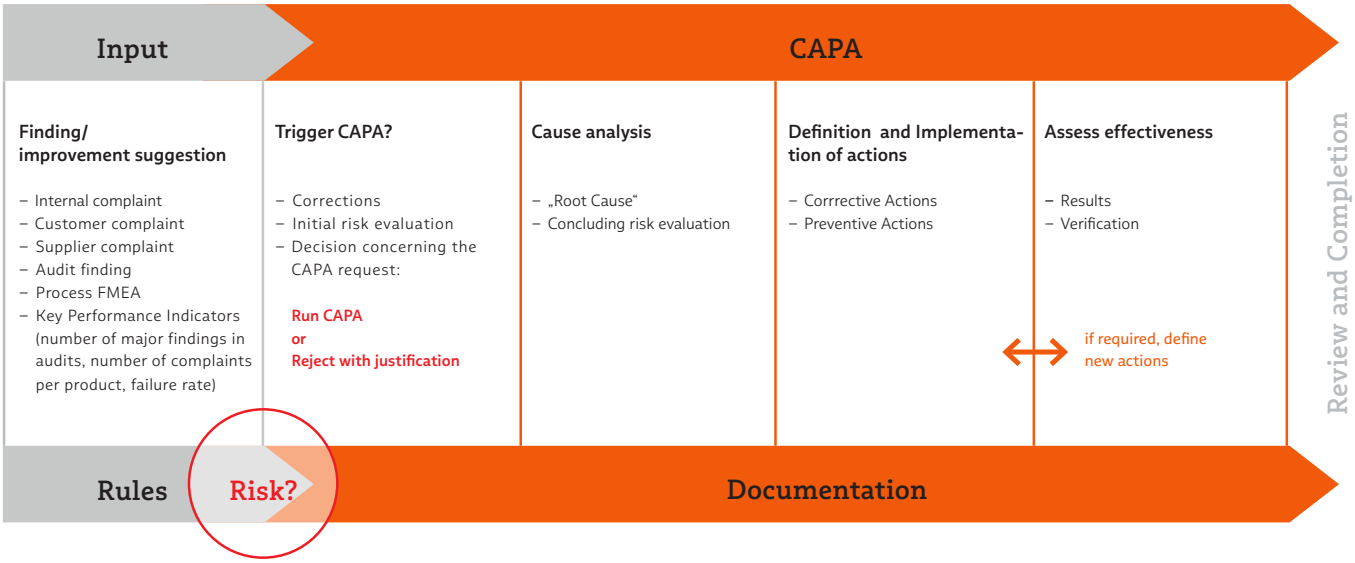
Babtec.CAPA
Successfully Improving Products and Processes

Quality and reliability are the fundamental requirements for products and processes used in the highly complex sector of medical technology. There is absolutely no room for failure when even the minutest variation can put lives at risk.

As a company involved in this extremely sensitive market, you are required to set up and implement **effective quality processes.** This is the only way you can ensure that suggested improvements, or any potential or identified variations in medical products or processes that impact on quality, can be handled in a fast and systematic manner. Having a structured method of approach for identifying the correct causes and assessing their risks is an absolute necessity. This approach makes it possible to find and implement effective **Corrective Actions** and also carry out sustainable **Preventive Actions** to avoid future mistakes. CAPA management has established itself as an **effective and strategically** applicable tool for improving the quality of products and processes.

Working in Compliance with Standards

Every medical product used anywhere in the world is subject to a multitude of country-specific regulatory requirements. Understandably enough, these also affect issues of quality management. Specific requirements are defined in standards and in legal guidelines (for example, DIN EN ISO 13485 or FDA 21 CFR 820.100). **Corrective and preventive actions** are central elements of a quality management system. Babtec's CAPA Management provides **process-oriented** support when you are designing and implementing your own CAPA process.



