
Dm
bluenext
Digma
Digital
maintenance
—
Optimize the management
of maintenance, calibrations
and spare parts: anytime,
anywhere.



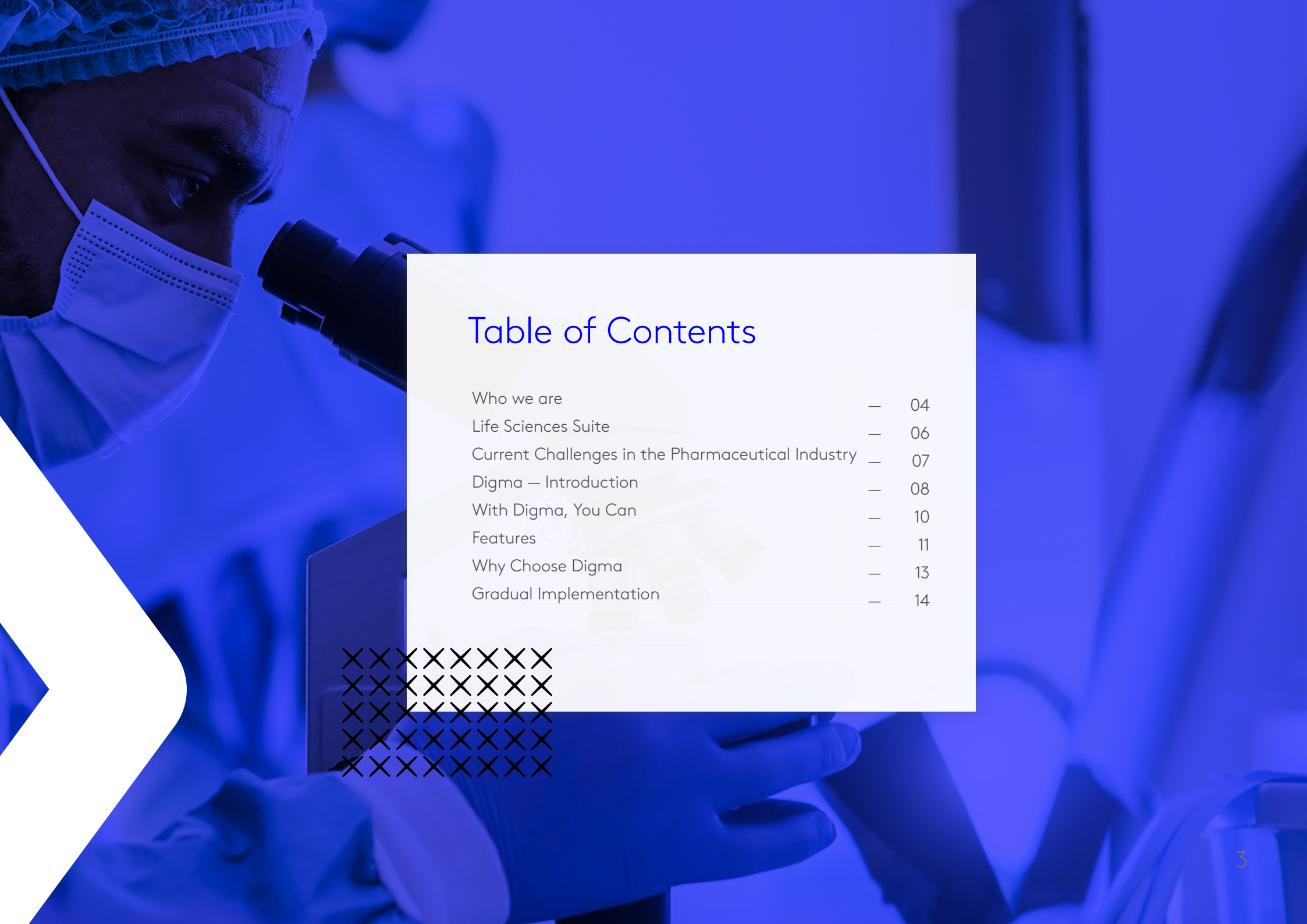


Table of Contents

Who we are — 04
Life Sciences Suite — 06
Current Challenges in the Pharmaceutical Industry — 07
Digma — Introduction — 08
With Digma, You Can — 10
Features — 11
Why Choose Digma — 13
Gradual Implementation — 14



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.



