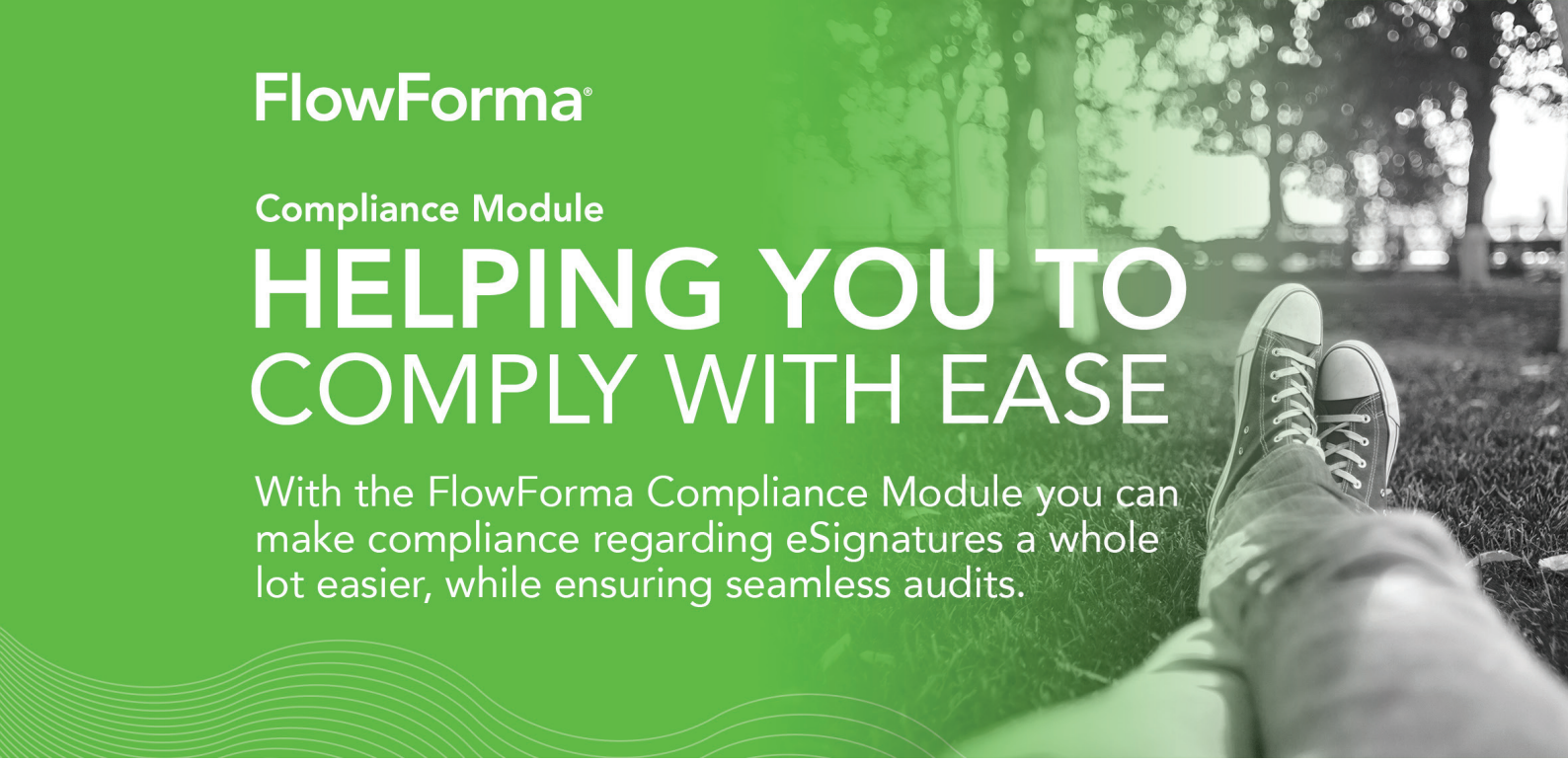
FlowForma®

Compliance Module

HELPING YOU TO COMPLY WITH EASE



With the FlowForma Compliance Module you can make compliance regarding eSignatures a whole lot easier, while ensuring seamless audits.

An award-winning Office 365® App, FlowForma® Process Automation addresses your digital transformation needs by empowering business users to automate business processes with speed and flexibility, no matter what the complexity.

Sitting on the SharePoint® platform, the FlowForma Process Automation tool incorporates forms, workflow, document generation and decision making all in one place.

A proven no-code, logic only approach enables business users and Heads of Departments to quickly implement any process online from employee onboarding to insurance policy renewals and product innovation, increasing organizational efficiency and productivity, while driving positive customer experiences.

The Compliance Module adds new functionality to the fundamental FlowForma Process Automation product features to enable advanced auditing. The Compliance Module is easily integrated into the FlowForma product with customers being able to easily add this new functionality to their existing processes.

How it Works

The Compliance Module is a set of features built on top of the FlowForma Process Automation tool. These features provide advanced functionality required within regulated industries. When combined with the forms and workflow functionality in the FlowForma tool, customers are able to design and build processes that can be fully certified to meet regulatory requirements on electronic records e.g. ISO 9001 and 21 CFR Part 11.

The audit abilities of FlowForma Process Automation are enhanced, capturing additional data and providing audit histories that are easy to examine by auditors.

