

>bluenext<

# Digital Solutions for Life Sciences

—  
The perfect compliance for  
GxP, FDA, EU Annex 11





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# About Us

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**Bluenext** is an Italian software company with strong expertise in the **digitalization of regulated processes**. For years, we've supported pharmaceutical, biotech, and cosmetics companies with solutions designed to:

- Ensure full **regulatory compliance** (GxP, FDA, EU Annex 11)
- **Optimize operations** in production, quality processes, laboratory, and maintenance
- **Reduce inefficiencies** and operational risks

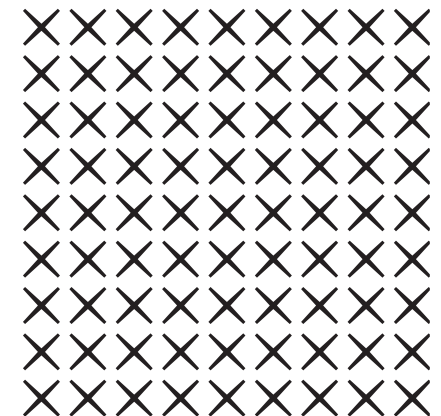
Our approach is based on **listening to our clients' needs** and **adapting our solutions** to their operational reality, not the other way around. We serve clients of all sizes, both in Italy and internationally.

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

## Key Strengths

- Extensive industry experience in Life Science
- Solutions built to meet regulatory compliance requirements
- Modular and flexible: adapt to your existing processes
- Help reduce inefficiencies and ensure operational continuity
- Scalable approach for both SMEs and large enterprises
- Dedicated support and local presence

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# Life Sciences Suite

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



## Iol | Integration Of Instruments

A platform for **compliant data acquisition** from lab and production instruments, even non-digital ones



## DiForm | Digitalizes paper-based forms

Digitalizes **paper-based forms**, checklists, and logbooks with manual or automatic data input



## Adiuto 4 Life Sciences

A **modular, GxP/FDA-compliant eQMS** for integrated management of quality processes, documents, and training



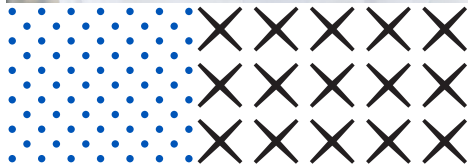
## DiBatch | Electronic Batch Record

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



## Digma | Digital management of maintenance

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



## lol - Integration Of Instruments

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

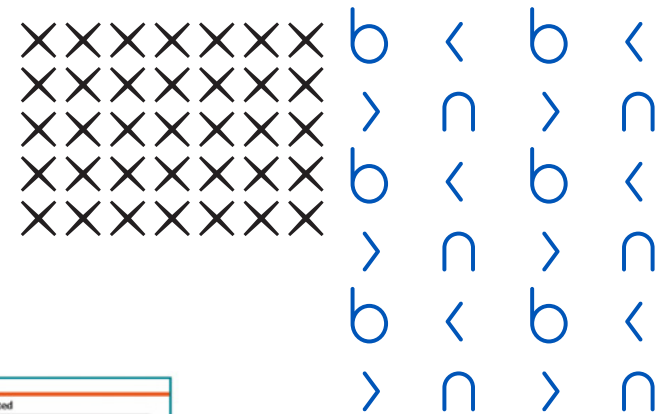
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lol is a software platform designed to automatically and compliantly **acquire data** from laboratory and production instruments, even **outdated** or **non-connected** ones.

It enables the **full digital management** of measurement, review, and approval phases, with complete **traceability** and **validation**.

# Key Features

- Integrates instruments of any brand or generation
- Captures data via print port, digital signal, or even camera (Manual Measurement)
- Provides a secure and centralized database for GxP measurements
- Includes modules for IPC (In-Process Control), electronic review, report generation, and approval workflows
- Easily connects to LIMS, MES, ELN, EBR via middleware or smart gateway



