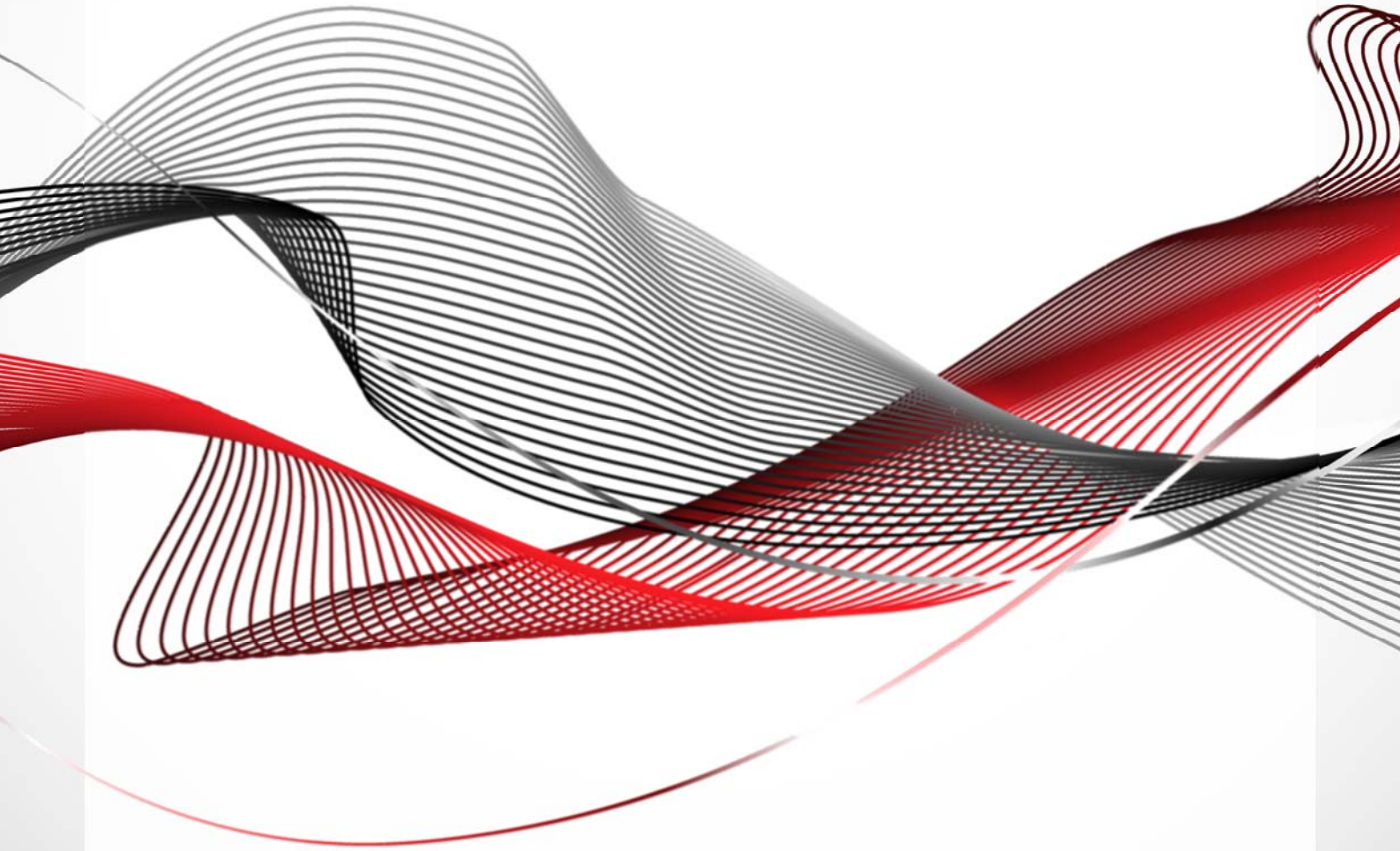
Solutions for DOCUMENTS

We design excellent business processes.
To perfection.

