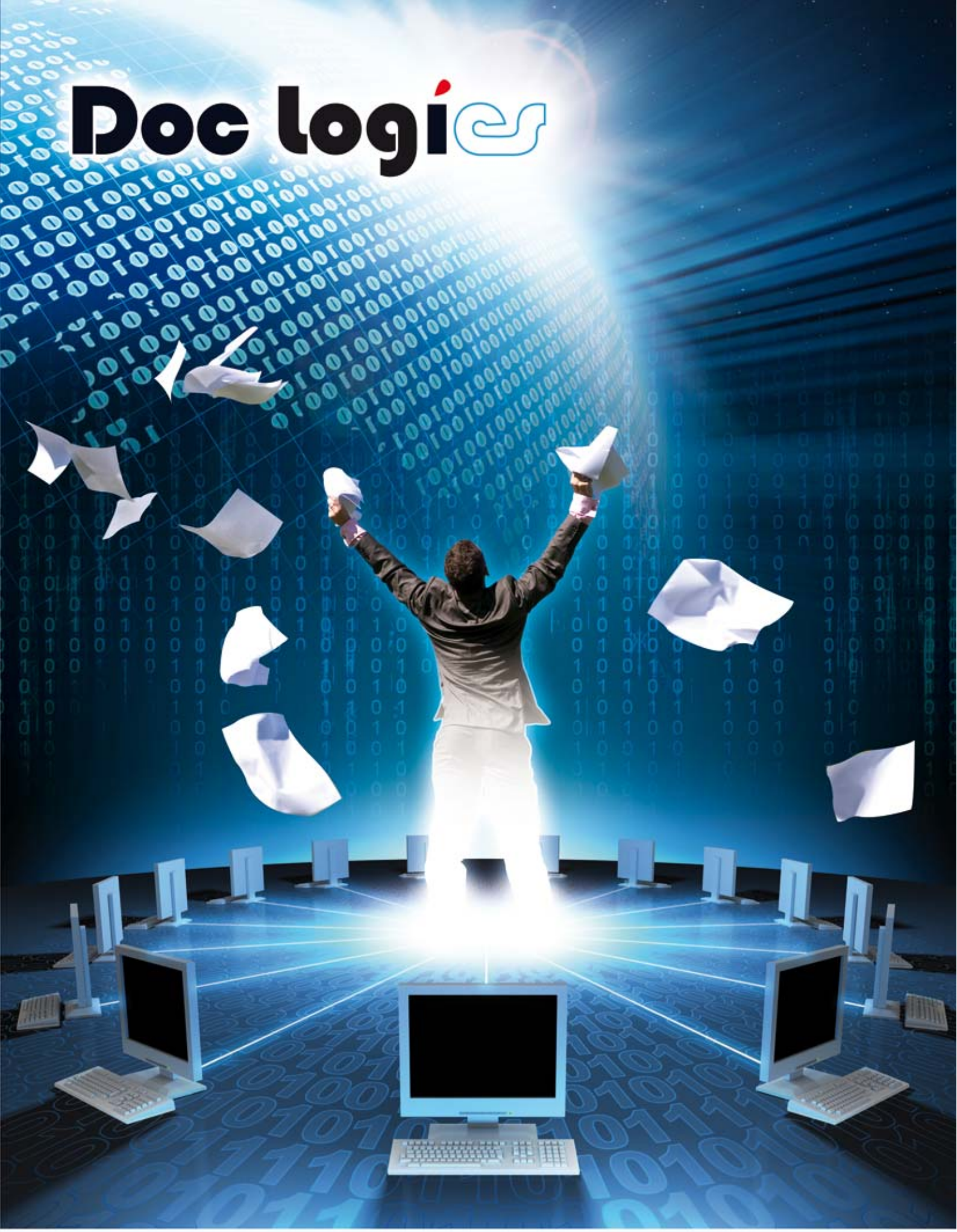
Doc logic



ALTER SOLUTION
A Different Business

CTP SYSTEM
INTEGRATED COMPETENCE

The Solution

Doc Logics has been developed particularly to manage **Critical Data,** as expected by **Good Practices Requirements** - **GCP, GMP, GLP, GDP** - supporting daily activity in:

Innovation

Doc Logics combines the main features of **Document Management System** with the high potential of **Business Intelligence** transferred into the operating process using **Workflow** logic. Therefore Doc Logics supplies **Innovative & Integrated tools** for those business figures building **"Quality"** inside the company, in order to get a more effective **Process Control**.

