OGI-IT LIMS

a visual introduction

What is a LIMS

LIMS - **Laboratory Information Managent System**

a **Computer Application** to **manage** a **Laboratory**

Information is represented on a **Computer** as a **data model**

the **data** is transformed (sorted, queried, aggregated) so that **management** decisions can be made

Data Model

The **data model** is tightly coupled to the „place“ where the data is stored, the **database**.

- **relational** database - many **tables**, each table can have many **columns**, each column can hold only one **type** of data, each cell holds one **value**

- **document oriented** database - many **collections**, each collection consists of many similar **documents**, each document has a **complex structure** (objects, attributes, array’s etc.)

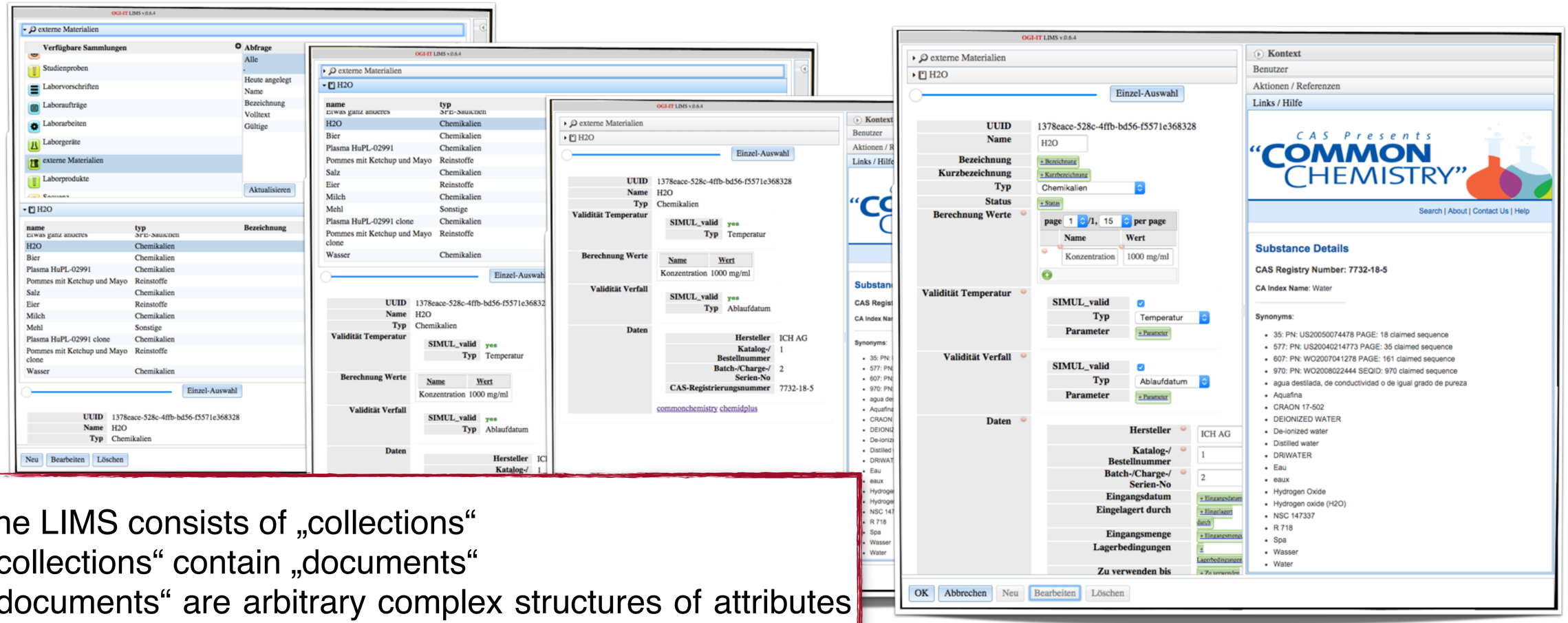
Data Model of a Laboratory

Some entities in a Laboratory are:

- Studies (Studien)
- Samples (Studienproben)
- Operating Procedures (Laborvorschriften)
- Batches (Laborarbeiten)
- Equipment (Laborgeräte)
- External Materials (externe Materialien) i.e. chemicals, pure substances, matrices, etc.
- etc.

in a **document oriented** LIMS these are **collections**

Collections and Documents



- the LIMS consists of „collections“
- „collections“ contain „documents“
- „documents“ are arbitrary complex structures of attributes like „strings“, „numbers“ but also „array’s“ of data or „links“

Customization

~~**Laboratory**~~ **Information Managent System**

IMS the foundation of a **LIMS**

LIMS - a customized IMS

individually define the **Laboratory**

Business Process

business process - **a sequence** of related, **structured activities** or **tasks** that produce a specific service or product (http://en.wikipedia.org/wiki/Business_process)

