bluenext

Adiuto 4 Life Sciences

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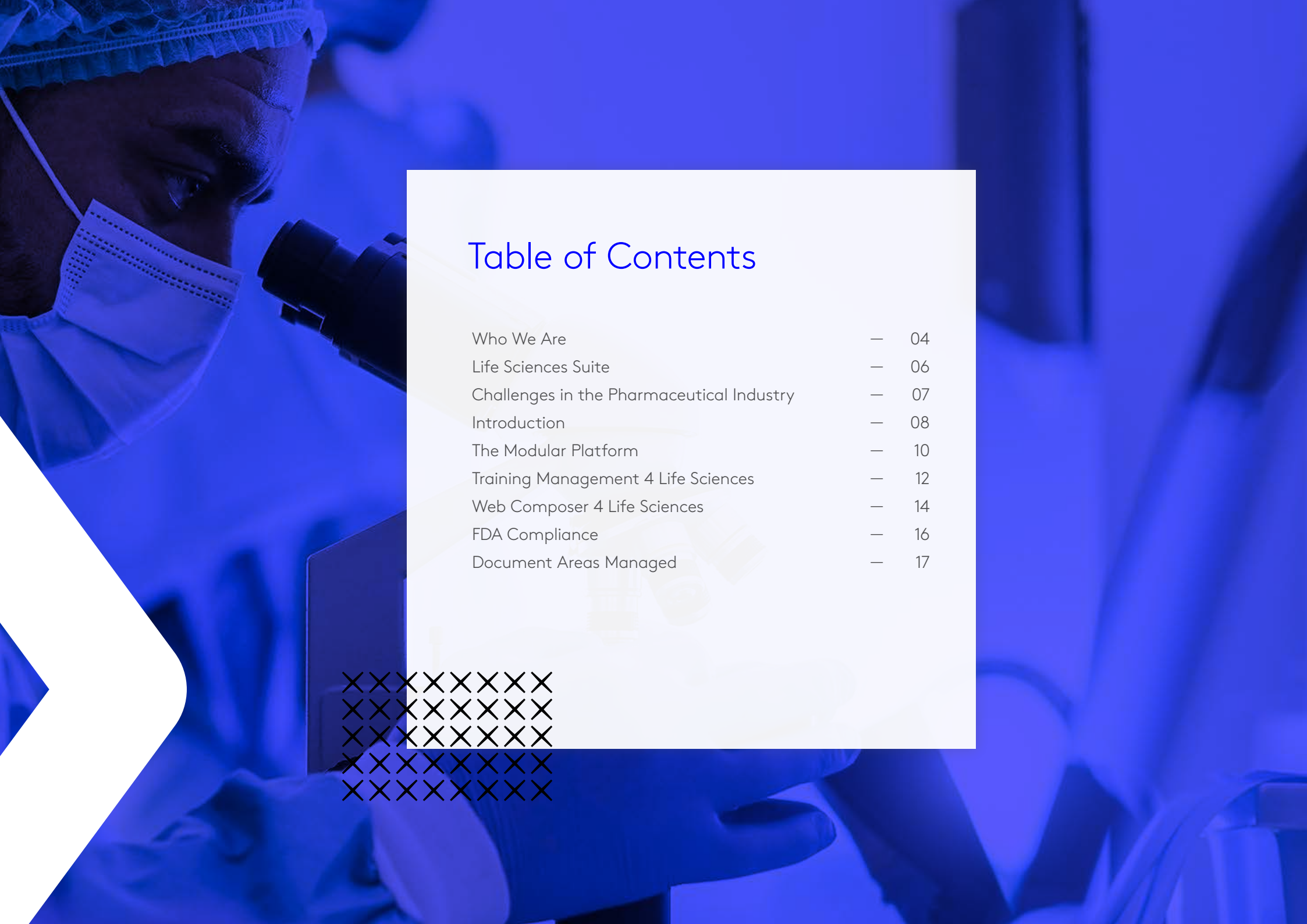
Your GxP-Compliant Ecosystem: a platform to manage Quality, Document, Content, and Training