SESSION DETAIL				
Shift ID 1: SH00285 - Shift Status: Accepted				
Shift start:	29/Jan/2021 10:19:24 CET	Shift end:	29/Jan/2021 10:38:24 CET	
Average (g)	51,68 (102,85%)	Std. deviation (g)	0,44 (16,32%)	Min (g)
				77,06 (153,25%)
				Max (g)
				39,45 (78,51%)
				Delta (g)
				37,61 (74,80%)
Tare average:	1,71 g			
Type	Overall	Accepted	Rejected	Anomalous
Gross Samplings	2	2	0	0
Tare Samplings	1	1	0	0
Timer:	1	Tolerance:	1	
<math><PL</math>	<math><T4</math>	<math><TD</math>	<math><T2</math>	<math><T1</math>
0	0	1	3	4
ok -	ok +	>T1+	>T2+	>T3+
0	2	1	0	1
>T4+	>PL+			
0	1	1	0	1
Action	Date/Time	User		
Shift start	Verificata 29/Jan/2021 10:19:25 CET	inpharmatic		
Shift end	Verificata 29/Jan/2021 10:38:13 CET	inpharmatic		
Shift Approval/Notes	Accepted 29/Jan/2021 10:38:21 CET	inpharmatic		
TIMER WARNINGS				
Shift	Date/Time	Ack by user	Timer	Constraint
1	29/Jan/2021 10:37:17 CET (SA00346)	inpharmatic/EMMANUELE.DICERTO	Timer	Blocking
SH00285 (AC)	29/Jan/2021 10:37:50 CET (SA00346)	inpharmatic/EMMANUELE.DICERTO	Tolerance	Blocking
2	29/Jan/2021 10:46:39 CET (SA00348)	inpharmatic/EMMANUELE.DICERTO	Timer	Blocking
SH00286 (AC)				
Legend: PR= In progress - UN= Completed - AP= In approval - AC= Accepted - RF= Rejected - AB= Completed with anomalies				
Shift start	Verificata 29/Jan/2021 10:38:31 CET	inpharmatic/EMMANUELE.DICERTO (EMMANUELE.DICERTO)		
Shift end	Verificata 29/Jan/2021 10:47:09 CET	inpharmatic/EMMANUELE.DICERTO (EMMANUELE.DICERTO)		
Shift Approval/Notes	Accepted 29/Jan/2021 10:47:17 CET	inpharmatic/EMMANUELE.DICERTO (EMMANUELE.DICERTO)		

Session summary report and timer warning



## Some integrable tools

### BASIC



*Scale*



*pH meter*



*Polarimeter*



*Tritator*

### ADVANCED



*UV spectrophotometer*



*IR spectrophotometer*

## Why It Matters

- **Instant digitalization** without replacing existing instruments
- Guaranteed **compliance** with **Data Integrity** standards (21 CFR Part 11, GAMP 5 cat. 4)
- **Drastically reduces human errors** in data transcription
- **Saves time** in review processes through electronic signatures and automatic reports
- **Improves IPC control** with built-in locks, alerts, and traceability

# What Makes It Unique

- Multi-brand and multi-generation support = maximum flexibility with your existing devices
- No-code configuration = no need for custom scripting per instrument
- Simplified validation for GxP environments
- Native integration with enterprise systems
- Includes a Test Environment to simulate and configure instruments, roles, and approval workflows

Channel L  
 Format: GLP  
 Date: 25-OCT-2019  
 Time: 09:31  
 Sensor ID: INLAB413  
 Sensor SN: 5051234  
 Last Cal: 24-OCT-2019  
 Cal. time 11:25  
 Instrument ID: ANA1  
 Instrument SN: 123456789  
 Exp.unit ID: PH1  
 Exp.unit SN: 230006p  
 User: MEIER  
 Method: LAP1  
 Endpoint: Automatic  
 ATC/MTC MTC  
 Time int: 120s  
 Automation: Pos.:3  
 Sample ID: WATER  
 Result : 6.997pH  
 mV: 0.2mV  
 Temperature: 23.0°C  
 Alarm: Max pH  
 Min Temp  
 Signature: \_\_\_\_\_



Measure ID: 87576  
 PO: 202015526  
 Date/Time: 15/Jan/2021 13:02:57 CET  
 User: inpharmatic:toi

**INFORMATION**

PO: 202015526 Lot: CD0L49 Code: 50900200  
 Phase: Sublot:  
**PESO BULK** Sub 2

**MEASUREMENT RESULTS**

Measure	Result	Value
15/Jan/2021 13:02:57 CET	Gross weight [kg]	226,86
87577	Net weight [kg]	197,72
	Tare weight [kg]	29,14

**INSTRUMENT INFORMATION**

Instrument ID: BI-101-G0 Model:  
 Type: Scale  
 Manufacturer: Mettler Toledo Serial Number:

**MEASURE CHECK**

Measure signed as: Valid Date/Time:  
 User: inpharmatic:toi

Complete set of reports based on:  
 single or multiple measurements,  
 instrument logbook, Audit Trail...

