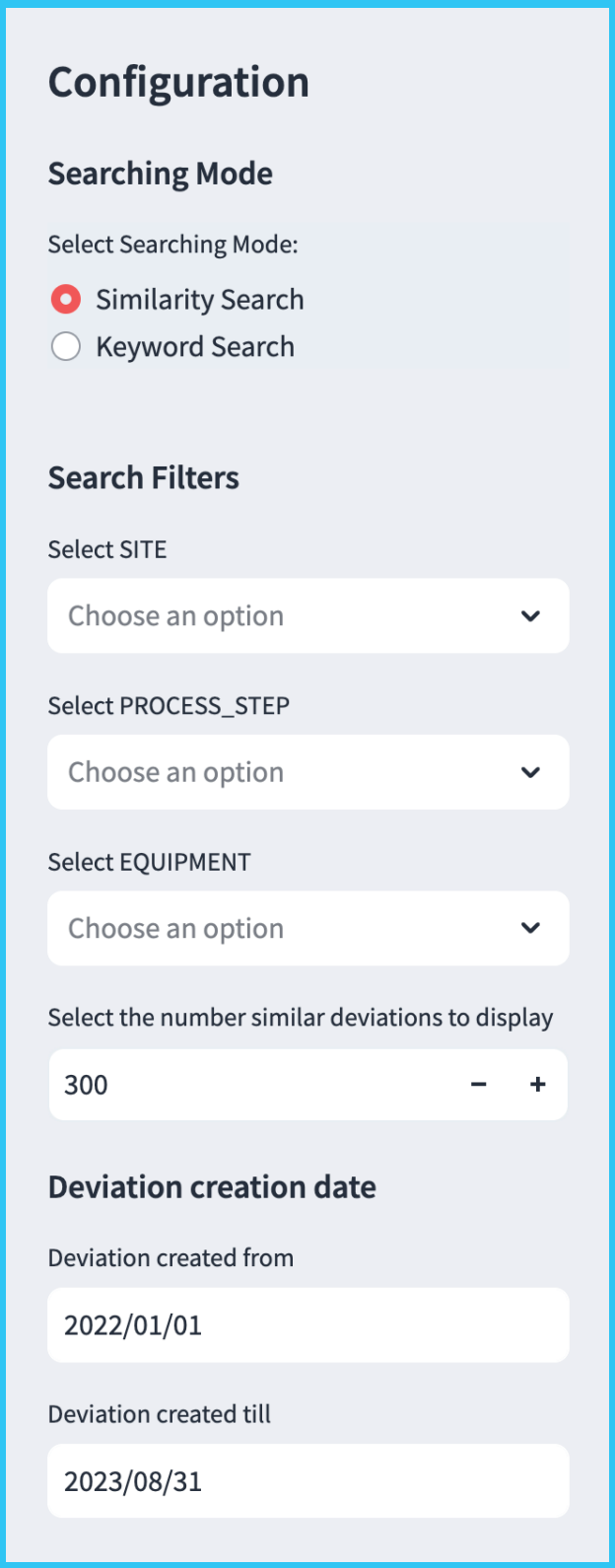
Search bar

rushing.

Results

| | Classification | Deviation Main Category | Deviation Sub-Category | Root Cause Category |
|---|---|---|---|---|
| [illegible] | Major | Production | Presence of foreign particles | Environment |
| [illegible] | nan | Production | Presence of foreign particles | nan |
| [illegible] | Major | Environment | Presence of foreign particles | Environment |
| [illegible] | Critical | Production | Contamination | Process / Method |
| [illegible] | Critical | Production | Contamination | Materials |
| [illegible] | Critical | Production | Contamination | Materials |
| [illegible] | Critical | Production | Contamination | Process / Method |
| [illegible] | Critical | Production | Contamination | Materials |
| [illegible] | Minor | Production | Presence of foreign particles | Machine |
| [illegible] | Critical | Production | Contamination | Process / Method |