CAPA process

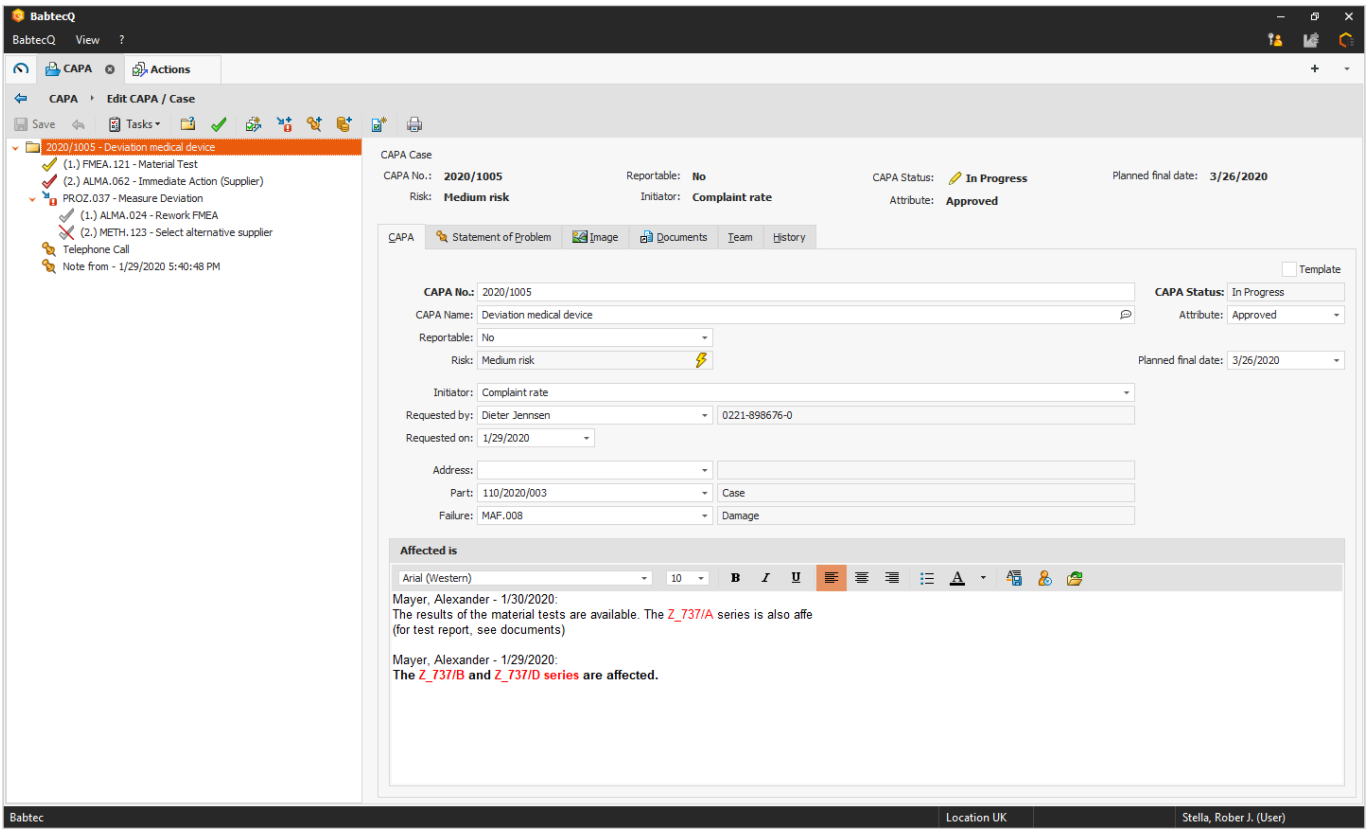
Triggering the CAPA Process

You have already analyzed your company and identified the areas and processes in which CAPA could be implemented to look out for any possible findings. The rules, events or key values that trigger a CAPA process are defined in the SOP (Standard Operation Procedures). Benefit from the advantages of an **integrated** software solution: in a single CAPA project you can reference, among other things, complaint triggers or audit findings which you can then manage in the BabtecQ modules. This means the initial event or finding can be **fully documented and tracked** and the stored information can be accessed again at the click of a button.