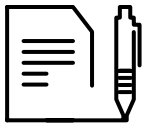
Ioi | Integration Of Instruments

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

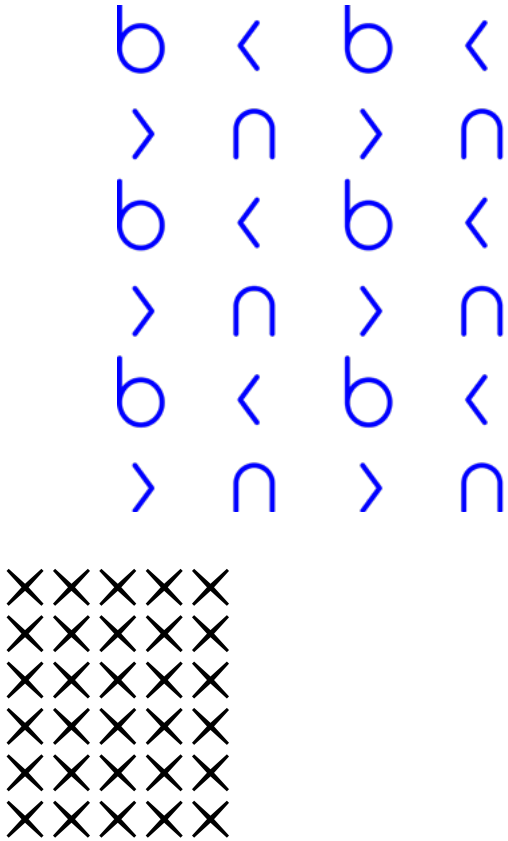
Digital management of maintenance, calibration and spare parts, integrated with ERP, MES and quality systems.

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.





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 i**ntegrable 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.**



With Digma You Can



Plan processes

Real support for maintenance activities.

Examples: scheduling, planning, execution, real-time availability of information and documents, alert and notification management, spare parts warehouse status.



Monitor

Verification of technical and economic performance.

Examples: reports and KPIs.



Decide and approve

Decision support and performance improvement.

Examples: data historization, processing, evaluation.

Key Features



Complete Maintenance Management

Full management of corrective, preventive and predictivemaintenance.



Technical-Production Ecosystem Management

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



Master Data & QR Code Management

Master data management and precise asset classification for better traceability.



