› bluenext ‹

Dibatch

Electronic Batch Record

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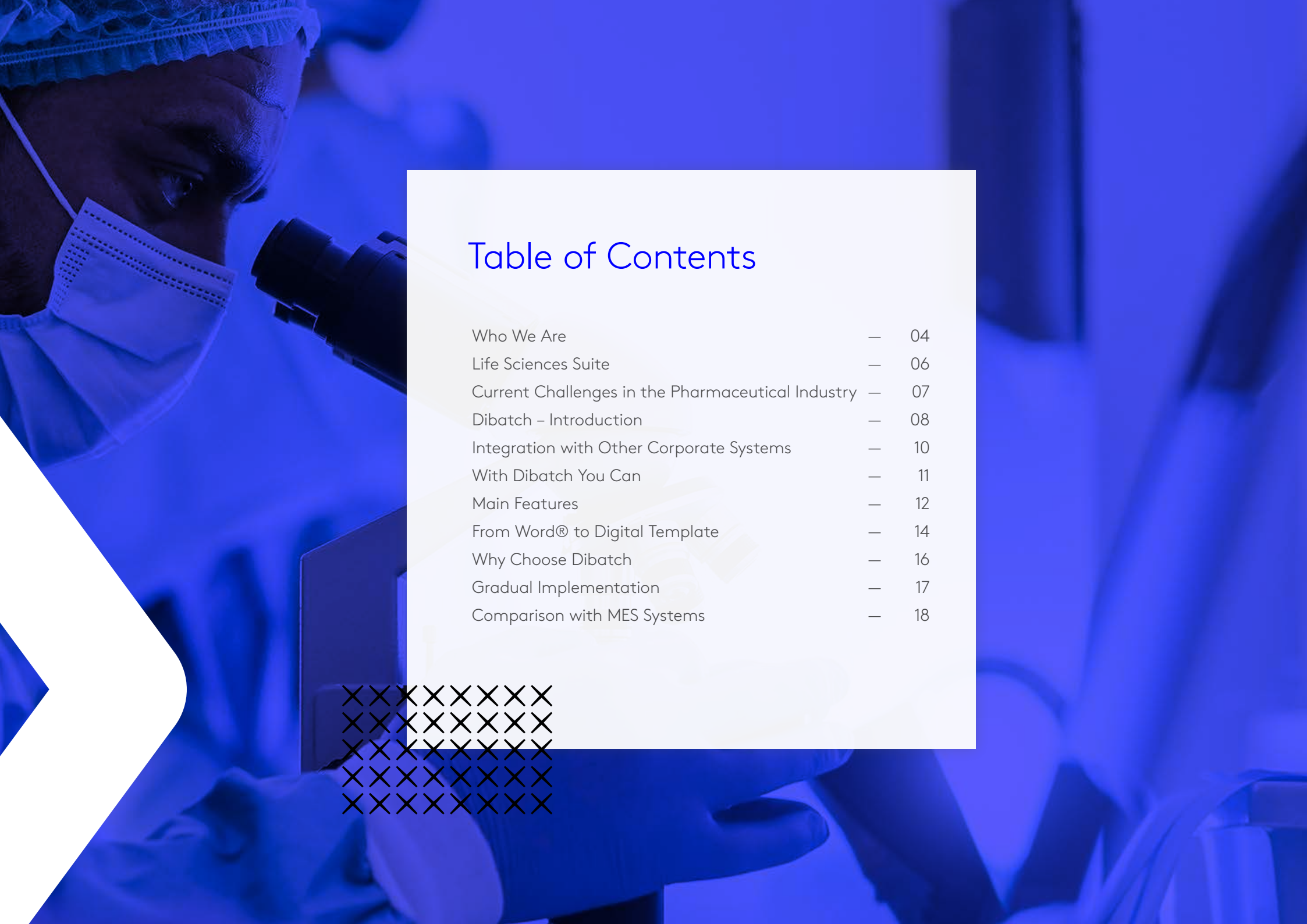
Digitalize your Batch Records. Keep your processes under control.



