



# COSMO Regulatory Affairs

## based on Microsoft Dynamics 365 Business Central



## Improving Efficiencies And Compliance

Within manufacturing industry worldwide, there is immense pressure to streamline and become more efficient across businesses with clearly demonstrated cost justifications. As an enterprise resource planning (ERP) system, Microsoft Dynamics 365 Business Central automates and simplifies existing processes. There is a need for an ERP system that would readily generate data in an acceptable format to support all internal investigation and reporting functions. In consequence, organizations require a system to improve approval processes for their departments, so that relevant data can be accessed directly.

Microsoft Dynamics 365 Business Central has one of the largest installed user bases of any ERP system, serving over 150,000 companies. It is important for these organizations to provide accountability throughout its business processes—approval of business transactions via a pre-defined process forms one part of this. Workflows in Microsoft Dynamics 365 Business Central enable you to define the approval processes for your organization so that business transactions requiring an approval can be completed with the appropriate authority.

## Approval Workflow Management

You can devise simple or complex rules, to suit your organization's requirements, which form part of your overall business flow. The workflow engine has been designed with flexibility and performance as the key cornerstones of its architecture.

One of the prime features of Microsoft is to enable you to define simple or complex approval workflows without resorting to writing programming code. You can define

these workflows by deciding what conditions should be met before approvals are required.

An approval workflow automatically routes approval requests, assigns approvers and tracks their progress, and sends reminders and notifications when needed. The activity in a workflow can be monitored at record, and the history of approvals in a workflow run is maintained.

Approval Entries Log   Work Date: 12.04.2021							
Search Approve Reject Delegate Record Comments Open in Excel							
Status	To Approve	Details	Sender ID	Approver ID	Date-Time Sent for Approval	Approval Type	
Approved	FA-Komponente: Released.101009.10000.40000	Prod. Order Component: Insert Released Prod. Order No. 101009 Prod. Orde...	NTADAJEWSKI	ALANG	27.09.2021 10:27	Approver	
Rejected	FA-Komponente: Released.101009.10000.20000	Prod. Order Component: Released Prod. Order No. 101009 Prod. Order Line ...	NTADAJEWSKI	ALANG	27.09.2021 10:26	Approver	
Rejected	FA-Komponente: Released.101009.10000.30000	Prod. Order Component: Insert Released Prod. Order No. 101009 Prod. Orde...	NTADAJEWSKI	ADMIN	27.09.2021 10:25	Approver	
Canceled	FA-Komponente: Released.101009.10000.10000	Prod. Order Component: Released Prod. Order No. 101009 Prod. Order Line ...	NTADAJEWSKI	ALANG	27.09.2021 10:25	Approver	
Canceled	Benutzergruppenmitglied: D365 ACCOUNTANTS,...	User Group Member: Delete SRUNOW D365 ACCOUNTANTS CRONUS DE	NTADAJEWSKI	THARNACK	27.09.2021 10:24	Workflow User Group	
Approved	Benutzergruppenmitglied: D365 ACCOUNTANTS,...	User Group Member: Delete SRUNOW D365 ACCOUNTANTS CRONUS DE	NTADAJEWSKI	MHERING	27.09.2021 10:24	Workflow User Group	
Approved	Benutzergruppenmitglied: D365 ACCOUNTANTS,...	User Group Member: Delete SRUNOW D365 ACCOUNTANTS CRONUS DE	NTADAJEWSKI	ALANG	27.09.2021 10:24	Workflow User Group	
Approved	Benutzergruppenmitglied: D365 BUS PREMIUM,6...	User Group Member: Insert ISTENDER D365 BUS PREMIUM CRONUS DE	ALANG	ADMIN	27.09.2021 10:13	Approver	
Approved	FA-Komponente: Planned.101002.10000.90000	Prod. Order Component: Planned Prod. Order No. 101002 Prod. Order Line ...	MHERING	ADMIN	27.09.2021 10:07	Approver	
Approved	FA-Komponente: Planned.101002.10000.140000	Prod. Order Component: Insert Planned Prod. Order No. 101002 Prod. Order ...	MHERING	ADMIN	27.09.2021 10:07	Approver	
Approved	FA-Komponente: Planned.101002.10000.130000	Prod. Order Component: Insert Planned Prod. Order No. 101002 Prod. Order ...	MHERING	ADMIN	27.09.2021 10:06	Approver	
Approved	FA-Komponente: Simulated.1232332.10000.10000	Prod. Order Component: Simulated Prod. Order No. 1232332 Prod. Order Lin...	ALANG	ADMIN	27.09.2021 10:02	Approver	
Approved	Benutzer Einrichtung: ALANG	User Setup: ALANG: CCS RA Reset Password changed from No to Yes	ALANG	ADMIN	27.09.2021 09:57	Approver	
Rejected	Benutzergruppenmitglied: D365 ACCOUNTANTS,...	User Group Member: Insert ALANG D365 ACCOUNTANTS CRONUS DE	NBRAGA	ADMIN	27.09.2021 09:50	Approver	
Approved	Artikel Buch.-Blattname: ARTIKEL.STANDARD	Item Journal Batch: Post ARTIKEL STANDARD Item	NBRAGA	ADMIN	27.09.2021 09:50	Approver	
Approved	FA-Arbeitsgang: Released.101007.10000.1100.20	Prod. Order Routing Line: Delete Released Prod. Order No. 101007 Routing R...	NBRAGA	NTADAJEWSKI	27.09.2021 09:44	Approver	
Approved	Benutzer Einrichtung: ADMIN	User Setup: ADMIN: CCS RA Reset Password changed from No to Yes	ADMIN	ADMIN	24.09.2021 11:48	Approver	