# Search Option Bar




## Similarity Search

Search using AI for deviations with similar problem statement

## Keyboard Search

Similar to TrackWise, search deviation including certain keywords

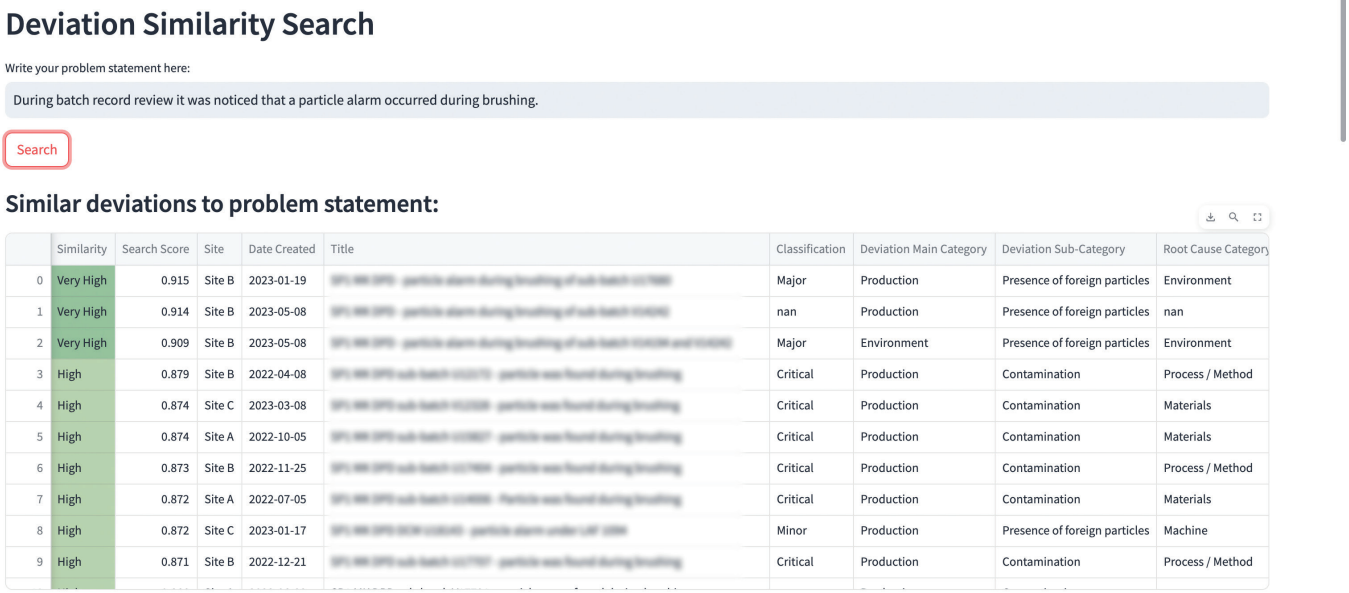
## Filters

You can filter the search result for Site, Process Step, Equipment.
You can also select the max number of results to display and it is possible to filter the results by data range.

## Performing the Search

Input in the search bar a **full problem statement** or **simple keywords** and click Search.

**Similarity** shows how similar each result is with the imput: Very High, High and Medium will be shown only. If there are **no deviations** satisfying the search criteria, no results will be shown.




| | Similarity | Search Score | Site | Date Created | Title | Classification | Deviation Main Category | Deviation Sub-Category | Root Cause Category |
|---|---|---|---|---|---|---|---|---|---|
| 0 | Very High | 0.915 | Site B | 2023-01-19 | [redacted] | Major | Production | Presence of foreign particles | Environment |
| 1 | Very High | 0.914 | Site B | 2023-05-08 | [redacted] | nan | Production | Presence of foreign particles | nan |
| 2 | Very High | 0.909 | Site B | 2023-05-08 | [redacted] | Major | Environment | Presence of foreign particles | Environment |
| 3 | High | 0.879 | Site B | 2022-04-08 | [redacted] | Critical | Production | Contamination | Process / Method |
| 4 | High | 0.874 | Site C | 2023-03-08 | [redacted] | Critical | Production | Contamination | Materials |
| 5 | High | 0.874 | Site A | 2022-10-05 | [redacted] | Critical | Production | Contamination | Materials |
| 6 | High | 0.873 | Site B | 2022-11-25 | [redacted] | Critical | Production | Contamination | Process / Method |
| 7 | High | 0.872 | Site A | 2022-07-05 | [redacted] | Critical | Production | Contamination | Materials |
| 8 | High | 0.872 | Site C | 2023-01-17 | [redacted] | Minor | Production | Presence of foreign particles | Machine |
| 9 | High | 0.871 | Site B | 2022-12-21 | [redacted] | Critical | Production | Contamination | Process / Method |