Assessing Risk

The foundation of a successful CAPA process is the detailed and **precise description** of the finding or the problem. Here you can benefit from the extensive free text options and access to your central failure catalog. The finding's description is then used to perform an initial risk assessment. You can then decide which CAPA project is to be involved. Depending on what type of risk is identified, the system calculates a scheduled end date for processing which is then monitored on an ongoing basis.

You can define targeted and appropriate **Immediate Actions (corrections)** to resolve problems quickly in the short term. You can quickly inform the responsible person about the new immediate actions **automatically**, for example, by using Babtec.Q.Agent to send them an e-mail.



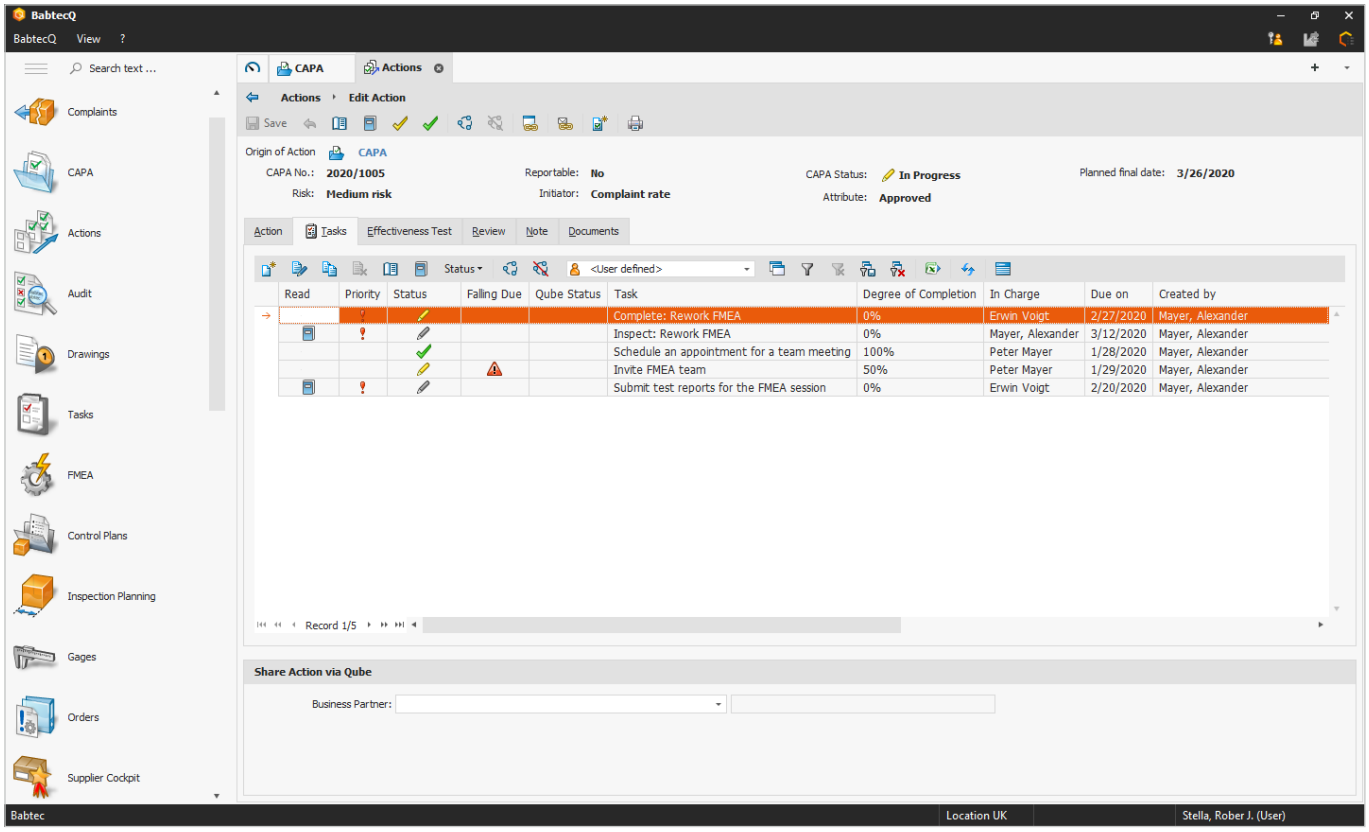
Processing and documenting a CAPA case

Monitoring Actions Centrally

The primary aims of all the actions performed as part of the CAPA process are to correct identified findings for the long term, to avoid potential quality problems and to minimize possible risks. The decisive factor here is to analyze the **causes** of the finding. It is only after you have identified the actual causes that you can work together in the team to design the appropriate **Corrective Actions** and also the **Preventive Actions**, if necessary. By using this method you can avoid similar findings in the future.

In the relevant CAPA procedure you can then write a detailed description of the proposed **suggestions** and, whilst taking into account the costs and benefits involved, assess how successful the action would be if it were to be **implemented**. Authorized users then finally decide whether the planned actions are to be performed. They also define who is to be **responsible for them, and the schedule**. To ensure a corrective action is implemented successfully and in a timely manner, you can, if necessary, define **additional tasks** such as responsibilities and deadlines. By using BabtecQ, you can always be on the safe side when monitoring the agreed corrective and preventive actions. Every action to be implemented is monitored in the **central Action Management** system (Babtec.MM). You can process any of these actions either directly in the relevant CAPA process or in Babtec.MM. Easy and quick access to your **personal tasks and schedules** is ensured by filterable to-do lists. Babtec.Q.Agent automatically informs the relevant people about new tasks and deadlines via e-mail. It can also be used in your company intranet to keep the relevant staff members informed about

the progress of the various actions. Members of staff can use Babtec.Q.Manager, a **company-wide information portal**, to work on their actions and report back results without needing direct access to BabtecQ.

