bluenext

Diform

Digital Form

—

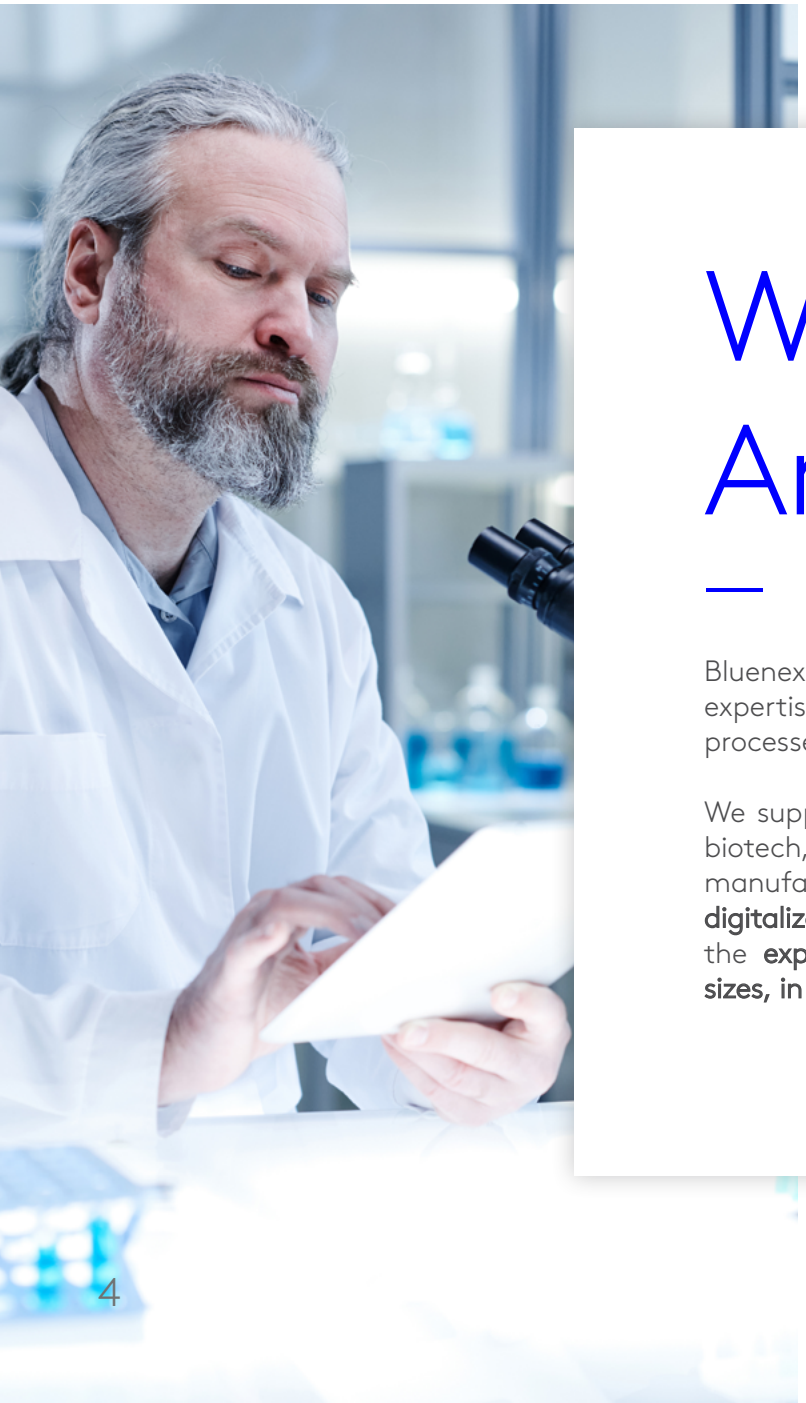
Digitalize your paper forms, checklists, and logbooks. Start from what you already use.