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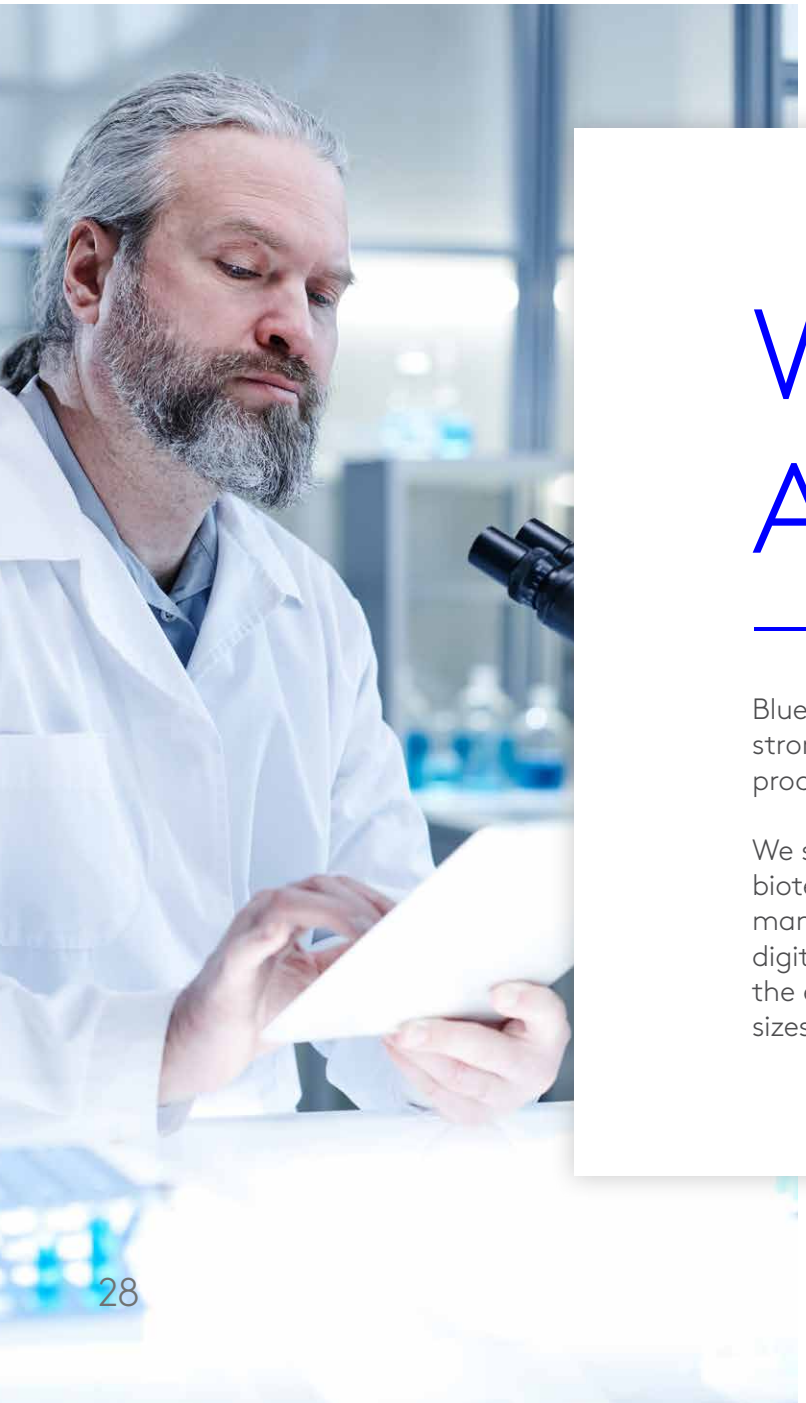


Who We Are

Bluenext is an Italian software house with strong expertise in the digitalization of regulated processes.

We support companies in the pharmaceutical, biotech, cosmetic and medical device manufacturing sectors with solutions for the digitalization of regulated processes, leveraging the experience gained in organizations of all sizes, in Italy and abroad.

Every project starts by listening to our customers' needs: we adapt our solutions to the company's operational reality, to ensure effective and sustainable integration.
Our software for the Life Sciences world combines unique and innovative features to guarantee:

- GxP Compliance (FDA 21 CFR Part 11, EU Annex 11)
- Ease of implementation, with rapid adoption times
- Increased productivity, from the very first use

Thanks to Bluenext software you can optimize activities in production, quality, laboratory and maintenance, reducing operational inefficiencies and risks.