Measure ID: M21000452  
 LOT: 210630  
 Date/Time: 07/Sep/2021 06:02:54 CET  
 Department: A1A29-F1UA0-Preparazione SOLIDUAD-120-I  
 User:

**CONTEXT**

Lot: 210630 Phase: BICH21.1903

**MEASUREMENT RESULTS**

Result	Min.	Average	Std.Dev. (%)	Range
Loss weight [%MC]	1,17	1,34	1,268	0,082 (6,45)
Final weight [g]	1,189	1,617	1,4018	0,1778 (12,69)
Initial weight [g]	1,205	1,639	1,4198	0,1803 (12,70)

**Measure**

Measure	Result	Value
	Drying Program	Standard
	Final weight [g]	1,360
	Initial weight [g]	1,377
07/Sep/2021 06:02:54 CET	Method	TEST A PESO COSTANTE
M21000453	Switch-Off	3(1mg/50s)
	Temperature set	100
	Loss weight [%MC]	1,23
	Drying Program	Standard
	Final weight [g]	1,441
	Initial weight [g]	1,458
07/Sep/2021 06:05:01 CET	Method	TEST A PESO COSTANTE
M21000454	Switch-Off	3(1mg/50s)
	Temperature set	100
	Loss weight [%MC]	1,17
	Drying Program	Standard
	Final weight [g]	1,617
	Initial weight [g]	1,639
07/Sep/2021 06:07:07 CET	Method	TEST A PESO COSTANTE
M21000455	Switch-Off	3(1mg/50s)
	Temperature set	100



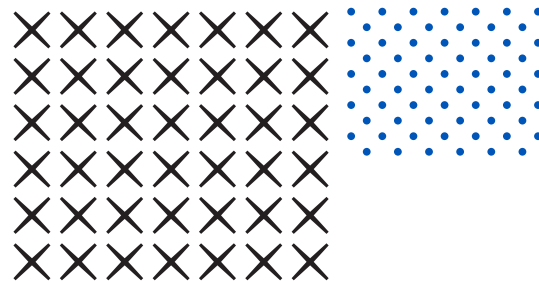
# DiForm

## Digitalizes paper-based forms

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

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DiForm is a **GxP-compliant web application** for the digitalization of paper-based forms and logbooks, managing their full **lifecycle**: configuration, review, approval, data entry, final review, and **electronic signature**.



## Key Features

- Enables **direct import** of existing paper forms from **Microsoft® Word files**, preserving layout and allowing a **smooth, low-impact transition** to digital
- Supports both **manual and automatic data entry**, including from measuring instruments, QR/barcodes, photos, and integration via **web services** (e.g., LIMS, ELN, EBR)
- **Securely stores** all collected data, making it available for **analysis, traceability**, and full **audit trail**



