



QUMAS Electronic Submission (eCTD) Health Check

Whether you are currently paper-based, have started the transition to an electronic document management process, or are fully up and running with an EDMS, QUMAS Professional Services offers an eCTD Health Check to help you assess your readiness for the eCTD or to help kick-start your readiness initiatives. The QUMAS eCTD Advisory team (lead by an RAC certified Regulatory Advisor) conducts a detailed risk assessment, including a technology, process, and personnel gap analysis. Our team will develop an eCTD readiness roadmap that defines critical milestones, KPI's, and performance objectives to drive your eCTD initiative. We will also develop the internal processes for the delivery of quality submissions to regulatory agencies. We will show you how best to utilize existing systems and tools to put you on the path to "going electronic" with your regulatory agency applications.

The QUMAS eCTD Health Check consists of:

- Consultation regarding best practices for EDMS configuration, document collaboration, taxonomy and other business processes
 - An assessment of your documentation for eCTD compliance, including the 'Top 10' Questions you should be able to answer (workflow processes, PDF rendering, submission lifecycle processes, etc.)
 - A detailed assessment of internal procedures for document authoring (templates, style guides)
 - Tailored advice regarding the format requirements for regulatory documentation
 - Review of options and resource support available for setting up internal procedures for guiding document authors
- Overview of services available for formatting, reworking or scanning documents to make them "submission ready" (both electronic and paper documents)
 - Review of Document Processing Services to ensure that they are following common and best practices in regards to Study Reports, CRF's, Scanned OCR documents, and so on

QUMAS eCTD Health Check Program Approach

A typical QUMAS eCTD Health Check program consists of:

1. Document Authoring Process Analysis
 - Review of Current Template Use
 - Template Lifecycle Management
 - Submission (CTD/eCTD) Authoring Granularity
2. Document Workflow Process Analysis
 - Review, Edit, and Approval of Documents
 - Electronic Signature Validation & Processes
 - Collaborating with External Resources (for example CROs)
 - Achieving Submission Ready Documents
3. Document Management Process Analysis
 - Developing Workflows based on Business Processes
 - Document Types for R&D (Extended Attributes etc.)
 - Document Types & Document Templates
4. Submission Publishing / Outsourcing Process Analysis
 - Submission Compilation Processes
 - Permissions, Granularity, Rendering, etc.
 - Submission Review and Approval Processes

- Submission Publishing & Archiving Processes
- Submission Lifecycle Management
 - Amendments, & Revisions
 - Global Submissions & Product Management

QUMAS eCTD Health Check Program Deliverables

- A comprehensive eCTD Health Check Summary report, including suggested next steps
- An accompanying eCTD Health Check Presentation (PPT provided)
- Subsequent 'Next Steps' Consultation with your QUMAS eCTD Practice Advisor and Account Executive

The result of this eCTD Health Check will be the assurance that your documents and your processes are on the road to being truly eCTD ready!

If you're interested in scheduling a QUMAS eCTD Health Check Program, please contact your Account Executive, or e-mail us at qsales@qumas.com or info@qumas.com

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