Table of Contents

Who We Are	—	04
Life Sciences Suite	—	06
Challenges in the Pharmaceutical Industry	—	07
Diform – Introduction	—	08
Integration with other business systems	—	10
With Diform you can	—	11
Key Features	—	12
From Word® to digital template	—	13
Why choose Diform	—	16
Gradual Implementation	—	17
Diform in brief	—	18



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

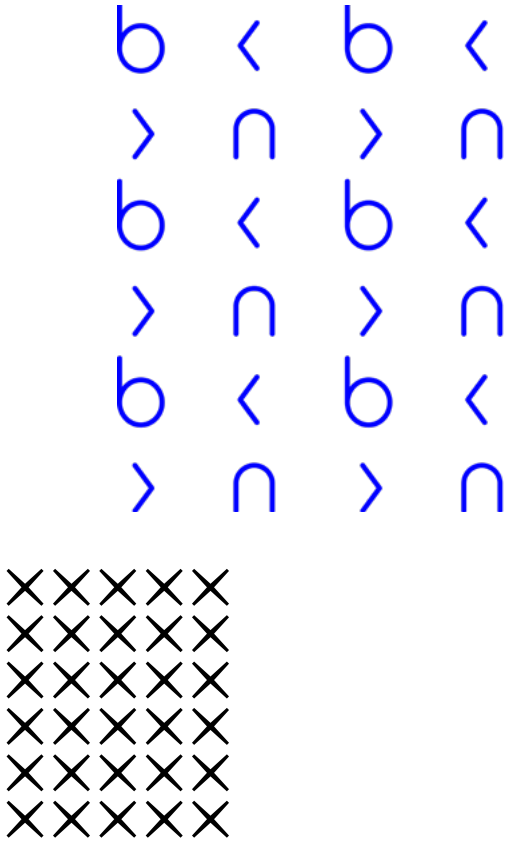
Digital management of maintenance, calibration and spare parts, integrated with ERP, MES and quality systems.

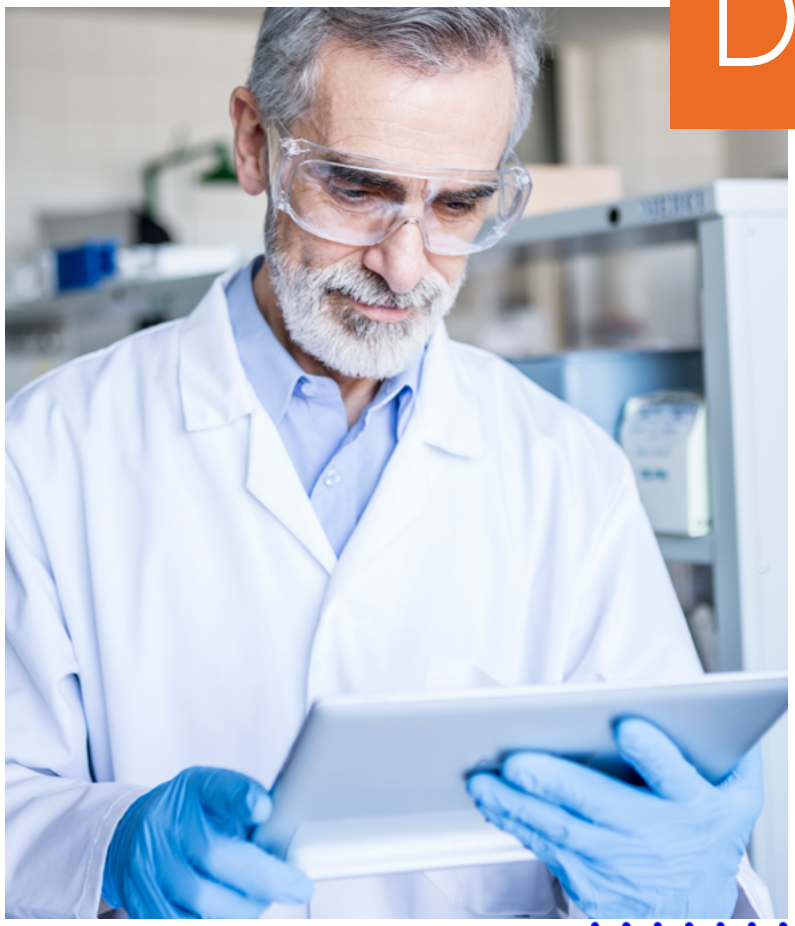
Current Challenges in the Pharmaceutical Industry

- **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.





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)**.

