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# Diform

Digital Form

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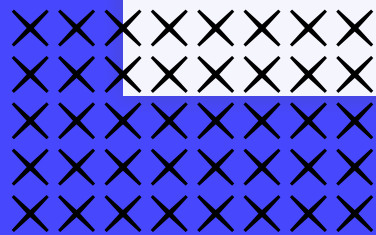
Digitalize your paper forms, checklists, and logbooks. Start from what you already use.

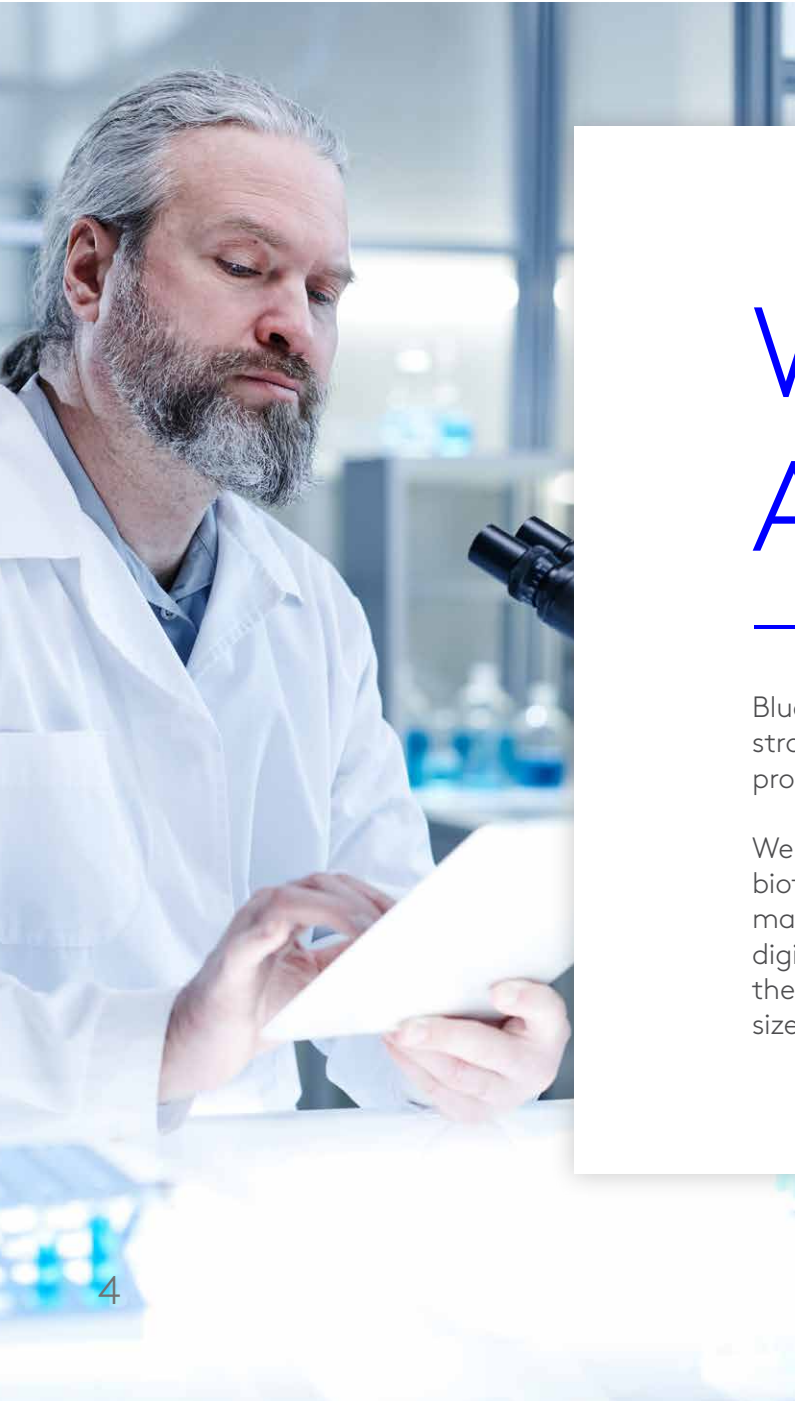




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# Who We Are

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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

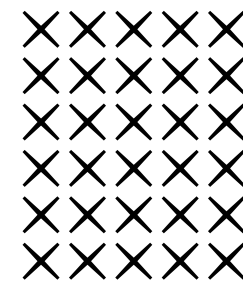
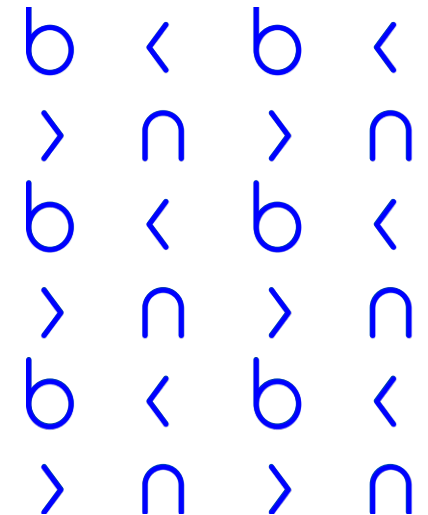
Digital management of maintenance, calibration and spare parts, integrated with ERP, MES and quality systems.