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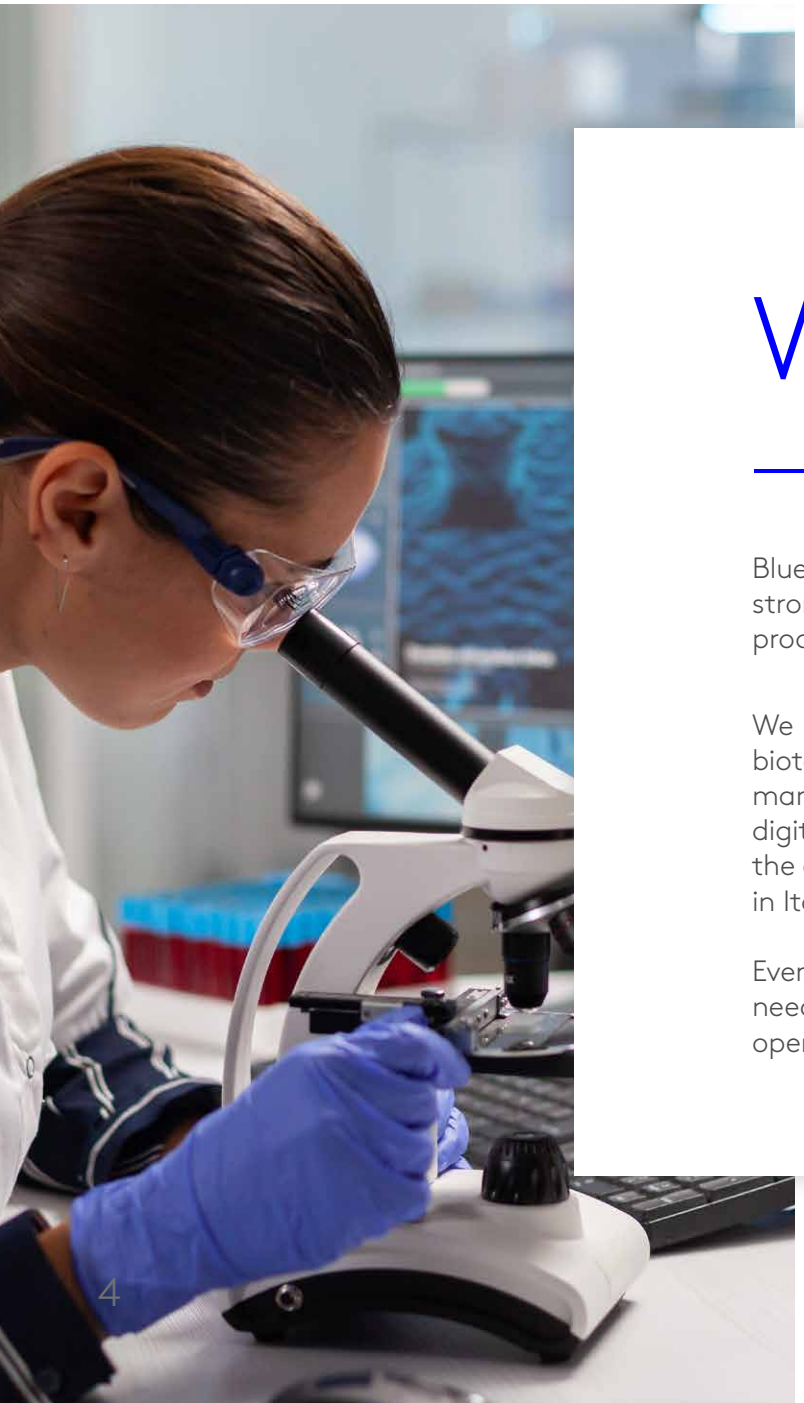


Who We Are

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

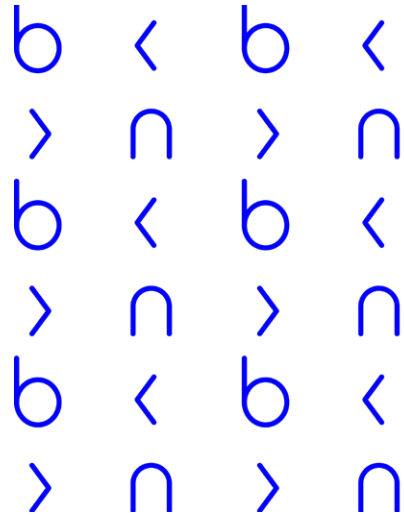
Digital management of maintenance, calibration and spare parts, integrated with ERP, MES and quality systems.

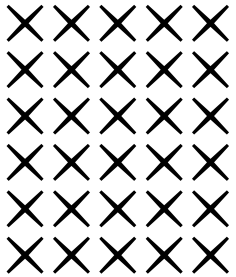
Current Challenges in the Pharmaceutical Industry

- **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.





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.

Integrable with other business systems

Data integration (exchange) via Web Services

Compliance

- Full Audit Trail (including MBR configuration).
- Electronic Signature (simple attribution or full 21 CFR Part 11 compliance).
- MBR Lifecycle (revision-based).
- Review by Exceptions.