Module Highlights

- ✓ eSignatures
- ✓ integrated Form Audit Record
- ✓ Flow Snapshots that provide a document describing the Flow Definition

Together, these features provide all the functionality required to validate processes to 21 CFR Part 11 compliance. The same features can be used for compliance in other industries where regulatory compliance is required on the storage of electronic records.

eSignatures

The Compliance Module enables eSignatures on step submissions. The default signature is designed for 21 CFR Part 11 compliance and requires the user to enter their password while prompting for role of signatory and purpose for signing. Alternatively, where CFR compliances are not required, a standard eSignature is an option which only requests the password.

Form Audit Record

The integrated Form Audit Record feature captures all actions that happen on a form throughout the process and stores the audit record within the form. An audit viewer provides a human readable view of the audit record.

Flow Snapshot

The Flow Snapshot allows the user to generate a document describing the content of the Flow Definition (the process template). The snapshot lists out every process step, question and business rule in the Flow. The feature is aimed at compliance requirements where auditors require a human readable description of the Flow at a set point in time. This is a requirement for 21 CFR Part 11 compliance and is useful across many industries.

The feature includes a simple graphical representation of the process. A downloadable document is generated that contains all information about the process. The document is designed in a logical format so that it can be read by process auditors.

Key Benefits

With the Compliance Module, users are able to construct an environment that can be independently audited against regulatory requirements.

Processes can be designed so that process steps are signed, historical form activity is clearly visible, and a snapshot of the workflow design can be captured at a specific point in time.

The records are easily and quickly understood by external auditors who may not have any prior knowledge of FlowForma or the processes that have been implemented in the organization.

The major benefit for any regulated company is that they are not being forced to adopt a new process in order to get certified, nor are they buying a locked down piece of software that won't change as their organization does. Organizations can take advantage of the tools flexibility and features specific to their industry.

Example Use Cases

- **PV – Pharmacovigiliance**
  FlowForma Process Automation records pharmacovigiliance signals in a controlled manner, keeping an audit of all activity from the initial recording of an ADR (Adverse Drug Reactions), through to the review of the case and implementation of recommended actions.
- **ECO – Engineering Change Order**
  Using FlowForma you can record the request for an ECO, the associated documentation, the approval and ultimate implementation of the change. You can also route the activity to resources while ensuring that each stage of the process is signed by the appropriate person.
- **GxP – General 'Good Practice' Guidelines**
  FlowForma Process Automation has intelligent forms and workflow that ensure good practice is followed every time. The Compliance Module adds features that ensure processes can be audited, so that external regulators can quickly verify compliance to GxP guidelines. This same functionality extends to all GxP activity in the Life Sciences sector and beyond.

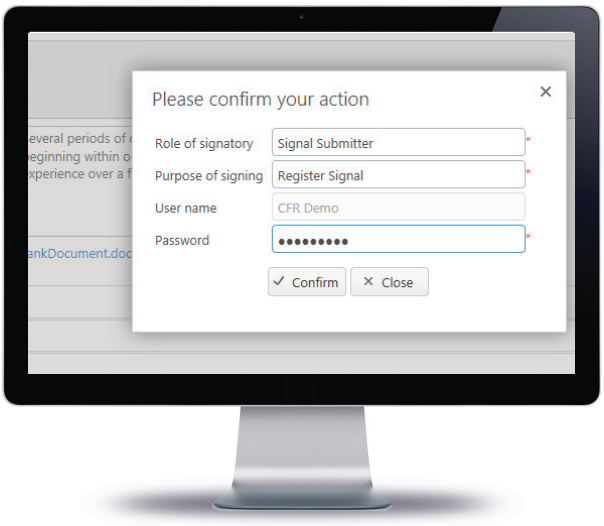


Fig 1: eSignatures Feature

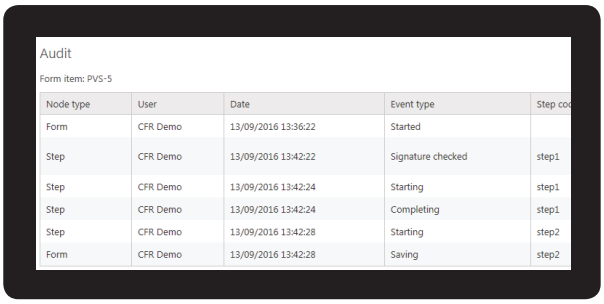


Fig 2: Form Audit Record Feature

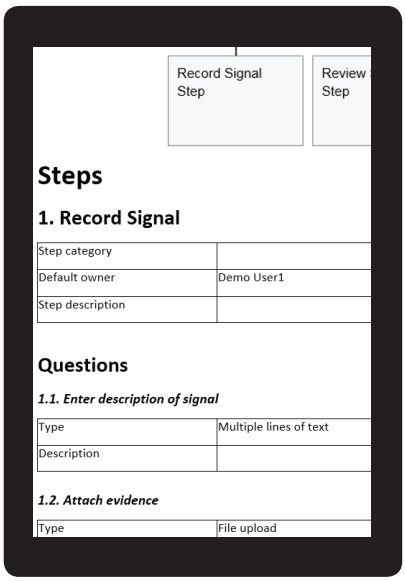


Fig 3: Flow Snapshot Feature

About FlowForma

FlowForma, the leading provider of Process Automation tools for Microsoft Office 365® has been revolutionizing the traditional BPM space with an innovative approach to developing award winning products that empower users to create and streamline processes smarter and faster, utilizing the familiar SharePoint platform, without any coding.

FlowForma is a Gold Microsoft Partner, with over 150,000 users across Europe, America and Asia. The company is headquartered in Dublin with offices in London and Boston and is motivated by its values to innovate, evolve and achieve with employees, customers and partners.

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