

CHIESI FARMACEUTICI S.p.A.

ENABLING GLOBAL ELECTRONIC SUBMISSIONS WITH QUMAS



About Chiesi Farmaceutici S.p.A.

Founded in Parma, Italy in 1935, Chiesi Farmaceutici S.p.A. is an international research-focused group, dedicated to developing innovative pharmaceutical solutions to improve the quality of human life.

The company has global operations spanning five continents and consisting of 22 direct affiliates. Chiesi has research centers in Italy, France and the United States and manufacturing plants in Italy, France, and Brazil. In June 2008, the company opened an office in China. The company employs over 3,000 people worldwide.

Strategic alliances with international pharmaceutical groups ensure that Chiesi drugs and technology are available in over 50 countries.

The Chiesi Challenges

In 2004 Chiesi undertook a project to determine the best way to implement a solution that could address the global content-management and submission-management requirements of the organization. A team, consisting of Chiesi personnel from the R&D and IT groups

as well as outside consultants, was assembled to evaluate the pros and cons of building a solution in-house versus purchasing an off-the-shelf solution. The team was also tasked with defining project plans with requirements for the following three different phases:

- Electronic Document Management System (eDMS) Phase
- Submission Management Phase

One of the primary objectives for the eDMS phase of the project was to make sure the solution could manage the complete lifecycle of R&D documents related to the electronic Common Technical Document (eCTD) format. This included protocols, reports, forms, and eCTD sections originating from various functional groups such as clinical, non-clinical and regulatory affairs.

Lifecycle management capabilities such as version control, audit trails, controlled and limited access to confidential documents and electronic workflows were critical requirements for the document management solution.

When defining the project plan for the Submission Management phase of the implementation, Chiesi identified the need to be able to publish in any submission format. Chiesi decided to use the eCTD format as a source submission, which would allow a paper submission to be directly printed out on an as needed basis.

QUMAS eDMS Solution

After performing a "make" versus "buy" analysis, and analyzing numerous software vendors, the Chiesi team selected QUMAS DocCompliance™ as its Electronic Document Management System (eDMS).

Based on superior product capabilities, strong customer references, and the ability to interface with a wide variety of submission solutions, the Chiesi team felt that QUMAS was the right company to partner with for an end-to-end solution that could meet all of their requirements.

The QUMAS solution has been installed across multiple departments and sites and enables Chiesi to manage the complete lifecycle of R&D documents related to an eCTD. Now that the eCTD submission systems are in place, Chiesi is able to build an eCTD and publish in various submission formats including paper, electronic or hybrid.

"The Regulatory Affairs, Safety, Manufacturing (in Italy), Clinical, CMC, Pre-clinical and QA departments at Chiesi are all able to access the product information housed in the QUMAS solution," said Marco Alberici, Project Manager, Corporate Drug Development at Chiesi. "This ensures effective collaboration and improves corporate compliance and consistency across the various R&D teams."



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Some of the key benefits of the QUMAS solution are:

- Complete management and control of documentation required for eCTD submissions
- Enhanced regulatory and manufacturing compliance enabled through a single, controlled content repository
- Improved collaboration between departments which enables better-informed product decisions
- Reduction of paper documents throughout the organization
- Better visibility and awareness of product information and critical regulatory data
- Comprehensive audit trail that captures and reports on more than 270 auditable events
- Potential reporting capabilities that make it easier to identify processes that can be improved

Successful Submissions!

Since the implementation of the QUMAS solution, Chiesi has successfully submitted the following applications:

- An eCTD for a new pharmaceutical combination for inhalation in three European Countries – Belgium, the Netherlands and the UK
- Variation in eCTD format of a Notice to Applicants submission
- Variation in eCTD format of a CTD submission and a variation in eCTD format for an eCTD submission

- In addition, Corporate Regulatory Affairs in Italy prepares eCTD Modules 1 to 5 for Netherlands, Belgium, United Kingdom, Spain and EMEA. These are dispatched to HAs on DVDs or uploaded on the portals.

"Prior to the roll of the QUMAS eDMS solution our product information was managed primarily on paper and the electronic documents were scattered across many data repositories"

**Marco Alberici, Project Manager,
Corporate Drug Development.**

About QUMAS

QUMAS is the leader in Enterprise Regulatory Compliance Solutions with more than 250 customer deployments and over a decade of experience helping companies in highly regulated industries provide a proactive regulatory defense. QUMAS solutions for life sciences are designed to achieve compliance with industry and government standards for 21 CFR Part 11, cGxP, Quality, R&D, Regulatory Affairs and Clinical Operations.

QUMAS enables organizations to bring new drugs to market faster with better quality submissions while proactively managing regulated content and controls, reducing costs, and improving customer satisfaction.

For more information visit:
www.qumas.com

Chiesi has successfully deployed QUMAS DocCompliance as its Electronic Document Management System (eDMS) to manage all of the R&D documentation required for an eCTD.



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