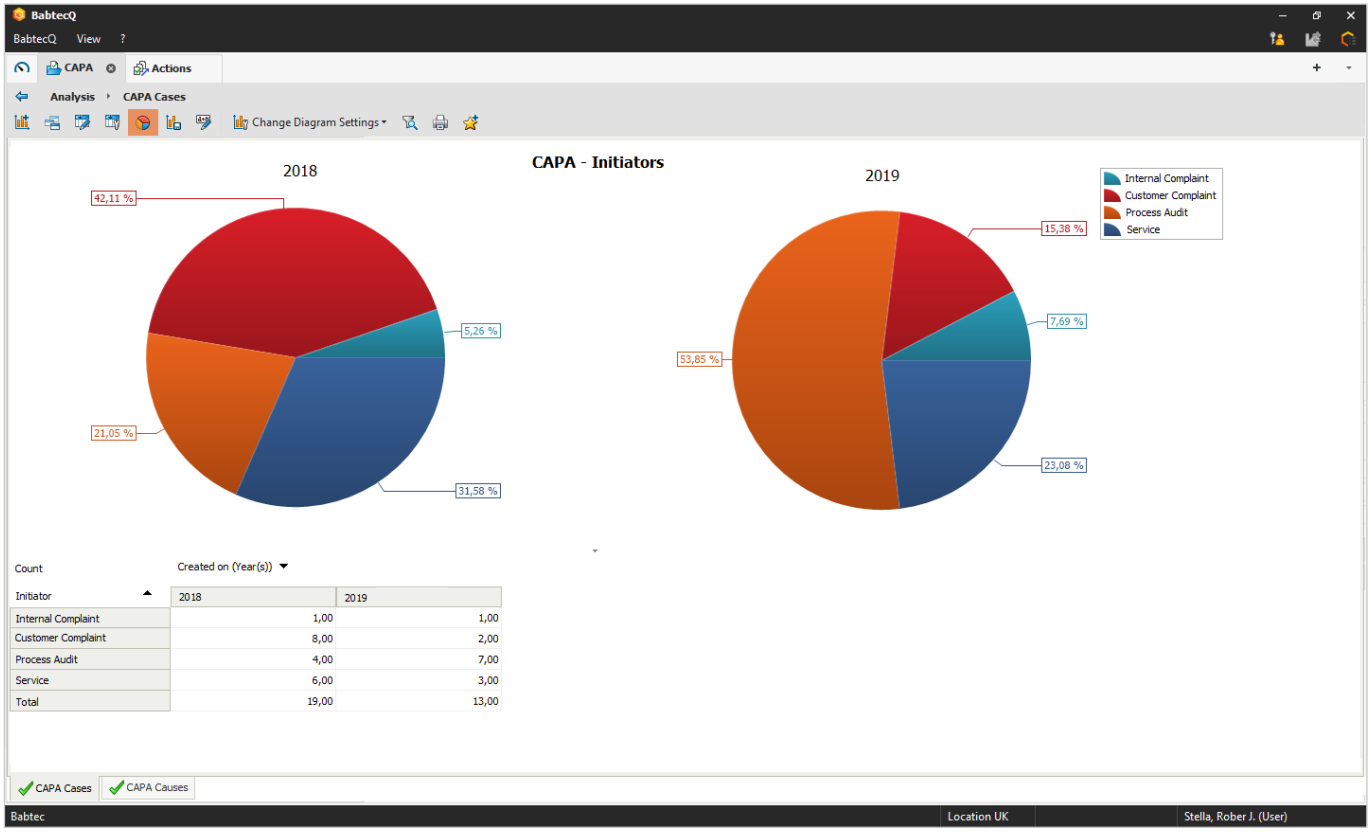


Processing and tracking of a corrective action in central Action Management

Assessing Effectiveness

Throughout the entire CAPA process, you can access the latest information and feedback from the team at any time in the CAPA module. This includes, the progress of every action, decisions that have been taken and additional documents. In the result you can review the corrective and preventive actions that have been taken and, most importantly, assess their effectiveness.

To do this, use the well-established BabtecQ **"approval by a second person"** principle in Action Management. Here, every action taken is checked by an independent person, in addition to the person responsible for it. The CAPA project can only be closed once it has been confirmed that the measures have successfully resolved the identified causes. A range of flexible graphical analysis options have been provided as **reporting tools**. You can use them for focus analysis and to document trends. Just click on a button to summarize all the details in a CAPA project into one document. You can then easily print it out or convert it into a PDF file.



Graphical analysis of focus analyses and trends

Unbroken Documentation

BabtecQ helps you maintain oversight of all your CAPA processes whilst also meeting the stringent requirements for detailed documentation and ensuring the **traceability** of every decision taken. Using flexible access rights you can map responsibility within the software and guarantee data security. In addition to this, the designated users can confirm important decisions using their **electronic signature**. Every approval and decision taken during the CAPA process is documented seamlessly and reproducibly in the **CAPA history**.

Babtec.CAPA
At a Glance

- Process-oriented software support for multi area CAPA processes with the aim of improving quality (continuous improvement process)