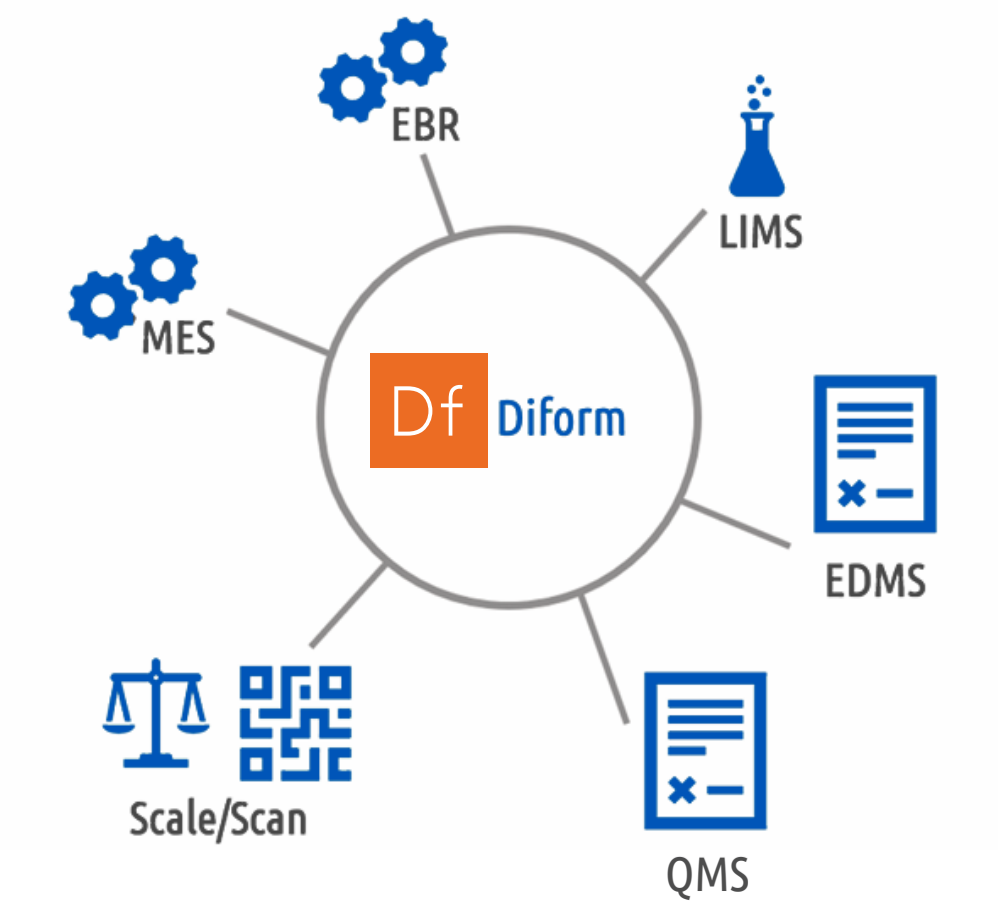
Who is it designed for?

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.



Control

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



Archiving and analysis

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



Forms and logbook lifecycle management

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



Data collection workflow

Definition of data entry sequences by user and form sections.



Electronic signature

Electronic signature capability in approval processes.

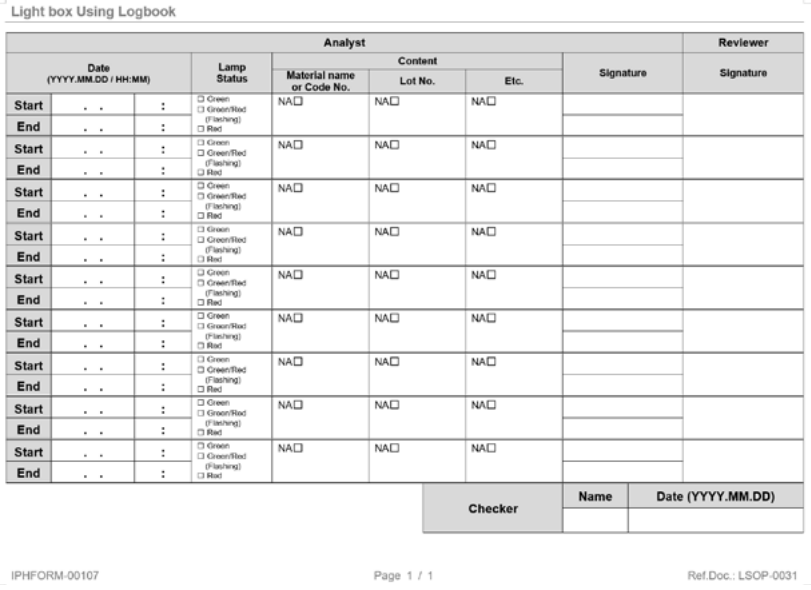
From Word® to digital template

A first step towards digitalization, with minimal impact on the operators who use and fill in the forms.

