bluenext

loi

loi

Integration of Instruments

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Digitalize your instruments.
Don't replace them.

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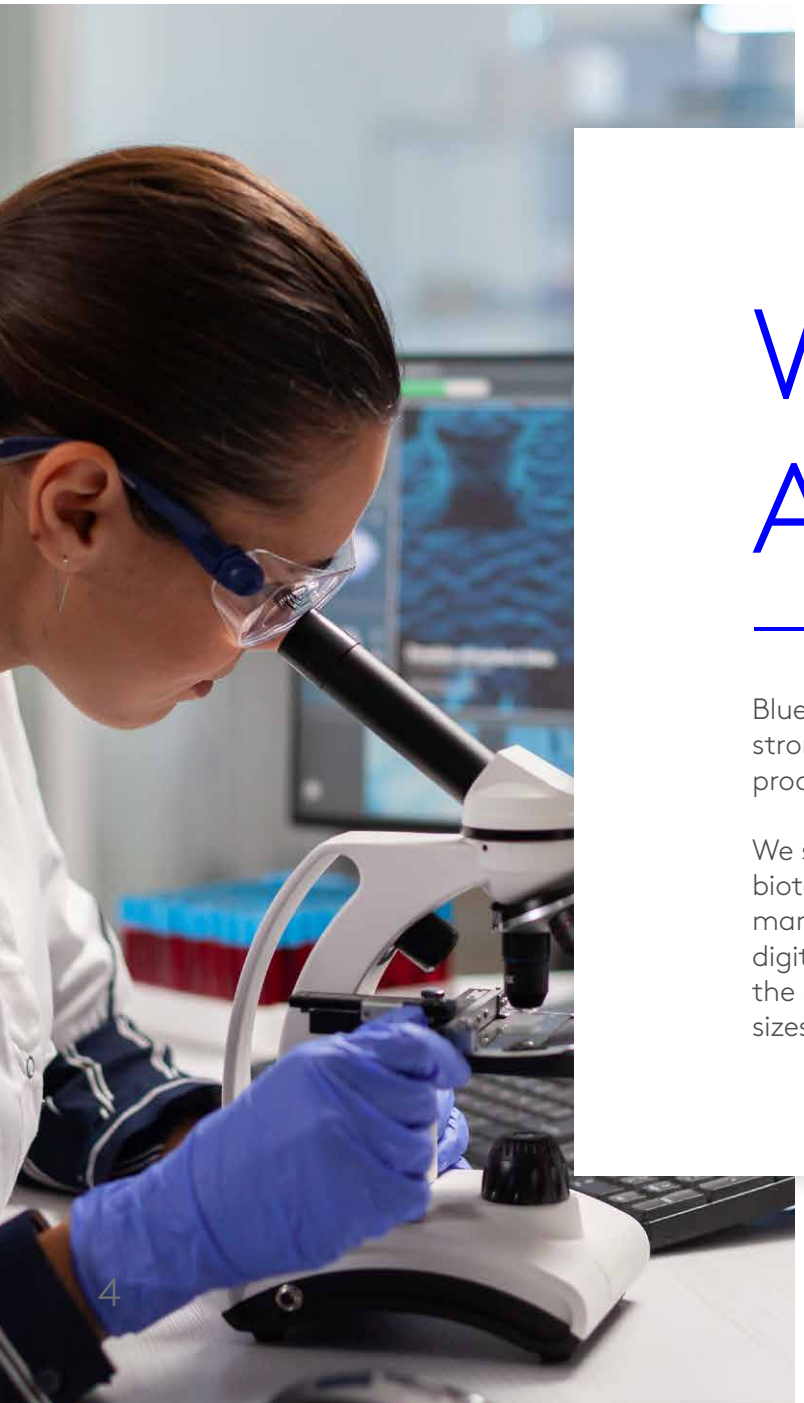