## Why It Matters

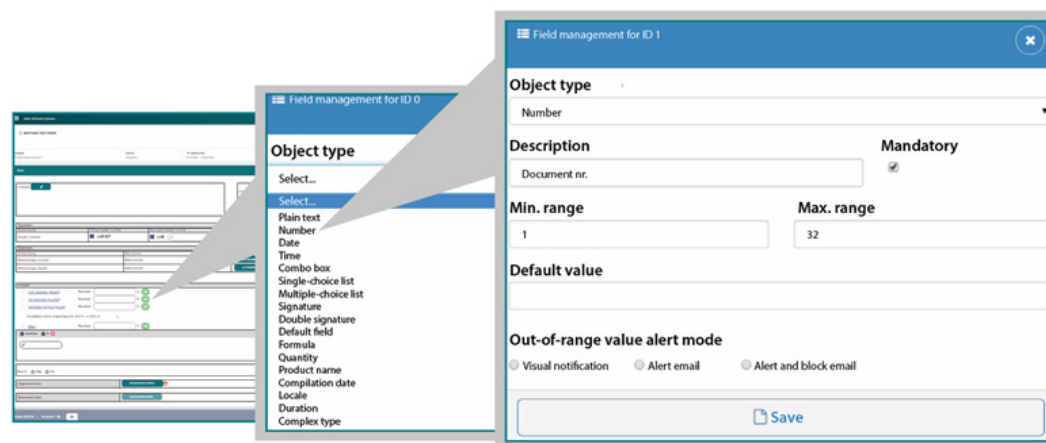
- **Fast and smooth digitalization:** import Word documents already in use = no process overhaul, no IT skills required
- Ensures full **compliance:** audit trail, **electronic signatures** (including full 21 CFR Part 11), version control, validity dates, role-based access
- **Reduces errors and rework:** dynamic fields with **validation, limits, formulas, dropdowns, buttons, etc.**
- **Easy to use:** browser-based access, **simple interface**, role- and area-based access control
- **Efficient data entry:** usable from mobile devices in labs or production areas
- **Review by exception:** speeds up data validation by highlighting only anomalies
- **Scalable:** start with one form and expand progressively

Light box Using Logbook

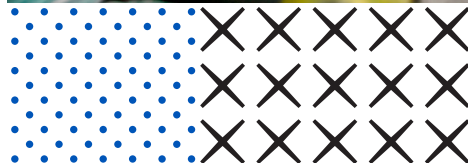
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		Material name or Code No.	Lot No.	Content		
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End	<input type="checkbox"/> Green <input type="checkbox"/> Green-Red <input type="checkbox"/> Red	NA	NA	NA		
Start	<input type="checkbox"/> Green <input type="checkbox"/> Green-Red <input type="checkbox"/> Red	NA	NA	NA		
End	<input type="checkbox"/> Green <input type="checkbox"/> Green-Red <input type="checkbox"/> Red	NA	NA	NA		
Start	<input type="checkbox"/> Green <input type="checkbox"/> Green-Red <input type="checkbox"/> Red	NA	NA	NA		
End	<input type="checkbox"/> Green <input type="checkbox"/> Green-Red <input type="checkbox"/> Red	NA	NA	NA		
Start	<input type="checkbox"/> Green <input type="checkbox"/> Green-Red <input type="checkbox"/> Red	NA	NA	NA		
End	<input type="checkbox"/> Green <input type="checkbox"/> Green-Red <input type="checkbox"/> Red	NA	NA	NA		
Start	<input type="checkbox"/> Green <input type="checkbox"/> Green-Red <input type="checkbox"/> Red	NA	NA	NA		
End	<input type="checkbox"/> Green <input type="checkbox"/> Green-Red <input type="checkbox"/> Red	NA	NA	NA		
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End	<input type="checkbox"/> Green <input type="checkbox"/> Green-Red <input type="checkbox"/> Red	NA	NA	NA		
Start	<input type="checkbox"/> Green <input type="checkbox"/> Green-Red <input type="checkbox"/> Red	NA	NA	NA		
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End	<input type="checkbox"/> Green <input type="checkbox"/> Green-Red <input type="checkbox"/> Red	NA	NA	NA		
Start	<input type="checkbox"/> Green <input type="checkbox"/> Green-Red <input type="checkbox"/> Red	NA	NA			

# What Makes It Unique

- **Starts from Word:** gives customers **maximum autonomy** in creating digital forms, with no need for technical steps
- **Configurable objects:** full library including **QR codes, images, formulas, dropdowns, signatures, attachments, etc.**
- **Interoperable:** integrates easily with other systems via **web services**
- **Compliance by design:** validated as **GAMP 5 Category 4 software**
- **Immediate ROI:** eliminates paper, reduces errors and rework, increases efficiency = **measurable savings from the start**



Configuration of dynamic fields



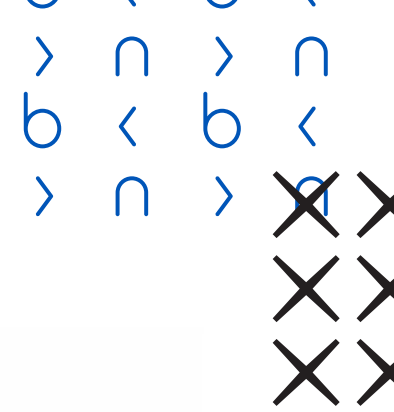
# DiBatch

## Electronic Batch Record

*Digitize your Batch Records. Keep your processes under control.*

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DiBatch is a GxP-compliant web application for the electronic management of Batch Records (EBR), providing full control over the **Master Batch Record (MBR) lifecycle**: configuration, review, approval, execution, final review, and electronic signature.