# 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.*





# Diform

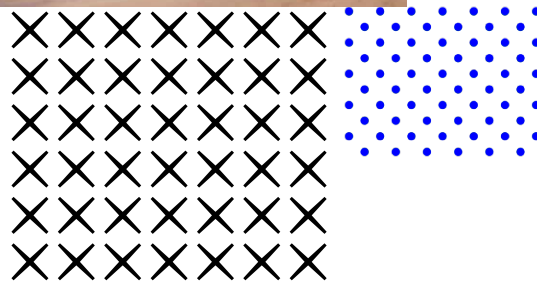
## Digital Form

*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.



# Integrable with other business systems

Data integration (exchange) via Web Services.



## Compliance

- Audit Trail in full compliance.
- **Electronic Signature** (simple attribution or full compliance with 21 CFR Part 11).

## Accessibility

- Accessible from any browser with a simple interface.
- Access privileges based on profiles and areas.
- Local or network login credential.

# With Diform you can



## Fill digital fields

Collect data: completed activities (including checklists), operators, critical parameters, approvals, electronic signatures...

Prevent errors and omissions thanks to real-time controls, automatic data acquisition (barcode/QR) and the use of familiar templates.



## Review and approve

The entered data are:

- Complete
- Compliant with Data Integrity
- Automatically verifiable



## Create reports and monitor

Provides a complete set of reports: e.g. data, logbook, audit trail, APQR reports.

Interfaces with third-party systems such as LIMS, ELN, MES, EBR, ERP, HR systems, etc.

# Key Features



## Digitalization - Paper on glass

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



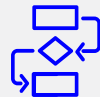
## Forms and logbook lifecycle management

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.



## 2) Configure the digital form in a few steps

The fields of the digital form and register are configurable in the system, using an extensive library of pre-configured objects.

The image displays a digital form configuration interface. The main form in the background shows various fields and sections, including 'Lavorazione', 'Tossicità', 'Materiali', and 'Analisi'. Overlaid on this are two configuration windows. The first window, titled 'Gestione campi per id 0', shows a 'Scelta Tipo Oggetto' dropdown menu with a list of options: Testo Semplice, Numerico, Data, Ora, ComboBox, Lista scelta singola, Lista scelta multipla, Firma, Firma Doppia, Campo Predefinito, Formula, Quantità, Nome Prodotto, Data Compilazione, Locale, Durata, and Tipo Complesso. The second window, titled 'Gestione campi per id 1', shows configuration options for a field: 'Scelta Tipo Oggetto' set to 'Numerico', 'Descrizione' set to 'Nr Bolla' with an 'Obbligatorio' checkbox checked, 'Range Min' set to 1 and 'Range Max' set to 32, and 'Valore di Default' set to an empty field. At the bottom of this window, there are radio buttons for 'Modalità di avviso in caso di valore fuori Range': 'Solo notifica visiva', 'Email di avviso', and 'Email di avviso e blocco'. A 'Salva' button is located at the bottom of the configuration window.

Pre-configured object types:

- QR code
- Attachments
- Images
- Manual data entry (number, text, date...)
- Formulas
- Single-choice buttons
- Drop-down lists

Dynamic field configuration



**Staal**

Limslabel:	Leveringsdatum
	Resource sheet LEEG-SPC-..... V.....

**Toestellen**

Omschrijving	Primair toestel nummer	Equivalent toestel nummer	Check kalibratie status	Check verificatie status	Check validatie status
Oxygen analyser	<input type="checkbox"/> LAE-627	<input type="checkbox"/> LAE- .....	<input type="checkbox"/>	<input type="checkbox"/>	

**Materialen**

Omschrijving	RS nummer	Lotnummer	Vervaldatum
Referentiegas zuurstof	RS01114-QC		
Referentiegas stikstof	RS01116-QC		

**Analyse**

- "LO" kalibratie (stikstof) Resultaat: .....
- "HI" kalibratie (zuurstof) Resultaat: .....
- Verificatie (omgevingslucht) Resultaat: .....

Acceptatie criteria omgevingslucht: 20,9 % ± 0,2% O<sub>2</sub> PASS / FAIL

- Staal Resultaat: .....

