



Quality Management System

Codesplice Ltd.

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Quality Management made **simple for your business**

A risk-based QMS offering industry best practices to manage your compliance needs and meet current regulatory requirements.



Certificate Number: 11918-QMS-001
ISO 9001



GDP Compliance with TraxQM

TraxQM is a Risk based digital Quality Management System that supports an organisation's regulatory compliance mandate. Designed for Wholesalers, Parallel Importers, MIA and ISO, the application enables your organisation to focus on meeting compliance through a structured and quality orientated language.

A data-centric model compared to a traditional document centric model allows the application to adhere to ALCOA principles. It addresses inspection deficiencies such as unrealistic risk assessment, lack of formal definition of severity, lack of details within controls and weak methodologies for Root Cause Analysis.

GDP Pharma Consulting are pleased to recommend TraxQM as a robust and practical risk-based e-QMS for WDA holders.

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Peter Coombs and Claire Glenister,
ex-MHRA GDP Inspectors and
founders of GDP Pharma Consulting*

Designed to be used by business of all sizes, the application comprises of different modules to provide a quality eco-system based on recorded risks.

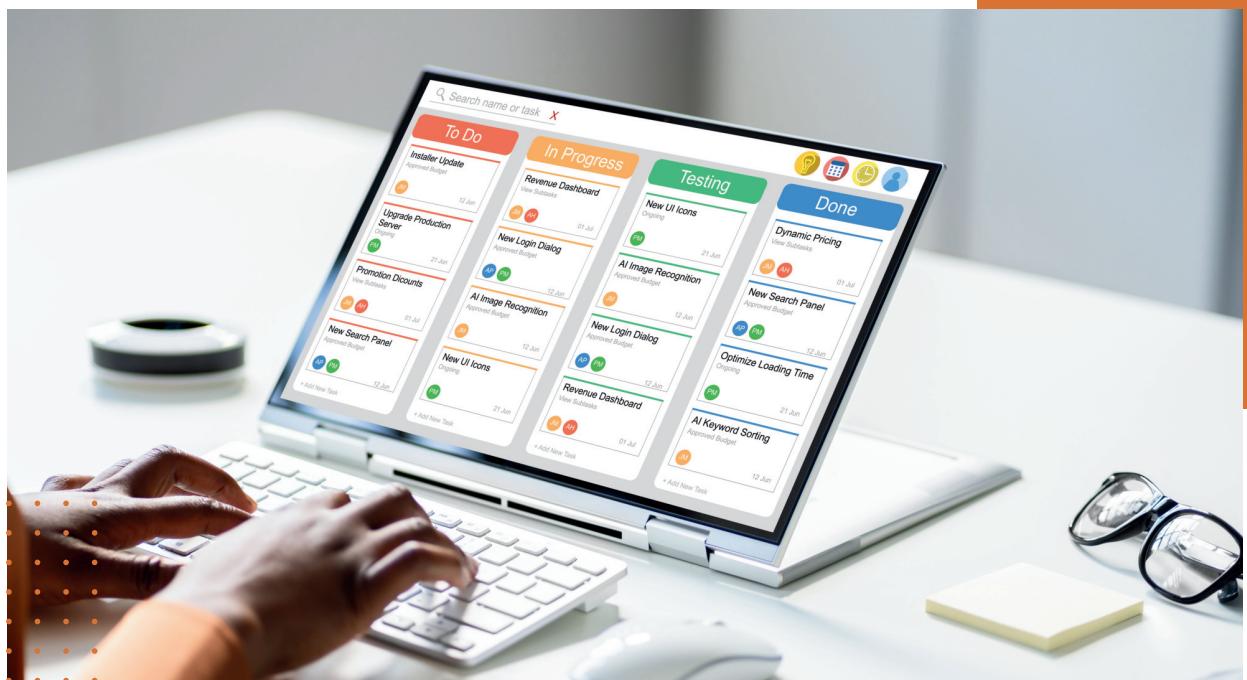
Maximise efficiency and security in your daily operations

TraxQM leverages AWS well-architected framework and Microsoft Azure services. The application lends itself to GAMP 5 category 3 validation. Accessed via a web browser, the application can be accessed from a desktop or tablet.

