eCTD-Pharma

is the eCTD Solution

which allows Pharmaceutical Companies to easily design and electronically submit the Dossier of Medicinal Products to the Agency, in accord with the CTD/eCTD Standards

eCTD - DMF Pharma SASI

and efficiently transforms the Pharmaceutical Product Documentation Process addressing all its phases:

- creation
- review
- lifecycle management
- and archival of the electronic submission

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eCTD Pharma

Objectives of the eCTD-Pharma Solution:

I allows the generation and management of the Dossier of Medicinal Products, re-orienting the organizational model of a Pharmaceutical Company toward Product Documentation Processes compliant with the indications and rules of the new eCTD standards, without requiring users additional competencies or additional workload

II gives the user a planning and control tool to coordinate 'as a project' the documental activities associated to Pharmaceutical Products during their Life Cycle

III allows to concentrate the activities of valuable professionals to high added value tasks, by leaving them free from the burden of additional tasks not related to their expertise but aimed at complying with the rules

IV allows the management of the Dossier Life Cycle and simplifies its Maintenance Process with the capability to generate at the same time:

- a printed output of the Dossier in CTD format
- and its electronic Submission

V protects the Company investments and choices; in fact the whole Company production made with the eCTD-Pharma Solution can be quickly exported and made available in the CTD standard

Characteristics of the solution (elements of value):

VI

the eCTD-Pharma Solution is a software application designed specifically to address all the issues of the CTD/eCTD and implemented with the use of Pharmaceutical Customer expertise in order to attain the best mix of efficacy, quality and simplicity of use

VII

eCTD-Pharma allows a strict control of the process and of all its operation sequences, thus allowing the involved Company functions to give their contribution timely and properly

VIII

eCTD-Pharma has a web based architecture and allows to gather and to organize in a simple way a wide typology of documents (word, pdf, etc …)

IX

eCTD-Pharma is a Solution:

- capable to satisfy the Documentation Management needs of a Pharmaceutical Company
- which guarantees continuity in the operations
- which protects the investments made in the past, as it can easily import the pre-existing Dossier Portfolio

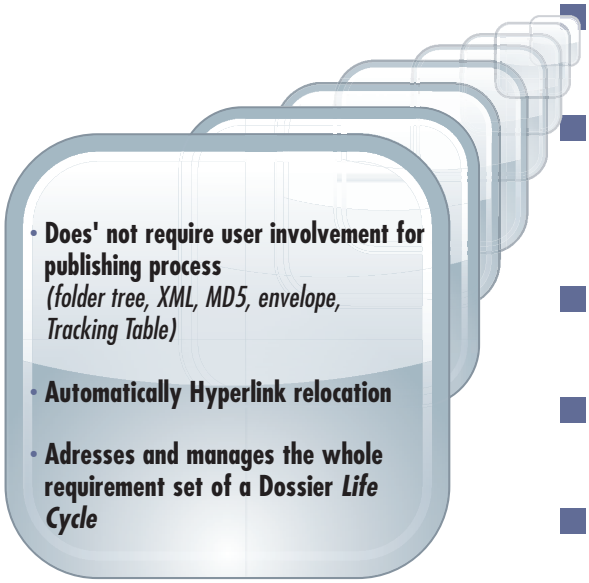
X

the eCTD-Pharma Solution is up-to-date with the issued level of standards and the product will be timely kept up-to-date with the future releases of new rules and requirements of the standards or modification of the existing ones

eCTD-Pharma

Regulatory Affairs document management system

- Supports documental cycle to produce *CTD/DMF*
- Manages the profiles of granularity
- Publishing
- Automatically develops Module 1
  for each specific type of among different countries
  (EMA - GCC - Swiss)
- Automatically manages the *document content database*
- Automatically manages the document *versioning*
- Automatically manages the transaction *Audit Trail*
- Complies with the rules of *CFR 21 part 11*
- Automatically reports delays and critical situations
- Compatibles with the main EDMS



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