Key Strengths

- Solid experience in the Life Sciences sector
- Solutions developed to meet regulatory requirements
- Modularity and flexibility: they adapt to existing processes
- Support the reduction of inefficiencies and operational continuity
- Scalable approach, suitable for both SMEs and large enterprises
- Dedicated support

Life Sciences Suite

Our solutions are **modular, scalable and integrated**, enabling companies to **progress in their digital transformation journey**.

Adiuto 4 Life Sciences

Modular QMS compliant with GxP/FDA for the integrated management of quality processes, documents and training.

Ioi | Integration Of Instruments

Platform for **compliant data acquisition from laboratory and production instruments**, even non-digital ones.

Dibatch | Electronic Batch Record

Electronic Batch Record with **Review by Exception**, for efficient and traceable production management.

Diform | Digital Form

Digitalization of paper-based forms, checklists and logbooks, with manual or automatic data entry.

Digma | Digital maintenance

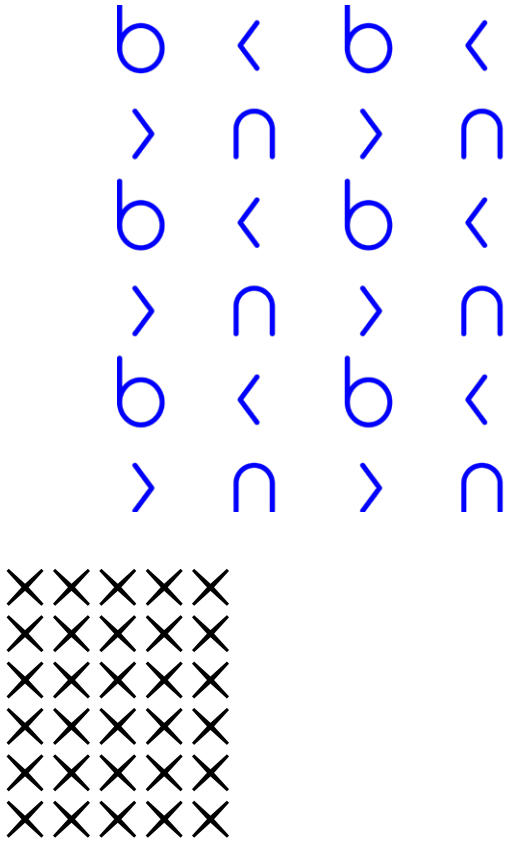
Digital management of maintenance, calibration and spare parts, integrated with ERP, MES and quality systems.

Current Challenges in the Pharmaceutical Industry

- **Regulatory compliance:** Data Integrity is not optional. Inspectors require secure data.
- **The paradigm shift:** guidelines (e.g. PIC/S) explicitly state that digital is safer than paper.
- **Risk of Warning Letters** (fines/shutdowns) **due to transcription errors.**
- **Bottlenecks:** the review of paper Batch Records is slow and delays batch release.
- **Inefficiency due to physical paper management.**

In the Life Sciences sector, the real value is not the software: it is the ability to pass an inspection stress-free and release batches when they are ready, without unnecessary delays.

Our solutions directly address these challenges.

