LabX Software Solution

METTLER TOLEDO

Data integrity at the bench

- Balances
- Titration
- Karl Fischer
- Density
- Refractometry
- UV / VIS Spectrophotometers
- Melting Point
- Dosing System
- pH

One solution for multiple instruments

LabX powers the bench !

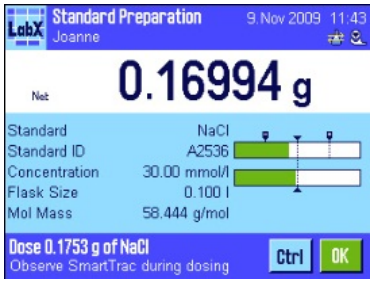
LabX® software brings power to your laboratory bench with automatic data handling, high process security and full SOP user guidance.
Full step-by-step guidance is brought directly to the instrument touch screen.

- One software powers multiple instruments
- Integrate to other Lab systems (e.g. LIMS)
- One common interface on all instruments
- Optimized and flexible workflows
- Complete data security and full regulation support
- Automatic report and label printing

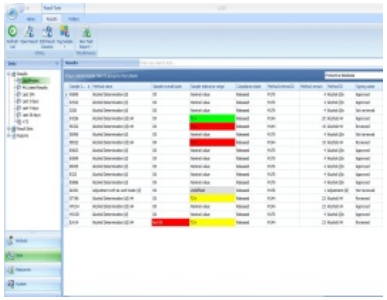
All steps in one solution…

Process Setup

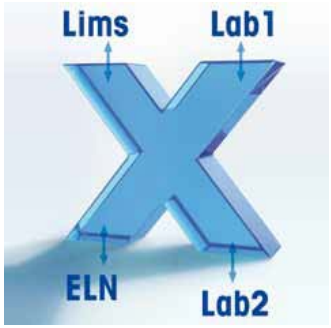
Easy Lab Routines



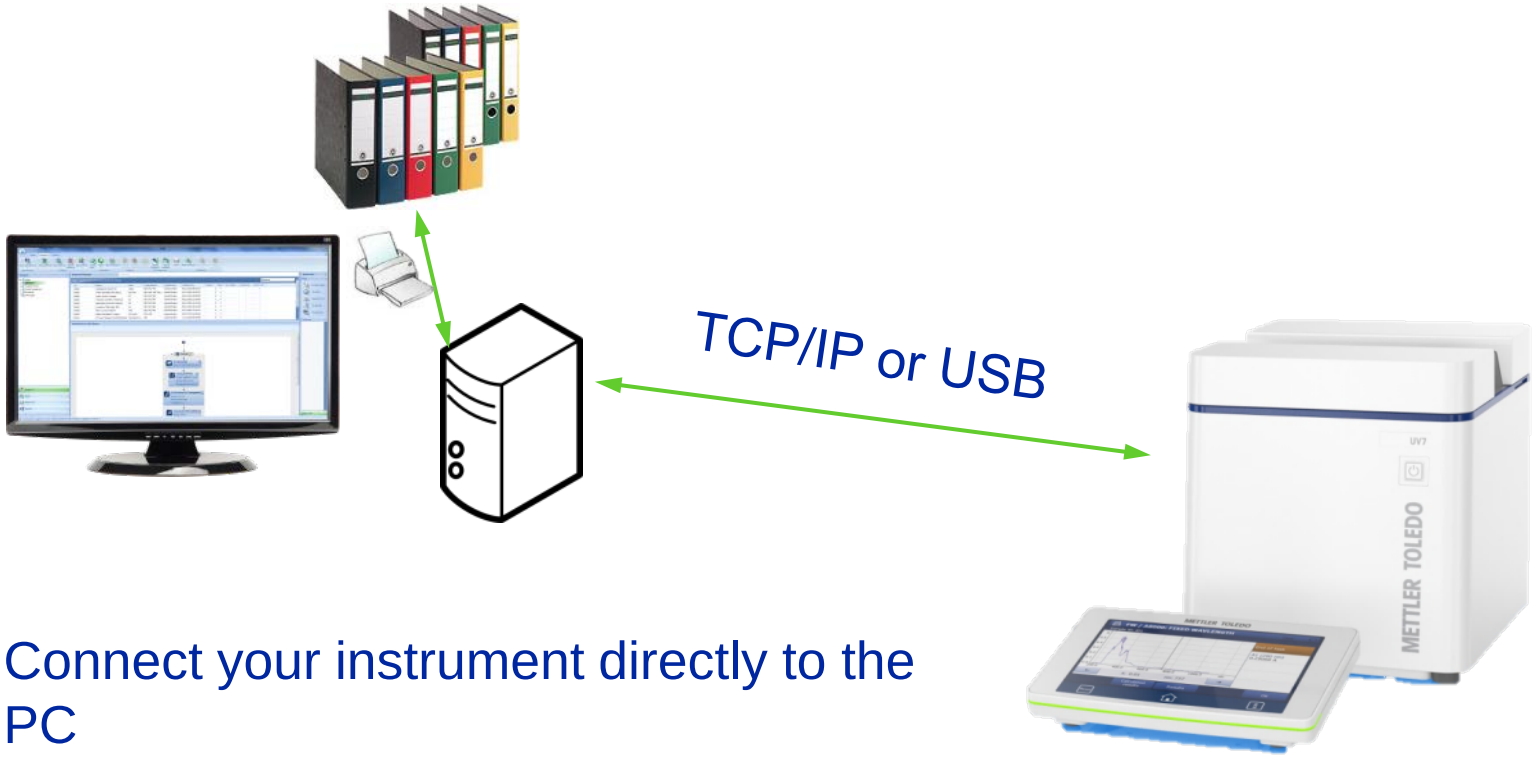
Centralized Management



Documentation & Integration



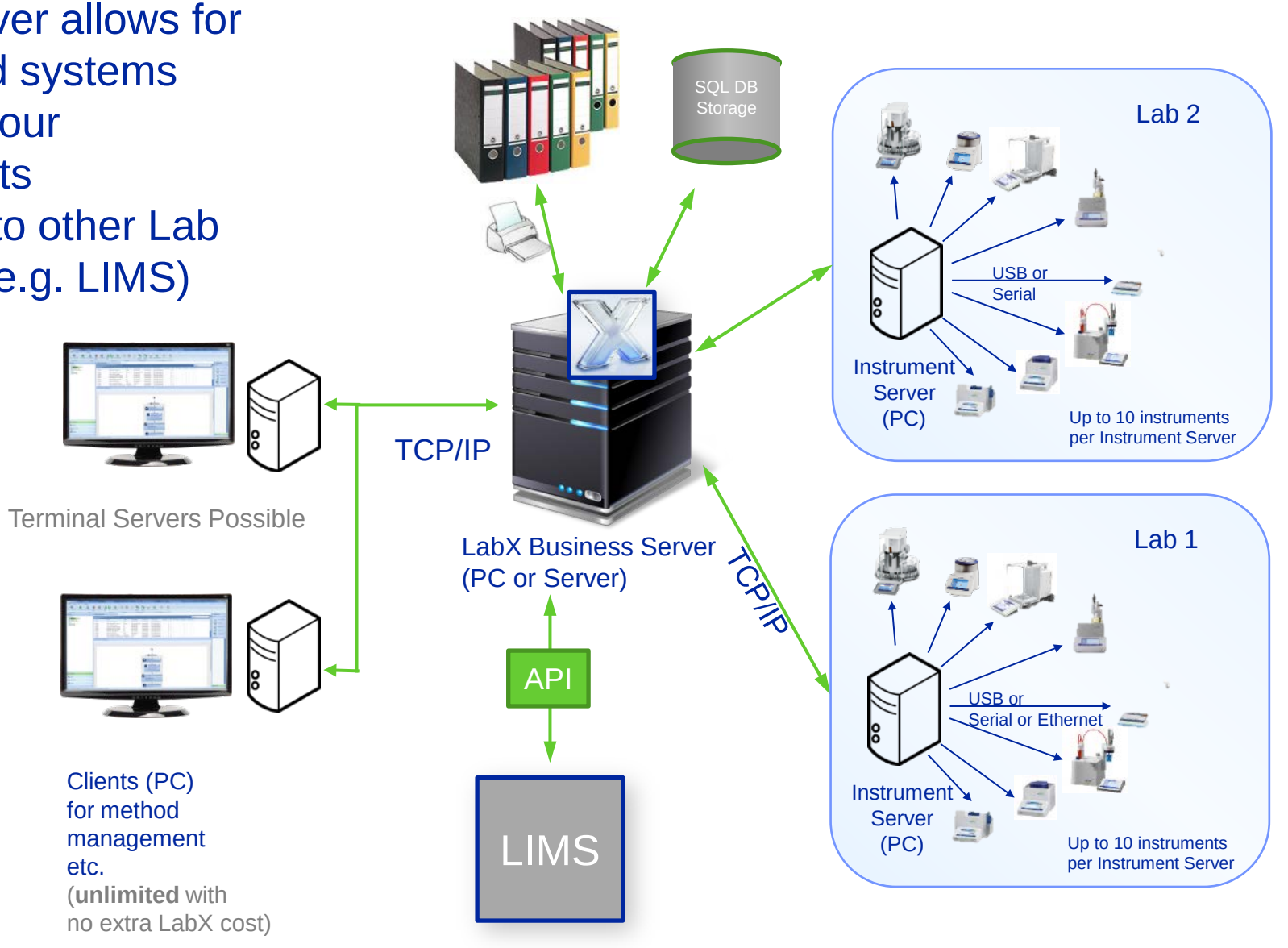
Possible setups with LabX (small system)



- Connect your instrument directly to the PC
- Enhance automation and workflow capabilities
- Secure database
- Generate customized reports

Possible setups with LabX (large system)