- Creation of CAPA requests, documentation of risk evaluation and approvals
- You can define the CAPA team and control access rights on an individual basis
- Workflow support thanks to freely definable tasks for processing CAPA cases, including schedules and responsibilities
- You can process and monitor immediate actions (corrections) from the central Action Management system (Babtec.MM)
- You can document cause analyses
- Definition of suggested corrective actions or preventive actions and also approve their implementation
- You can process and monitor approved corrective actions and preventive actions in the central Action Management system (Babtec.MM), including schedule monitoring
- Process actions on the Web (Babtec.Q.Manager, Babtec.MM)
- Extensive note functions and documentation options (including options for the products concerned and problem description)
- You can save additional external documents and files directly for the CAPA case
- Transparent status and schedule tracking, including flexible definition of processing status
- Other freely definable fields for documenting company-specific data in the CAPA case
- Electronic signatures for decisions and approvals
- Traceable CAPA history for unbroken logging of decisions
- You can create a comprehensive CAPA report quickly and conveniently
- Design company-specific reports and forms with the report designer (Babtec.RPT)
- Powerful management statistics and key performance indicators
  - > CAPA overviews (frequency and risks)
  - > Trends and focus analyses for products, findings and causes
  - > Effectiveness of actions
- Integration in BabtecQ (including Babtec.MM, Babtec.AM, Babtec.REK, Babtec.AUDIT and Babtec.FMEA) for central monitoring of actions and documentation by the CAPA initiator
- Automatic information distribution: communication and reporting using Babtec.Q.Agent (for example, e-mail messaging for the responsible editor in the case of new actions)