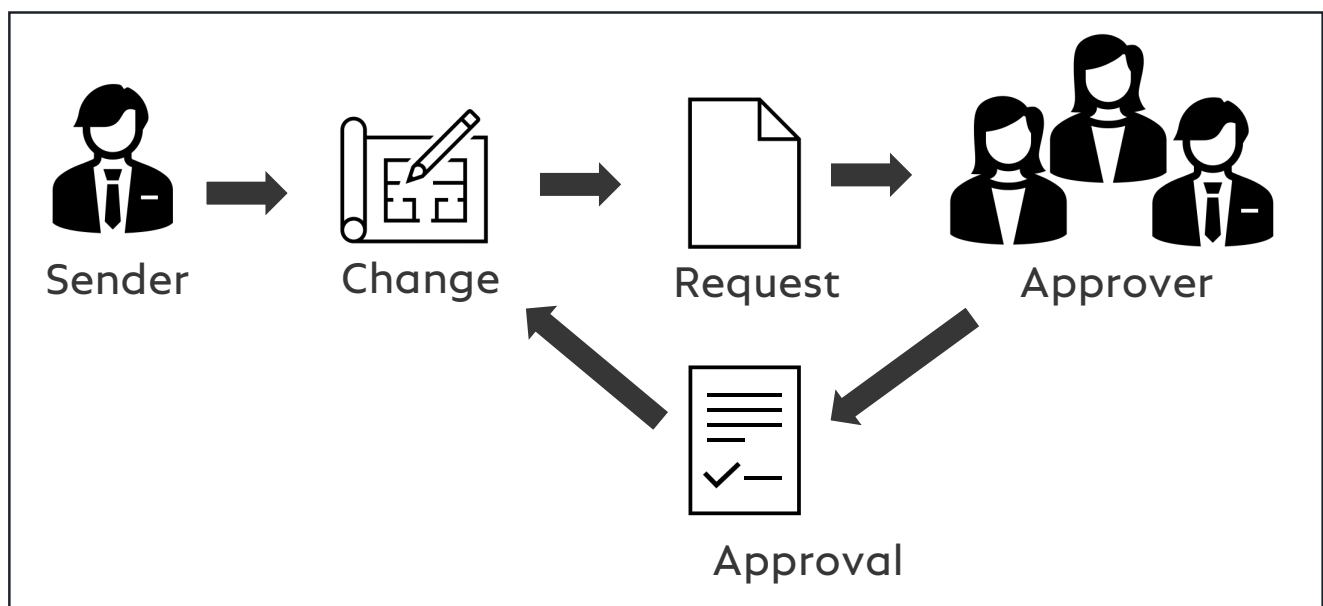
Approval log

You can add configurable workflows and enable these for individual processes. **COSMO Regulatory Affairs** includes a number of preconfigured workflow templates that you can copy to create workflows. Each workflow that you add is unique and can be individualized as needed.

When enabled, approval workflows react in some scenarios automatically or requires users for approval to continue processing. Automatic runs are activated based on triggering events, like modifying records in production order components.

The workflows are designed to create requests for approval of a new value while keeping the old value in case the request is not approved. The new value will not be implemented until the last request is approved.

Workflows in Microsoft Dynamics 365 Business Central let you route requests to one or more people for their approval. Based on how the workflow is set up, the appropriate approver is then notified that the record requires their approval.