Who We Are

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

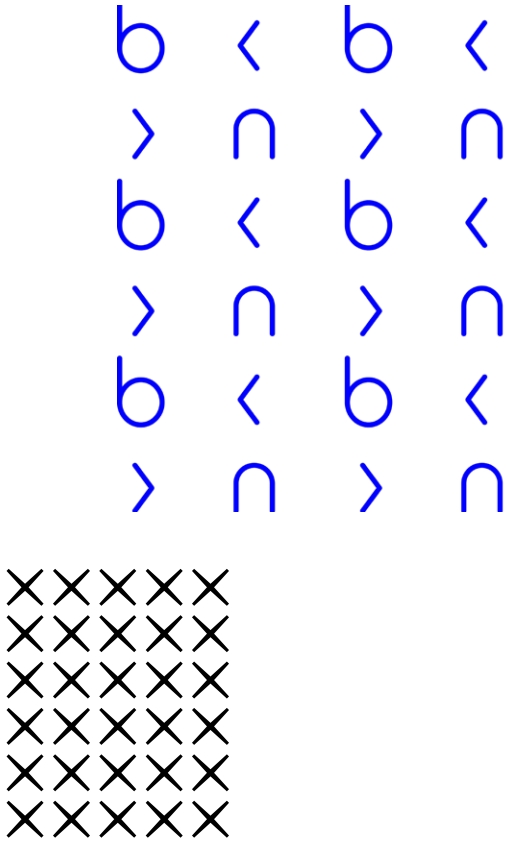
Digital management of maintenance, calibration and spare parts, integrated with **ERP, MES and quality systems.**

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.



loi

Integration of Instruments

Digitalize your instruments.
Don't replace them.

loi is a web-based software platform designed to automatically and compliantly acquire data from laboratory and production instruments.

It enables the full digital management of measurement, review and approval workflow, ensuring Data Integrity, traceability and validation, even in the presence of obsolete, unconnected or non-natively compliant instruments.

What is it?

loi is a web-based software platform for the automatic and compliant acquisition of data from laboratory and production instruments, including those not compliant with Data Integrity requirements.

What does it do?

It enables complete digital management of the measurement, review and approval phases of instrumental data, with full traceability and GxP compliance. It supports In-Process Control (IPC) checks in production and easily integrates with LIMS, MES, ELN and EBR systems via the Middleware Module and Smart Gateway Module.

How?

By communicating with instruments via our black box — or via camera for instruments without communication ports — and automatically recording measurements and metadata in a secure database, eliminating manual transcriptions and ensuring rigorous and compliant processes.

How is it validated?

As a Category 4 software (GAMP 5).

Who is it designed for?

For analysis laboratories of pharmaceutical, food, chemical, cosmetic and manufacturing companies operating in a GxP environment that want to digitalize instrument data acquisition without replacing existing instruments.

Core Module

Measurement and data processing in the QC laboratory

Identify the material

Identify the instrument

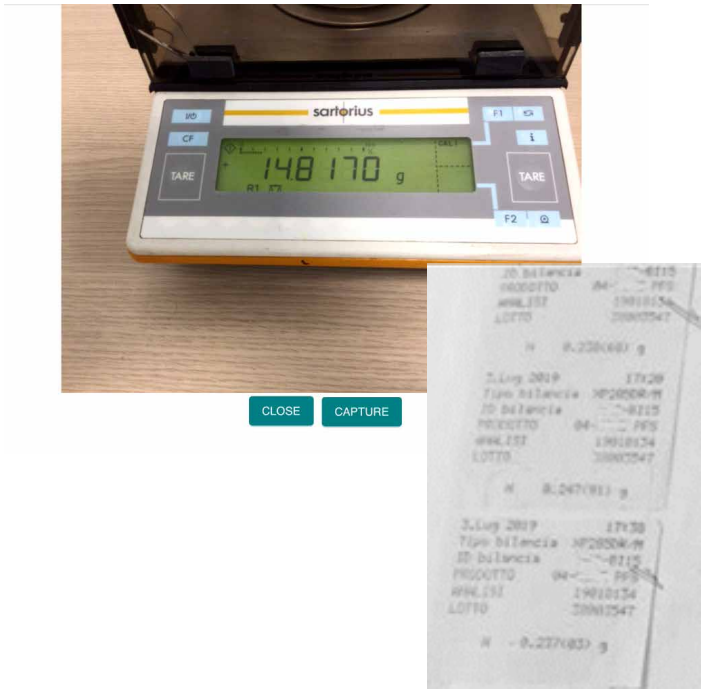
Start measuring

With these simple steps it is possible to acquire measurements and record them in a secure database.

loi communicates with instruments by capturing the print signal.

