Quality

cara LIFE SCIENCES PLATFORM

Quality Reimagined

Gain control and understanding of your global processes to drive compliance

A comprehensive guide to Quality on the CARA Life Sciences Platform.

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QUALITY REIMAGINED:
GAIN CONTROL AND UNDERSTANDING
OF YOUR GLOBAL PROCESSES
TO DRIVE COMPLIANCE

Connectivity

Leverage a centralised system for all your global processes with a cloud-first solution.

Visibility

Gain true oversight with easy reporting, dashboard and a 'where-used' system.

Consistency

Take control of all your information with best practises across the board to reduce re-work and time wasted.

Proactivity

Automate work for your colleagues with collaboration and AI, ready for the challenges of tomorrow.

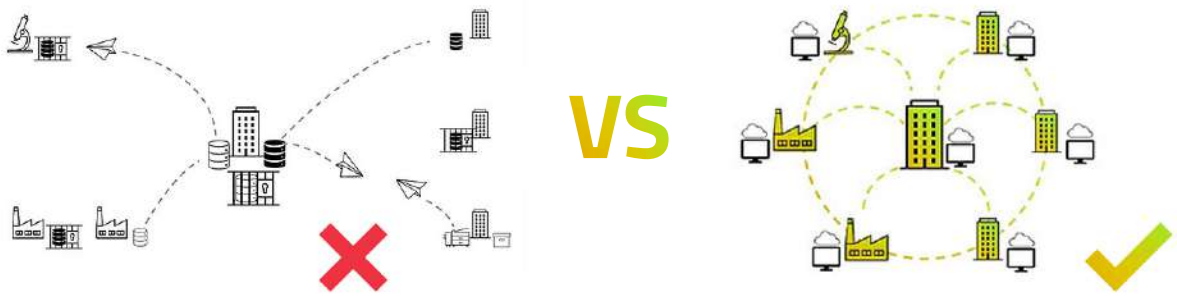
Quality

QMS:

Deviations Management
Complaints Management
CAPA
Audits Management

Change Control
Quality documents
Learning Management (LMS)
Laboratory Management
Electronic Batch Records (EBR)
Annual Product Quality Review
Supplier Quality Management
Preventive Quality

Achieve excellence across your enterprise.



Quality Events

Capture everything that happens in your business, planned or unplanned, from audit findings to complaints, deviations and planned changes.

Deviations

Following controlled processes is a regulatory requirement to ensure Quality remains high – tracking and managing Deviations from this process is a key part of your QMS. Track the resolution of Deviations through the linked data and documents, and ensure that you can plan preventive measures to avoid recurrence of the Deviations.

Complaints

Managing Complaints is not just a regulatory requirement but impacts the public image of your company, and CARA allows you to ensure that Complaints are quickly and automatically routed on workflows and escalations through to the resolution

CAPAs

Capture, track and resolve. Data fields based on industry best practise for capturing CAPA information. Capture root cause analysis, risk assessment, tag to particular products, or relate to individual processes, including assigning responsible people and dates, and using these to trigger and monitor workflows.

CAPA are automatically related to the Quality Event and may result in related Change Controls. You can also link documents that require modifying to the CAPA, or create new actions required for the CAPA implementation. Automations ensure that CAPA cannot be closed before associated Change Controls are completed, and once CAPAs are closed, the parent Quality Events can then also be resolved and evaluated for effectiveness.

Change Controls

Having a Change Control mechanism that is seamlessly connected to every part of the CARA Life Science Platform (Quality, Regulatory, Safety and Clinical) is a true differentiator and brings large business value to you, with a true enterprise view of your business activities.

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Quality Documents

Quality Documents Management on the CARA Life Sciences Platform™ provides a modern, central DMS for all types of Quality documentation, fully compliant with 21 CFR Part 11.

Beyond the standard functionality of content creation, review, and approval, CARA supports publishing, training, eSignature, controlled printing, and site-control to support enterprise needs.

Bring Quality documentation to your employees, with QR codes for laboratories and manufacturing, portals for rapid searching and viewing across the business, and the CARA Mobile App for on-the-go work.

Benefits

Designed to be Used

Different experiences for consumers and authors ensure that the system is intuitive and functional for all users.

Compliance & GxP

Visibility and automations across your processes keeps your content up to date, and your business compliant.

Integrate Quality into your Business

Connect seamlessly not only with QMS, LMS and Audits Management, but across Regulatory, Safety, and Clinical.

Audit Readiness

Clear and flexible views of your audit trails, a network of connected quality information, and instant search.

Generate Content Automatically

From simple template-based authoring to PDF concatenation and full document generation.

Time Saving Automation

From simple template-based authoring to PDF concatenation and full document generation.

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Quality Documents

Create compliant content efficiently with templates, overlays and automatic numbering.

Flexible workflows for Collaborative Authoring, Review, Approval, Periodic Review and Obsoletion bring consistency to your content management

Provide simple views of Approved and Effective content for consumption, while bringing the latest versions of that content to your authoring team and superseding old content.

Get notifications automatically for content requiring Periodic Review, and promote documents to Effective automatically on their Planned Effective Date.

Watermarks, overlays, eSignature, and time stamps help to drive your corporate compliance.

With Controlled Printing, QR Codes for viewing on portable devices (e.g. in a lab or factory), and the Mobile App, employees can access controlled content anywhere.

Audits

Managing audits with internal and external parties is one of the most manual and time-consuming processes within Quality Management. CARA provides the tools to automate, collaborate and provide external partners with limited access in order to reduce the manual work as far as possible. CARA also offers Remote Supplier Quality Audit for extra accessibility.