## Key Features

- Allows **direct import** of existing paper-based batch records from **Microsoft® Word**, preserving layout and easing the **transition to digital**
- Offers a **library of configurable objects** (QR codes, formulas, photos, dropdowns, etc.) to dynamically populate MBR fields
- Supports **manual and automatic data entry** (e.g., instrument readings, QR/barcode scanning, photos), plus **web service integration** (e.g., ERP, LIMS)
- Tracks every action compliantly, with a **complete audit trail** and **electronic signatures**



## Why It Matters

- **Smooth digitalization:** start from existing Word batch records = no major disruptions, no IT skills required
- Ensures full **compliance:** complete audit trail, electronic signatures (up to 21 CFR Part 11), versioning, validity controls, and access management
- **Reduces errors:** guided data entry using dynamic objects and familiar layouts, minimizing deviations

- **Easy to use:** browser-based interface, with role- and area-specific access
- **Review by exception:** focuses only on critical data points, accelerating approvals
- **Scalable:** start with a single MBR and expand progressively

The image shows a screenshot of a traditional Word Batch Record form. It is a complex, multi-sectioned document with various fields and tables. The sections include: 'Staat' (State) with fields for 'Leveringdatum' and 'Resource staat'; 'Toetsplan' (Test Plan) with columns for 'Omschrijving', 'Primaire testnummer', 'Equivalent testnummer', 'Check testplan status', 'Check verificatie status', and 'Check validatie status'; 'Materialen' (Materials) with columns for 'Omschrijving', 'RS nummer', 'Labnummer', and 'Vervaldatum'; 'Analyse' (Analysis) with a list of items and their results; and 'Opmerkingen' (Remarks). The form is filled with text and has a 'Bestuurt: PASS / FAIL' field at the bottom.

Batch Record

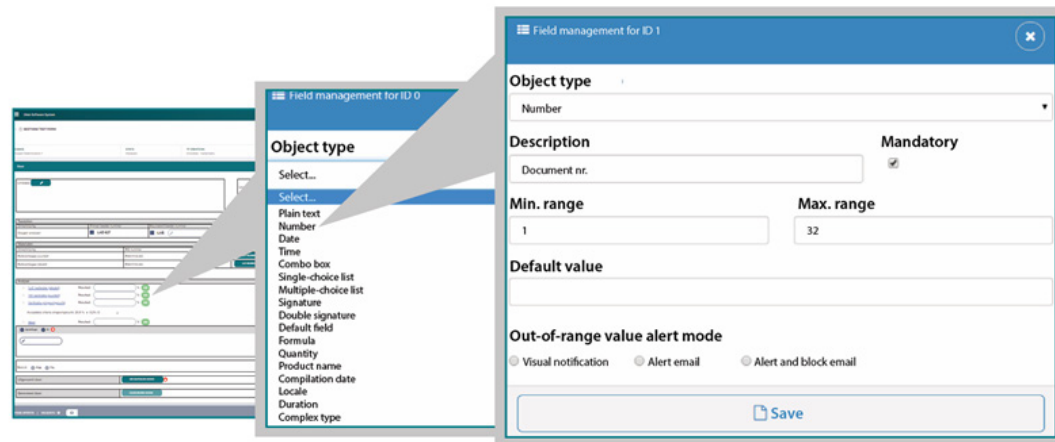


The image shows a screenshot of an Electronic Batch Record (EBR) interface. It is a modern, web-based application with a clean, structured layout. The interface includes a header with navigation and search options, followed by a main content area with various data entry fields, tables, and status indicators. The layout is more organized and user-friendly than the traditional Word form, with clear sections for data entry and review.