**Opmerkingen**  / NA

**Besluit:** PASS / FAIL

**Uitgevoerd door:** \_\_\_\_\_ **Datum:** \_\_\_\_\_

**Gereviseerd door:** \_\_\_\_\_ **Datum:** \_\_\_\_\_

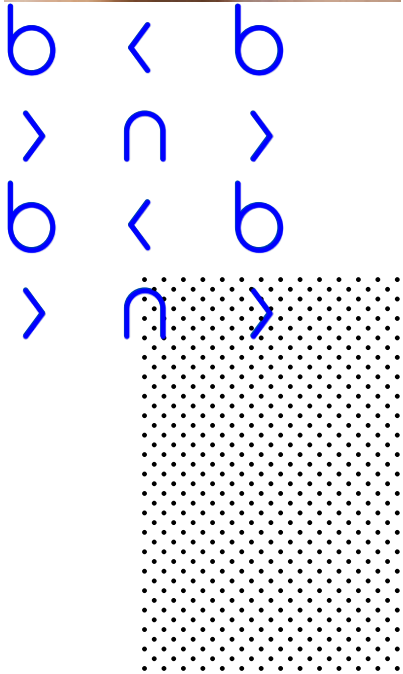


Identical Layout: Diform uses your original Microsoft Word® forms.

Zero learning curve: the operator sees the same sheet of paper on the tablet as before.

Guided Entry: Automatic checks and required fields, data verified and corrected in real time.

The screenshot shows the Diform tablet interface with the same form layout as the Microsoft Word document. The interface includes a header with the title 'Staal' and a 'Open' button. Below the header, there are input fields for 'Limslabel', 'Leveringsdatum', and 'Resource sheet'. The 'Toestellen' section is a table with columns for 'Omschrijving', 'Primair toestel nummer', 'Equivalent toestel nummer', 'Check kalibratie status', 'Check verificatie status', and 'Check validatie status'. The 'Materialen' section is a table with columns for 'Omschrijving', 'RS nummer', 'Lotnummer', and 'Vervaldatum'. The 'Analyse' section contains a list of items with 'Resultaat' fields and a 'Result' field. The 'Opmerkingen' section has a text input field. The 'Besluit' section has a dropdown menu. The bottom section has input fields for 'Uitgevoerd door', 'Datum', 'Gereviseerd door', and 'Datum'. The interface is designed to be identical to the Microsoft Word form, but with interactive elements like dropdowns, checkboxes, and real-time data verification.



# Why choose Diform

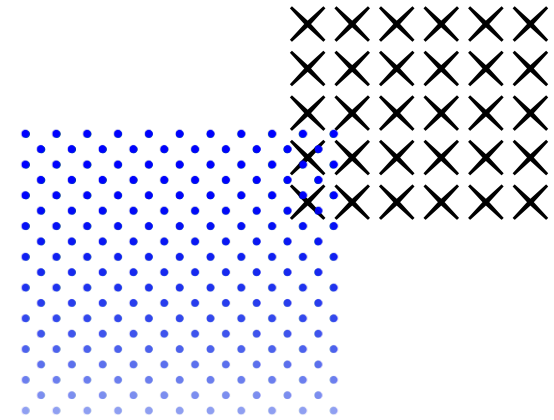
**Easy and intuitive import:** import existing forms in Word or other formats, keeping templates already familiar to users. Minimizes impact on staff.

**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.



# Gradual Implementation

Your pace, your budget.

Start with a single form or register and expand usage progressively.

Minimizes organizational impact:

- **Start Small:** begin with a single form or a single critical process. Minimum investment.
- **Consolidate:** see immediate results. The team gains confidence. Digitalize the rest of the department.
- **Scale:** roll out the solution across the entire company or add advanced modules (e.g. maintenance).

## Project steps

- 1. Initial configuration
- 2. Training and Adoption
- 3. Integration with other systems
- 4. Testing and validation phase

For a not too extensive project  
– i.e. 5 forms – we are talking  
about just a few weeks.

# Diform in brief

**Diform eliminates paper registers** that need to be printed, signed, bound and physically archived. It generates infinite digital rows, tracked and signed. It is perfect for replacing Excel spreadsheets (widely used) which are not compliant for pharma.

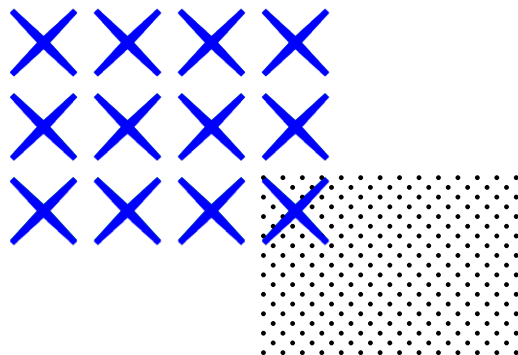
**Key strength:** extremely simple configuration, import from Word of forms already in use, low impact on operations.

Ideal for companies looking to eliminate paper from laboratories or warehouses.

It allows direct import of existing paper forms from Microsoft® Word files, preserving the layout and enabling a smooth, low-impact transition to digital.

It supports both manual and automatic data entry, including measuring instruments, QR/barcode codes, photos, and integrations via web services (e.g. LIMS, ELN, EBR).

It securely stores all collected data, making it available for analysis, traceability and complete audit trail.







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