The route taken from the initial triggering of the workflow can vary depending on the nature of the approval.

- Approval by specific user
- Approval by multiple user of a group (e.g., 4-eyes-approval)
- Approval by sequential approval chain triggered by user (e.g., request must be approved by the first approver before the request is sent on to the next approver. If the request is not approved by the first approver, the request will never go to the next approver.)

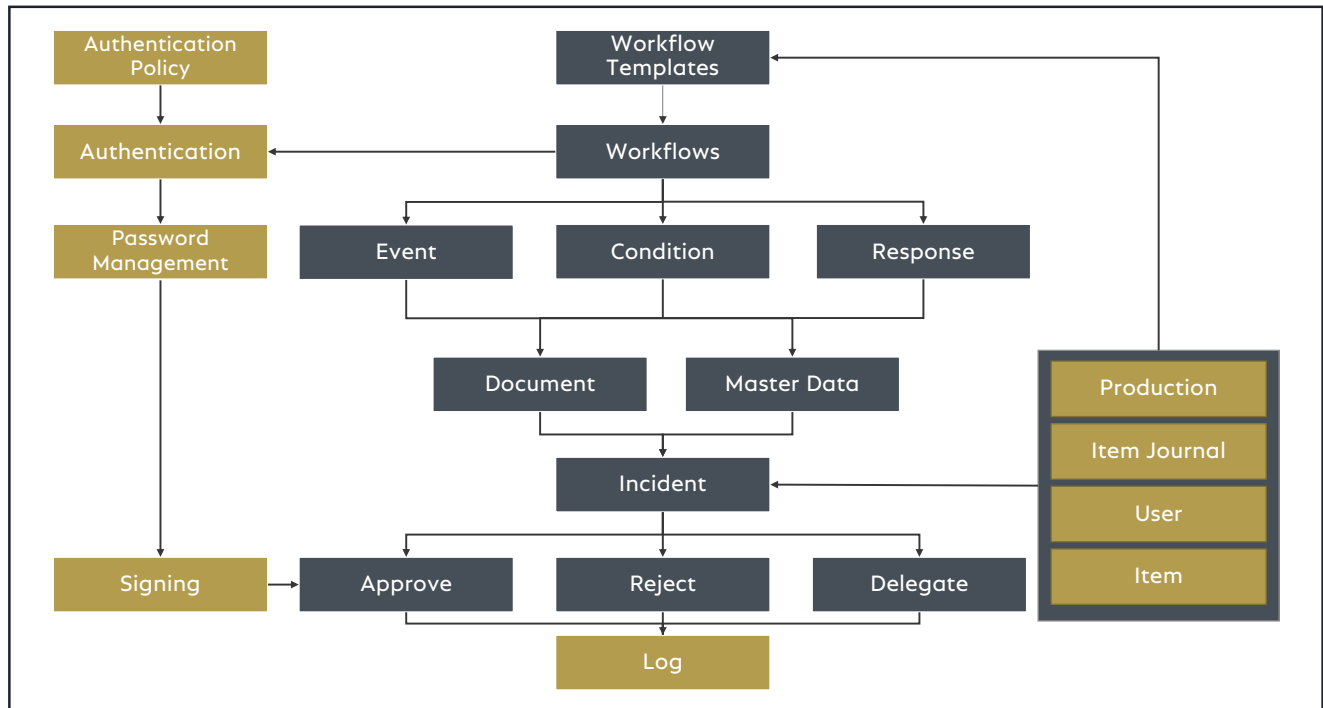
If configured, automatic reminders are sent to approval workflow users who fail to meet deadlines.

When the workflow is complete, the history of that run can be reviewed. The Approval Entries Log in **COSMO Regulatory Affairs** contains a record of all approval requests that have been triggered by a policy with an approval workflow action. This log provides details (status, approvers, decisions, comments, timestamp) at all times for a given record that is submitted for approval.

## Authentication

Unlike paper, digital business processes are executed immediately and workflow rules make it impossible to skip steps and omit signatures. Workflows in Cosmo Regulatory Affairs are designed to collect signatures.

User authentication plays a crucial role in signing transactions. It is the layer of security that is put in place to associate a signature to the approval person, thereby reducing the risk of repudiation.



COSMO Regulatory Affairs uses its own password-based authentication instead of Windows credentials. An approval user needs to create a unique and robust

password to ensure no one else can sign an approval request with their identity.