In the case of instruments without communication ports, loi is able to record measurements via a camera, thanks to the Manual Measurement function.

From measurement to digital report



Measure ID: 87576

PO: 202015526

Date/Time: 15/Jan/2021 13:02:57 CET

Valid

User:

INFORMATION

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

MEASUREMENT RESULTS

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

INSTRUMENT INFORMATION

Instrument ID:	BI-101-G0		
Type:	Scale	Model:	IND890
Manifacturer:	Mettler Toledo	Serial Number:	B821896036

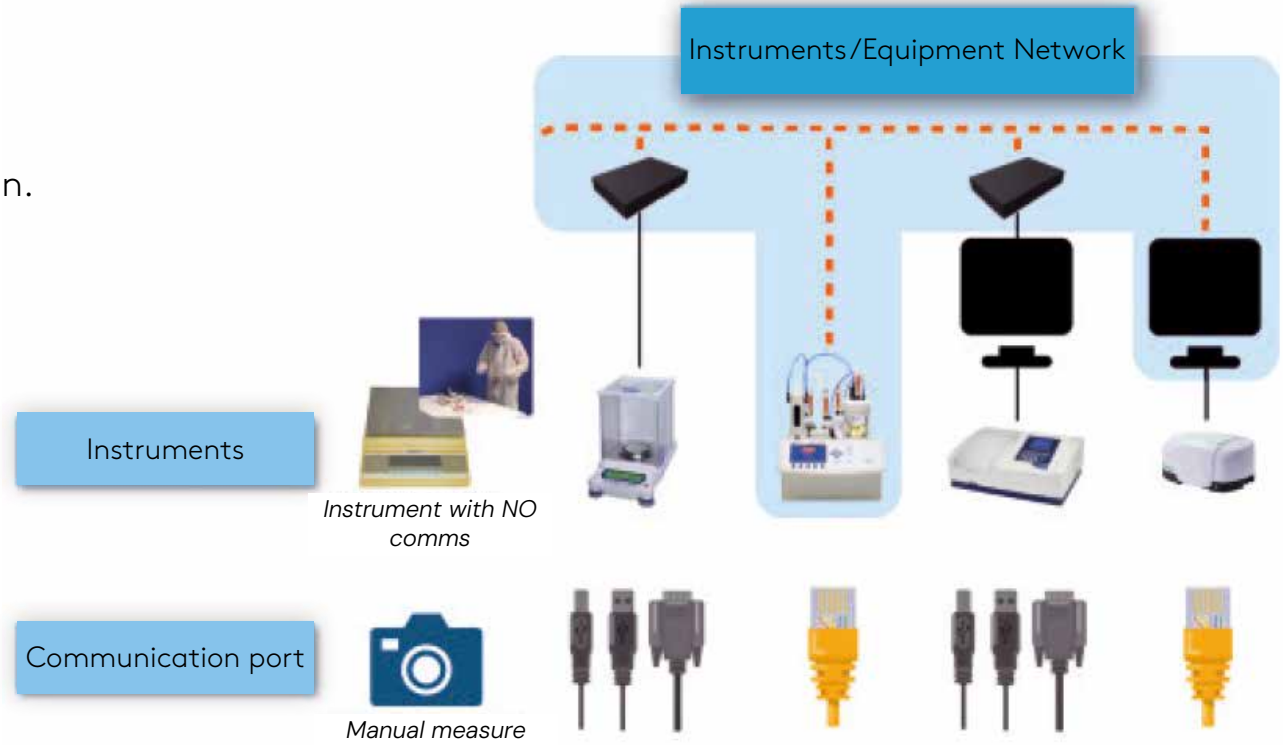
MEASURE CHECK

Measure signed as:	Valid	Date/Time:	15/Jan/2021 13:17:41 CET
User:			

Instrument Connectivity

loi communicates with instruments by **capturing the print signal.**

In the case of instruments without communication ports, loi is able to record measurements with a camera using the **Manual Measurement** function.



