

>bluenext<

# Digital Solutions for Life Sciences

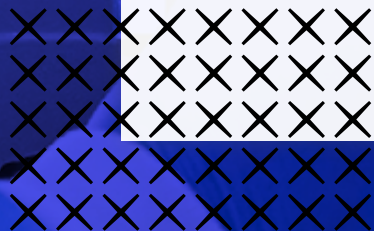
—  
From paper to digital  
integrity





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# Who We Are

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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.



## loi | Integration Of Instruments

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



## Adiuto 4 Life Sciences

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



## 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

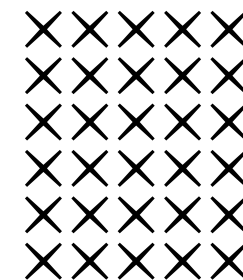
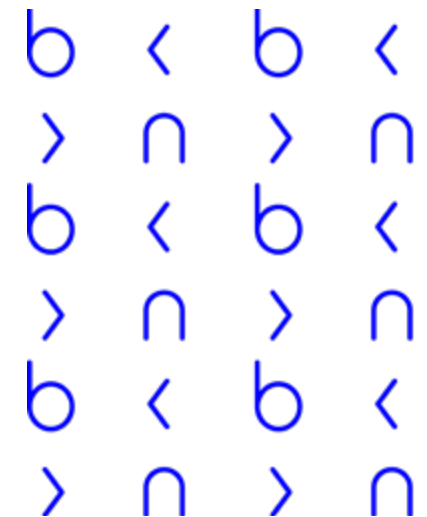
Digital management of maintenance, calibration and spare parts, integrated with ERP, MES and quality systems.

# 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

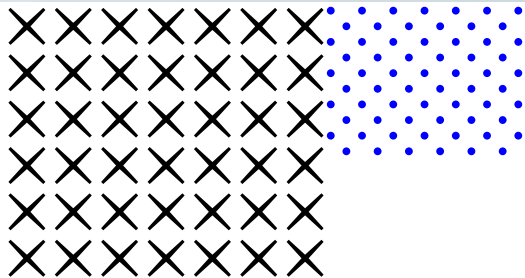
*Your GxP-Compliant Ecosystem: a platform to manage Quality, Document, Content, and Training*

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In **regulated companies**, **quality and document management** are inherently collaborative activities. Each process involves multiple stakeholders — such as Quality Managers, Operators, Reviewers, Approvers, HSE Officers, and external Suppliers — each with defined responsibilities and the need for timely access to accurate information.

**Adiuto 4 Life Sciences is designed around this complexity.** It is a modular, web-based platform that unifies people, **processes**, and **documents** within a **controlled digital environment**, replacing fragmented paper-based workflows with a **structured, auditable, and fully traceable system**.

All processes follow predefined steps and role-based access controls, while **every action** — including review, approval, signature, and distribution — **is recorded and permanently available for inspection**.



## 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 workflow engine**, each process — **from SOP approval to CAPA management and supplier qualification** — is digitally modelled, defining roles, sequence, and conditions. Automated routing, deadline notifications, and escalation rules ensure clear task ownership and prevent skipped or bypassed steps. Electronic Signatures and Audit Trails provide complete traceability across all process stages.

## How is it validated?

Developed in accordance with **GAMP 5**, and compliant with **FDA CFR 21 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.

# Configurable platform for Digital Management

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**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

CAPA, Change Control, Deviations, Compliants and Audit management, Non-Conformances. Master Batch records, Reconciliations.

**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.

## Clear workflow. Total control

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**At the heart of Adiuto is a powerful, no-code configurable workflow engine.** Each process — whether it is the approval of an SOP, the management of a CAPA, or the qualification of a supplier — follows a defined sequence of steps, with each step assigned to a specific role or user group.

## The result

Every actor always knows what they need to do, every document is always in the right state, and nothing is ever lost, duplicated, or uncontrolled.

# Main Features



## Initiation

Any authorized user can open a process: create a document, report a deviation, submit a change request. The system automatically routes it to the next actor in the workflow.



## Parallel or sequential flows

Workflows can be configured to run steps in parallel or in sequence, adapting to the actual approval structure of the company — no rigid templates, no workarounds



## Escalation and deadlines

If a task is not completed within the defined timeframe, the system automatically sends reminders and escalates to the responsible supervisor — keeping every process on track.