Let Us Advise You

Individual Consulting

We would be happy to introduce you to the module in a personal appointment in which we can show you how our solution can optimize your processes. In doing so, we record the current status and explain the further procedure.

Make an appointment

Our Solutions

Are you interested in further modules that support your processes even better? Just have a look around on our website.

To the website

Overview of Our Portfolio

Would you like to get an overview of our entire range of products? In the current overview we present you our software solutions and services.

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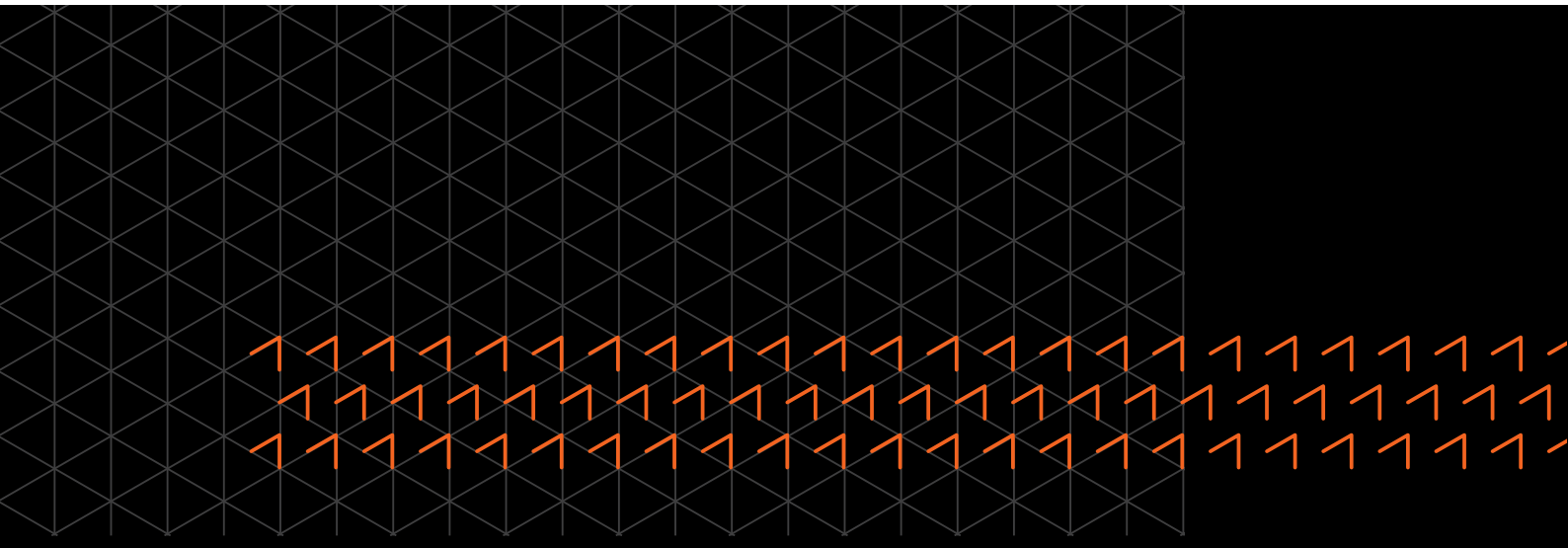

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The Software for Quality