Applicability

- ☑ **Multi- Brand:** integration of instruments of any brand and age
- ☑ **Fast configuration: no specific code required for individual instruments**

Some integrable instruments

BASIC

Scale

pH meter

Polarimeter

Tritator

ADVANCED

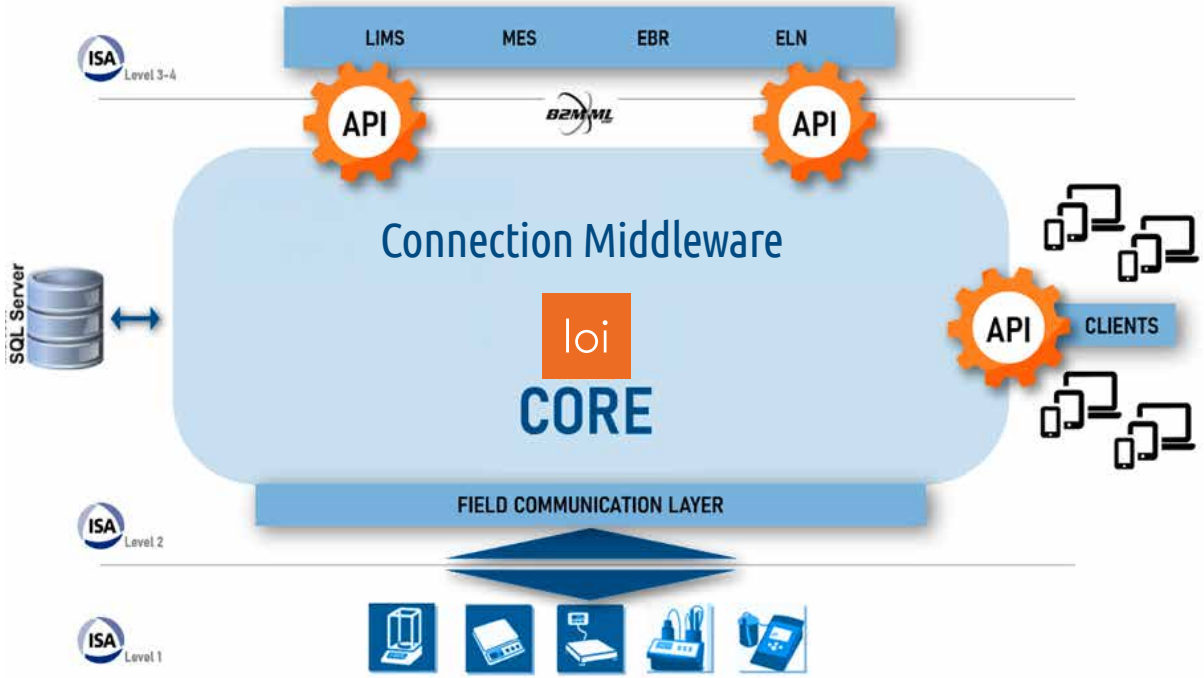
UV spectophotometer

IR spectophotometer

Connection Middleware Module

Enables communication between the loi platform and third-party systems such as LIMS, MES, EBR, etc.

It also allows **third-party systems to operate directly in the management of measurement acquisition**, using loi as a measurement signal processing interface.



Integrable with other business systems

Communication between loi and other systems (LIMS, MES, ELN, EBR, ERP, logbook) is based on REST API.

With loi you can

Measure

Automatic acquisition of measurements and recording in a secure database.

Association of manual notes to measurements and instruments.

Review and approve

Context-based electronic review with configurable review flows.

Create reports and monitor

Complete set of standard reports.

Communication with third-party systems such as LIMS, MES, EBR...

Key Features

Reviews and approvals

Context-based electronic review with configurable review flows. Supports up to three electronic signatures.

Communication with third-party systems

Such as LIMS, MES, ELN, EBR... via Connection Middleware Module and Smart Gateway module.

Configuration

Instrument configuration by area and access management by area and role.

Automatic measurement acquisition

Identify samples and instruments and capture measurements and related metadata. Manual notes can also be associated with measurements and instruments. Recording in a secure database.

IPC Module (In-Process Control)

Module designed for offline In-Process Control with setpoints, timers, and thresholds (alarm or block).