Our Modular application comprises of a Document Manager, Events Manager, Risk Analysis Manager, Change Control Manager, Audit Manager, Training Manager, Management and Planner modules.

- ➡ Risk Analysis using FMEA with weighted scoring for Severity, Occurrence and Detection
- ➡ Leverage Azure AI for intelligent insights for file reviews, risks and KPIs.
- ➡ Formalises the use of Incidents, Deviations, Corrections and CAPA
- ➡ Eliminates Parallel interdepartmental programs
- ➡ Inter-departmental communication with in-built collaboration tools
- ➡ Record and Track for trend analysis
- ➡ Oversight and timely management of Tasks with notifications
- ➡ QMS data dashboards
- ➡ Data integrity by removing deliberate fraud, bad practices, poor organisational behaviour, and weak systems
- ➡ Accommodates exponential growth of documents and related functions of preparation, printing, version control, signatures, and filing
- ➡ Weekly email alerts to inform the users of outstanding tasks

Planner Module



TraxQM's Planner module offers a powerful task management solution designed to optimise your workflow and enhance productivity. Experience seamless collaboration and efficient task tracking with a comprehensive set of features tailored to your team's needs.



Visual Task Management -

Utilise the Kanban view to manage tasks visually, making it easy to see the status of each task at a glance.



Drag-and-Drop Simplicity -

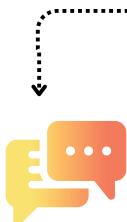
Organise tasks with simple drag-and-drop functionality, allowing for quick adjustments and prioritisation..



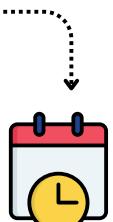
Checklists - Break down tasks into smaller, manageable steps with checklists, ensuring nothing is overlooked.



Attachments - Attach relevant documents and files directly to tasks, keeping all necessary information in one place..



Comments - Foster team collaboration by adding comments to tasks, allowing for ongoing discussion and updates.



Due Dates and Reminders - Set due dates and receive reminders, ensuring tasks are completed on time.

KEY BENEFITS



Efficient Assignment - Assign tasks to team members with ease, ensuring everyone knows their responsibilities.

Implementation - Raise tasks in order of priority with option to re-schedule. Attach evidence of completed tasks. Show status of tasks.



Centralised Dashboard - Access all your and your team's tasks from a centralised dashboard, ensuring nothing falls through the cracks.

Dashboard



TraxQM's Dashboard module provides powerful data visualisation tools that offer a comprehensive overview of your organisation's quality health. Empower your management team with actionable insights and real-time data to drive informed decision-making and maintain regulatory compliance.



Events - Visualise data related to Complaints, Deviations, CAPAs, and Change Controls. Identify trends, monitor progress, and ensure timely resolution of issues.



Risks - Assess and visualise risk levels and impacts. Implement and monitor risk mitigation strategies effectively.



Interactive Charts - Dive deeper into data with interactive charts and graphs that allow for detailed analysis.



Real-Time Monitoring - Keep your finger on the pulse of your quality management processes with up-to-date data and dynamic visuals.



Key Metrics -

Monitor key performance indicators (KPIs) relevant to quality management to ensure your organisation stays on track with its goals.

KEY BENEFITS



Actionable Insights - Leverage data visualisations to gain actionable insights and enhance quality management processes.