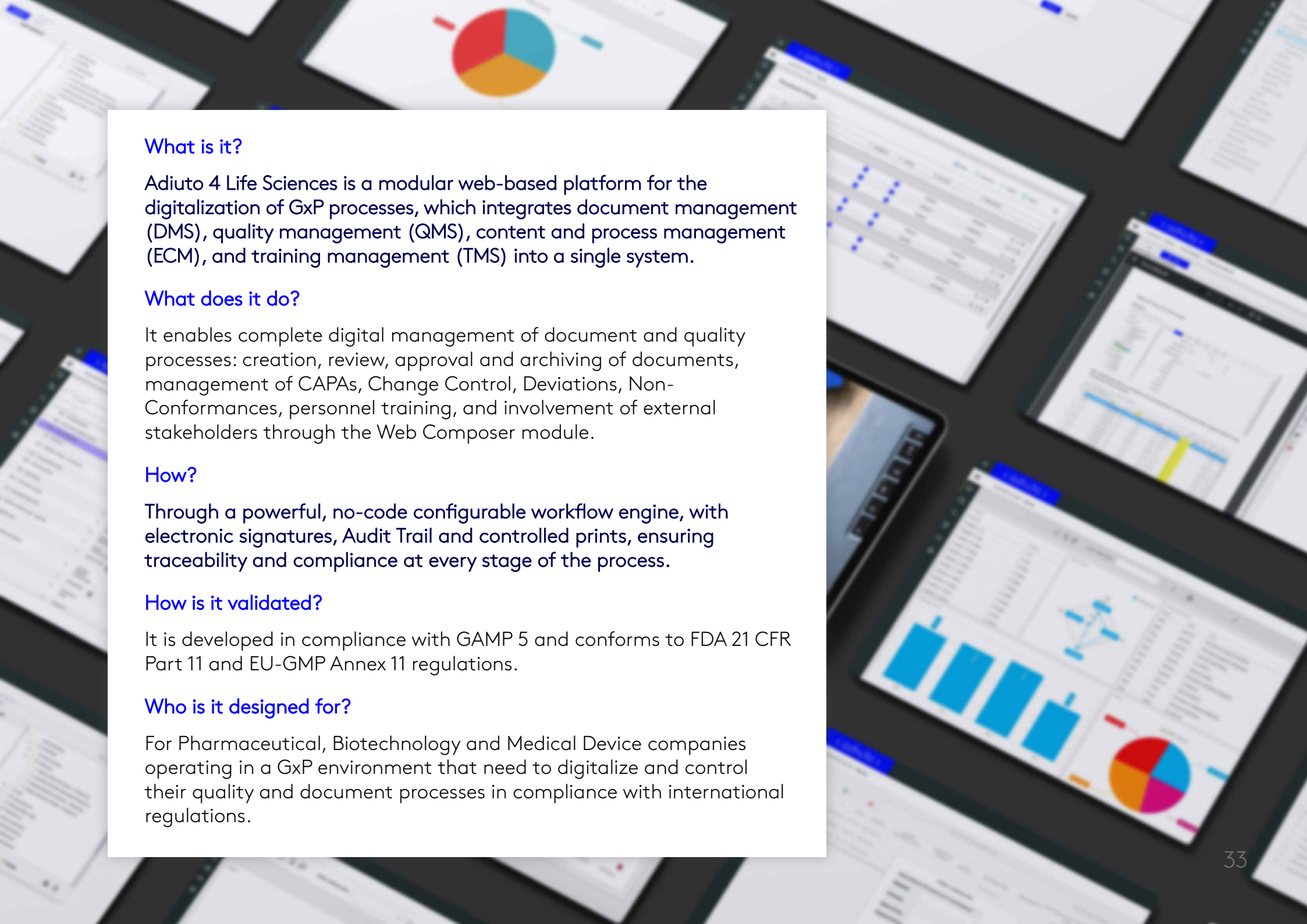


Adiuto 4 Life Sciences

Your GxP-Compliant Ecosystem: a platform to manage Quality, Document, Content, and Training

Adiuto 4 Life Sciences is the tailor-made GxP-compliant platform.

The platform is designed for the digital management of documents, quality processes and training in the Life Sciences sector (pharmaceutical, biotechnology, medical devices).



What is it?

Adiuto 4 Life Sciences is a modular web-based platform for the digitalization of GxP processes, which integrates document management (DMS), quality management (QMS), content and process management (ECM), and training management (TMS) into a single system.

What does it do?

It enables complete digital management of document and quality processes: creation, review, approval and archiving of documents, management of CAPAs, Change Control, Deviations, Non-Conformances, personnel training, and involvement of external stakeholders through the Web Composer module.

How?

Through a powerful, no-code configurable workflow engine, with electronic signatures, Audit Trail and controlled prints, ensuring traceability and compliance at every stage of the process.

How is it validated?

It is developed in compliance with GAMP 5 and conforms to FDA 21 CFR Part 11 and EU-GMP Annex 11 regulations.

Who is it designed for?

For Pharmaceutical, Biotechnology and Medical Device companies operating in a GxP environment that need to digitalize and control their quality and document processes in compliance with international regulations.

Configurable platform for Digital Management

Adiuto 4 Life Sciences, thanks to its Workflow System, allows the management of all processes and links them to any Information, Content or Document present in the company.

QMS | Quality Management System

Master Batch Record, Reconciliation, Operational Batch Records, CAPA, Change Control, Deviations, Complaints, Audit Reports, Non-Conformances.

DMS | Document Management System

Audit Reports, Supplier Certificates, Assessment Questionnaires, Batch Record, Validation Reports, Regulations, SOP – I.O., Forms, Monographs, Validation Protocols.