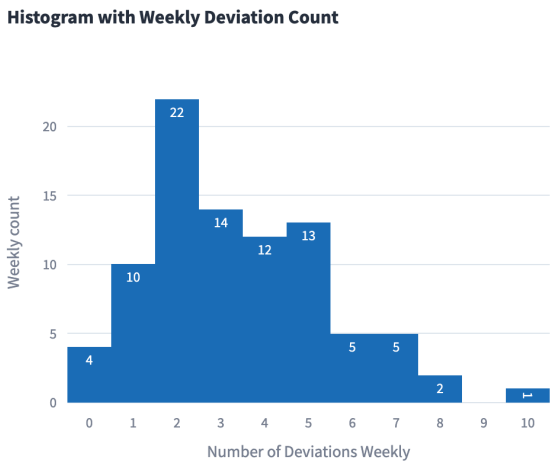
**Deviations detail are shown**

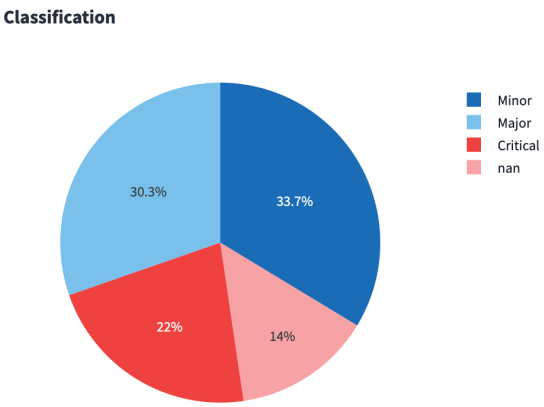
**“Having to dedicate less time and energy to the deviation research phase means having more time to analyze information and structure potential strategies or solutions, and this, in turn, translates to greater control and the ability to minimize the risk of future deviations.”**

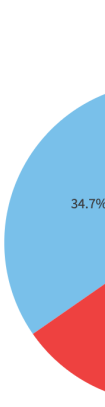
# Charts

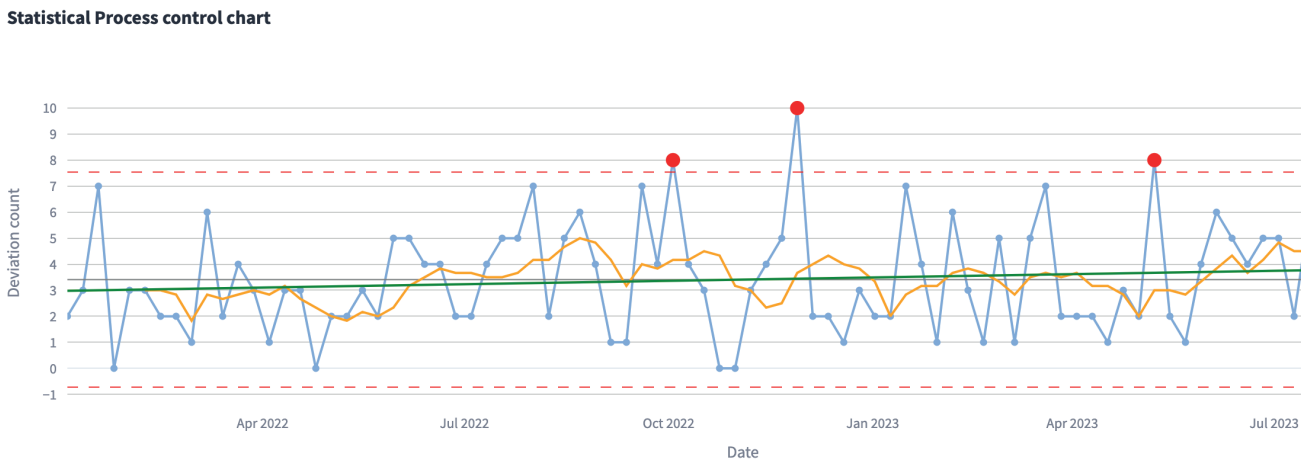
Charts include histogram **showing the deviations distribution** plus pie-charts about **type of deviation and impact** category.