Electronic Batch Record

# What Makes It Unique

- **Rapid setup:** fully configure your first MBR in **3 weeks** instead of 3 months
- **Starts from Word:** transform existing batch records into digital ones while maintaining user familiarity
- **Configurable objects:** QR codes, images, attachments, formulas, dropdowns, checklists, buttons, timers, and more
- **Interoperable:** integrates with ERP and other systems via **web services**
- **Compliance by design:** validated according to **GAMP 5 – Category 4**
- **Immediate ROI:** less paper, fewer errors, fewer reworks = **measurable savings from the very first months**



Configuration of dynamic fields



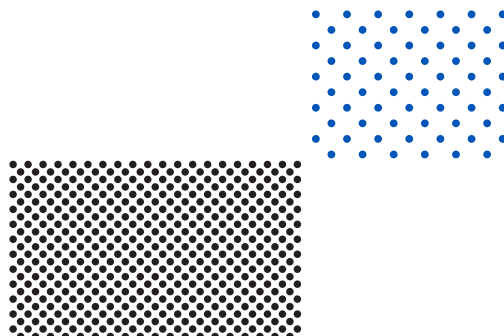
# Digma

## Digital management of maintenance

*Streamline your maintenance,  
calibration and spare parts  
management: anytime,  
anywhere.*

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Digma is a GxP-compliant web and mobile solution for the digital management of maintenance, calibration, qualification, and spare parts inventory.



## Key Features

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- Manages **instrument inventory**, **intervention planning** (scheduled or breakdown), **equipment qualification**, and **stock levels**
- Maps your entire technical and production ecosystem, organizing by **sites**, **lines**, **plants**, **equipment**, and **personnel**
- Provides **real-time information**, integrated **document management**, **notifications**, **alerts**, and **analytics**
- Integrates data from external sources (e.g., **ERP**, **MES**, **SCADA**, **IoT**, **RFID**, **barcodes**) to ensure **continuity and synergy** across systems



## Why It Matters

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- **Digitalized technical processes:** full, centralized control of maintenance activities, accessible via **browser and mobile devices**
- Ensures **regulatory compliance:** supports adherence to **quality and safety standards** (GxP, QMS, etc.)
- Enhances **operational efficiency:** intervention planning and scheduling reduce machine downtime and **optimize resources**
- **User-friendly and accessible:** intuitive interface, role-based access, local or network-based credentials
- Empowers **control and decision-making:** technical/economic reporting, **KPIs**, and historical data analysis to drive performance
- **Collaborative workflow:** supports the daily activities of all stakeholders involved in the technical asset lifecycle

## What Makes It Unique

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- **Proactive by design:** reduces delays in interventions and **optimizes spare parts inventory**
- Highly **flexible:** adapts to existing organizational structures with minimal disruption to people and processes
- Fully **interoperable:** communicates with major enterprise systems (**ERP, MES, LIMS, SCADA/DCS**)