No IT skills are required to create a new digital form; the configuration steps are quick (just a few weeks).

1) Import the paper form or register

Starting from an existing Microsoft® Word document, Diform allows a digital form to be created with the same layout as the original paper version.



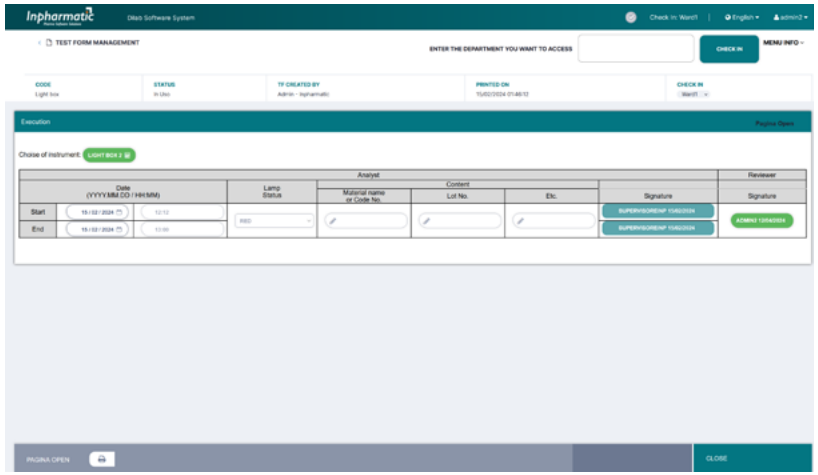
Light box Using Logbook

	Date (YYYY.MM.DD / HH:MM)		Lamp Status	Analyst: Content: Material name or Code No.	Analyst: Content: Lot No.	Analyst: Content: Etc.	Analyst: Signature	Reviewer: Signature
Start	. .	:	☐ Green ☐ Green/Red (Flashing) ☐ Red	NA☐	NA☐	NA☐		
End	. .	:						
Start	. .	:	☐ Green ☐ Green/Red (Flashing) ☐ Red	NA☐	NA☐	NA☐		
End	. .	:						
Start	. .	:	☐ Green ☐ Green/Red (Flashing) ☐ Red	NA☐	NA☐	NA☐		
End	. .	:						
Start	. .	:	☐ Green ☐ Green/Red (Flashing) ☐ Red	NA☐	NA☐	NA☐		
End	. .	:						
Start	. .	:	☐ Green ☐ Green/Red (Flashing) ☐ Red	NA☐	NA☐	NA☐		
End	. .	:						
Start	. .	:	☐ Green ☐ Green/Red (Flashing) ☐ Red	NA☐	NA☐	NA☐		
End	. .	:						
Start	. .	:	☐ Green ☐ Green/Red (Flashing) ☐ Red	NA☐	NA☐	NA☐		
End	. .	:						
Start	. .	:	☐ Green ☐ Green/Red (Flashing) ☐ Red	NA☐	NA☐	NA☐		
End	. .	:						
Start	. .	:	☐ Green ☐ Green/Red (Flashing) ☐ Red	NA☐	NA☐	NA☐		
End	. .	:						

Checker	Name	Date (YYYY.MM.DD)