Knowledge Sharing

Doc Logics assures an high level of "Data Integration" related to data coming by different departments of the same company (**R&D, Regulatory Affairs, Production, Laboratory, Ware House, Distribution, Sales & Marketing**, ...) to obtain the desired harmonisation and a "shared vision".

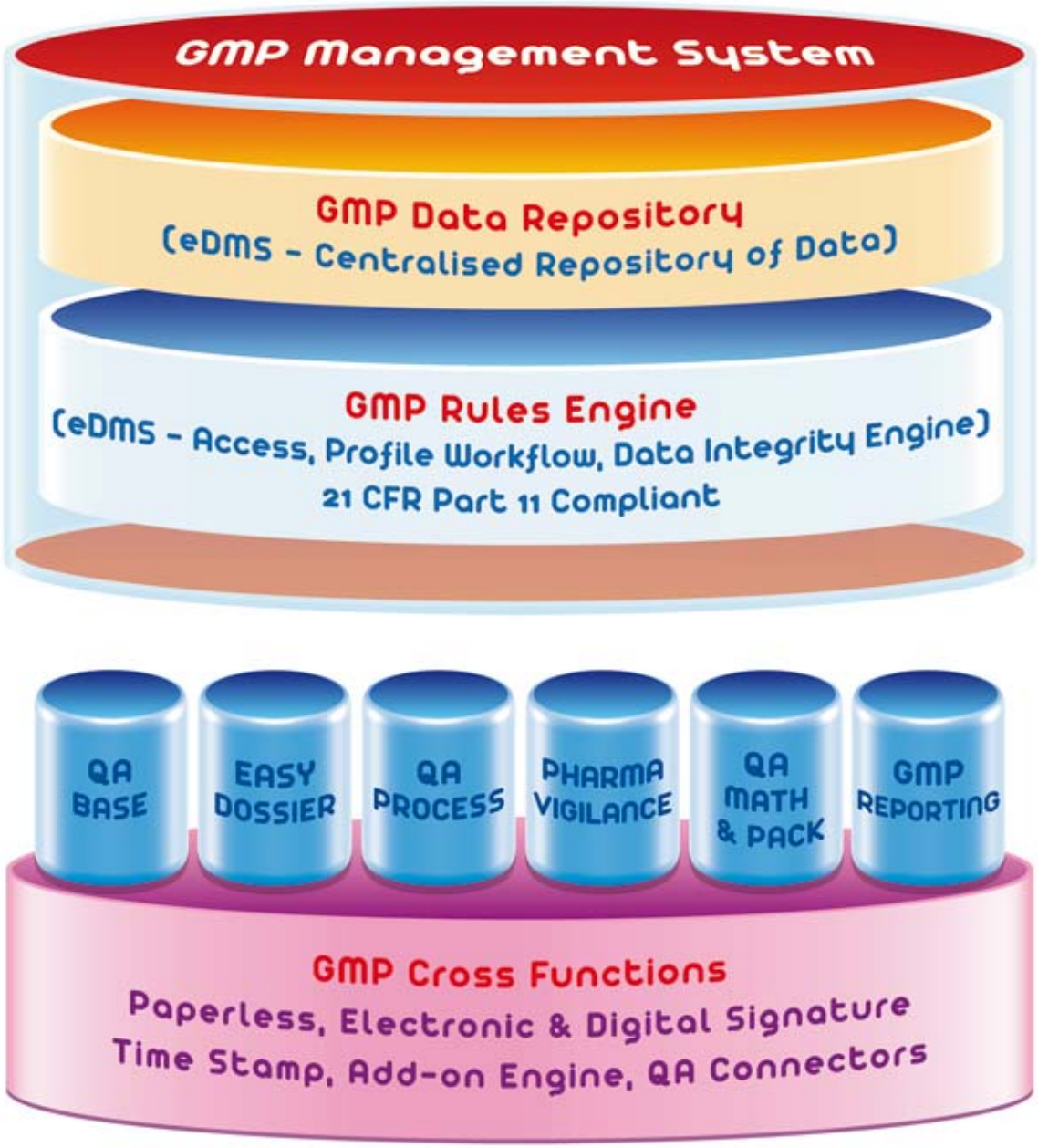
Doc Logics

Improve **Knowledge** · *Manage* **Process** · *Delivery* **Quality**

Functional Innovation and Technological Improvement to meet the new challenges of the market may become the winning element in the corporate team to ensure:

Compliance Assurance + Cost Effectiveness + Delivery Time

Doc Logics is the software solution for "**Data, Document & Content Management**" in compliance with the requirements of **Pharma, Chemical & Food** markets.



Solution's Architecture

GMP Management System represents the **GxP Data Repository**, to handle data produced by the different Company's Processes, typical of a regulated environment, but is even the engine for a correct Data management, which utilises configurable logics, which has been developed compliant to both, Regulatory Requirements and Production Site's Policies.

System's Features

GMP Management System even provides the Main System's Features, as Security, Access Controls, common rules available for the different modules.

Some Commons Functions:

- **Authentication**
- **Electronic Signatures**
- **Workflow Engine**

Furthermore, other common **Functions** are available for the "**Systems's Modules**", even if different depending by **Users Profile**:

- *System's Administration Tools*
- *Centralised Repository*
- *Data Security Rules*
- *User's Profile for*
  - *Access Control*
  - *User's Profiling*
  - *User Group's Management*
- *Electronics Records Management Rules*
- *Time Stamp & Electronic Signature*
- *Audit Trail*
- *Configuration Traceability (Audit Trail)*
- *Workflow (managed in graphic mode)*
- *Document's Master & Template Management*
- *Data Governance Rules (Access - Separation - Maintenance)*
- *Access to GMP Data, based on User Profiles*

Document Flow

QA BASE

EDMS & Document Life Cycle , Formal Documents, Standard Operating Procedures, Working Instruction, Change Request Recording and Training Material Archiving.

- Document's & SOP Life Cycle (Workflow, Versioning, Status, Working Areas...)
- SOP Distribution & Controlled Printing
- Change Request
- Training Data Management

EASY DOSSIER

Document Management System to collect, archive & organise the documents used to prepare the Registration Dossier.

- Project Control - Project Portfolio
- Document Life Cycle & Workflow Management
- Dossier Life Cycle & Dossier Variation Management
- Template Management for Dossier Harmonisation
- Preparation of a "Virtual" Dossier Structure for Publishing Tool Interface
- Native Interface for Publishing tool Integration for CTD & eCTD

QA PACKAGING

"Packaging Material Document Management" to manage Packaging Specification Document.

- To share registration Dossier Contents for Packaging Material
- To Archive Artworks (Document Management Module to Archive leaflets, blister and carton's documentation, etc.)

PHARMA VIGILANCE (GCP)

Archiving Clinical Data & Adverse Event, managing data coming from Clinical Studies & Adverse Events Systems.

- Archiving Clinical Study Data
- Adverse Event Submission Archiving

Process Flow

QA PROCESS

Process Data Management & Data Collection, thought Manual Data Entry and/or interface to on field Process Management Systems (SCADA, MES, DCS, HVAC), integrating data with Quality Contorl (LIMS) & Regulatory, to handle Electronic Batch Record (Paperless by Exception).

- Master Batch Records Archive Management (Master batch Record import&/or creation)
- Processes' Graphic Modelling Function to manage relationship between Events & GMP Electronic Data Recording (EBRs)
- Event Tracking
- Claims
- Change Management Life Cycle
- Corrective Action /Preventive Action
- Production Data Warehouse, Business Intelligence & Data Analysis (KPI, MMT, PPT)
- GMP & Quality Data Elaboration & Reporting (even APR/QPR - Annual Quality Product Review)
- Electronic Batch Record preparation
- Quality Assurance Trends & Statistics (deviation status and number, changes management, etc.)

REPORTING

Quality (GMP) & Process Data Report "on demand" for an analytical data analysis & reporting, based on collected Electronic Records & Quality Documents.

