COSMO Incident Management

Part of COSMO Quality Management Pack



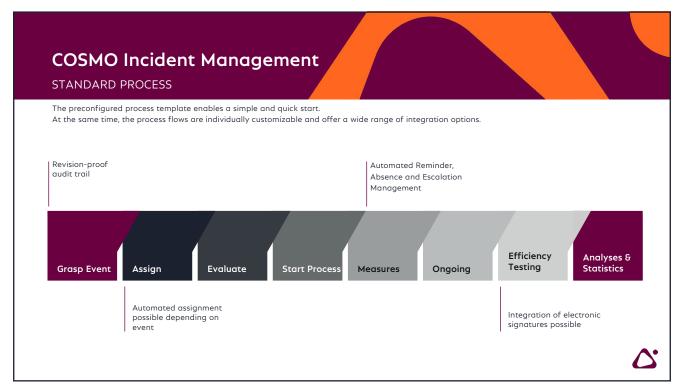


Diagram of COSMO Incident Management core process

COSMO Incident Management

To a certain degree, quality management for every company also includes some type of incident management. Parts of this are to be found in complaints processing, change management, or a CAPA process. The primary focus is on centralized entry, processing, and documentation of quality-relevant events, to avoid future incidents and ensure continuous improvement of the internal service processes. This method ensures that you are well equipped to deal with upcoming audits and avoids defects that are often identified as aberrations during official inspections.

And this is precisely where COSMO Incident Management comes into play as a central component in the COSMO Quality Management Pack. The solution has been designed to allow completely discrete, platform-independent operation. At the same time, it can

be enhanced with more processes and can also be integrated into the existing system landscape. Integration in Microsoft 365, SharePoint Online, and Microsoft Teams is already part of the standard software. It is also easy to add further Microsoft Dynamics products, or systems from other providers.

The low-code/no-code concept makes the solution flexible in process terms and all areas can be configured. This allows forms, workflows, views, or reports to be redesigned and extended, according to your own requirements.

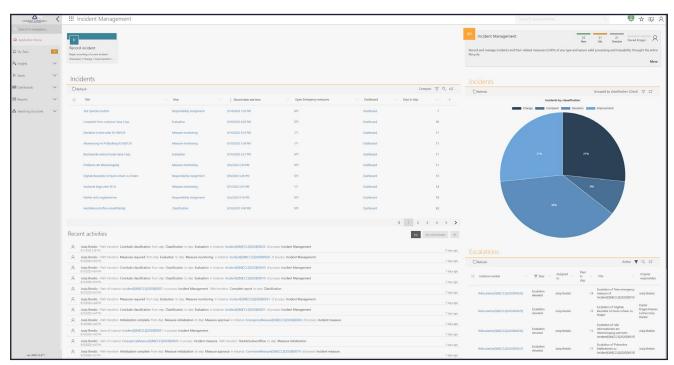
To help you make a quick start, COSMO Incident Management contains comprehensive standards such as clear dashboards, online help or reports for critical key figures.

Highlights

- Quick and easy entry of quality-relevant events/incidents
- · End-to-end management and checking of measures
- · End-to-end monitoring of quality tasks
- · Simple incident reporting and full process transparency for measures
- Easy integration into modern applications—e.g., Microsoft Teams, Microsoft 365, Microsoft Dynamics 365 Business Central
- · Easy-to-use notification system with functions for monitoring open tasks, escalations, or delegations
- · Suitable for use in validated environments—whether on-premise (in-house) or as a cloud solution
- · Preconfigured user management

The benefits for you

- You always have an overview of your incidents and the measures associated with these.
- · You no longer miss deadlines and appointments.
- You gather all the information from various sources in one transaction, thereby ensuring seamless documentation.
- You enable straightforward audits thanks to complete process transparency and a clear audit trail in the system with no gaps.
- Quick and easy to get started with the preconfigured process template, reducing the training and implementation effort required.
- You remain independent of complex systems like ERP or CRM, whilst retaining flexibility with versatile integration options.

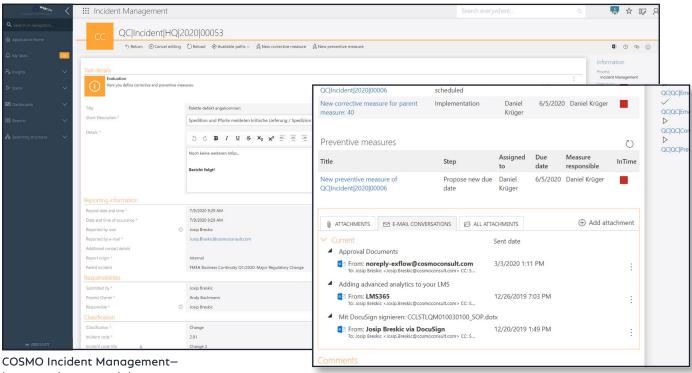


COSMO Incident Management landing page and dashboard

Further highlights and features

- Incident and Measure Management in accordance with ISO 9001, 21 CFR 820.100, ISO 13485
- Entry of incidents related to customers or suppliers, as well as internal incidents—for example, as a suggestion for improvement or a change with user-defined details/specifications.
- Integrated management and tracking of CAPA measures
- Any number of error details, also with any number of instant and remedial measures
- Transaction-related inclusion of attachments, such as PDFs, photos, scans, videos, and screenshots, including the link to preceding and subsequent transactions
- Escalation management for tracing status, measures, and deadlines

- Integrated reports and dashboards—others can be configured
- Inbox monitoring and automatic starting of the Incident Management process
- Archiving of all transactions, all communication, and the audit trail (e-mails, scans, history of transactions in the system, tasks, etc.)
- Optional connection of external portals for data exchange with suppliers/customers
- COSMO Quality Management Pack is completely integrated in the COSMO industry solution for process manufacturing, life sciences, and medical technology.



integrated event and document management

Industry Focus

- · Medical technology
- · Pharmaceutical industry
- · Food and dietary supplement industry
- Cosmetics
- · Paint and coating industry
- · Chemical industry

Additional add-ons

COSMO CONSULT provides a wide range of additional modules for quality management, as well as solutions from the ERP and CRM environment that may also be of interest to you:

- COSMO Document Control (QM document management)
- · COSMO Workflow and Form Management
- Microsoft Dynamics 365 Business Central (ERP) for process manufacturing / medical technology / life sciences industry
- · COSMO Unique Device Identification (UDI)
- · Microsoft Dynamics 365 Customer Engagement (CRM)
- · Data Science and Data Analytics

Austria · Chile · China · Columbia · Ecuador · France · Germany · Hungary Mexico · Panama · Peru · Romania · Spain · Sweden · Switzerland

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