IPHFORM-00107 Page 1 / 1 Ref.Doc.: LSOP-0031

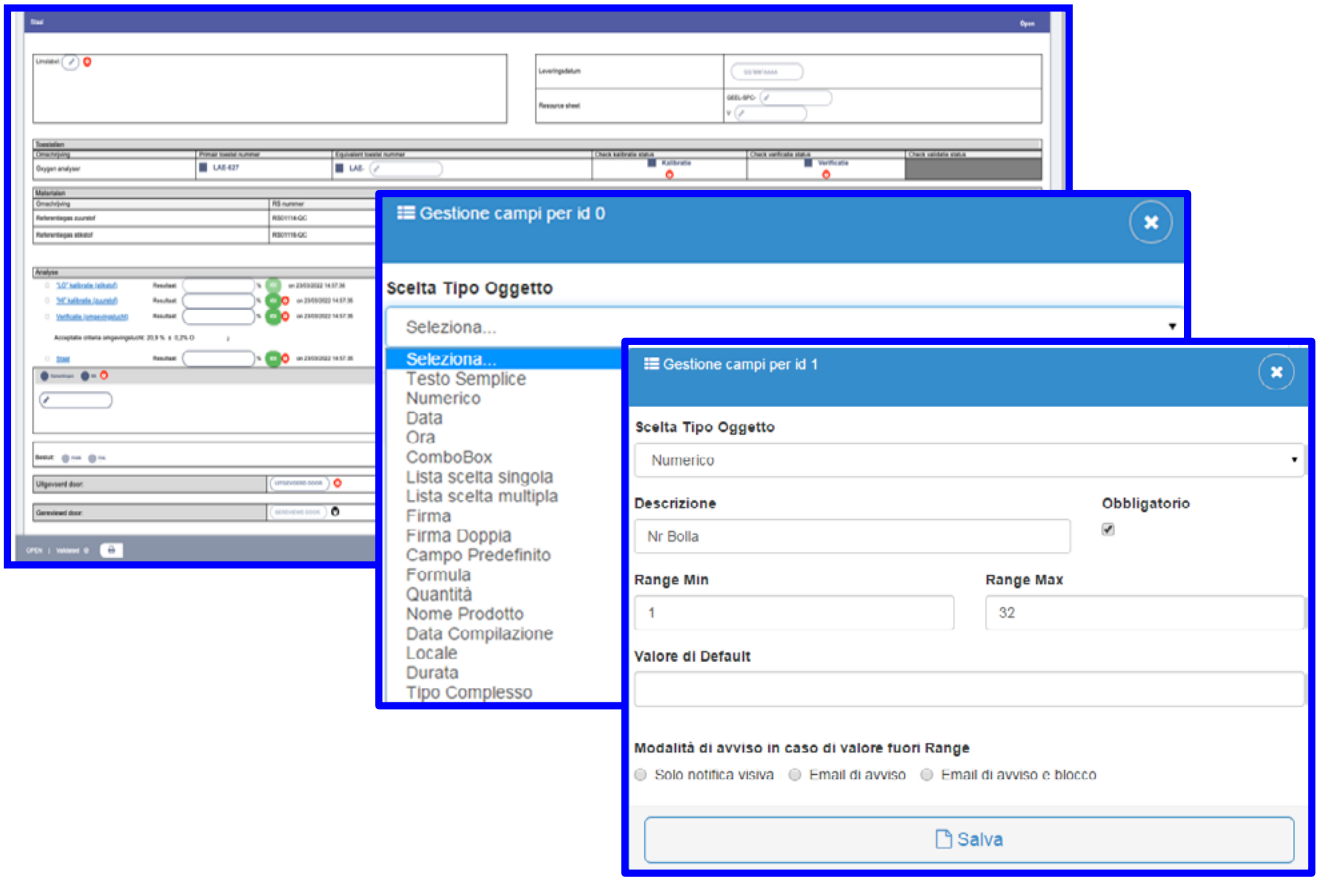
Paper form or register



Digital form

2) Configure the digital form in a few steps

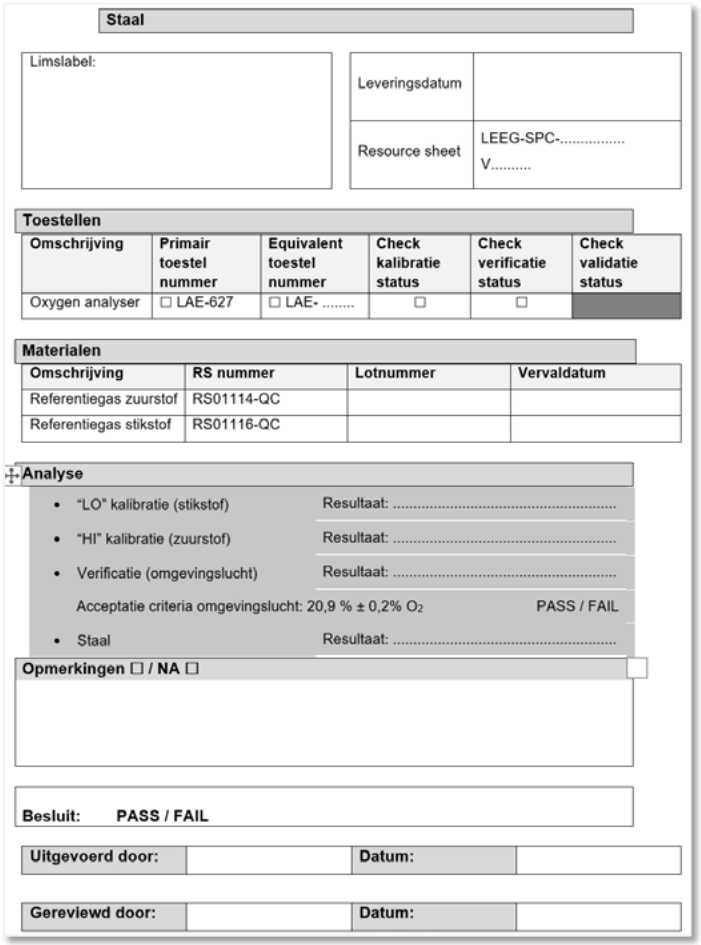
The fields of the digital form and register are configurable in the system, using an extensive library of pre-configured objects.



Dynamic field configuration

Pre-configured object types:

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



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	☐ LAE-627	☐ LAE-	☐	☐	

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_2 PASS / FAIL