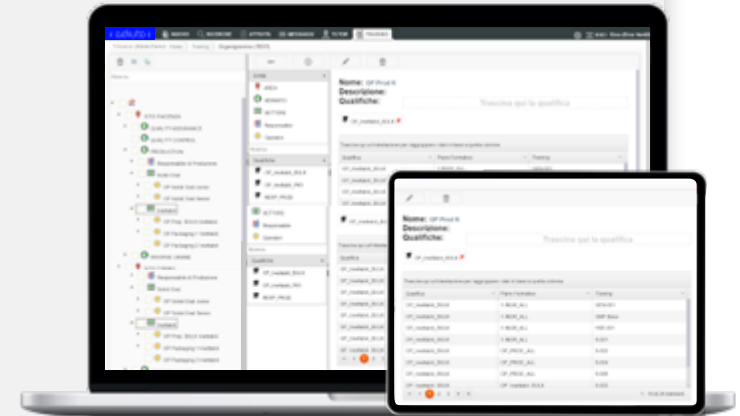
## Review and approval

Each actor receives a task notification (in-platform and by email), accesses only what they are authorized to see, and advances the workflow with an electronic signature.

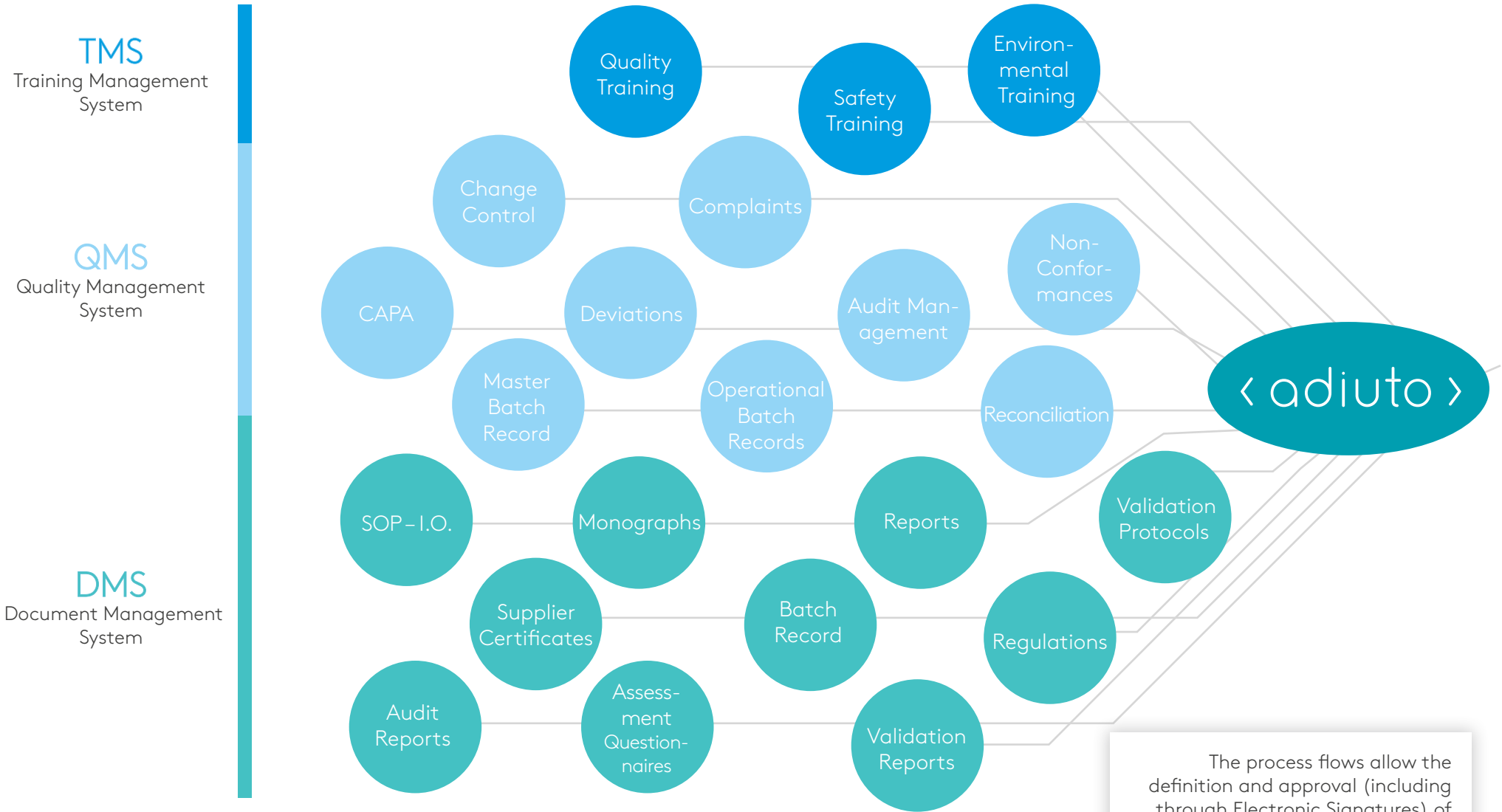


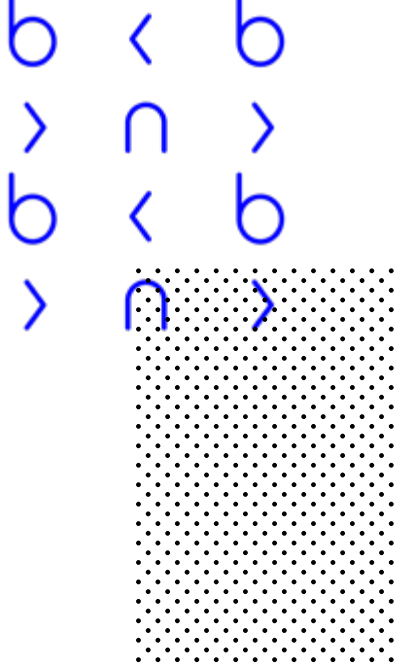
## Closure and archiving

Once all steps are completed and signed, the process is closed, archived, and fully traceable — ready for any inspection or audit, at any time.



# Document Areas Managed





# Why choose Adiuto

**Regulatory compliance ensured:** The platform complies with GAMP 5, FDA CFR 21 PART 11, and EU-GMP Annex 11, making inspections simple and stress-free.

**A single integrated platform:** Adiuto brings together DMS, QMS, ECM, and TMS in one system, eliminating fragmentation and data silos.

**Flexible no-code workflows:** Processes—from SOPs to CAPAs—are visually configured without code and adapt to real approval flows, sequential or parallel.

**Automation and control:** Automatic notifications, reminders, and escalations eliminate manual follow-ups, allowing quality teams to focus on decisions

**Complete traceability:** Electronic signatures and a full audit trail ensure every action is recorded and traceable, always ready for audits and inspections.

**Extended collaboration and scalability** External stakeholders collaborate securely, even remotely; the modular platform scales from SMEs to large enterprises, with rapid adoption and immediate productivity gains.



# loi

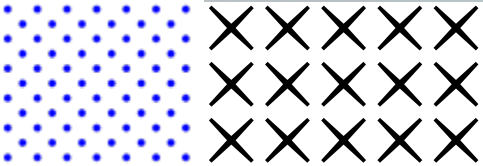
## Integration of Instruments



*Digitalize your instruments.  
Don't replace them.*

loi is a web-based software platform designed to **automatically and compliantly acquire data from laboratory and production instruments.**

It enables the full digital management of measurement, review and approval workflow, ensuring **Data Integrity**, traceability and validation, **even in the presence of obsolete, unconnected or non-natively compliant instruments.**



## What is it?

loi is a web-based software platform for the **automatic and compliant acquisition of data from laboratory and production instruments**, including those not compliant with Data Integrity requirements.

## What does it do?

It enables complete digital management of the measurement, review and approval phases of instrumental data, **with full traceability and GxP compliance**. It supports **In-Process Control (IPC) checks in production and easily integrates with LIMS, MES, ELN and EBR systems** via the connection middleware module.