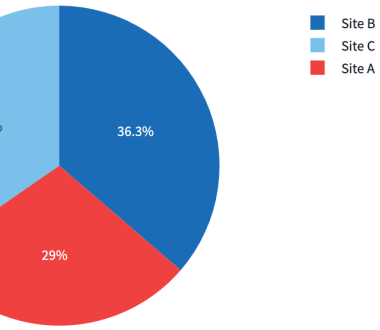
Additionally a Statistical Process Control Chart is generated. This **helps you understand trends and periods** where problems happens more frequently

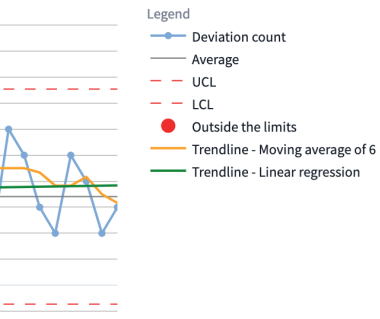





## Novelty and Recurrence of Similar Deviations

### Select granularity for the analysis

Select granularity:

- (•) Weekly
- ( ) Monthly
- ( ) Quarterly

**Total number of Similar Deviations: 300**

**Average Weekly Frequency: 3.4**

The first part of the charts section let vou decide the Frequency you want to display your results (weekly, monthly quarterly)

## Novelty Detection

It tells key info such as total numer of deviations found and their average frequency in time

### Novelty Detection: select maximum number of deviations in a given period

5 − +

### Not a Novelty Deviation

During selected time period of time there were more deviations than selected threshold of 5

Novelty is detected if the engine cannot find enough similar deviation in the set time frame. This means: «the problem has not happened before, therefore it is a novelty!»

When we say “not enough deviation”, this is defined by the threshold you can select here

# 05. Outcomes

At the Outcomes level, this experience has led to some **remarkably interesting results**, demonstrating in practice the value that the use of AI-powered digital solutions can bring to the client.

Beyond the numbers and performances outlined in the first part of this dossier, the main outcomes can be summarized as follows:

* **Improved search for deviations.**
* **Simplified definition of standard categories.**
* **Provided a foundation for evaluating an extension of the AI-based approach to other areas.**

## Review the results

The **first point** is closely linked to the specific purpose of the tool, namely, to become the o**nly reliable tool for exploring past deviations**.

Before the introduction of Quality Copilot, deviation search and analysis operations **were conducted manually through keyword-based searches**, resulting in numerous searches with various keyword combinations and highly variable search accuracy.The **AI-based approach**, on the other hand, has made **analyzing and searching for deviations faster, more efficient and more precise**, making it easier to organize deviations into groups while allowing for a higher degree visualization and control of information, thanks to the use of graphs and the possibility of extracting data.

Regarding **standardization**, the point is about to the categories in which deviations are organized. Thanks to Quality Pilot, if a person wants to create a new deviation, **they can search for similar deviations in the tool and see how it was logged before**, what categories were used, and so on. Once done, they can select the most used category and log it in the same way as previous deviations, thus avoiding creating numerous one-time categories and **facilitating not only the use of the same standards** but also any analyses conducted based on them.

The **third and final point** was an unintended but fundamental side effect of introducing Quality Pilot. The results obtained and the **benefits recorded** in the field of Production Quality have indeed prompted the client to initiate a brainstorming phase to understand **how and in which other sectors of the company a similar approach could be applied**. Among the various extensions under consideration, some of the most interesting have to do with **Global Quality**. These include, for example, CAPA search, Complaint Recurrence Search or Issues Analysis.

# Contact Us

Get in touch now
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