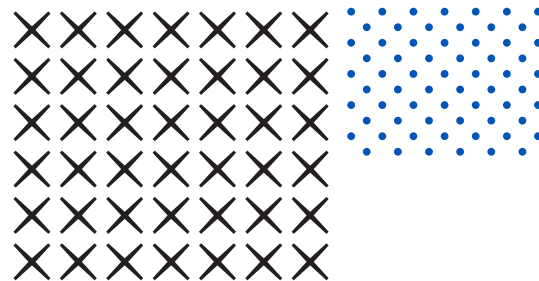


# Adiuto 4 Life Sciences

*One platform to manage quality, documents and training: GxP ready.*

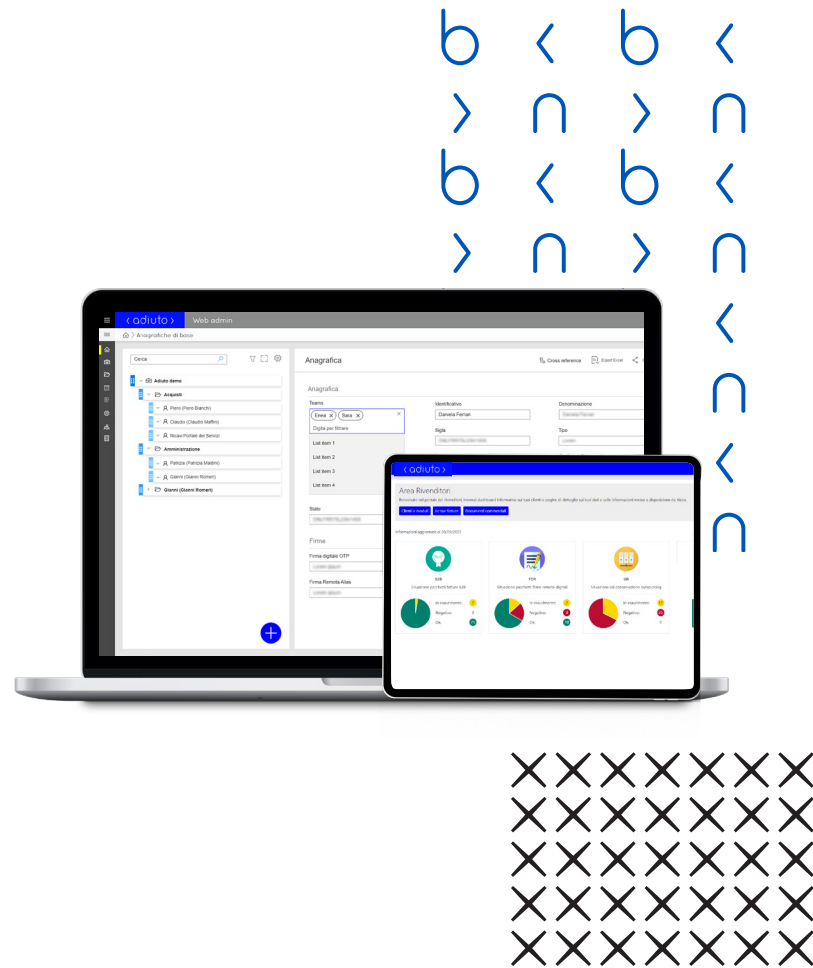
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Adiuto4LifeSciences is a GxP-compliant platform designed to **digitally manage documents, quality processes, and training** in the **Life Sciences** sector (pharma, biotech, medical devices).



# Key Features

- Manages the **lifecycle of regulated documents** (SOPs, work instructions, protocols, batch records, etc.), as well as **deviations, CAPAs, change controls, and training activities**
- Fully compliant with **FDA 21 CFR Part 11, EU-GMP Annex 11, and GAMP 5 (Category 4)**, with **audit trail, electronic signatures, and controlled printing**
- Accessible via **browser** from any device, with **granular access management** by profile, role, and area
- Enables **centralized, traceable, and validated** management of critical business processes in an integrated way

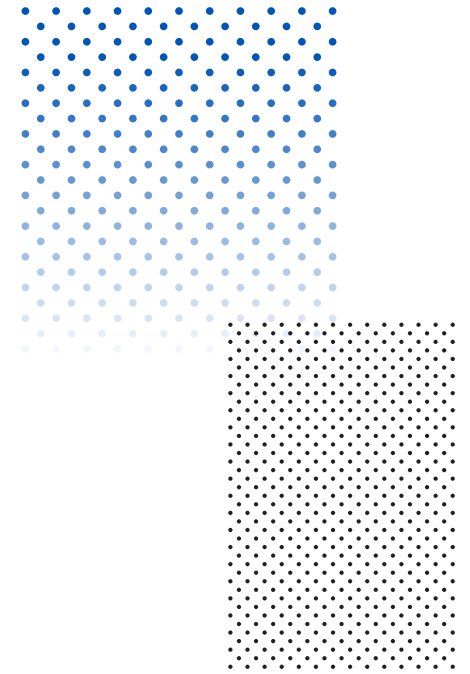




## What Makes It Unique

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- **Single ECM for three critical areas:** unified platform for **Document Management (DMS), Quality (QMS),** and **Training (TMS),** integrated and coherent
- **Guaranteed Data Integrity:** built according to **ALCOA+ principles,** ensuring data reliability for both regulators and customers
- **Ecosystem integration:** interoperable with ERP, LIMS, SCADA, DCS, and other systems via **web services**
- **Built-in Business Intelligence:** dashboards and **KPIs** to monitor processes, assess performance, and drive continuous improvement
- **Structured implementation:** clear methodology in phases (analysis, setup, validation, training) for **fast and controlled go-live**





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