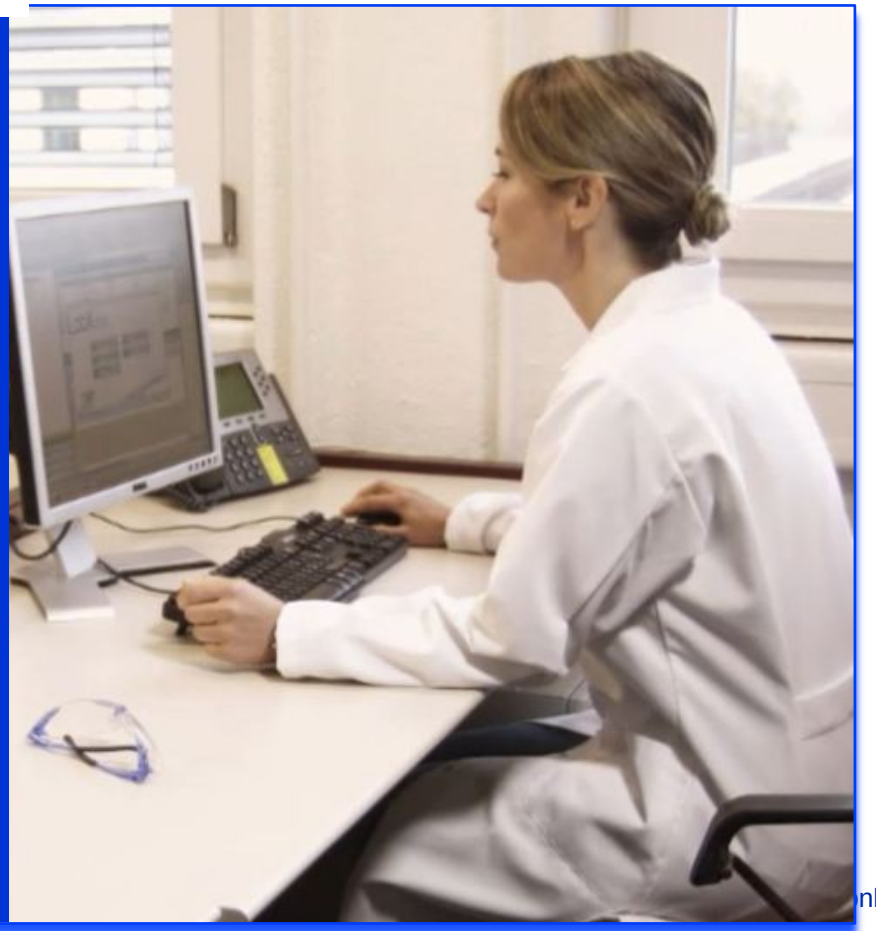
- LabX Server allows for distributed systems
- Manage your instruments
- Integrate to other Lab systems (e.g. LIMS)



The lab with LabX is simply powerful

IN the Lab
- **ON the instrument**

IN the office
- **ON the PC**



"I get my work done faster and more accurate"

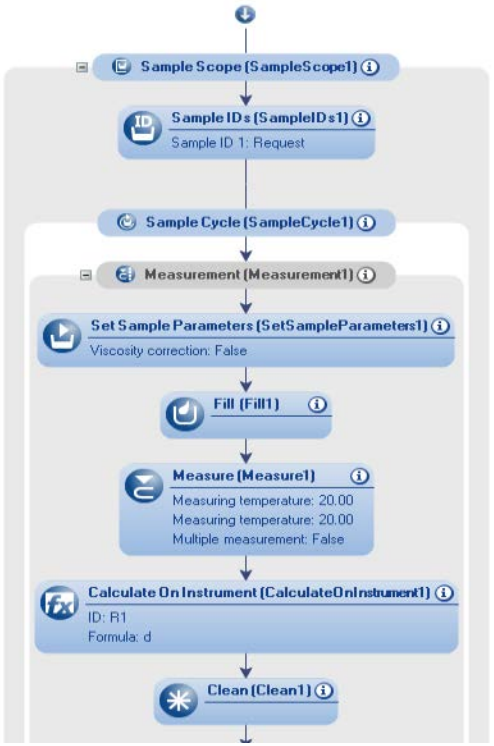
Workflow Flexibility

- My technicians are guided step by step
- I can easily configure workflows based on my SOP
- I am guaranteed my SOP is followed
- My technicians focus on their work and not a computer

Analysis & Methods

Methods taylored to the process

- Build methods intuitively
- Customize to reflect your SOP‘s
- Library of inbuilt methods
- Method History



Analysis & Methods

- Quick understanding of the method
- Easy to start

Documentation

Automatic reporting

- Automatic reporting from the method
- Report Editor
- Advanced Report Designer
- Print Reports and Labels

Documentation

- No need to plot the curves yourself
- Only print information as needed
- Get customized reports

"I need a solution to remove errors"

Data Security

- My 'out of spec' instruments are automatically blocked
- Transcription errors are removed with automatic data transfer
- Archived and current data are easily found and printed

Instrument Management

Instrument control

- Manage Tests and Adjustment Sets
- Schedule Tasks and Tests
- Alarm if test fails
- Block Instrument (Tests, Service,..)
- Notifications (Service)

Instrument Management

- Ensuring high quality data
- No paper logbooks
- Overview of state

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Data Integrity
Starts at the bench

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Data integrity definition

- Data Integrity: The degree to which a collection of data are **complete**, **consistent** and **accurate**.
  - FDA Glossary of Computer Systems Software Development Terminology (1995)

- Data Integrity: The extent to which all data are **complete**, **consistent** and **accurate** throughout the **data lifecycle**.
  - MHRA Guidance for Industry on data Integrity 2015