- GMP Analytical Reports (GXP)
- Audit Trail
- GXP Analytical Data warehouse, Process's Data Business Intelligence Reports & GXP Trends
- GxP Report Creation on demand (by users)

Document Management

The Powerful **Document Management Functions** are aimed to optimise Document's Life Cycle.
The System Manages:

- **Document Life Cycle, Work-Flow, Versioning, Status, ...;**
- **Rendition** (documents transformation & Protection from standard offices to not editable format);
- **Watermarking** (addition of harmonised text & watermarks e to managed documents to control extraction or export phase: Header, Footer, expiry date...);
- **Approved Document Distribution** & **Controlled Printing**, with the possibility to **Schedule**;
- **NON Documental Records & Data Collection** managed by Parametric Data Entry Form (user's definable).

Using specific configuration of the **Common Utilities**, each Module can enable shared functions, wich have **specialized extension** for the different **environment/departments** covered by the system. Configuration should active:

- **Users** & **Profiles Creation**, and the configuration of & Specific **Working Areas** with conditional access, (System Administrator, System Owner, Author, Reviewer, Approver, ...);
- **Modulo Security Rules** (independent, for each module);
- Working Areas, Folder Structures and Hierarchy user's definable.

Document Management System's Benefits

System's Functions	Optimisation & Benefits
Template & Master Document	Rapidity, Efficiency, harmonisation & Controlled Knowledge Sharing
Document's Property & Meta Data	Security, Research & Archiving Policy
Legacy Document's Acquisition	Cost Reduction & Existing Documents Reuse
Working Space / Folders	Project Management, Knowledge Organisation, Reuse
Project Portfolio	Reactivity, Monitoring, Impact Assessment, Resources Management
Dossier & Documents Life Cycle	Optimisation, Know-How Protection, Efficacy & Time to Market
Configurable Interface (to external Systems)	Flexibility, Compatibility, Integration
Versioning	Document's Consistency, Errors Reduction
Delegation (for Electronic Signature)	Continuity, Time Saving, Absence & Contingency Management
Document's Check-out e Check-in	Collaborative Working & Single Access
Monitoring	Evaluation & Control, Reactivity
Rendering	Document's Protection &Transportation
Watermarking	Document's Copies Clear & harmonised identification
Controlled Printing	Security, Scheduling, Expiry Management
e-Mail Notification	Event's Management, synchrony and alignment

Process Management

QA Process has been developed to apply **Business Intelligence & Data Warehouse** principles to GMP & Process Data Collection, even using **Reporting Functions**.
These Functions are partially available on **Process Control System's** (e.g.: SCADA, MES, HVAC), but usually such system doesn't integrates GMP related data (e.g. : Analytical Data, environmental Data, specific GXP trends, ...).
The target of this Module is the Integration with existing platform, to obtain **Regulatory Compliance significant data**, and not the replacement of **Process Control System**; this Module is deeply configurable, for System's Functionality, Data Entry and Configurable Interface (**ETL**), to abstract data by on field systems.
Specific Functions makes available a sort of shared Master Batch Record Management, in combination with existing Process Control System.
This module allows **Electronic Batch Records** and **Annual Product Quality Review** Management.
To better support an easy use and the maximum flexibility, the system provide the "**Process Graphic Modelling**".
The combination with internal tools for **Risk Management Assessment**, allows the users to better identify **Relevant GMP/Process Steps**, and to associate them:

- ***Notifications***
- ***Event's Recording, Claim, Deviations, Data, Authorisation, Electronic Signature, ...***

QA - Process, provides two instances which are separate but integrate, to share following data:

QA Management Tool

- **GMP Event Monitoring & Tracking**
  Processes Event Identification - Recording & Monitoring
- **Deviation Management**
  Deviation Life Cycle
- **Complaint Management**
  CLAIMS Management
- **CAPA**
  Corrective Action / Preventive Action Management
- **Change Management**
  Change Request / Control life Cycle
- **MBR e EBR**
  Master Batch Record & Electronic Batch Record
- **APR & QPR**
  Annual & Quality Product Review