Work Plan & Work Order Planning

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



Instrument Management: Calibrations and Qualifications

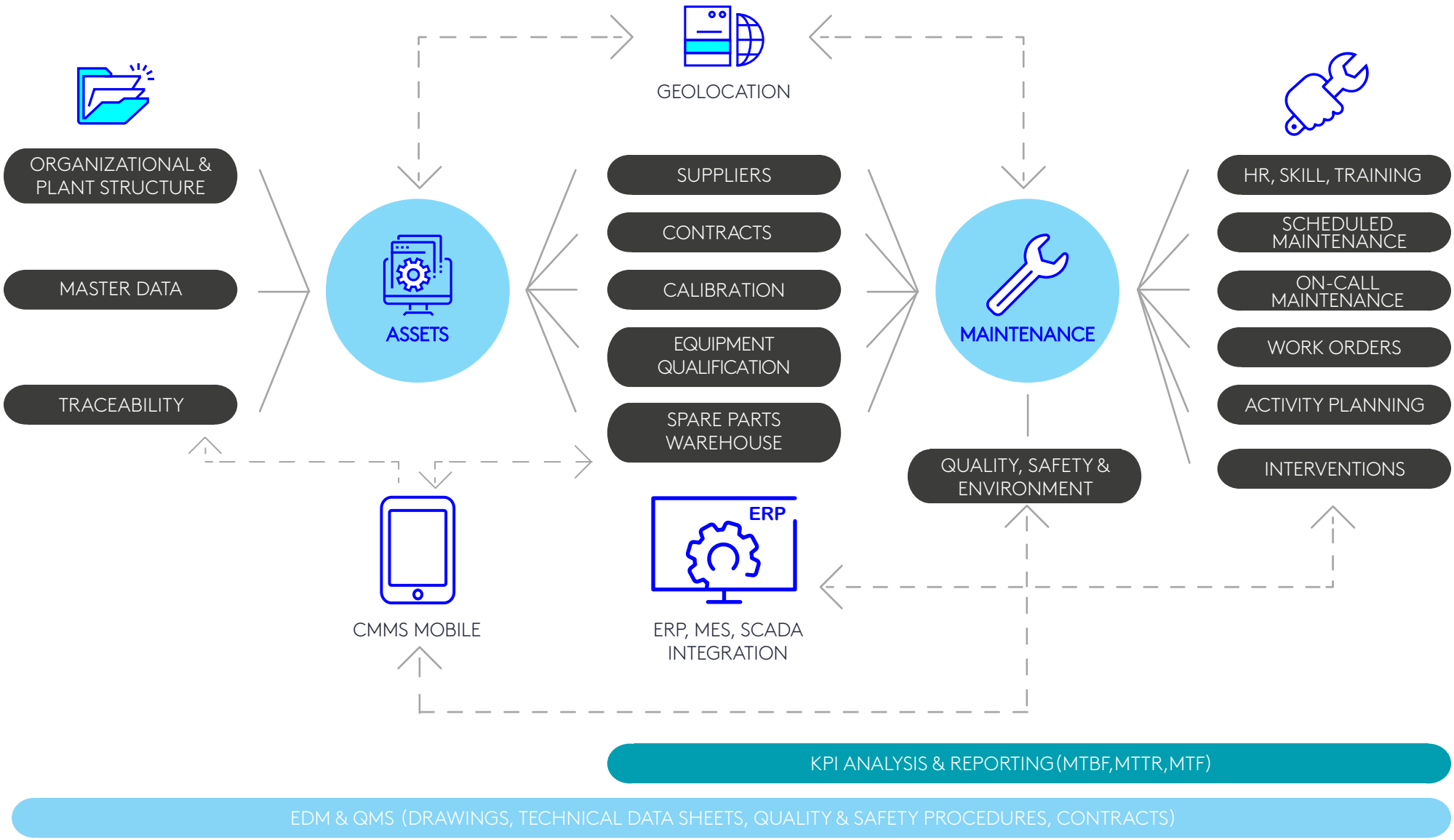
Management of instruments, related calibrations and equipment qualification activities in a traceable and compliant manner.



GXP, Quality and Safety Compliance

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

How It Works


GEOLOCATION
ORGANIZATIONAL & PLANT STRUCTURE
MASTER DATA
TRACEABILITY
ASSETS
SUPPLIERS
CONTRACTS
CALIBRATION
EQUIPMENT QUALIFICATION
SPARE PARTS WAREHOUSE
MAINTENANCE
HR, SKILL, TRAINING
SCHEDULED MAINTENANCE
ON-CALL MAINTENANCE
WORK ORDERS
ACTIVITY PLANNING
INTERVENTIONS
QUALITY, SAFETY & ENVIRONMENT
CMMS MOBILE
ERP
ERP, MES, SCADA INTEGRATION
KPI ANALYSIS & REPORTING (MTBF, MTTR, MTF)
EDM & QMS (DRAWINGS, TECHNICAL DATA SHEETS, QUALITY & SAFETY PROCEDURES, CONTRACTS)



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.

Gradual Implementation

Thanks to Digma's minimal impact on operations, you can scale your digitalization project:

- Start using Digma immediately, configuring one module/logbook at a time
- Add new items to the library and validate them at any time
- Minimize the possibility of errors with automatic data entry in a familiar model
- Limit the impact on current SOPs (max 10%)

Project Steps

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

A Digma project can be completed in just a few months!