COI-PharmaSuite

Prescribe Efficiency and Quality for Your Drug Approval Processes



An exclusive recipe for success without undesirable side effects: COI-PharmaSuite!

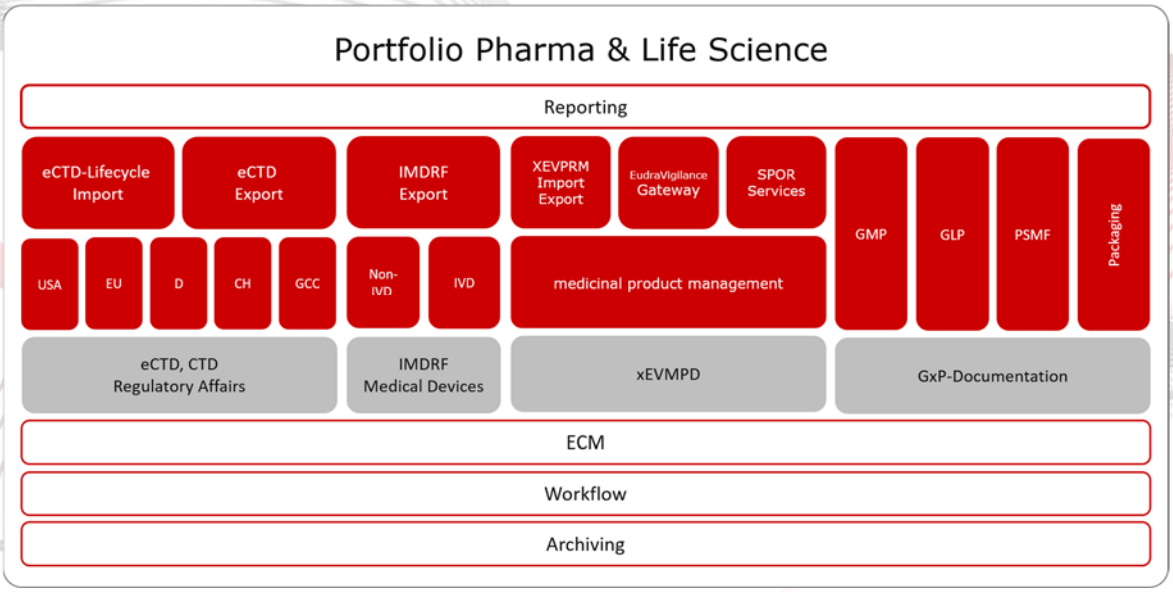
Drug approval processes are complex, lengthy and cost-intensive. Countless documents and dossiers have to be created and managed, numerous regulations must be considered to satisfy regulatory authorities. Just one small error – even if it's "just" a gap in the documentation – can lead to failure, and the marketing authorization may become void. Nowadays, no business can take such a risk, as too much is at stake. Therefore, the developers of COI – in collaboration with leading pharmaceutical industry experts – have created a practical solution.

COI-PharmaSuite offers easy-to-use application – considering all regulations while mapping every process and production step related to drug approval – to deliver high quality, transparency and security, with shortened time-to-market.

COI-PharmaSuite supports you throughout the product lifecycle from initial research results, drug development through to approval and market launch and beyond – providing unique comprehensiveness.

Perfect prophylaxis: effective components for lower risk and more convenience!

COI-PharmaSuite is based on an integrated archive, document and workflow management system that brings together all information flows across divisions and processes. To support your business processes, COI-PharmaSuite provides preconfigured modules, for example, in the areas of Regulatory Affairs and GxP-compliant documentation.



The modular structure of COI-PharmaSuite offers the user decision-making competence in every respect. From single application of one module to individual combinations through to gradual implementation into a global system, almost everything is conceivable and possible – just as you wish and according to your budget.

It's all about flexibility – with a system that adapts!

Thanks to its modular design, COI-PharmaSuite can not only be precisely customized, but also integrated with every IT layout as well as all forms of organizational structure. Interfaces are available for system layouts such as SAP®, R/3®, mySAP.com® and other ERP systems. E-mails from Microsoft Outlook® or of Microsoft Office® documents can also be archived. All the requirements of pharmaceutical industry have been taken into account.

