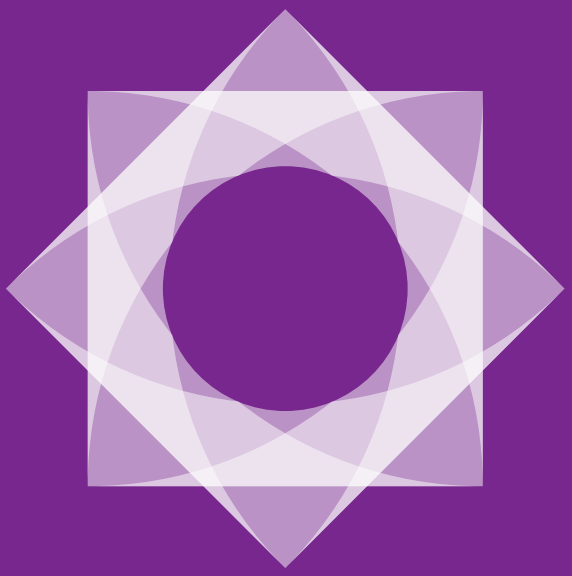

Platina QMS
by Formpipe

Quality Management for Life Science

- Document management
- Training management
- SOP management
- Deviation management
- CAPA management
- Change control
- Customer complaints
- Audit management
- etc.

Formpipe.

Platina QMS is a fully integrated Electronic Quality Management System solution (EQMS) that maximises both control and efficiency.

Automated workflows help to create, manage and connect quality related documents, records, cases and processes in a way that is impossible with manual paper-based systems, or stand-alone software solutions. A solid platform combined with the web-based and easy-to-use software delivers an unprecedented level of flexibility. As well as for key compliance applications the system can be used to manage any number of regulated or non-regulated documents, tasks and processes.

Configurable modules – ready to use

The flexible and web-based system comes with pre-defined and ready-to-use modules enabling a quick and easy start-up process. These modules with all related information are easily managed and overviewed in the same system. Compared to using manual paper-based systems or stand-alone solutions, you gain full traceability and searchability on top of required compliance and control.

Let the system work for you

With Platina QMS all information is always presented in its right context. Access control adjusts what information to be presented to whom and when. This makes the information relevant and easy to find for each specific user. In the same manner, the system serves you tasks without having to search for them in the system. It simply tells each user what to do, when and how.

Through utilisation of the transparent and holistic system, elaborate processes such as annual reports and periodic reviews are a lot easier managed. Compiling the information necessary will no longer be a hassle.

SOP Management
- 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).
- Automatisation of periodic reviews.

Training Management
- 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, logging, storage and distribution – automatically linking steps to relevant personnel.
- Allows creation, editing and management of a variety of documents such as: SOPs, specifications, records, reports, notes, external documents etc.
- Includes access-authorised security together with electronic approval routines
- Powerful search function for fast and easy retrieval of correct document versions.

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.

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

Change Control
- Powerful change control system ensuring regulatory compliance and continued product quality and safety.
- Automated workflow covering entire process from planning and implementation to verification and closure,

linking each step directly with relevant personnel.
- Includes automatic collection and tracking of data, supporting classification and prioritisation of requests.
- Integration with other quality processes 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 the 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.

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 continous improvment.

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

Efficiency
Electronic records, documents and cases 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 many 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.

Platina QMS by Formpipe

Platina QMS is a powerful and fully integrated Enterprise Quality Management Software solution for pharmaceutical, medical device and other life science companies operating within strict regulatory environments. Using Platina QMS you can ensure regulatory compliance across your entire enterprise – from research and development to drug manufacturing and distribution. The solution puts you in complete control and provides full support for meeting regulatory compliance with FDA Title 21 CFR Part 11 and EU Annex 11 requirements, involving eg. data security, data integrity, traceability/audit, and electronic signatures. Using the flexible software solution it is possible to automate routine operations and improve efficiency on every level.

Who is it for?

Whether looking for a system to manage regulatory documents, SOPs, or case management such as Corrective and Preventative Actions (CAPA), change control, training etc., Platina QMS provides a comprehensive and user-friendly sofware solution that facilitates easy creation, management, and tracking of all quality-related documents, records, cases and processes.

Failure to comply with regulations is a risk with potentially dire consequences. But how much time and effort is being wasted on the way? For the majority of life science companies the potential for quality and efficiency improvement is enormous. If you are one of these, Platina QMS may revolutionise the way you work.

Implementation and validation

Our solutions are implemented with the support of a Platina QMS certified partner. Our skilled partners know your business and can ensure a successful result, whether that is improving a specific critical task or increasing efficiency across your entire enterprise.

In addition to Formpipe's in-house competence with high level of experience from the life science industry, our certified partners offer their expertise to our customers in terms of e.g. validation support.

About Platina QMS by Formpipe

Platina QMS has been developed on Formpipe's proven Platina platform. 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 and efficiency 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 e.g. Karolinska Institutet, AstraZeneca and Kemwell along with many of Sweden's regional healthcare organisations.

About Formpipe

Formpipe 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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