TMS | Training Management System – Human Resources

Quality Training, Safety Training, Environmental Training.

ECM | Content and Process Management System

BPM e CMS Adiuto is a highly configurable system that enables content and process management in any area where it is necessary to manage a process at company level.

One platform for 4 systems

QMS | Quality Management System

Drafting, verification, approval and distribution of the approved document.

Key benefits

• Revision alerts • Constant monitoring of document status and its progress, with the possibility of receiving notifications about possible delays in document issuance • Publication of documents and retention of different versions as required by regulations • Approval with electronic signature • Viewing of documents directly from mobile devices without mandatory printing • Printing of documents with a controlled print system • Document reconciliation.

DMS | Document Management System

Documents can be entered in any format (PDF, Word, Excel, JPG, etc.). Non-digital documents are scanned and imported into the software, which acts as a document "cabinet".

Key benefits

• Access to the archive and documents with one click, anywhere and on mobile devices • Speed of consultation and retrieval of information • Management of a deadline scheduler that notifies the user via an alert system.

TMS | Training Management System – HR

Training plans are linked to the profiles managed by the organizational chart, keeping track of the training needs of each managed user.

Key benefits

• Pro-active system that suggests which training sessions need to be carried out based on SOP procedures, revisions performed, newly hired employees or those who have had a change of duties • Generates the training list for each user and monitors required training • Plans the list of expiring training sessions and enables planning of new courses.

ECM | Content and Process Management System

Management of documents required to ensure the company's quality system and coordinate information related to document processes.

Key benefits

• Transformation of forms from paper to digital and completion of all parts of the document by the various managers involved in the process • Management of process lists, alerts and tasks • Electronic Signatures.

Training Management 4 Life Sciences

The solution for managing corporate training in a regulated environment.

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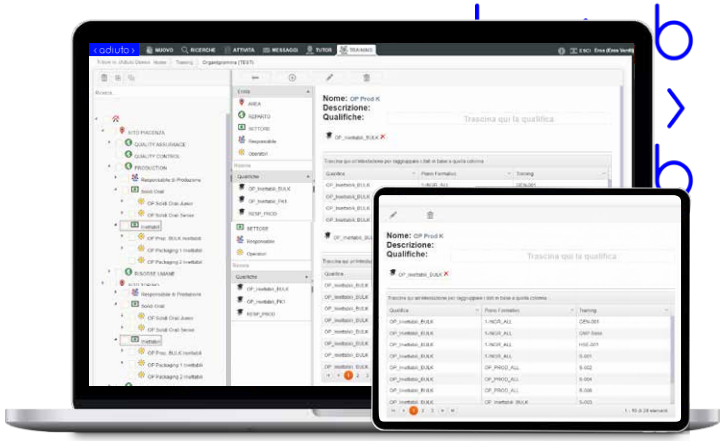
TMS is the solution dedicated to Corporate Training Management, developed as an extension of the Adiuto Platform in compliance with the GAMP guidelines for the validation of automated systems in the pharmaceutical sector.

The solution is equipped with Electronic Signatures and Audit Trail functions.

The Training Management System solution provides for the management and archiving of all documents relating to training courses linked to user training, and enables the digitalization of all management activities related to training.

Enabling the modelling, automation, planning and digital filing of user information and data, as well as their training, represents Adiuto's response to the HR/Training market.



Web Composer 4 Life sciences

The winning tool for publishing content, data, documents and processes to the web.

The WebComposer module is Adiuto's CMS, the dynamic heart of your digital content: it easily creates, manages, and publishes websites and web pages, offering total control, brand consistency, and an always updated and engaging user experience.

The module allows documents to be published privately to clients, suppliers, third-party contractors, or any party with whom the company needs to interact, and enables external entities and stakeholders to upload

information or documents in a parameterised and secure manner.

