Quality Management
QMS and Quality Documents (SOP, GxP)

CARA for Quality Management is a configuration package with functionality required for managing Quality documentation as well as Quality Events, CAPA, Change Requests, and Quality Evaluations. This package covers all the standard document creation, review, approval, signature and publishing functionality required, as well as training (e.g. To Be Read and Understood), reporting and full workflow / lifecycle and Change Request Management, together with Controlled Printing and QR code document viewing. Available with this package is also the CARA Portal with dedicated search and viewing for consumers.

DIA EDM Reference Model

Document and metadata set - starting from the reference model.

QMS Management

Create and manage Quality Events, CAPA, Change Requests.

eSignature, Controlled Printing

Capture and manifest eSignatures as part of a workflow. Watermark documents, and manage controlled printing.

Training Management

Build training matrices and manage training on SOPs and other documents, or logging training on external systems.

Documentation Features

- Document numbering (based on any combination of properties)
- Viewing Effective versions even when more recent Draft versions exists
- Dynamic Security based on any combination of properties
- Workflowsfor Review, Approval, Periodic Review, Making Obsolete etc
- Mechanism for Superseding previous Effective versions
- Periodic Review workflows and notifications
- Automatically make documents Effective on a particular date (e.g. Planned Effective Date)
- Viewing documents by scanning a QR code (e.g. on iPad in a lab)
- Change Request mechanism
- Watermarking depending on status or any other attributes -including different overlays for viewing, printing, exporting and controlled printing
- Capturing eSignature on user actions and adding eSignature pages
- Controlled printing including print numbers, reason for printing, print addressee

QMS Features

- Create Quality Events (internal or external, for Audit Findings, Compliants, etc)
- Undertake and capture Risk Based Assessments
- Undertake and capture Root Cause Analysis
- Create and manage CAPA items for a Quality Event, including sharing with external auditees to allow them to update CAPA information directly
- Automatically generate events/CAPA into a single document, to create e.g. Audit Reportor CAPA Report
- Create and manage Change Requests, and link them to documentation to ensure traceability and dependency (e.g. do not allow closing a Change Request until the associated document is Approved)
- Automatically relate Quality Events, CAPA, Change Requests and associated content to ensure wider traceability
- Write requirements, test scripts and text execution reports
- Undertake Quality Event Effectiveness checking to ensure the deviation solution was successful

Configuration Package and options

Pre-configured

- Document types used in the DIA Reference Model
- Metadata from the DIA Reference Model
- Document Lifecycle
- Security definition based on typical groups and lifecycle
- Workflows for Review, Approval, Periodic Review, Making Obsolete
- Change Request mechanism
- Client-side Controlled Printing
- Templates definition
- 3 document views including search, columns, widgets and dimensions
- Standard reports (user, controlled prints, training, administrative)

Included but need config

- 1 Signature page template
- 1 overlay template
- 1 autonaming/ numbering scheme

Optional extras

- Additional signature page templates
- Additional overlay templates
- Additional autonamingschemes
- Additional Lifecycles
- Additional workflows
- Changing permissions model
- Additional views and reports

Documentation and timelines

Documentation

For all pre-configured items, and for those included but having specific customer configs:

- User Requirements Specification
- Functional Requirements Specification
- System Design Specification
- System test scripts
- Traceability matrix

Additional optional extras which are configured can be added to documentation.

Timelines

The typical timelines (depending on customer processes) for the out-of-the-box deployment:

- Project planning – 1 week
- Requirements (included items) – 2 weeks
- Build (included items) – 3 weeks
- Documentation (included items) – 3 weeks
- Validation & installation – 6 weeks

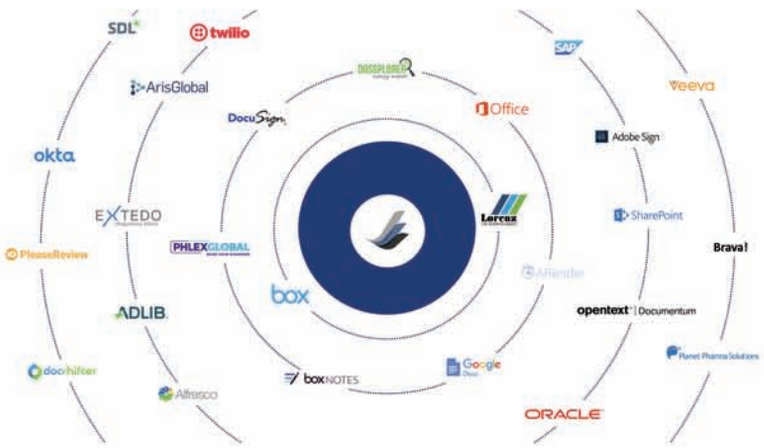
Optional extras include architecture, installation, and training and add to the time.

Enterprise Central Source of Truth

CARA is designed to serve as a seamless platform for all regulatory application requirements. However, we realise that there are other applications and many tools that your business relies on.

The concept of a central source of truth is to create a single place to access all that content and data regardless of where it is stored and managed.

While a particular business group may use a particular tool for their niche process, that content and data is available in CARA to be tracked, managed and re-used across your business.



- Search & Report Across the Enterprise
- Prevent Content, Information, and Effort Duplication
- Provide a Central Authority