Entry No.	User ID	Log Type	Attempt	Details	Entry Date-Time ↓	Approval Entry Text
129	NTADAJEWSKI	Authenticated	0	Prod. Order Component: Planned Prod. Ord...	9/27/2021 10:49 AM	Approval Entry: 1585
128	NTADAJEWSKI	Authenticated	0	Prod. Order Component: Planned Prod. Ord...	9/27/2021 10:47 AM	Approval Entry: 1584
127	NTADAJEWSKI	Authenticated	0	Prod. Order Component: Insert Planned Pro...	9/27/2021 10:44 AM	Approval Entry: 1582
126	MHERING	Authenticated	0	User Group Member: Delete SRUNOW D36...	9/27/2021 10:30 AM	Approval Entry: 1576
125	MHERING	New Password	0	Nothing to approve	9/27/2021 10:30 AM	
124	MHERING	Authentication failed	2	User Group Member: Delete SRUNOW D36...	9/27/2021 10:30 AM	Approval Entry: 1576
123	MHERING	Authentication failed	1	User Group Member: Delete SRUNOW D36...	9/27/2021 10:29 AM	Approval Entry: 1576
122	ALANG	Time Based Authentication	0	User Group Member: Delete SRUNOW D36...	9/27/2021 10:29 AM	Approval Entry: 1575
121	ALANG	Authenticated	0	Prod. Order Component: Insert Released Pr...	9/27/2021 10:28 AM	Approval Entry: 1581
120	ALANG	Authentication failed	1	Prod. Order Component: Insert Released Pr...	9/27/2021 10:28 AM	Approval Entry: 1581
119	ADMIN	Authenticated	0	User Group Member: Insert ISTENDER D36S...	9/27/2021 10:14 AM	Approval Entry: 1574
118	ALANG	Time Based Authentication	0	Prod. Order Component: Insert Planned Pro...	9/27/2021 10:09 AM	Approval Entry: 1572
117	ALANG	Time Based Authentication	0	Prod. Order Component: Insert Planned Pro...	9/27/2021 10:09 AM	Approval Entry: 1571
116	ALANG	Authenticated	0	Prod. Order Component: Planned Prod. Ord...	9/27/2021 10:08 AM	Approval Entry: 1573
115	ADMIN	Authenticated	0	Prod. Order Component: Simulated Prod. O...	9/27/2021 10:05 AM	Approval Entry: 1570
114	ALANG	Time Based Authentication	0		9/27/2021 10:00 AM	Approval Entry: 1566
113	ALANG	Authenticated	0		9/27/2021 10:00 AM	Approval Entry: 1567

Approval log

When a user enters a new password, the password is validated against the authentication policy. The configurable policy includes:

- password complexity rules that indicate the minimum of each character type that a password must contain
- minimum password length
- password expiry to enforce users to change their passwords frequently
- minimum iterations before reuse of a password (password change history) dictates when a previous password is available for reuse
- number of invalid attempts that the system can allow before locking the user

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## Business Challenge of Good Manufacturing Practices

Intense regulatory scrutiny means an informatics solution must satisfy both internal and external auditors, including the flexibility to support widely varying review and approval workflows for static data (e.g., product specs) and dynamic data (e.g., test results, batch disposition). For instance, an ERP system deployed at a pharmaceutical company would have to be validated

and satisfy stringent MHRA, good automated manufacturing practice (GMP), and FDA requirements.

Audit trail reviews are not limited to data which influence the product quality directly. History of approval workflows need to ensure reviews processed approvals and in particular, the authentication of each approver.

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## Conclusion

Whatever industry you're in, you can benefit from implementing an approval management process. Approvals are a core component of workflows and a cornerstone of effective process management.

Workflows enhanced by **COSMO Regulatory Affairs** help you auto-mate your critical business processes, making them both more consistent and more efficient.

### Benefits

- Enable efficient review and approval of only required aspects as defined by your business
- Approval workflows as seamless part of operations
- Maintain a proper authority structure
- Contextualize approvals and streamline communication with approval notes in your workflows
- Authentication to establish the necessary controls to prevent fraud, error, and theft
- Easily accessible data, ease of entry, increased processing time, task automation

### Additional Applications

COSMO CONSULT also offers the following products to support critical process within Microsoft Dynamics 365 Business Central and to meet regulatory requirements:

- COSMO Quality Assurance
- COSMO Process Manufacturing
- COSMO Vendor Rating
- COSMO Quality Management Pack
- and more

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Mexico • Panama • Peru • Romania • Spain • Sweden • Switzerland

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