

# FORMPIPE

**FormPipe Life Science**

**Quality Management for Life Science**

*Compliance, Control and Flexibility*

...Customer Complaints...Deviation management...CAPA...  
Change control...SOP management...Training...Validation...

# FormPipe Life Science

FormPipe Life Science is a powerful quality information management system for pharmaceutical and other life science companies operating within strict regulatory environments. It offers greater flexibility and is easier to use than alternative comparable solutions. As well as giving you complete control over all quality related documents and processes, FormPipe Life Science improves efficiency on every level – reducing time lines and the effort required to ensure compliance.



## Who is it for?

Companies operating within FDA, EMEA or ISO regulated environments that are currently using separate, independent systems for fulfilling quality tasks. These may be manual (paper-based) or legacy IT quality systems. For example, Excel generated SOP registers and deviations recorded and filed in paper systems.

There is no alternative than to make the systems work. Failure to comply with regulations is a risk with potentially dire consequences. But how much time and effort is being wasted? The sheer volume of information means these types of systems are extremely labour intensive, slow to perform, and complicated to control.

The question you need to ask is – does your system work for you, or do you work for it? For the majority of life science companies the potential for improvement is enormous. If you are one of these, FormPipe Life Science could revolutionise the way you work.

# Efficient Quality Management

## Compliance

Supports validation and use in full accordance with current US and EU GMP standards for pharmaceutical manufacturing as set forth by regulatory bodies. It also supports the validated use of electronic records and electronic signatures in compliance with FDA Title 21 CFR Part 11 and EU Annex 11.

## Control

Provides structured management of quality-related documentation and processes with full traceability. Includes powerful tools for carrying out key quality tasks, as well as managing and retrieving documents and records. Also includes routine and ad hoc reporting tools for measuring processes (good basis for annual report) and supporting continual improvement.

## Flexibility

Provides a scalable system able to grow with your needs. You decide what functionality you require and which applications should be installed over what time-frame. Applications are configured to meet your specific needs, but as they are based on standard functionality they are always fully upgradeable.

## Efficiency

Electronic records and documents as well as events combine with automated processes to create extremely efficient workflows. Connecting people, data and routines reduces process cycle times and shortens time to market, as well as saving valuable time for the individuals involved.

## User friendly

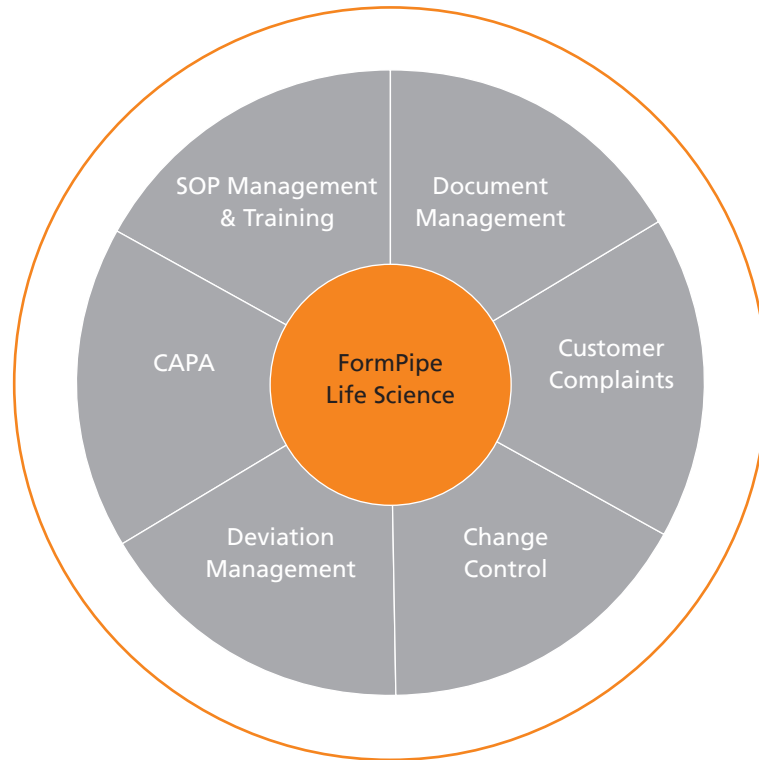
A simple graphical interface and intuitive configuration tools make the system very easy to use. This means the system can be implemented and configured more quickly than alternative solutions and ensures user participation and commitment.