Digma at a Glance

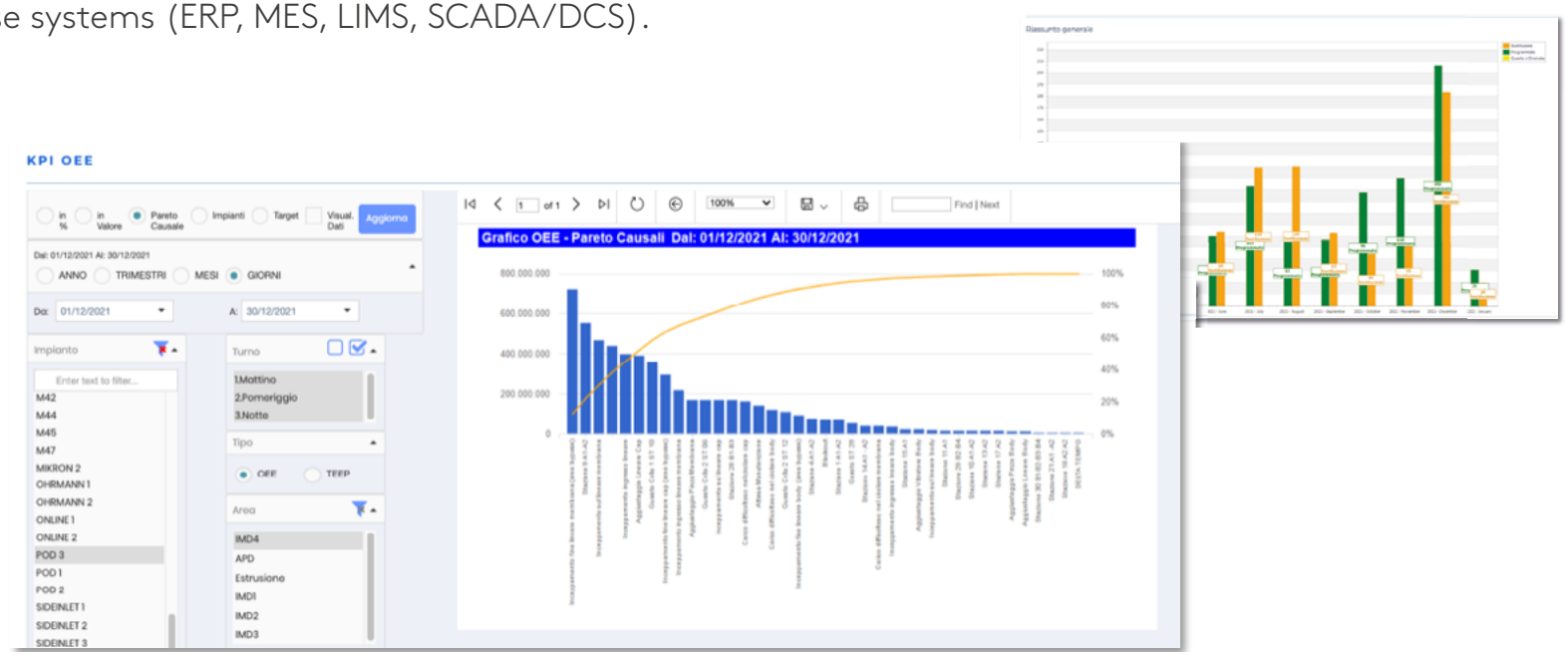
Proactive by design: reduces intervention delays and optimizes spare parts management.

Highly flexible: adapts to existing organizational structures with minimal impact on people and processes.

Fully interoperable: communicates with major enterprise systems (ERP, MES, LIMS, SCADA/DCS).

Always available: information and documents accessible in real time, anytime and anywhere.

Integrated suite: part of a complete software ecosystem (including solutions such as DiBatch, DiLab, QMS) for end-to-end management of the technical-production cycle.



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