GMP Production Tool

Analytical tools for **Process KPI, Material's & Services Level Evaluation.**

Doc Logics


Q.A. Process
Q. A. Process Management
• Graphics Process Modelling & Review
• Master Batch Record Management
Q. A. Management Tool
> GMP Event Monitoring & Tracking
> Deviation Management
> Complaint Management
> CAPA
> Change Management
> EBR (Electronic Batch Record)
> APR & QPR
(Annual & Quality Product Review)
GMP Production Tool
> Production Event Monitoring & Tracking
> Production Dashboard Tool
> Production Data Analysis Tool
> Production Dashboard Tool
>> MMT (Material Management Tool)
>> PPT (Product Performance Tool)


MMT : Materials Management Tools
> Stock
Stock Reporting & Management
> Supplier
Supplier Performance Monitor
> Capacity
Capacity Supervisor
> Scheduler
Production Order Compiler
> Efficiency
Efficiency in Production


PPT : Production Performance Tool
> PSL
Production Service Level
> DSL
Dispatch Service Level
> ITR (TRF)
Inventory Turn-Over Ratio Forward
> QSL
Quality Service Level
> FSL
Flexibility Service Level
> MSL
Manufacturing Service Level
> CSL
Customer Service Level

Fig. 01 ▸ Doc logics: Home Page

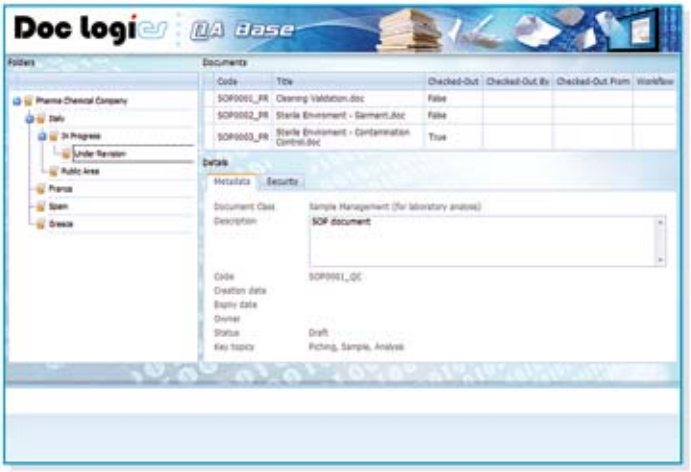


Fig. 02 ▸ Main: Metadata

Fig. 03 ▸ Authentication - User, Role, Function & Permission

Fig. 04 ▸ Workflow Template

Fig. 05 ▸ Documents Approval

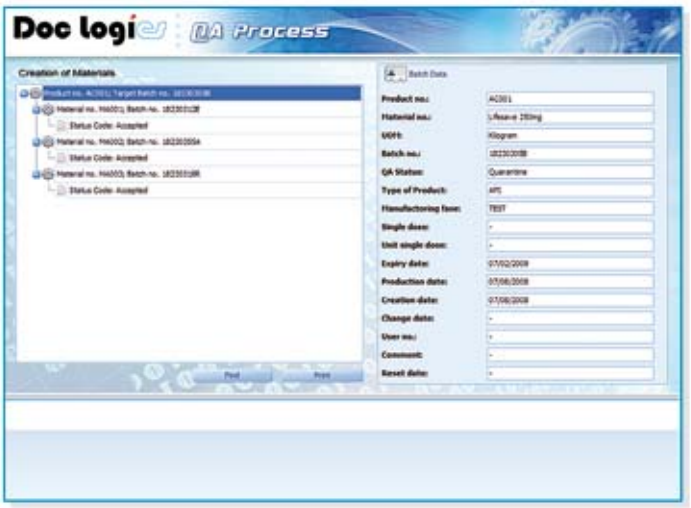


Fig. 06 ▸ Batch List

Fig. 07 ▸ PPT - Production Performance Tool

Fig. 08 ▸ PSL - Production & Service Analysis - Diagram

Fig. 09 ▸ Deviation Tracking

Fig. 10 ▸ Audit Trail & Opening Deviation

Fig. 11 ▸ Event Tracking

Fig. 12 ▸ Publishing

Improve **Knowledge** • *Manage* **Process** • *Delivery* **Quality**

ALTER SOLUTION

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