- Staal Resultaat: .....

Opmerkingen ☐ / NA ☐

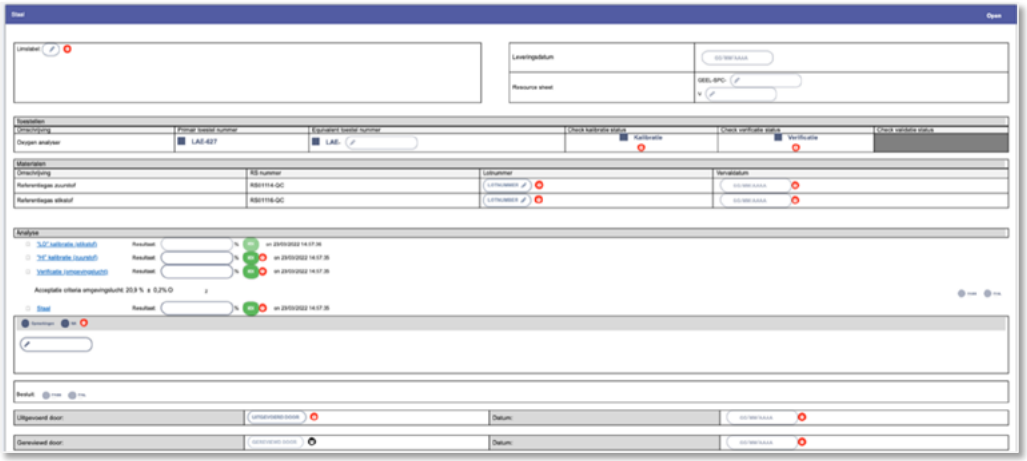
Besluit: PASS / FAIL

Uitgevoerd door:		Datum:	
Gereviewd 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.





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.

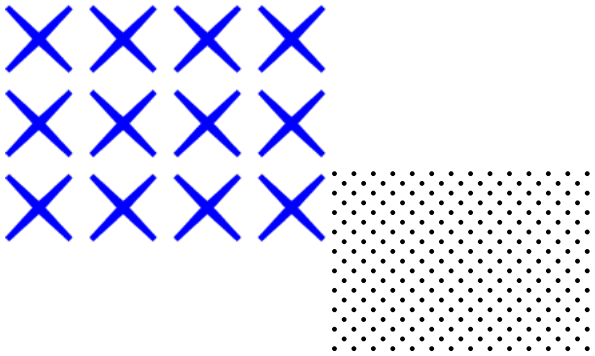
Key strength: extremely simple configuration, import from Word of forms already in use, low impact on operations.

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.







Bluenext Srl
VAT IT 04228480408
V.le XXIII Settembre 1845, n°95
47921 Rimini (RN), Italy
E: lifesciences@bluenext.it
www.bluenext.it