US GMP Regulations

- **21 CFR 211.194 (a)**

  - Laboratory control records should include **complete data** derived **from all tests conducted** to ensure compliance with established specifications and standard, including examinations and assays, as follows…

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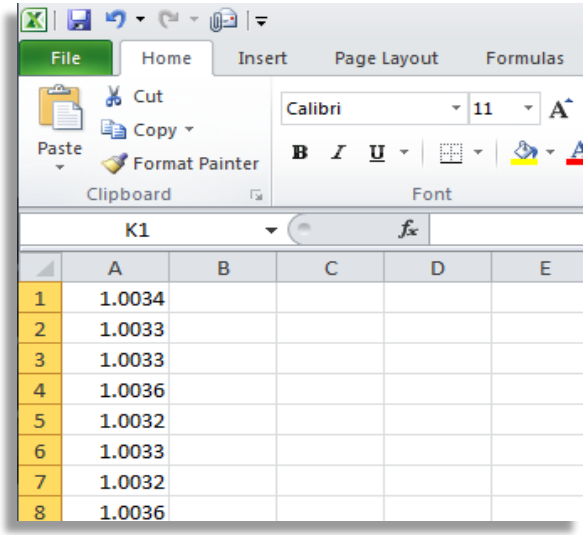
What does complete data mean?

- **Complete data** includes
  - **Raw data** / observations generated in the course of an analysis
  - Associated **contextual metadata**

"…**a number without the context of sample, unit, user, instrument, calibration and adjustment history... is worthless, difficult or dangerous…"**



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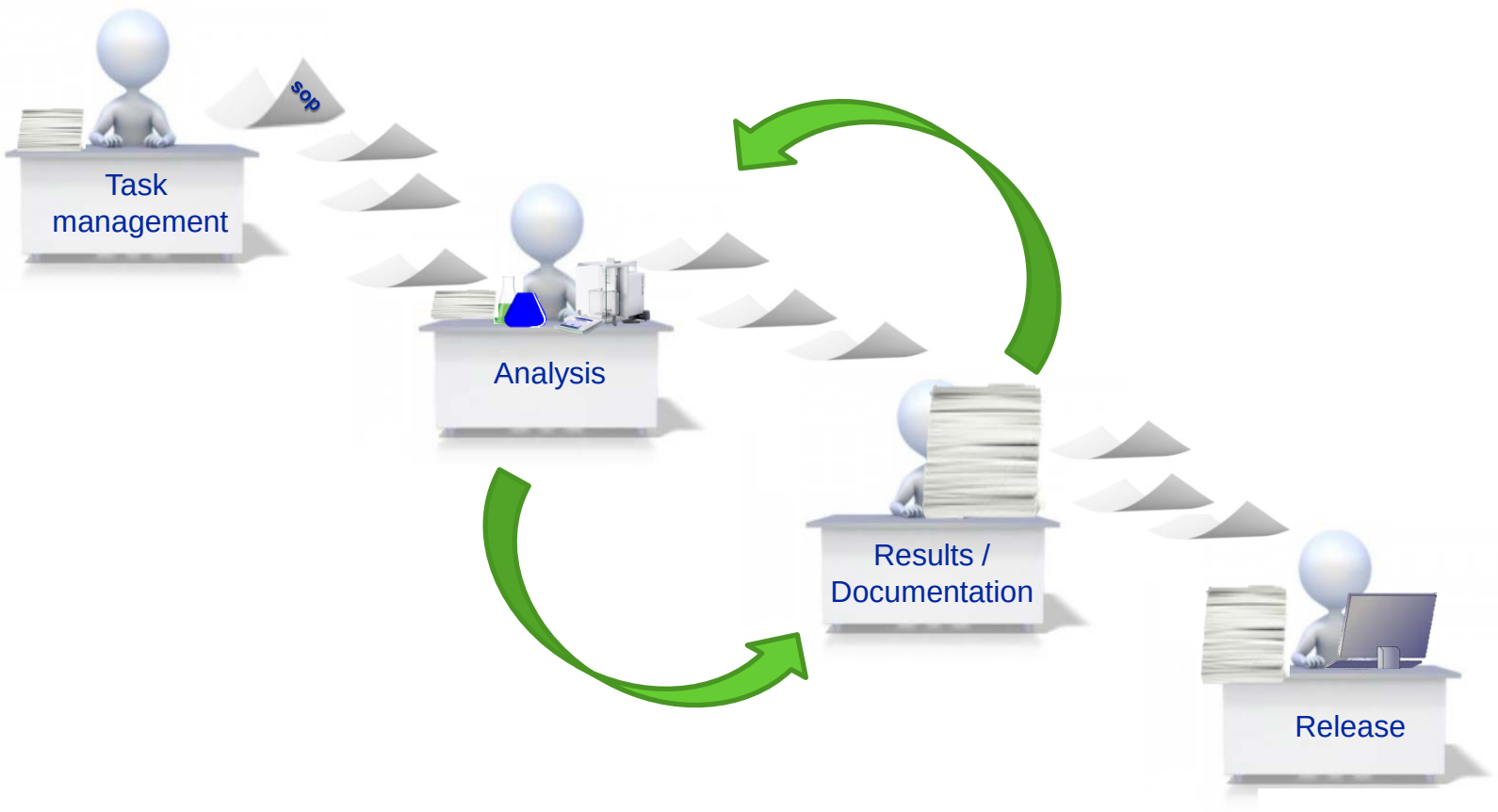
Criteria for Data Integrity – ALCOA+