Module: Regulatory Affairs

This module supports you with important steps of the submission process by considering legal requirements. The documents relevant for submission are already recorded and administered in the department where they originate and are thus made available to the other fields involved in the process (e.g. quality assurance, research and development). This supports collaboration across departments, prevents double work and reduces work. The entire lifecycle management is enhanced with efficiency and traceability. Security and convenience are a matter of course: from creating the first document to dossier management to publishing.

Module: eCTD-Lifecycle Importer

The optional expansion eCTD-Lifecycle Importer is used to take over parts of related lifecycle sequences of an Investigational Medicinal Product Dossier (IMPD) into COI-PharmaSuite. It is thus possible to import eCTD sequences created within COI-PharmaSuite as well as those created with any other eCTD tool. The only requirement is that the respective eCTD sequences correspond with the prevailing eCTD specifications.

Module: xEVMPD

Because of amended EU legislation in 2010, all holders of marketing authorizations for medicines within the European Union (EU) must submit extensive product information to the EU database (EudraVigilance). This is a legally binding requirement from the EU pharmaceutical legislation. COI-PharmaSuite offers all necessary functionality to comply with the EVMPD requirements of the European Medicine Agency (EMA). As an integrated platform, the COI-PharmaSuite manages all the data and essential documents for EVMPD and submits this data securely and transparently to the agency.

Module: GxP Documentation

The use of a document management system (DMS) improves the quality of the documentation within a GxP environment while permitting a sustainable reduction in costs. The system makes creating, controlling and archiving complex document volumes more efficient. Entire lifecycles and workflows of registration documents, SOPs, quality and management manuals as well as the manufacturing documentation required by the authorities are integrated in the DMS.

The GxP Documentation module for COI-PharmaSuite supports you in creating, structuring and the implementation of the required documentation. This tool helps to always keep relevant documents up to date and to make then accessible to employees anytime, anywhere.

Package: COI-Quickstart eCTD

COI-Quickstart eCTD is a completely preconfigured package for the process of electronic submission. It provides all functions of the module Regulatory Affairs necessary for the ICH-compliant eCTD procedure as well as every service required for a quick start. The package can be implemented in a minimum of time and offers comprehensive security covering all regulatory requirements.

The COI-Quickstart eCTD-Package can be individually expanded at any time by the entire spectrum of the COI-PharmaSuite and all its modules.

Process is guaranteed: COI-PharmaSuite is constantly being enhanced…

COI is constantly planning and developing new modules and extensions to keep the performance spectrum of COI-PharmaSuite always up to date and to meet client needs effectively.

The advantages at a glance:

- **Unique**: This solution is based on a lifecycle concept providing comprehensive – and in this form exclusive – support
- **Perfect**: Top quality with shortened time-to-market
- **Efficient**: COI-PharmaSuite simplifies the validation considerably while reducing the cost
- **Secure**: Transparency of the processes and complete traceability
- **Flexible**: The modular design, as well as the technological state, result in optimum adaptability to requirements, budgets and IT layouts
- **Comprehensive:** Archive, document & workflow management and publishing – all in one system

About COI

The COI Consulting for Office and Information Management GmbH was founded in 1988. The enterprise is among the technologically leading suppliers in the management of archives, storage, documents and workflows. Thanks to more than 30 years of experience, we are able to implement intelligent standard and turnkey project solutions on time and on budget while ensuring high quality.

Comprehensive support to your advantage

Do you think that efficiency has something to do with size? COI has been proving the opposite for more than 30 years with confidence and for good reasons:

We understand partnership as not a coincidence or an anonymous business contract, but rather as a precondition for beneficial cooperation. We listen carefully, establish the actual problems to be solved and carry on beyond the executive project phase into the after-sales services.

Our employees are enthusiastically committed to your satisfaction and do everything possible to keep your corporate knowledge in top form: with in-depth analysis, qualified expertise, technological competence, complete service – and personal dedication. For your benefit.

COI Solutions for DOCUMENTS

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