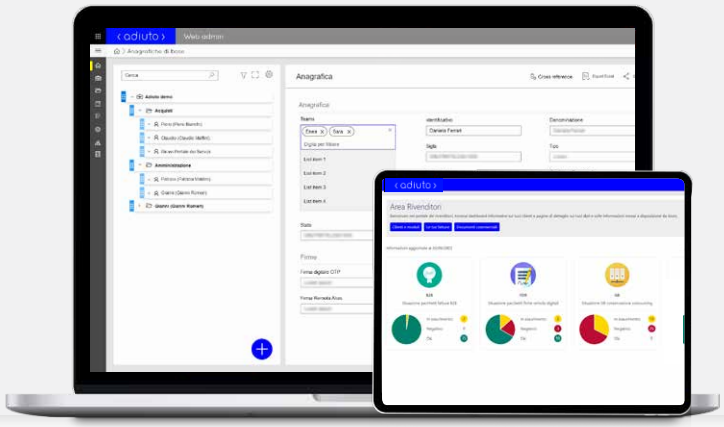
Web Composer is compliant with the requirements of the reference regulations for the Life Sciences sector: FDA CFR 21 Part 11 and EU-GMP Annex 11.

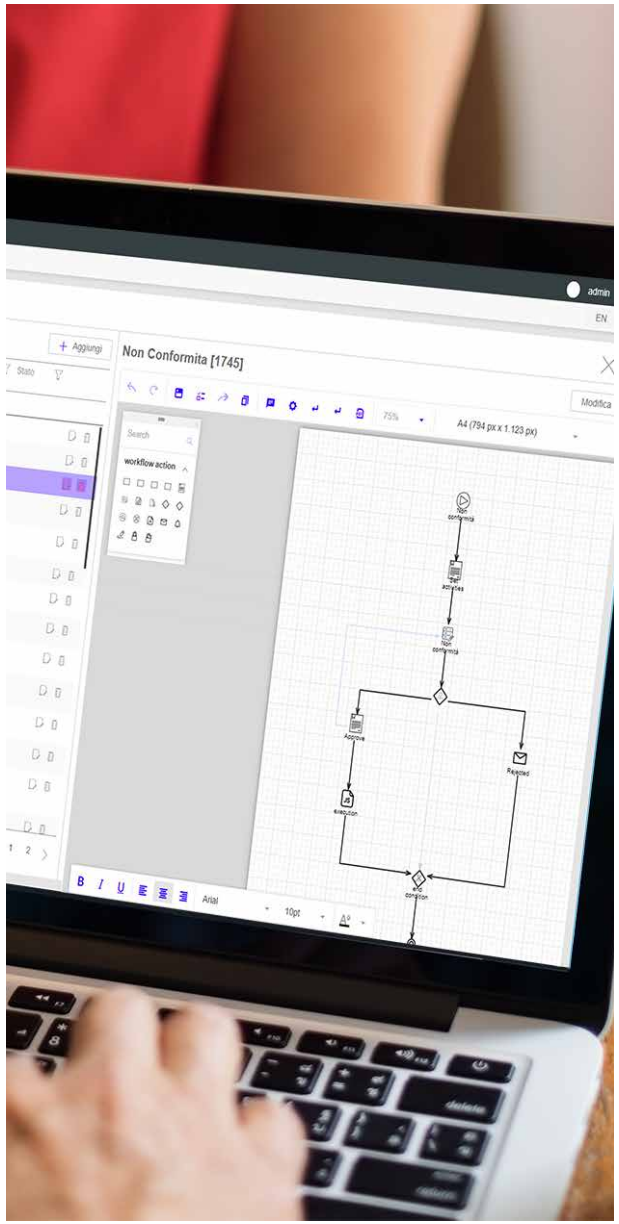
Web Composer allows companies to involve their external partners, giving them visibility of content according to the workflow and sharing rules configured in Adiuto, also providing maximum support for smart working activities.

Standard and configurable, Web Composer enables external users to be involved in the document and process management flows governed by Adiuto. Everything is configurable from the Adiuto administration panel, without writing a single line of code, using only the handy "Configuration Tool".

Managed Processes (examples)

- Supplier qualification process
- Contract and Technical Agreement management
- Document exchange and approval
- Involvement of external entities in quality processes (Change Control, Complaints, etc.)
- Remote document signing processes





FDA Compliance

The regulation governing the use of IT tools within GMP is 21 CFR (Code of Federal Regulations) Part 11, and it represents the essential tool for ordering, classifying and archiving all processes and their related attached files, and for enabling immediate and traceable searches.

In particular, Adiuto 4 Life Sciences complies with FDA CFR 21 Part 11 and EU-GMP Annex 11 regulations, meets all requirements necessary for software validation by official validation bodies recognized by international regulatory authorities.