## Cost effective

Efficiency improvements, consolidation of IT costs and saved time for personnel generate an improvement on your bottom line. It is not uncommon for companies to see a return on investment in as little as one or two years. It is of importance to highlight the potential usage of the system in other business areas to improve business efficiency and reduce costs.

# Fully integrated and flexible Quality Management System

## FormPipe Life Science



FormPipe Life Science is an integrated electronic quality management system (QMS) that maximises both control and efficiency. Automated workflows help to create, manage and connect quality related documents, records, events and processes in a way that is impossible with manual paper-based systems.

The simple platform concept together with easy-to-use web-based software delivers an unprecedented level of flexibility. As well as the key compliance applications the system can be used to support management of any number of regulated or non-regulated documents, tasks or processes.

### Implementation and validation

Solutions are implemented with the support of a FormPipe Life Science certified partner. This is someone who understands your business and can ensure a successful result, whether that is improving a specific critical task or increasing efficiency across your entire quality management system.

Our partners also provide validation support, including both services and validation documentation for needed specifications and execution.

## SOP Management & Training

- Effective management of Standard Operating Procedures (SOP) covering the entire life cycle of each document.
- Automatic routing of training requirements and processes, including requesting and capture of electronic signatures (complying with FDA 21 CFR Part 11).
- Enables a continuous training program approach covering the entire organisation.
- Provides clear overview of employees' training status and a central source for storing and managing all training documentation.

## Document Management

- Defined workflows support document creation, review, approval, version control, indexing, storage and distribution, automatically linking steps to relevant personnel.
- Includes access-authorized security together with electronic approval routines
- Powerful search function for fast and easy retrieval of correct document versions.

## CAPA

- Effective management of Corrective Action/Preventative Action (CAPA) processes improving product quality, patient safety and customer satisfaction.
- Tracks quality incidents and records the root cause of CAPA requests.
- Automates the entire CAPA workflow from initiation to closure, linking each step directly to relevant personnel.
- Integration with other quality systems automatically triggers related actions, such as SOP updates or new training requirements, etc.

## Customer Complaints

- Efficient management of customer complaints providing a standardised proactive process for the entire organisation.
- Provides a secure time-stamped audit trail covering the entire complaint handling process from initiation to completion.
- Report function facilitates reviewing of in-process complaints, as well as types of complaints, summaries and trends.
- Integration with CAPA process allows serious quality issues to be escalated and dealt with in a timely manner.

## Deviation Management

- Effective solution for tracking, managing and resolving deviations.
- Standardised incident form and automated routing ensures consistent company-wide process.
- Facilitates identification of the root cause and automates the entire process from initiation and investigation to resolution and approval.
- Integration with CAPA process allows serious quality issues to be escalated and dealt with in a timely manner.

## Change Control

- Powerful change control system ensuring regulatory compliance and continued product quality and safety.
- Automated workflow covering entire process from submission and implementation to verification and closure, linking each step directly with relevant personnel.
- Includes automatic collection and tracking of data, supporting classification and prioritization of requests.
- Integration with other quality systems automatically triggers related actions, such as SOP updates or new training requirements, etc.

## About FormPipe Life Science

FormPipe Life Science has been developed on FormPipe's proven Platina platform. FormPipe Platina is an industry-leading enterprise content management solution. It was initially introduced on the market over ten years ago. Since then, continual development and user feedback has ensured that quality has been built in on every level.

The platform has its origins in Swedish healthcare and public sectors. It has been implemented by more than 100 companies and organisations, including Karolinska Institutet, AstraZeneca, Kemwell and many of Sweden's regional healthcare organisations. Platina is developed in accordance with ISO Standards.

### For more information

[www.formpipe.com/lifescience](http://www.formpipe.com/lifescience)

## About FormPipe Software

FormPipe Software is a leading developer of Enterprise Content Management solutions, enabling organisations to capture, process, store, archive and supply information in a systemised and controlled manner.

Flexible and scalable solutions help customers to lower costs, minimise risk exposure, reduce lead times and improve quality control.

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