

# CAPA MANAGEMENT

---



*“Whoever strives for excellence in quality will win orders and gain an enduring competitive advantage. In order to achieve this, quality needs to be lived – in communication, managerial responsibility, project management, product development, validation, production, and maintenance.”*

*(StingOrg)*

## We change perspectives and make CAPA an efficient problem-solving tool for your employees!

An audit is approaching, and there is the risk that your notified body will discover a major finding. You have just finished one audit, and were only able to pass after investing a disproportionate amount of resources. You must ensure that you retain certification, and cannot continue jeopardising sales of your product any longer. We will solve the problem with you and show you how to avoid such situations in the future!

### **In our experience, there are three major problems in CAPA management.**

- 1 Time:** Often, CAPAs are planned incorrectly, resulting in the CAPA system encountering timing difficulties or even spiralling out of control.
- 2 Culture:** This area is rarely afforded the required attention. Processing CAPAs is perceived as a punishment by owners, and not as a problem-solving tool to improve product quality.
- 3 Evidence and documentation:** Insufficient care, attention to detail and specialist terminology is used in formulation and documentation.

Involve us in your CAPA management! We will assume interim control of your CAPA team or provide experts to advise and support your CAPA management.

### **What we do for you**

- CAPA processing devours valuable time in the preparation before and the follow-up after an audit. We step in at the technical preparation and implementation stage, offering the right support from the moment you need it.
- We look after the organisation, inspection and reviewing of CAPAs, giving you more time for higher-level tasks.

- We have the requisite experience and methodical expertise, having defended CAPA management in various audits and independently handled around 500 CAPAs. All this expertise is at your disposal!

### **Benefits for you**

- By using an appropriate CAPA system, you can outstrip your competition in terms of quality, earning you more turnover in the long term. After all, product quality is of paramount importance in the health sector.
- We will support you in changing the cultural perception of CAPA management in your company, leading your employees to regard it as an effective problem-solving tool. We have the perseverance and endurance to achieve this.

Rely on us to solve the issues surrounding your CAPA system – with us at your side, you can use this decisive factor to add value through quality.



## Overdue CAPAs reduced by 80%

An illustrative project overview from our practical experience

### Project Goals

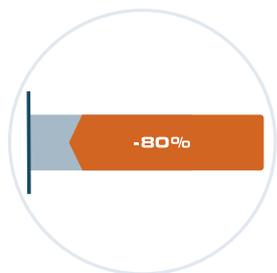
- ▲ Reduction of overdue CAPAs to 5% of all open CAPAs
- ▲ Reduction of long-running CAPAs by 30%
- ▲ Product quality improvements
- ▲ No non-compliance in external audits and inspections
- ▲ Changes to decision-making processes

### Project Content

- ▲ Analysis of existing problems
- ▲ Creation of a quality team responsible for coaching and document reviews
- ▲ Creation of a team of dedicated problem solvers
- ▲ Induction, training and coaching, as well as management through daily standing meetings
- ▲ Transparency through regular reporting
- ▲ Process and change management

## Results

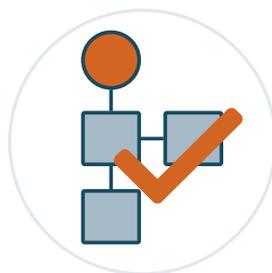
Our project together resulted in considerable improvements:



Reduction in overdue CAPAs of 80%



No non-compliance in internal and external audits



Procedure developed towards process-orientated decision-making



Changes to the corporate culture

## Project Flow: Reduction in overdue CAPAs by 80% in x-ray system component production



### 1. Measurement

- ▲ Establish uniform reporting and record the situation
  - Introduce weekly reports to middle and senior management
  - Weekly meetings to discuss the situation and establish immediate measures



### 2. Analysis

- ▲ Analyse and track problems
  - Analyse resource requirements based on typical project progression
  - Log the most common sources of malfunction
  - Evaluate problem-defining and problem-solving expertise
  - Assume interim control
  - Present results with measures



### 3. Implementation

- ▲ Implementation of short-term and mid-term measures for problem-solving and standardisation
  - Identify dedicated CAPA owners and create job description, establish a team
  - Identify dedicated inspectors in Q&R department and establish a team
  - Bring experts, quality professionals and owners together



### 4. Improvement

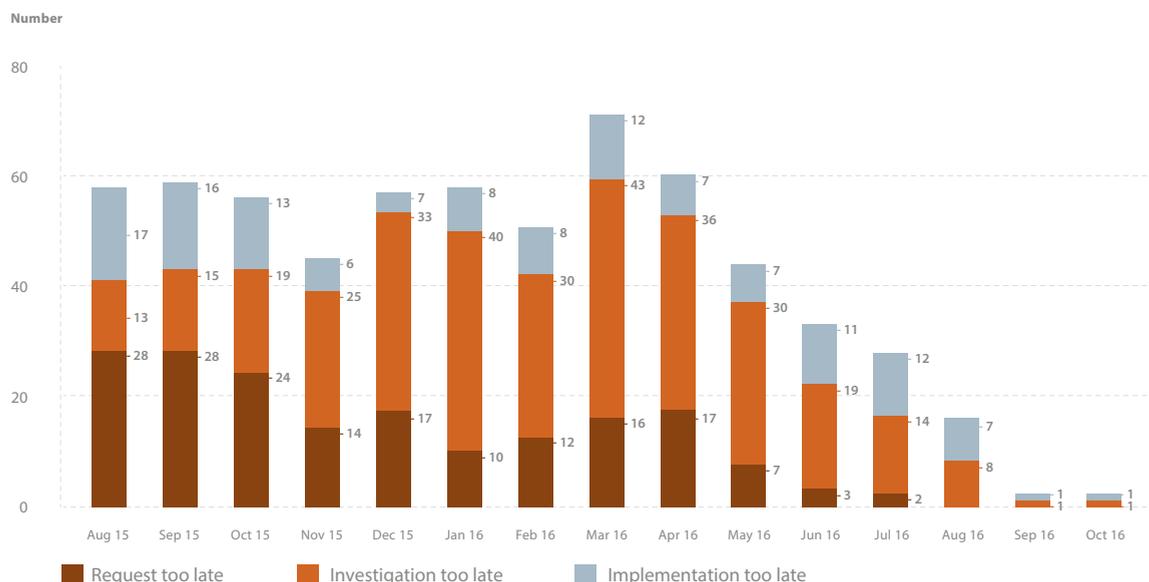
- ▲ Constant tracking of improvements and adherence to new standard
  - Introduce process changes – the decision lies in the process, not with management
  - Daily meetings with main stakeholders
  - Leadership of team meetings – intervention only when required
  - Maintain weekly reporting



### 5. Handover and Monitoring

- ▲ Handover of activities
  - Stabilisation of the situation
  - Training to the new standard
  - Quality improvement in decision process
  - Acceleration of decisions
  - Handover of direction to internal successors

## Number of Overdue CAPAs





**StingOrg GmbH**  
Robert-Hooke-Str. 6  
28359 Bremen  
Germany

Phone: +49 421 43480770  
Fax: +49 421 43480771  
[stingorg@stingorg.de](mailto:stingorg@stingorg.de)  
[www.stingorg.de](http://www.stingorg.de)

QUALITY · ENGINEERING  
PROCESS OPTIMISATION