The solution is developed in compliance with GAMP 5 according to the relevant reference guidelines.

The Adiuto solution is developed in accordance with GAMP 5 and complies with FDA 21 CFR Part 11 and EU GMP Annex 11 regulations.

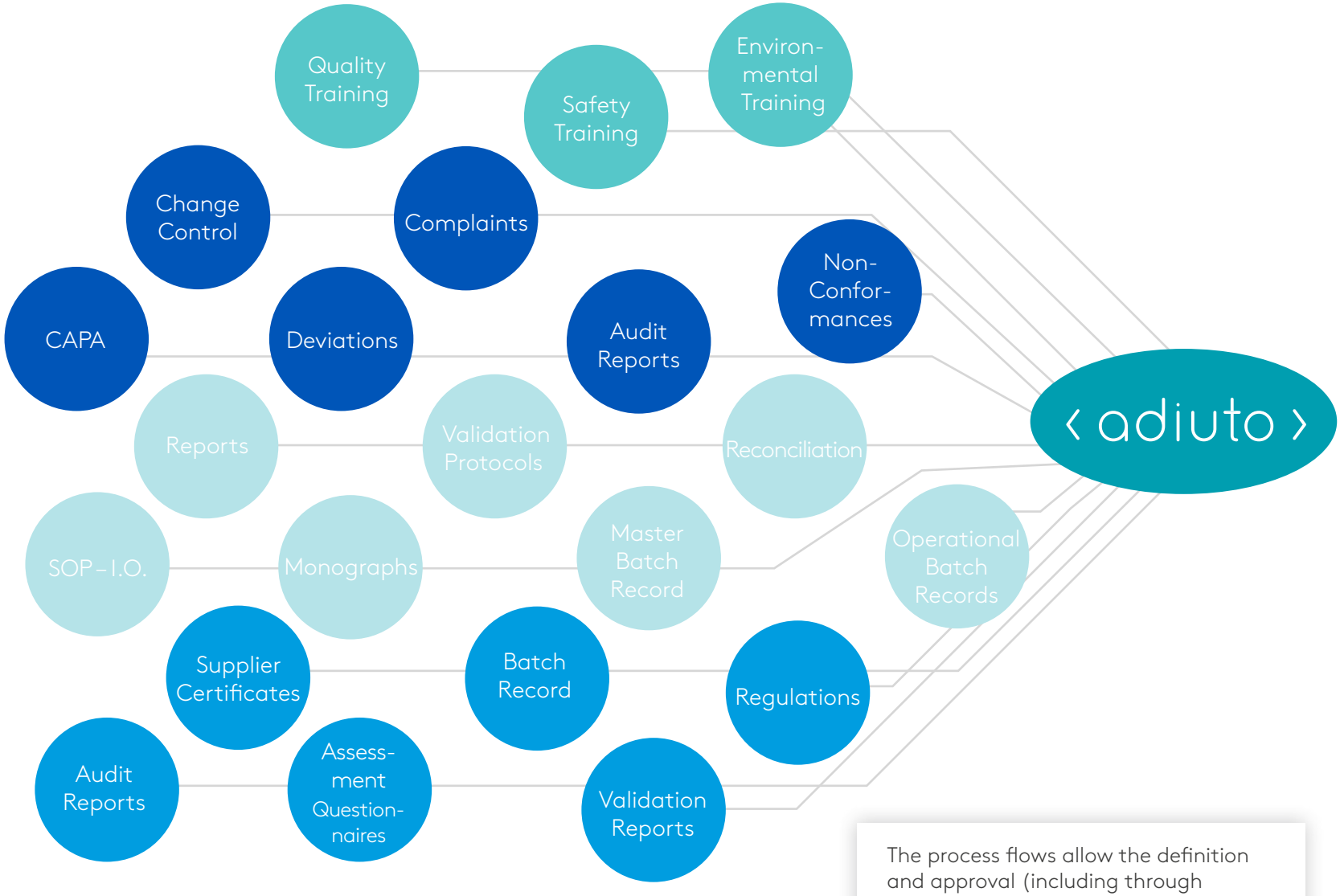
Document Areas Managed

TMS
Training Management System

ECM
Content & Process Management

QMS
Quality Management System

DMS
Document Management System



The process flows allow the definition and approval (including through Electronic Signatures) of the activities required to complete a business process.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