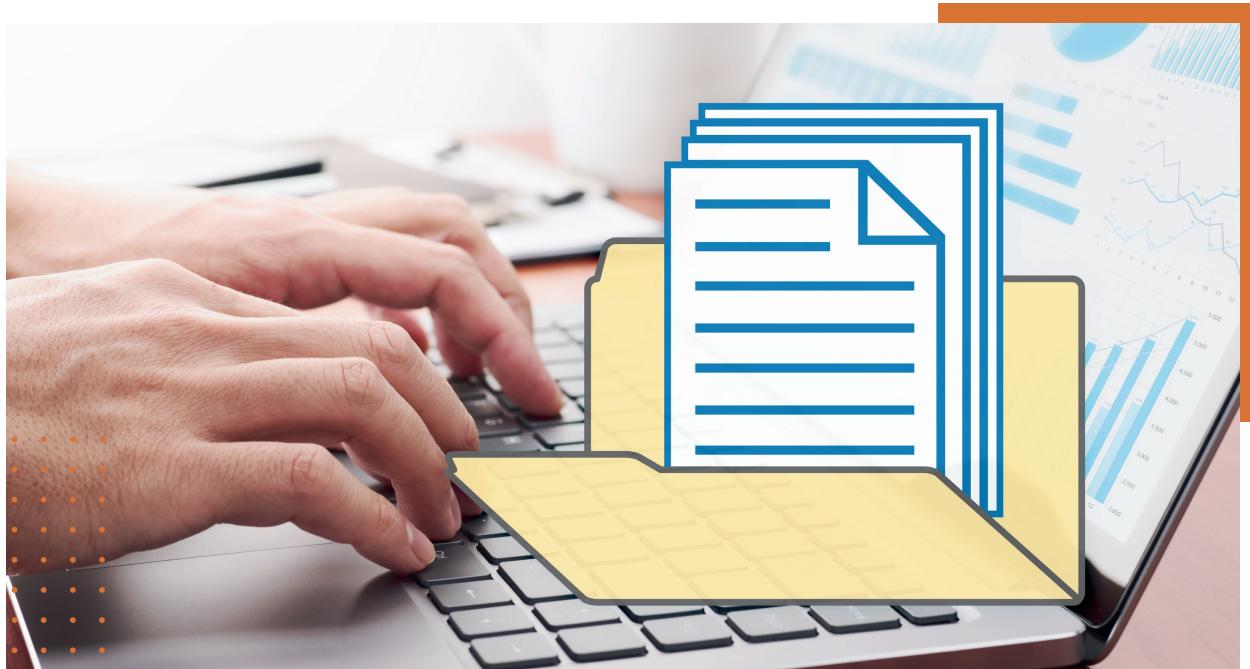


Improved Oversight - Ensure comprehensive oversight of all quality-related activities within your organisation.



Enhanced Productivity - Save time and improve productivity with an intuitive, centralised dashboard that consolidates all essential data.

Document Manager



Experience unparalleled efficiency and security with TraxQM's Document Manager, fully integrated with industry-leading platforms to enhance your compliance and collaboration processes.



Real-time Collaboration –

Easily Edit documents online and collaborate seamlessly with your team, leveraging SharePoint's advanced editing and collaboration tools.



Centralised Storage & Version

Control - TraxQM stores and manages all your documents in SharePoint Online, ensuring secure, centralised access with robust version control.

ADVANCED INTEGRATION AND COLLABORATION

Granular Permissions -

Define and manage access permissions for users, ensuring that only authorised personnel can access, edit, or approve documents.



File Preview – Preview documents directly within TraxQM using SharePoint's powerful preview feature, saving time and enhancing productivity.



Local Sync – Keep your files synchronised locally using the OneDrive client, providing flexibility to work offline and automatically update changes.

KEY BENEFITS



Configurable Reviews & Approvals - Support for single or multiple reviewers and approvers. Customise review and approval workflows to meet your specific requirements.

Automated Reminders - Monitor upcoming review dates and automatically create reminder tasks, ensuring timely reviews and approvals.



Digital Signatures - Built-in DocuSign Enterprise with CFR 21 Part 11 compliance, eliminating the need for printed documents. Enhance data integrity and conform to industry standards with secure digital signatures.

Events & Change Control



TraxQM's risk based Event Manager and Change Control modules are designed to help you effortlessly log and manage Complaints, Deviations, CAPAs, and Change Controls in full compliance with pharmaceutical regulatory requirements. Our wizard-driven processes ensure users follow every step accurately and efficiently.



Compliant Logging – Easily log Complaints, Deviations, CAPAs, and Change Controls through a guided, step-by-step wizard that ensures adherence to regulatory standards.



Approval Workflow – Submit each stage for approval, enabling close monitoring and timely feedback to maintain compliance and support an agile approach.