LIMS workflow - **all** possible **states** of a **document** in the **data model** of the **Lab**

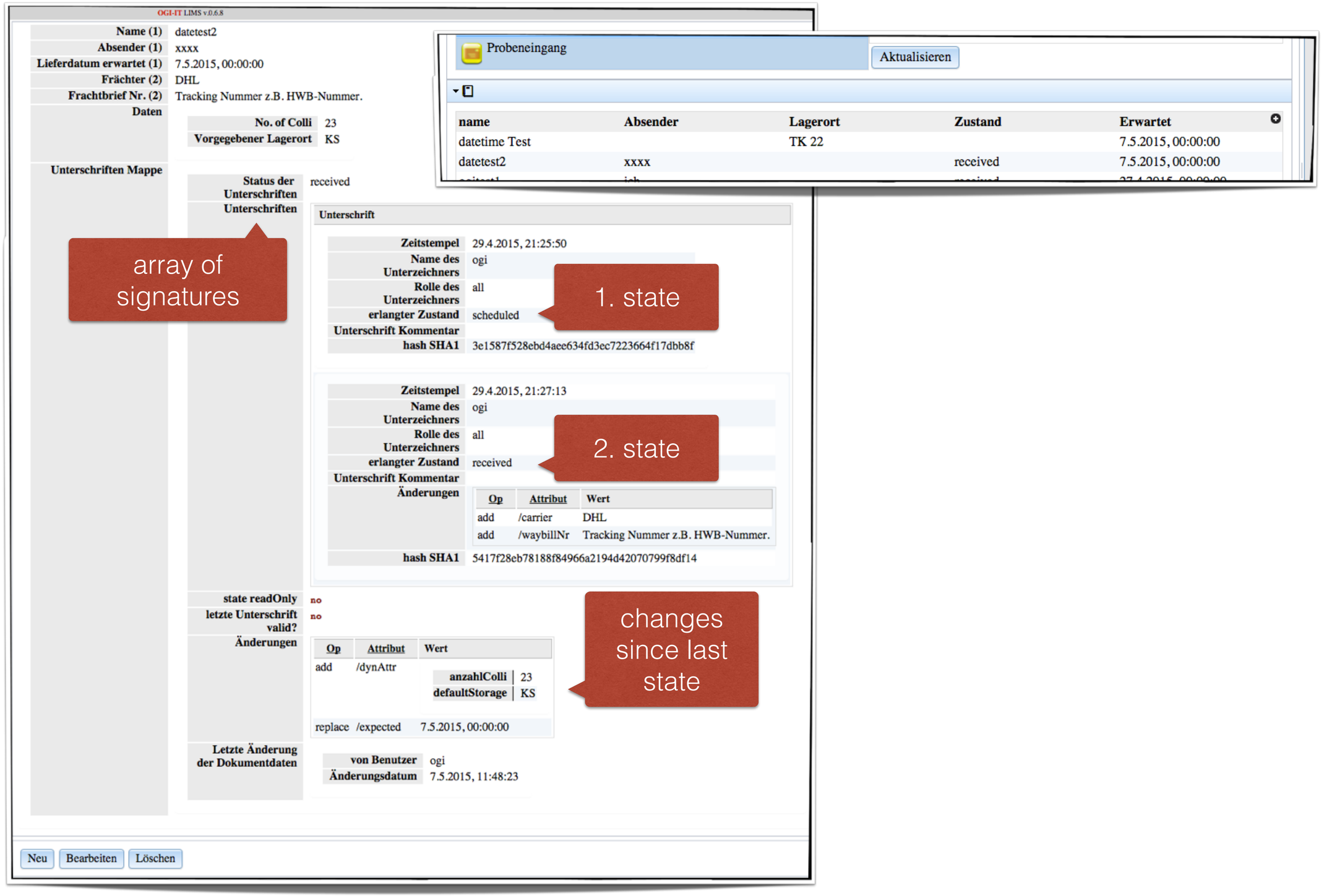
signature - the signee „**guarantees**“ the **content** of a **document** at the time of signing

Audit Trail - the **guaranteed** current and previous **states** of a **document**