## How?

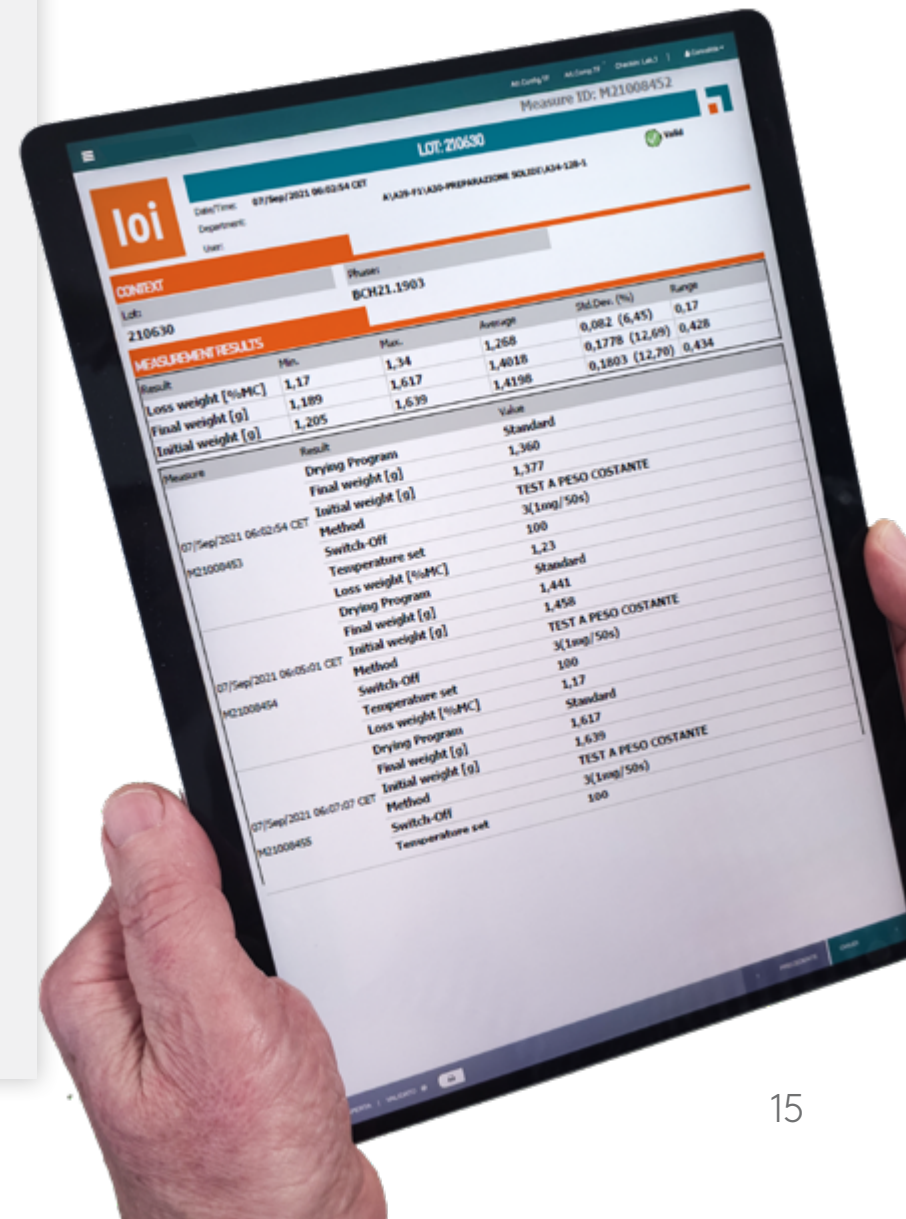
By communicating with instruments via our black box — or via camera for instruments without communication ports — and automatically recording measurements and metadata in a secure database, **eliminating manual transcriptions and ensuring rigorous and compliant processes**.

## How is it validated?

As a **Category 4 software (GAMP 5)**.

## Who is it designed for?

For analysis laboratories of pharmaceutical, food, chemical, cosmetic and manufacturing companies operating in a GxP environment that want to **digitalize** instrument data acquisition **without replacing existing instruments**.



# Main Features

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## Reviews and approvals

Context-based electronic review with configurable review flows Supports up to three electronic signatures.



## Communication with third-party systems

Such as LIMS, MES, ELN, EBR, etc via Connection Middleware Module.



## Configuration

Instrument configuration by area and access management by area and role.



## Automatic measurement acquisition

Identify samples and instruments and capture measurements and related metadata. Manual notes can also be associated with measurements and instruments. Recording in a secure database.