GxP-ready reporting

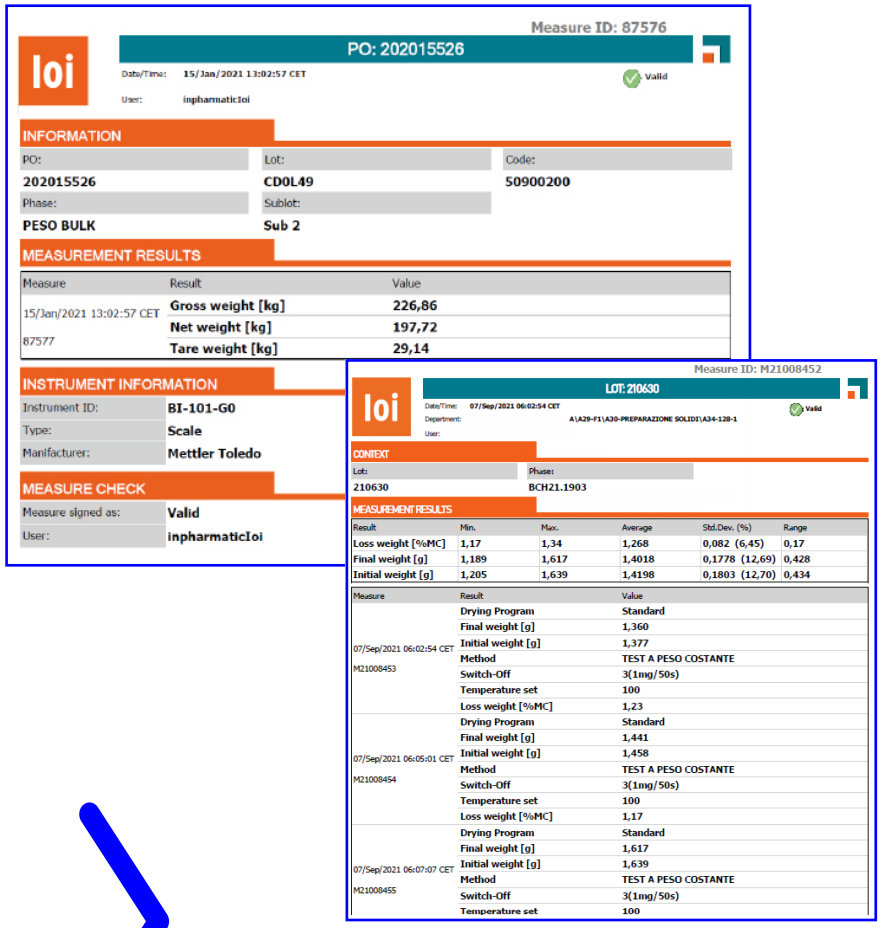
Complete set of standard reports, including instrument logbook and Audit Trail.

Reports and Review

Digital reports, review and approval workflow

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

Electronic review, with the possibility of setting up to three electronic signatures.



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: ____

IPC Module

Offline In-Process Control checks for production

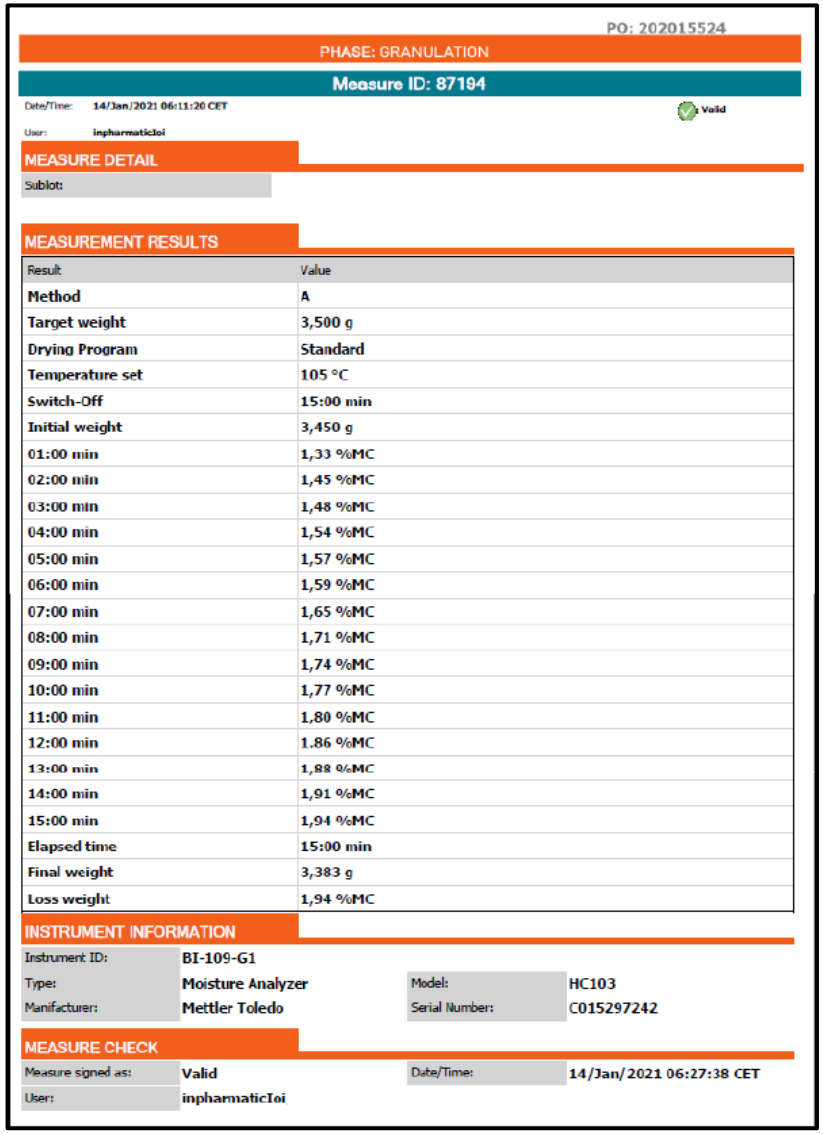
The IPC Module works in combination with the Core module.