How it Works

Create Audit Plan
Create a plan, assign auditors, and schedule. Alert auditees with a range of dates to choose from and confirm in their calendars.

Request Documents
Request documents prior to the audit from the auditee.

Upload Documents
Allow auditees limited controlled access to CARA to upload the documents so auditors can view before the audit.

Log Findings
Create Quality Events for all the Audit Findings.

Generate Audit Report
Automatically generate an audit report containing all the audit information, list of documents used, and the Quality Events – each one hyperlinked in the PDF to open CARA and view.

Provide CAPA
Auditees can use the hyperlinks in the report to access the Quality Events and create their CAPA directly in the CARA QMS module.

Track & Close Audits
Auditors have direct visibility on the progress of the CAPAs to track and close audits.

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APQR

The Annual Product Quality Review requires data and content from multiple sources and systems to write it – leading to long manual processes to author it and ensure the information is up to date.
The CARA Life Science platform not only allows you do hold the source data in the system, but to connect to external systems to programmatically retrieve it – and use this data to automate the creation of the content, with graphs and tables dynamically generated into the content from templates. Reduce the time it takes to assemble the content from weeks down to hours – leading to lower costs and more certainty that the data is up-to-the-minute correct.

Supplier Quality Management

Covering the entire lifecycle from supplier selection, auditing, verification, Service Level Agreement and collaborative quality improvements, this CARA capability gives you the ability to be able to manage and report on Supplier Quality internally and to regulatory authorities.

Preventative Quality

Log, track and resolve quality items, and report on them over time (analytics). The natural next step with all that data is to use it to spot and predict trends (e.g. equipment failing at 6 month intervals leading you to plan to replace it in a planned way every 5 months).

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Batch Records Management

Manage the correct documentation and batch record management process demonstrating that each product is manufactured according to industry standards and Good Manufacturing Practices (GMP). Empower easy communication with internal and external stakeholders including regulatory agencies. Gain oversight and keep track of the equipment, materials, staff, data, labels, events, supplies, laboratory information management systems, process control systems, and enterprise resource planning.

- 21 CFR Parts 210-211 certified
- Adherence to the FDA's CGMPs
- Versioning
- Traceability and reporting
- Granular – find and print a single page with ease
- Avoid data duplication and human error

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Learning Management System

Training and certifying employees in the same system as the documents themselves ensures a seamless experience with full compliance. CARA provides the ability to define courses, roles and curricula for such content, but also to log external training and attach or generate training certificates for those, which gives a complete training picture for employees. CARA can also be integrated with a number of different HR systems for easy connectivity and tracking.

Secure Document Management

Create and manage controlled documents such as SOPs and Policies, including e-signatures.

Video Assets & Discussions

Provide video and other media assets to guide or support the training. Facilitate a discussion thread relating to training and/or the controlled documents.

Training Library & Self-Service

Create a library of courses which users can browse and assign to themselves where it is optional to their job role.

Automatic Assignment

Automatically assign training for the appropriate training roles, including recurring training where annual or other periodic retraining is required. Remove training from users as they change job roles.

Connect to External Systems

Link to external systems for a variety of purposes including pulling / pushing data or documents and setting up training related to external systems.

Reporting & Analytics

Track and escalation training completion by user, course, job role, and visualize the trending over time in the CARA analytics dashboards.

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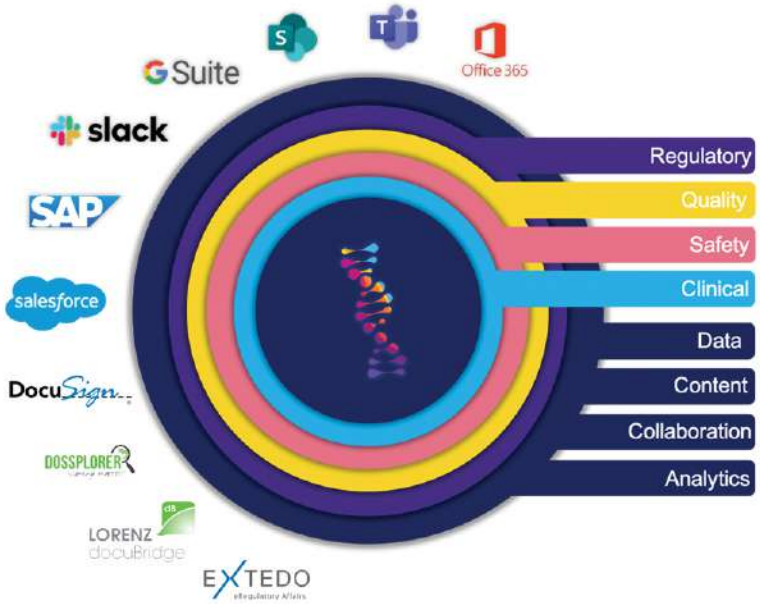
What is the CARA Life Sciences Platform?

The CARA Life Sciences Platform is an enterprise cloud for managing the content, data, and business processes throughout the whole R&D landscape.

The CARA Life Sciences Platform removes the technological, operational and financial drawbacks of a network of individual systems – instead, our customers can consolidate their processes, data and content onto a single platform of best of breed apps. Users can then create, locate, and re-use information instantly in any process across the organisation, leading to accelerated work with greater accuracy of information.

We provide standardised apps for Regulatory, Quality, Safety, Clinical and Enterprise processes powered by a single information lake that gives users instant access to cross-functional data and enables powerful process optimisation.



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