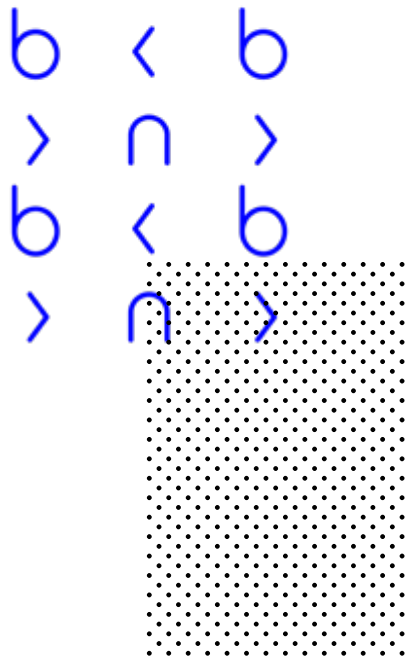
## IPC Module (In-Process Control)

Module designed for offline In-Process Control with setpoints, timers, and thresholds (alarm or block).



## GxP-ready reporting

Complete set of standard reports, including instrument logbook and Audit Trail.



# Why choose loi

**Compatible with all instruments:** immediate digitalization without replacing existing instruments. Integrates instruments of any brand, age or technology, via print port, digital signal or even camera.

**Compliance and data integrity:** automatic and compliant data acquisition, without manual transcriptions, with all metadata required by Data Integrity (attributability, context, date and time, any electronic signatures...). Simplified validation according to GAMP 5.2 software cat. 4.

**Measurable benefits from day one:** eliminates paper, reduces errors, automatically generates the instrument register and allows review and approval comfortably from the desk, improving operational efficiency.

**Rapid integration:** no-code configuration in 4 hours per instrument. Easily connects to LIMS, MES, ELN, EBR with Middleware or intelligent Gateway functions.

**Accessible from any device:** system accessible at all times, from any location and device. Supports operational continuity.



# Diform

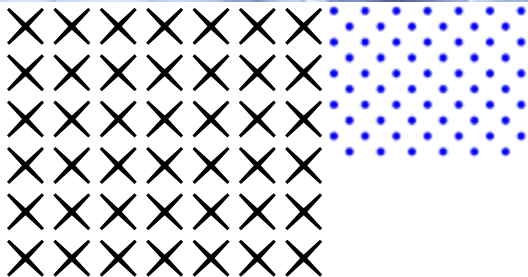
## Digital Form

*Digitalize your GxP forms and logbooks. Start from what you already use.*

Diform is a **GxP-compliant** web application for the **digitalization of a wide range of paper-based documents**, such as data collection forms, checklists, registers and notebooks.

Diform manages the **entire lifecycle of forms and logbooks**: configuration, review, approval, data entry, final review and electronic signature.

It allows data currently handled on paper to be collected and managed in digital format, **fully preserving the original layout**.



## What is it?

Diform is a web-based application for digital, **object-oriented and GxP-compliant forms and logbooks.**

## What does it do?

It allows forms and logbooks to be filled in, reviewed and approved in electronic format. **It digitalizes standalone forms, checklists and registers** (instruments, cleaning, etc.).

It digitally **manages the entire template lifecycle**: configuration, review, approval, execution, final review and electronic signature.

## How?

Templates in Microsoft® Word format are imported in a simple and intuitive way. **The built-in configurable objects enable auto-population of dynamic fields.**

## How is it validated?

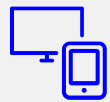
As a **Category 4 software (GAMP 5).**

## Who is it designed for?

Diform is a solution designed for **pharmaceutical, biotechnological and medical device companies** operating in a GxP environment.



# Main Features



## Digitalization - Paper on glass

Digitalization of forms, checklists and registers in any field and sector where paper-based forms are used.



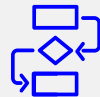
## Forms and logbook lifecycle management

Configuration, review, approval with version control and validity date. Execution, review and approval.



## Control

Automatic validation of entered data. Reduces errors and rework: dynamic fields with validations, limits, formulas, drop-down menus, buttons, etc.



## Data collection workflow

Definition of data entry sequences by user and form sections.