It integrates instruments of any brand, enabling fully electronic execution of offline In-Process Control (IPC) checks in production departments.

It allows the sampling recipe/method associated with materials to be defined:

- Reference values
- Timers
- Thresholds (alarm or blocking)

It provides pop-up blocking, with a request for justification and signature, in the event of expired timers and out-of-range values detected.



PO: 202015524

PHASE: GRANULATION

Measure ID: 87194

Date/Time: 14/Jan/2021 06:11:20 CET — Valid

User: inpharmaticIoi

MEASURE DETAIL

Sublot:

MEASUREMENT RESULTS

Result	Value
Method	A
Target weight	3,500 g
Drying Program	Standard
Temperature set	105 °C
Switch-Off	15:00 min
Initial weight	3,450 g
01:00 min	1,33 %MC
02:00 min	1,45 %MC
03:00 min	1,48 %MC
04:00 min	1,54 %MC
05:00 min	1,57 %MC
06:00 min	1,59 %MC
07:00 min	1,65 %MC
08:00 min	1,71 %MC
09:00 min	1,74 %MC
10:00 min	1,77 %MC
11:00 min	1,80 %MC
12:00 min	1,86 %MC
13:00 min	1,88 %MC
14:00 min	1,91 %MC
15:00 min	1,94 %MC
Elapsed time	15:00 min
Final weight	3,383 g
Loss weight	1,94 %MC

INSTRUMENT INFORMATION

Instrument ID:	BI-109-G1		
Type:	Moisture Analyzer	Model:	HC103
Manifacturer:	Mettler Toledo	Serial Number:	C015297242

MEASURE CHECK

Measure signed as:	Valid	Date/Time:	14/Jan/2021 06:27:38 CET
User:	inpharmaticIoi		

Why choose loi

Compatible with all instruments: immediate digitalization without replacing existing instruments. Integrates instruments of any brand, age or technology, via print port, digital signal or even camera.

Compliance and data integrity: automatic and compliant data acquisition, without manual transcriptions, with all metadata required by Data Integrity (attributability, context, date and time, any electronic signatures...). Simplified validation according to GAMP 5.2 software cat. 4.

Measurable benefits from day one: eliminates paper, reduces errors, automatically generates the instrument register and allows review and approval comfortably from the desk, improving operational efficiency.

Rapid integration: no-code configuration in 4 hours per instrument. Easily connects to LIMS, MES, ELN, EBR with Middleware or intelligent Gateway functions.

Accessible from any device: system accessible at all times, from any location and device. Supports operational continuity.

Gradual Implementation

You can start with a single instrument or a single laboratory and expand usage progressively.

Fast installation: you can integrate 20 instruments in one week, without the need to write any code.

Project steps

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


blue


next

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