Accessibility

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

With Dibatch You Can

Fill digital fields

Collected data includes: performed activities (including checklists), executors, critical parameters (IPC), component batch/lot numbers, approvals, electronic signatures, and more.

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

Review and approve

Generate exception reports

Data is complete:

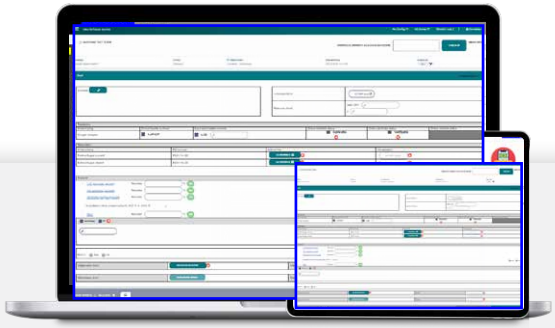
- data-integrity
- compliant
- automatically verifiable.

Generate reports and control processes

Provides a full set of reports (data, logbook, audit trail, APQR report).

Integrates with third-party systems (LIMS, ELN, MES).

Main Features



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.

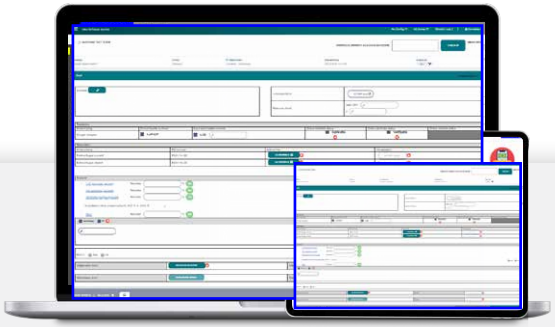
Manual and Automatic Data Entry

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

Other Features



Order management

Manual or automatic generation from ERP and creation of EBR controls.

Production workflow

Configuration of production phases and sequences.

Material Tracking

Material code, batch and quantity.

In Process Control (IPC)

With test plans and timers.

Equipment management

Maintenance and calibration status.

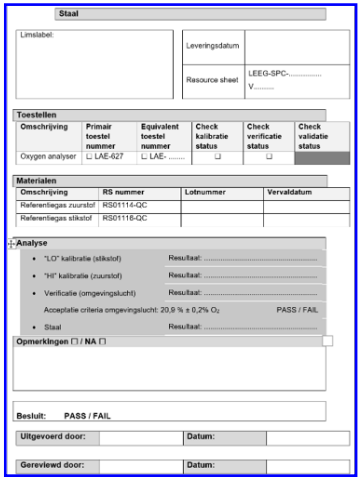
Check list

Check lists as part of the EBR or as asynchronous indipendent activities (e.g. cleaning)

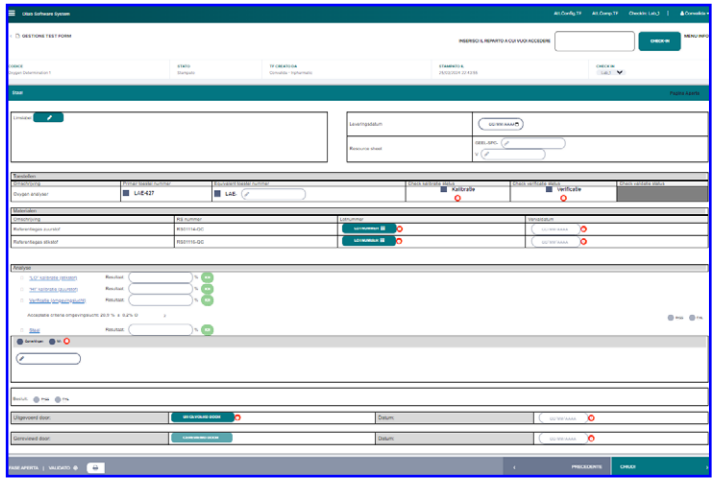
From Word® to Digital Template

1) Import existing Batch Records

Starting from an existing Microsoft® Word document, Dibatch allows you to create Digital Batch Records with the same layout as the original paper document.