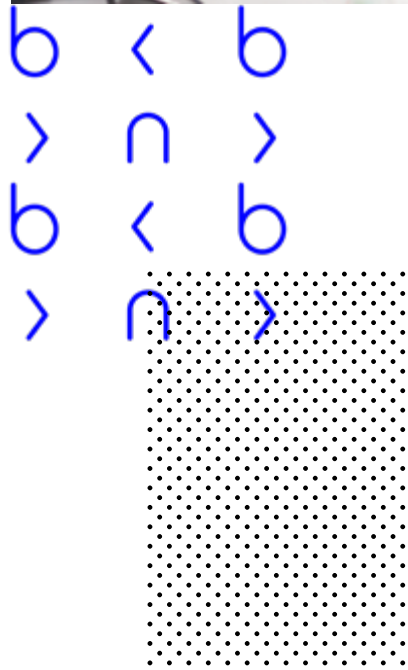
## Archiving and analysis

Data availability for trends, reports and assessments. Application of data compliance verification criteria.



## Electronic signature

Electronic signature capability in approval processes.



# Why choose Diform

**Easy and intuitive import:** import existing forms in Word or other formats, keeping templates already familiar to users. Minimizes impact on staff.

**Simple and fast configuration:** easy to configure thanks to a complete library of configurable objects. No software development required.

**Measurable benefits from day one:** eliminates paper, prevents errors, improves operational efficiency.

**Interoperable:** communicates with other systems to ensure continuous and integrated data flows. Simplifies and optimizes processes.

**Accessible from any device:** system accessible at all times, from any location and device. Supports operational continuity.



# Dibatch

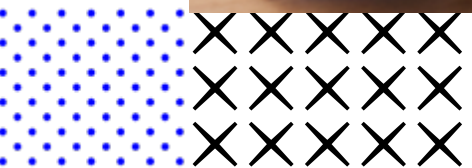
## Electronic Batch Record

*Digitize your batch records.  
Keep your processes under  
control.*

Dibatch is a GxP-compliant web-based solution for managing **electronic batch records (EBRs)** and **reducing review times** through **the review by exception.**

Dibatch provides **full control over the Master Batch Record lifecycle**—configuration, review, approval, execution, final review, and electronic signature.

It enables a **gradual digitalization approach** starting from the most critical processes, **without needing to revolutionize the entire production system.**



## What is it?

A GxP-compliant web solution for **EBR management**, reducing review time through **Review by Exception**.

## What does it do?

Manages the **full lifecycle of Master Batch Records (MBR)**: configuration, review, approval, execution, final review, and e-signature. It monitors, tracks and controls the entire production process from raw materials to finished product.

## How does it work?

**Existing Microsoft® Word templates are automatically imported into Dibatch**. Digital dynamic fields are configured afterward.

It enables a gradual approach to digitalization, starting with the most critical processes without having to revolutionize the entire production.

## Validation

Validated as a **Category 4 software (GAMP 5.2 Cat. 4)**.

## Who is it for?

Designed for **pharmaceutical, biotech, and medical device companies** operating in GxP environments.



# Main Features

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## Master Batch Record Lifecycle Management

Configuration, review, approval with version control and validity date.



## Review by exception

Reduce review time by focusing only on critical data and anomalies detected by the system.



## Import from Microsoft® Word docs

Quickly digitize your Batch Records from Microsoft® Word documents you already use, while maintaining the original layout.



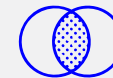
## Individual Batch Record Lifecycle Management

Execution, review, and approval of individual batch records.



## Manual and Automatic Data Entry

Fill in records with manual or automatic input by capturing data from barcodes/QR codes, photos, instruments, and integrations via web services (ERP, LIMS, MES...).



## Library of Configurable Objects

Use an extensive set of no-code elements (QR codes, images, checklists, formulas, signatures, etc.) to create dynamic MBRs.



# Why Choose Dibatch

**GxP compliance:** full audit trail compliant with CFR 21 PART 11, versioning and profiled access. Validated as Category 4 software (according to GAMP 5.2).

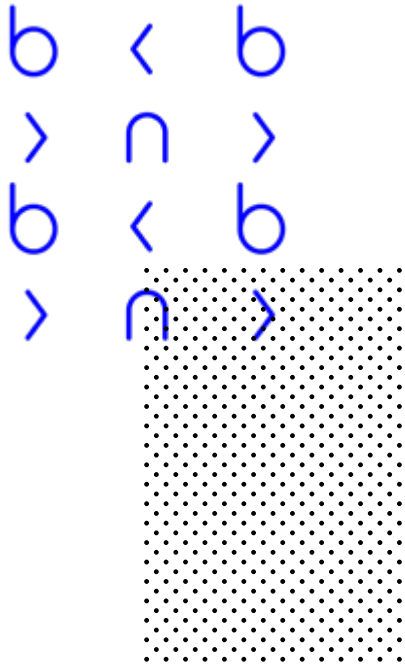
**Fast configuration:** set up MBRs in weeks, no IT skills needed thanks to a library of ready-to-use objects.