- **Attributable**: Who performed an action and when?
- **Legible:** Can you read the data file throughout life cycle?
- **Contemporaneous**: Documented at time of the activity
- **Original:** original record or a certified copy
- **Accurate**: no errors/editing without documented amendments

- **Complete**: All data including any test, repeat or reanalysis
- **Consistent**: All elements of the analysis such as sequence of events follow on and are date or time stamped as expected
- **Enduring**: Recorded in laboratory notebooks or validated systems
- **Available**: Can be accessed for review and audit or inspection over the lifetime of the record.

Paper integrity, security, transferability

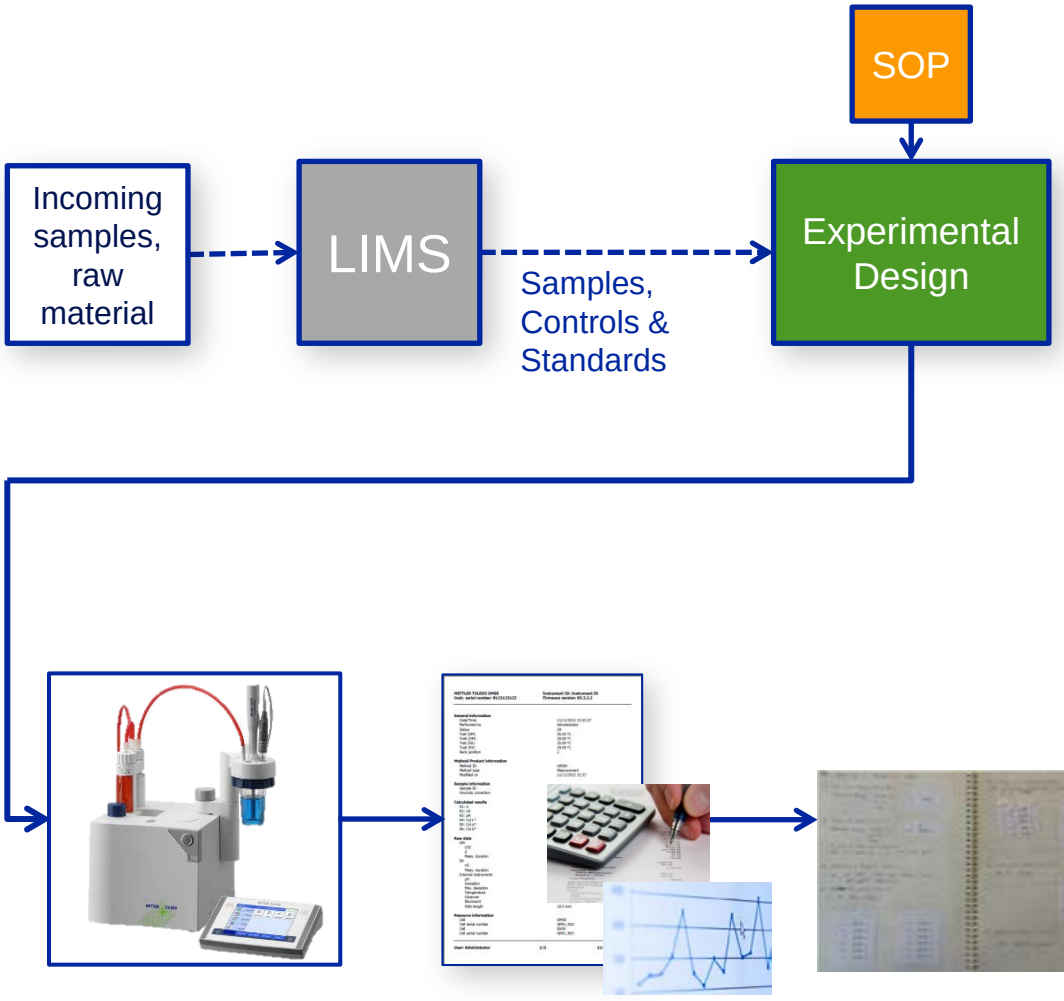
As secure as paper …



Requirements to prove correctness of measurement

1. **Correct instrument** is used for measurement
2. Instruments must be **calibrated and tested**
3. **Tests** must be **traceable**, down to…
   - Buffer, Solution, Weight, and certifications
   - Date & time
   - Person, Instrument, Method
4. Same process is followed by everyone
5. Each **measurement** must be **traceable**, down to…
   - Date & time
   - Person
   - Corresponding calibration data