Implementation Tracking – Monitor the progress of change implementations, ensuring that changes are executed as planned and any issues are promptly addressed.



Real-Time Monitoring – Keep track of every step and stage with real-time monitoring, ensuring no aspect of the process is overlooked.



Adaptive Changes – Quickly adapt to new regulatory requirements or organisational changes, maintaining compliance and improving efficiency.

KEY BENEFITS:



Enhanced Compliance - Follow a structured, compliant process for logging and managing critical events and changes.



Root Cause Analysis – Employ the 5 Whys technique to identify the root cause of problems by repeatedly asking "Why?" until the underlying issue is uncovered.



Integrated Collaboration – Facilitate team discussions and decisions with built-in committee reviews, enhancing the quality and speed of decision-making.

Risk Analysis



TraxQM's Risk Management module empowers your organisation to proactively identify, assess, and mitigate risks using the Failure Mode and Effects Analysis (FMEA) methodology. Ensure robust risk management with features designed to enhance your operational resilience and compliance.

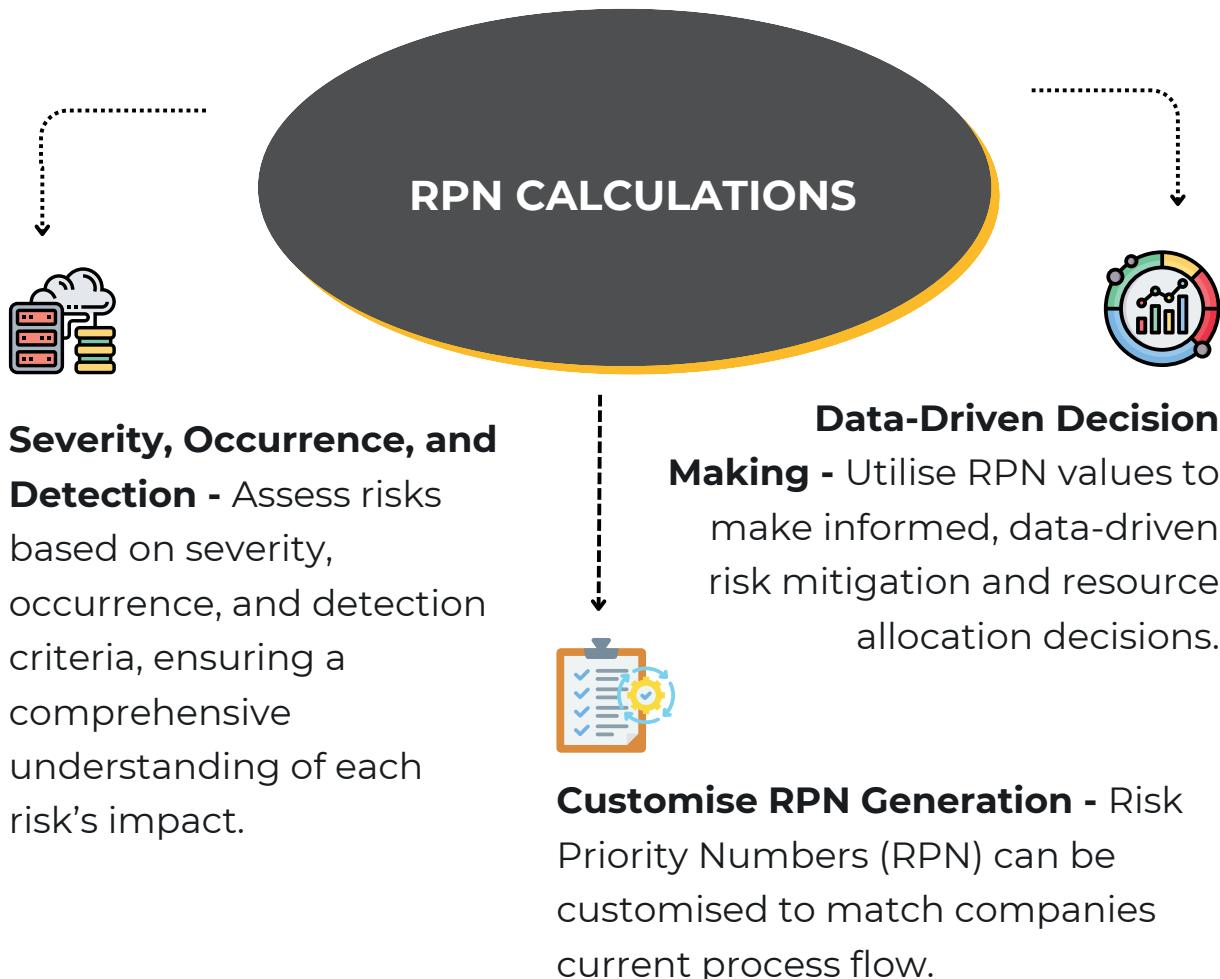


Current and Recommended Controls

Controls – Record existing controls and recommended actions to address identified risks, enhancing your ability to mitigate potential issues effectively.



Define KPIs – Set Key Performance Indicators (KPIs) to measure and monitor the effectiveness of your risk management activities.



KEY BENEFITS:



AI-Driven Recommendations – Leverage OpenAI to define recommended controls and KPIs, providing intelligent insights to enhance your risk management strategies.



Performance Tracking – Continuously track and evaluate KPIs to ensure your risk management processes are meeting organisational objectives and regulatory requirements.



Comprehensive Risk Reports – Generate detailed reports on identified risks, controls, and mitigation actions, providing valuable insights for stakeholders.

Audit Module



TraxQM's Audit module empowers your organisation with a robust, risk-based approach to managing internal and external audits. It enhances your audit processes with comprehensive features designed to ensure thorough compliance and continuous improvement.



Targeted Audits – Focus on high-risk areas to optimise audit resources and ensure critical compliance issues are addressed.



Thorough Documentation – Capture all necessary details and evidence to support audit findings and recommendations.



Efficient Scheduling –

Main auditors can easily schedule all audits, ensuring timely and systematic audit planning.

Team Definition –

Define and assign specific audit teams for each audit, ensuring the right expertise is applied to each audit.



Notification System –

Notify all interested parties about upcoming audits, keeping everyone informed and prepared.

KEY BENEFITS



Conformance Recording – Record conformance, non-conformance, observations, and suggested improvements during the audit.