**Optimized review:** review by exception focuses only on critical data. It allows you to focus only on what matters rather than examining every data point in the report.

**Integrable with corporate systems via Web Services**  
it interfaces with third-party systems such as LIMS, ELN, MES.

**Start from what you already use:** import your Batch Records directly from Microsoft® Word files or other formats, maintaining the original layout and reducing the impact on your staff.

**Reduce errors with manual & automatic data capture:** it supports manual and automatic data entry (e.g., readings from instruments, QR/barcode scanning, photos), as well as integration via web services (e.g., ERP, LIMS), with real-time control of the entered data.





Dm

# Digma

Digital management of  
maintenance

—  
*Optimize the management of  
maintenance, calibrations and  
spare parts: anytime, anywhere.*

**Digma** is a web and mobile-based **CMMS** (Computerized Maintenance Management System) **solution** that ensures safe and compliant processes.

Digma enables the **digital management of all maintenance activities**, reducing downtime, optimizing costs and improving the traceability of operations.

## What is it?

A web and mobile **GxP-compliant CMMS** solution for managing **corrective, preventive and predictive maintenance activities**.

## What does it do?

It enables the **digital management** of maintenance, calibration, asset qualification and spare parts warehouse activities.

The platform is easily **integrable with MES, SCADA and ERP systems, as well as IoT, RFID and barcode technologies**.

## How?

By **improving the traceability of operations**, ensuring rigorous, safe and compliant processes, reducing downtime and optimizing costs.

## How is it validated?

As a **category 4 software (GAMP 5)**.

## Who is it designed for?

For pharmaceutical, biotechnological and medical device manufacturing companies operating in a GxP environment, and for companies in any sector that want to **turn maintenance into a competitive advantage**.



# Main Features



## Complete Maintenance Management

Full management of corrective, preventive and predictivemaintenance.



## Work Plan & Work Order Planning

Management of work plans, work orders and maintenance scheduling (planned and breakdown) with automatic deadlines.



## Technical-Production Ecosystem Management

Asset and technical/production ecosystem management, organized by sites, lines, plants, equipment and personnel.



## Instrument Management: Calibrations and Qualifications

Management of instruments, related calibrations and equipment qualification activities in a traceable and compliant manner.



## Master Data & QR Code Management

Master data management and precise asset classification for better traceability.



## GXP, Quality and Safety Compliance

Support for regulatory compliance in the GxP, quality and safety domains.



# Why Choose Digma

**Flexible:** ability to conform to the existing reality in terms of managed processes and data. Minimize sorganizational impacts.

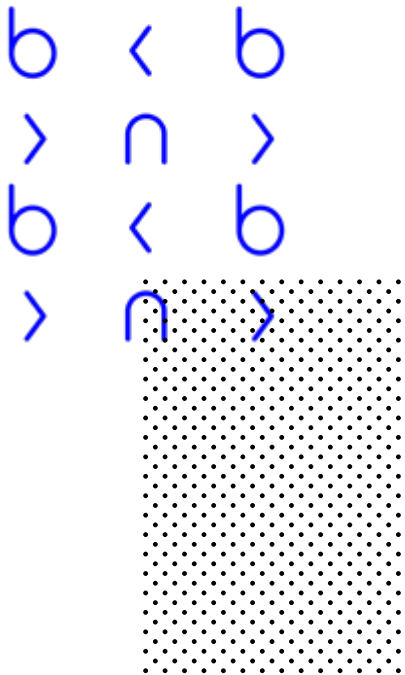
**Proactive:** control of planned deadlines and stock levels, automatic sending of alerts and notifications. Optimizes warehouse management and minimizes intervention delays.

**Available:** system accessible at all times, from any location and device. Supports operations — information is always available.

**Easy:** simple and intuitive navigation and interfaces, straight forward data handling (entry, retrieval,management). Minimizes impact on staff.

**Interoperable:** communicates with other systems to ensure continuous and integrated data flows. Simplifies and optimizes processes.

**Collaborative:** system supporting collaboration, communication and knowledge sharing among people. Makes the process efficient and effective.





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