The Lab of yesterday

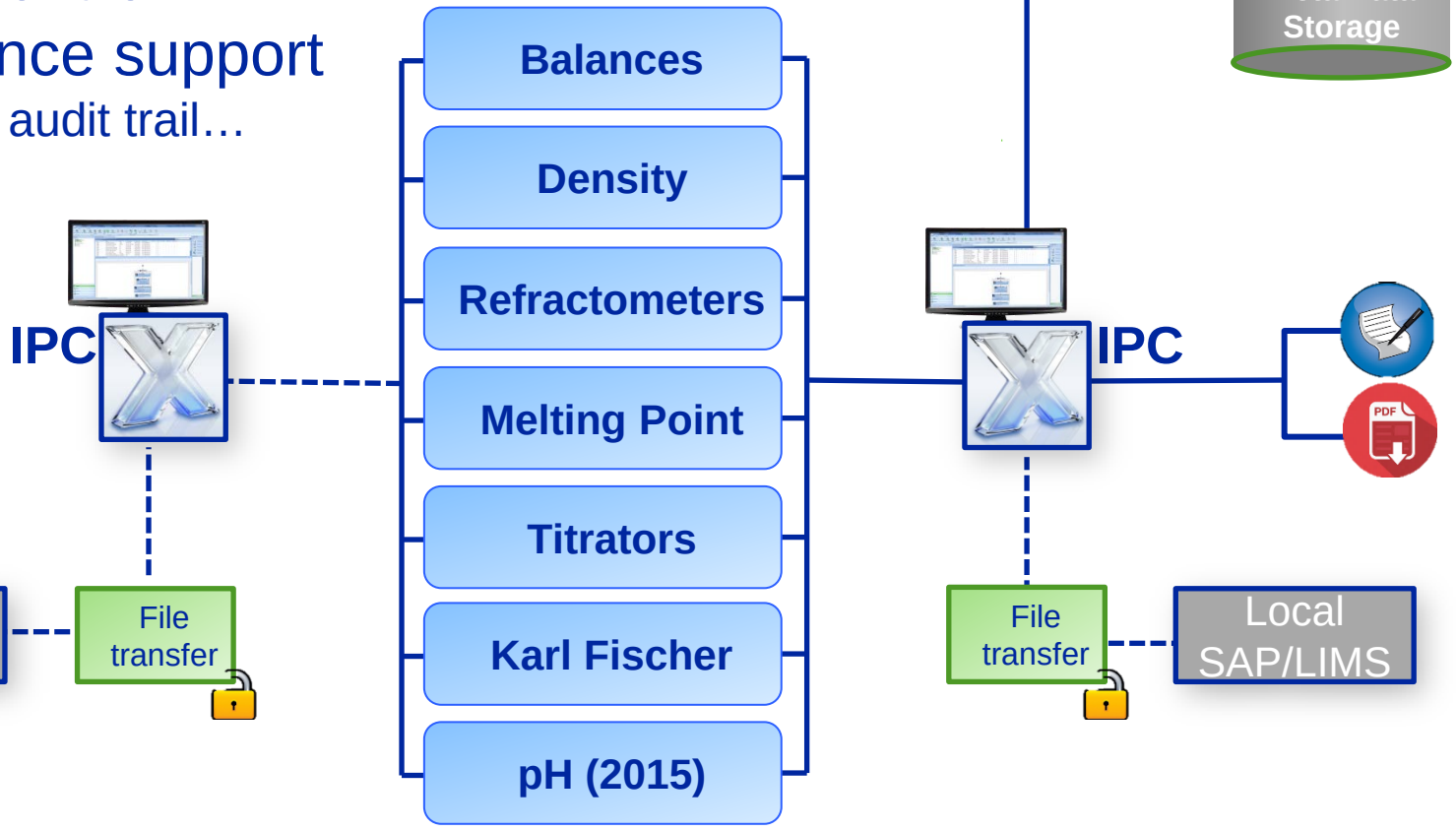


- Analysis Workflow
- Instrumentation
  - Verify calibration & readiness status
- Sample Preparation
  - Controls & Standards

Automatic result transfer can save up to 40% of the lab technicians time

The Lab as it is today

- ✓ Transcription Errors Eliminated
- ✓ Workflow/SOP control
- ✓ Instrument control
- ✓ Full compliance support
  - ✓ E-signature, audit trail…



Integrated data flow, available today with local IPC and local LIMS

Regulation Support

Built-in security features such as electronic signatures and user management assist to comply with regulations and ensure audit-readiness.

Full support for regulations like 21 CFR part 11, EU Annex 11, ISO 17025

Non compliant measurements are avoided by automatically blocking instruments outside of quality management specifications.

Complete traceability of data within reports and audit trail.

CFR 21 part 11 Compliance

Your daily support

- ✓ Traceable and secure results
  - No transcription errors
  - Secure SQL database
  - backup and restore, archiving
- ✓ Instrument checks and adjustments can be scheduled.
- ✓ Comprehensive audit trail
- ✓ Restricted access to specific areas of the workflow depending on the user‘s profile (advanced user management)
- ✓ Electronic signature
- ✓ Validation Service

System Integration

The entire process begins from the office and results are sent back automatically.

Easily integrate with existing lab systems.

Tasks generated by ELN and LIMS are shown directly on the instrument.

Centrally start and control tasks from LabX or from other lab systems.

Import product data and assign corresponding methods.