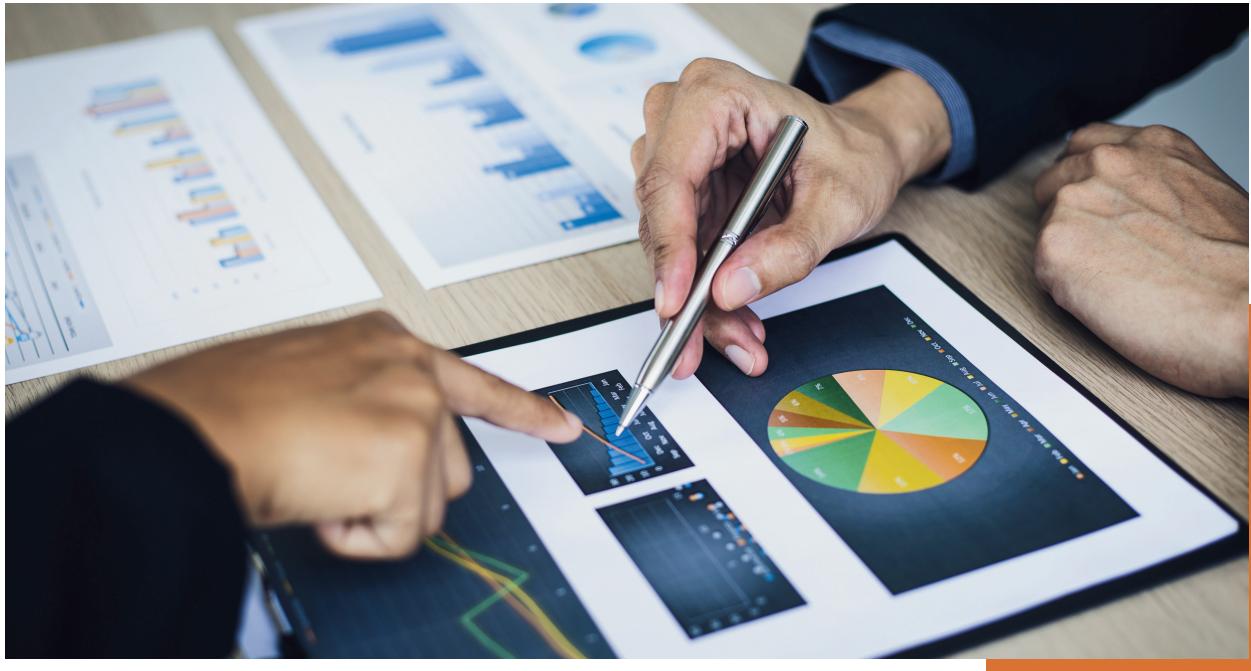


CAPA & Risk Linkage – Link CAPA (Corrective and Preventive Actions) and Risks with non-conformance findings to ensure comprehensive follow-up and mitigation.



Comprehensive Reporting - Benefit from a detailed, professional audit PDF report for the entire audit, providing a complete and professional audit summary.

Management Module



TraxQM's Management module offers a robust set of tools to help organisations manage their structures, assets, and strategic plans effectively. Tailored to meet real-world scenarios, our module ensures compliance and enhances operational efficiency.



Complex Organogram –

Design detailed organograms that reflect complex departmental setups, tailored to your organisation's unique structure.



Information & Asset Records –

Maintain accurate records of organisational information and hardware assets, ensuring comprehensive asset management.

SUPPLIER AND CUSTOMER MANAGEMENT



Approval Lifecycle Support

- Record and manage supplier and customer information with built-in approval lifecycle support, enhancing accountability and traceability.

Regulatory Compliance -

Auto-validate records against MHRA, HMRC, and General Pharmaceutical Council databases, ensuring compliance and reducing administrative burden.

KEY BENEFITS:



Review Minutes Creation - Generate detailed review minutes and link them with audits, plans, risks, and SWOT analyses, ensuring cohesive documentation and easy reference.



Context and SWOT Analysis - Create comprehensive contexts and SWOT analyses to identify strengths, weaknesses, opportunities, and threats, aiding in strategic decision-making.



Interested Parties - Identify and record information on interested parties, ensuring all stakeholders are accounted for in your planning processes.

Training Module



TraxQM's Training Module, powered by TalentLMS, provides a comprehensive platform to deliver, manage, and track training programs, ensuring employee development and regulatory compliance.



1000+ Ready-to-use courses

– A collection of over 1000 unique ready-made courses authored by experts, covering various skill sets.



Advanced Reporting –

Generate real-time user, group or course based reports on training progress, completion rates, and compliance status, facilitating informed decision-making.



Interactive Content Support - Easy to create custom courses by incorporating various media types and support for SCORM, xAPI, and cmi5 standards.



Blended Learning – Combine online and offline training sessions, including instructor-led training via videoconferencing, to cater to diverse learning preferences.



Gamification – Enhance learner engagement through badges, points, levels, rewards, and leaderboards, motivating continuous participation.

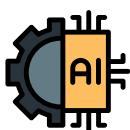
KEY BENEFITS:



Surveys and Assessments - Design surveys and a variety of tests, including multiple-choice, drag-and-drop matching, and open-ended questions, to gather insights and evaluate learner understanding.