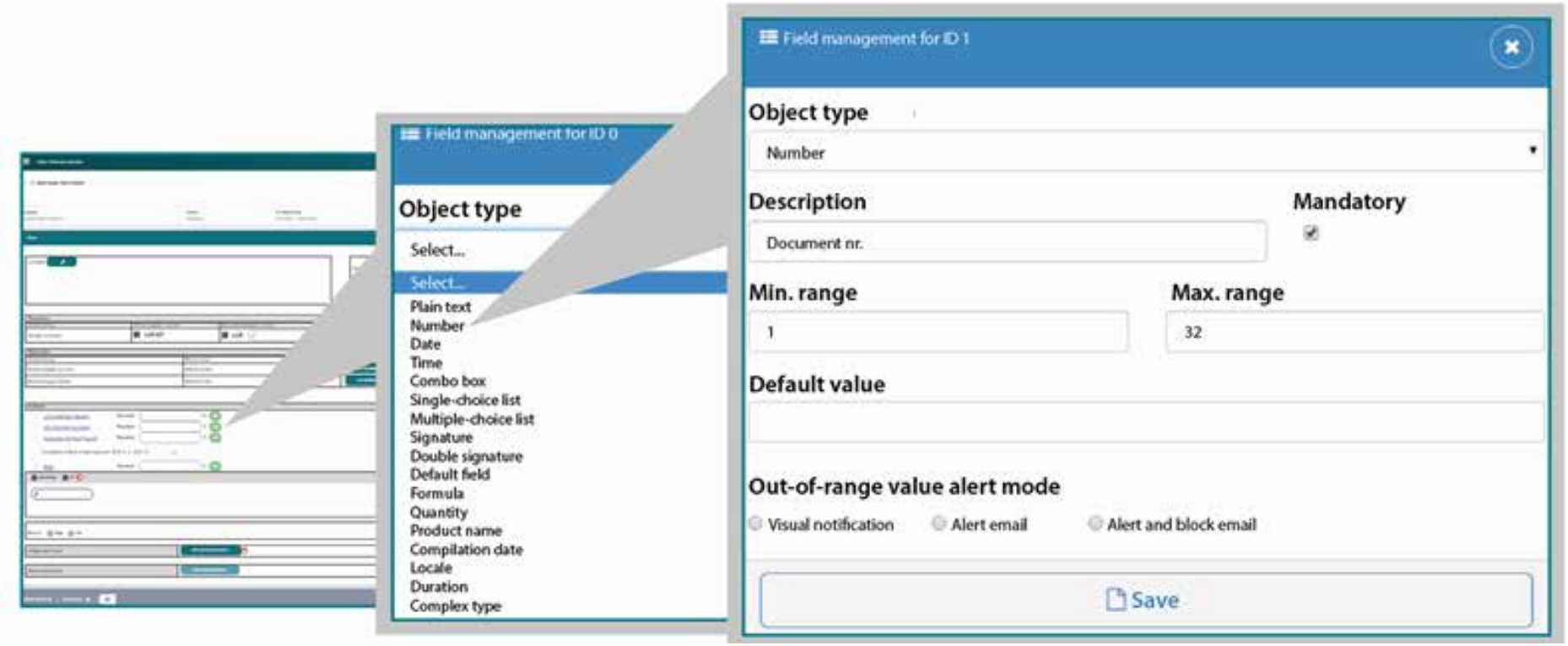
Batch Record



Electronic Batch Record

2) Configuring the Master Batch Record in few easy steps

Digital MBR fields are configured in a few simple (no-code) steps using an extensive library of preconfigured objects.



Configuring dynamic fields

Why Choose Dibatch:

GxP compliance: full audit trail compliant with 21 CFR 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.

Gradual Implementation

Thanks to Dibatch's minimal operational impact, you can scale your digitalization project:

- Start immediately by configuring one MBR at a time
- Add new objects to the library and validate them anytime
- Minimize errors through automatic data entry in a familiar template
- Limit impact on current SOPs (max 10%)

Project steps

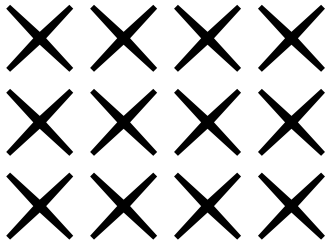
1. Initial configuration
2. Training and adoption
3. Integration with other systems
4. Testing and validation

Unlike competitors, an Electronic Batch Record process can be implemented in few months.

Comparison with MES Systems and solutions from other competitors

MES Solutions

- **"Big Bang" Projects:** costly, long implementation times
- **Require full review of production processes** sometimes drastically
- **Rigid and difficult to configure** without highly specialized experts



Our Dibatch solution

Covers the main MES functions (material management, instructions, signatures) with reduced costs, simplified and gradual configuration.

- **Word import:** unique on the market, we import the customer's existing Word document.
- **Gradual bottom-up approach:** we start by solving a specific Batch record and then scale up.
- **Easy to use:** No-code configurability preserving operator habits.
- **Sustainable:** affordable costs and immediate results.
- **Simplified Validation:** software GAMP 5 Cat.

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