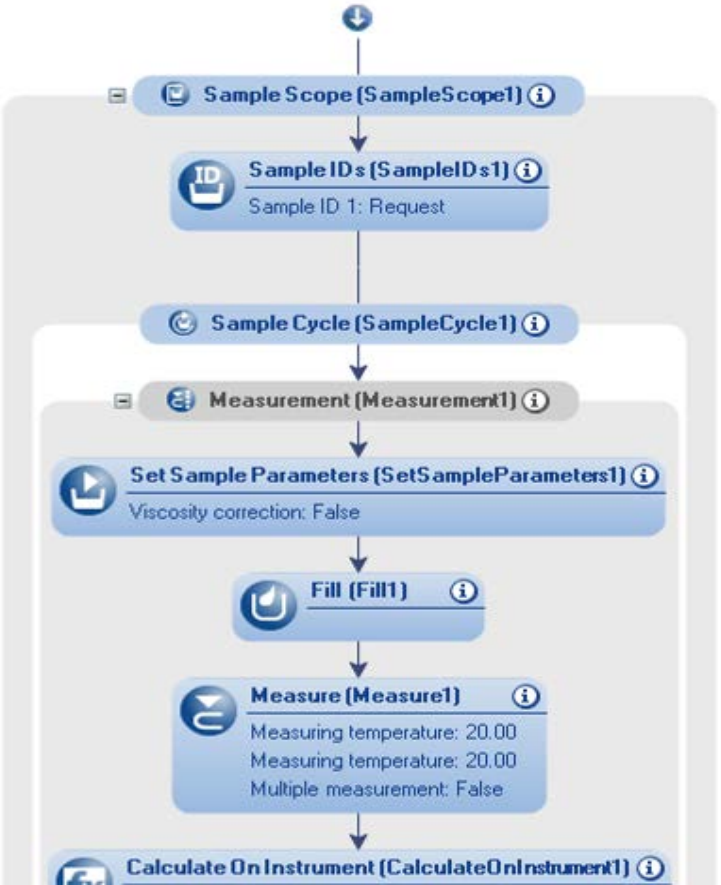
Schedule necessary testing or maintenance tasks to comply with GLP.

Workflow security

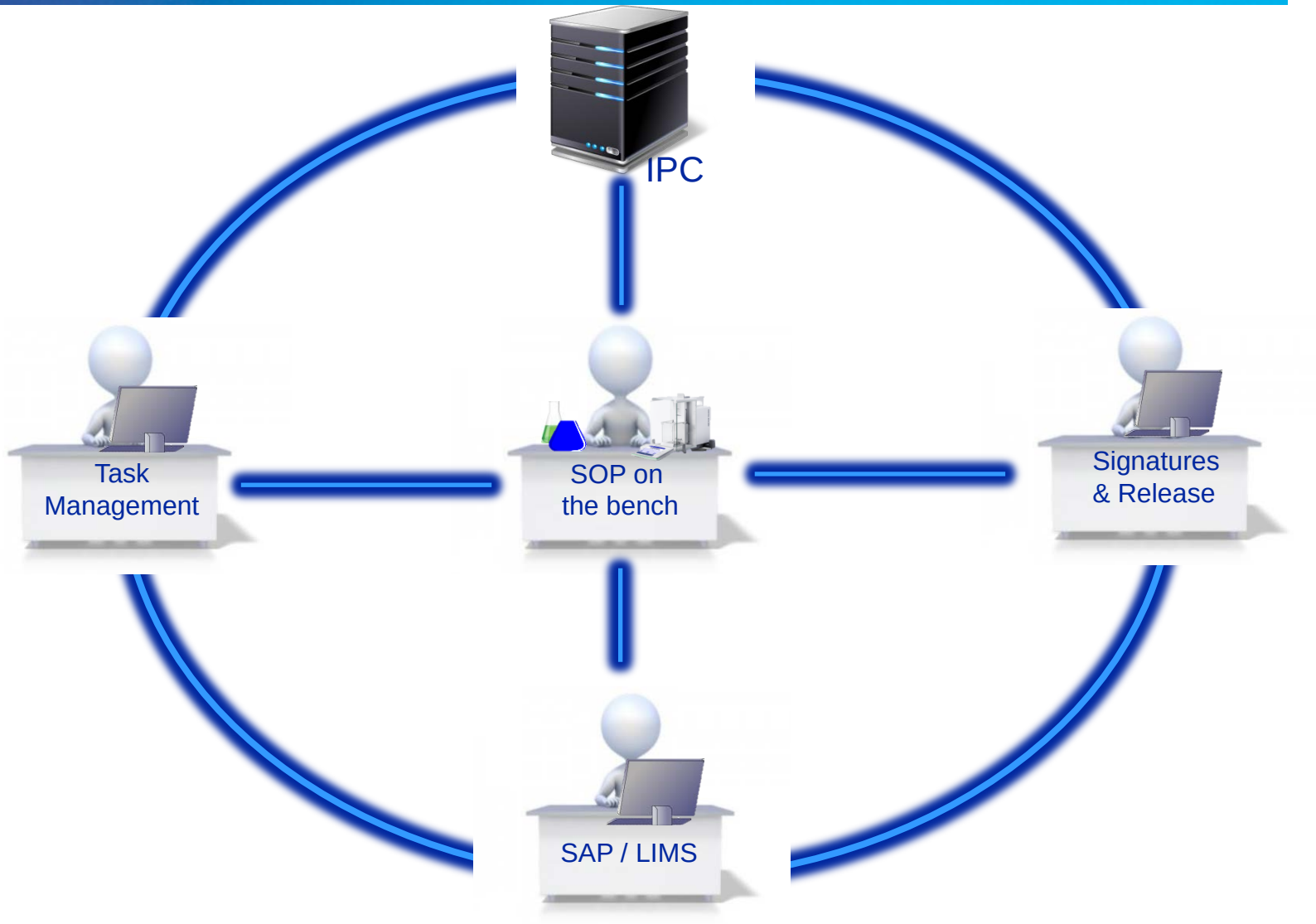
- User management
  (user rights, access protection)
- On-screen SOP guidance
  (on the instrument display)
- If-else workflow and loop functions
- No data transcription error