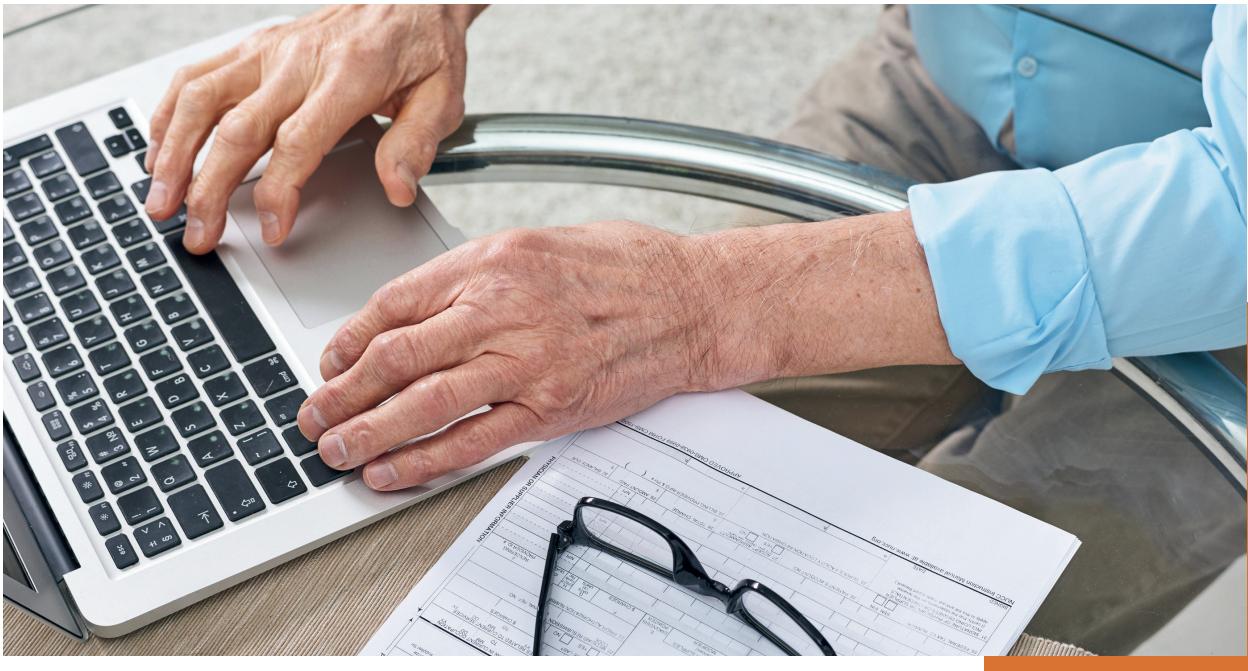


Certifications - Issue certifications upon course completion, ensuring recognition of learner achievements and compliance with industry standards.



AI-Powered Content Creation - Utilise AI to swiftly generate engaging training materials, from standalone content to complete courses.

Forms Module



Forms Module provides a secure, compliance-ready solution to capture operational data across quality-critical workflows, supporting documentation requirements and facilitating decision-making across the organisation.



Configurable Form Templates

– Create structured, reusable forms tailored to company-specific processes with field-level rules and smart logic.



Compliance-Driven Design –

Built in alignment with GxP expectations, ensuring accurate, traceable, and reviewable records across all quality operations.

ADVANCED CAPABILITIES

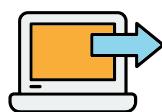


Dynamic Inputs &

Validation - Support for various input types: text, dropdowns, ratings, drag n drop — alongside conditional logic, calculations, and real-time validation.



Access Control - Assign forms to specific user groups. Submissions can be further processed for approvals with audit-ready traceability.



Data Export - Export responses in CSV or PDF. Also supports exporting blank forms in fillable PDF format.

KEY BENEFITS:



Version Control - All forms are version-controlled and require approval before user access.



User-Friendly Interface - Submit or review forms from tablets—ideal for manufacturing floors and field inspections.



Secure & Compliant - All forms are stored in an encrypted format with immutable logs and access controls.



About us

Codesplice Limited is an IT solution provider based in London, UK, and is the parent company of FMVerify (EU FMD), Trax2D (EMVS Track & Trace) and TraxQM (QMS).

Codesplice understands that there is never just one approach and never a “one size fits all” answer, so using innovative ideas to solve problems, Codesplice will work with you to assess all aspects of your requirements and then define and provide a solution for all your business needs.

A management team with over 100 years of combined experience in Information Technology, Business Management and Consulting leads a dynamic and experienced company, educated in all facets of technology solutions and service delivery.

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