LabX adapts the instrument display to the customer's needs and authorization level.

Method functions to adapt the system to specific workflows



Future: Fully automated workflow

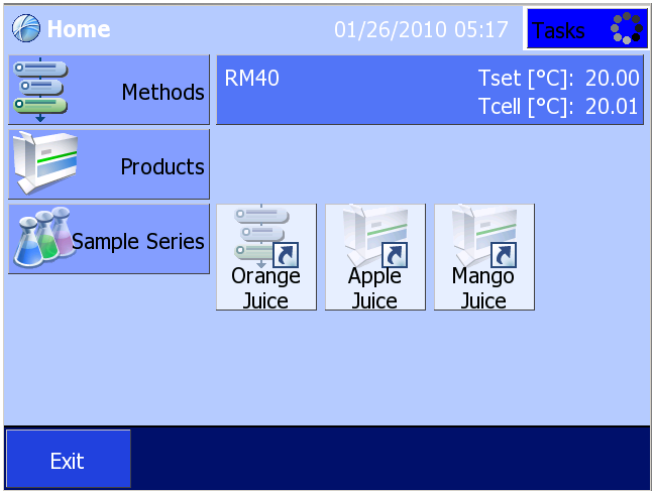


The analyst is in the center of the process and connection for all

Manage and monitor your Data

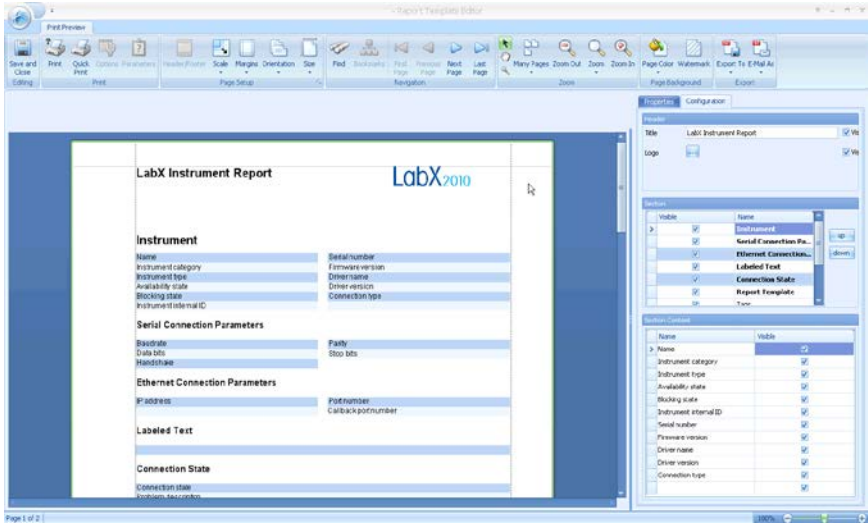
LabX

- Import of large product data base with target value and limits
- Clear overview of data and analysis results, operator and equipment information. Flexible filtering.
- Data export to LIMS or ERP (file or API)
- Customized reports



LabX collects all data, displays it in customizable views or adaptable reports.

Data export can be done in various ways



LabX as one solution for integration

ERP Layer (LIMS)
Data Archiving, Further Processing

Validated Results

Integration Software Layer
Result Generator

Each application in this has to be programmed, validated and maintained!!!

Numbers

Instruments on the Bench
Generate "Numbers"

LabX as one solution for integration

ERP Layer (LIMS)
Data Archiving, Further Processing

Results

Results

Integration Software Layer
Result Generator

Numbers

LabX

Workflow

Instruments on the Bench
Generate "Numbers"

Summary

- ALCOA+
  - Complete — All data including any test, repeat or re-analysis performed.
    - All data automatically captured and stored including metadata
  - Consistent — All elements of the analysis such as the sequence of events follow on and are date or time stamped in the expected sequence.
    - With every measurement the corresponding timestamp is stored
  - Enduring — Recorded in laboratory notebooks or in validated systems
    - All results stored in database, pdfs and/or print-outs can be generated
  - Available — Can be accessed for review and audit or inspection over the lifetime of the record.
    - Single place to search for data for every connected instrument

Conclusion

Electronic transfer starts at point of data origin

- Reduced risk and increased compliance
- Increased efficiency, improved data consistency
- Real time data access
- Simplicity of workflow and process
- Reduced total cost of ownership

Data integrity achieved!

Thanks for your attention

Streamline your Lab workflow with LabX