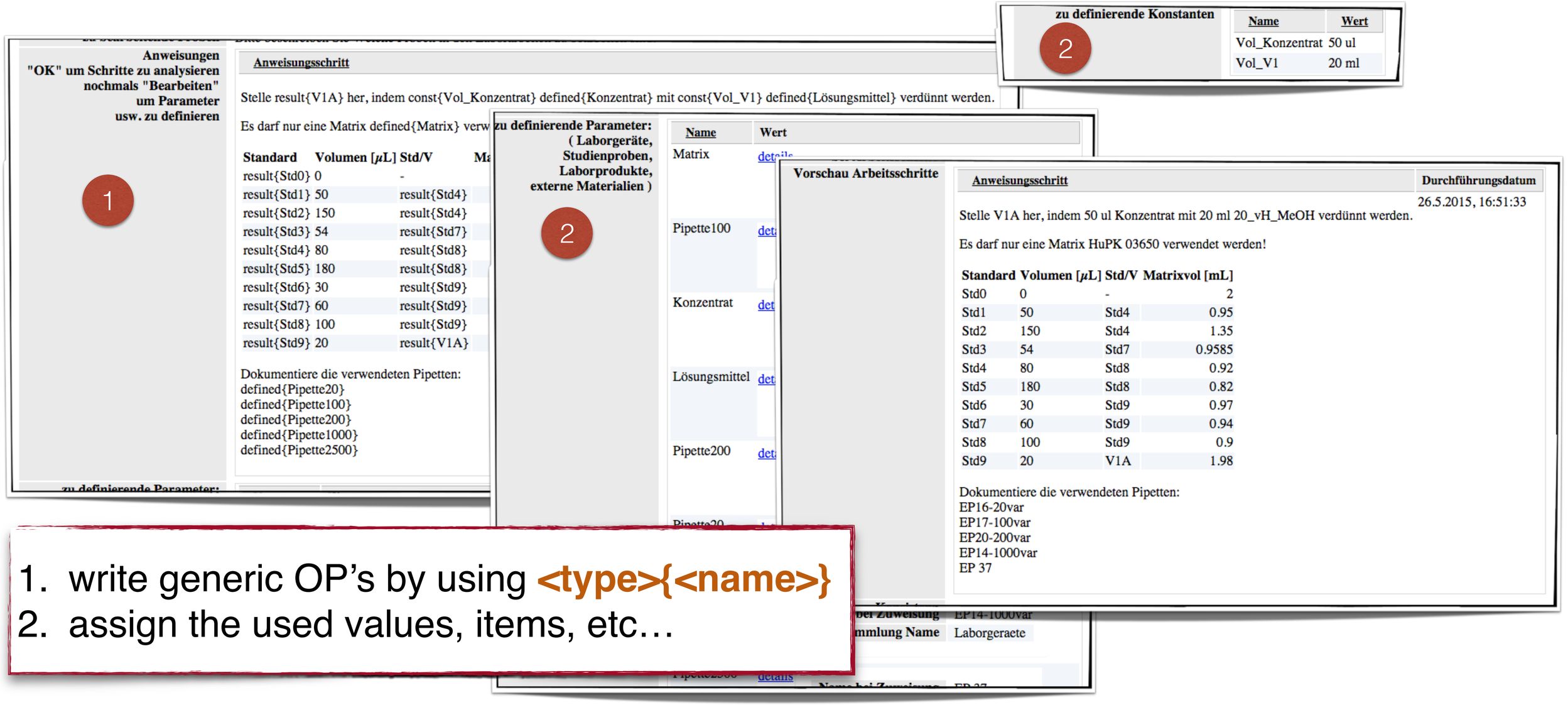
Audit Trail - the **array** of „**signatures**“ in a **document**

LIMS document workflow - the **array** of „**signatures**“ in a **document**

LIMS deleted documents - collection to store any kind of removed document


OGI-IT LIMS v.0.6.8
Name (1) datetest2
Absender (1) xxxx
Lieferdatum erwartet (1) 7.5.2015, 00:00:00
Frächter (2) DHL
Frachtbrief Nr. (2) Tracking Nummer z.B. HWB-Nummer.
Daten
No. of Colli 23
Vorgegebener Lagerort KS
Unterschriften Mappe
Status der Unterschriften received
Unterschriften
array of signatures
Unterschrift
Zeitstempel 29.4.2015, 21:25:50
Name des Unterzeichners ogi
Rolle des Unterzeichners all
erlangter Zustand scheduled
1. state
Unterschrift Kommentar
hash SHA1 3e1587f528ebd4aee634fd3ec7223664f17dbb8f
Zeitstempel 29.4.2015, 21:27:13
Name des Unterzeichners ogi
Rolle des Unterzeichners all
erlangter Zustand received
2. state
Unterschrift Kommentar
Änderungen
Op Attribut Wert
add /carrier DHL
add /waybillNr Tracking Nummer z.B. HWB-Nummer.
hash SHA1 5417f28eb78188f84966a2194d42070799f8df14
state readOnly no
letzte Unterschrift valid? no
Änderungen
Op Attribut Wert
add /dynAttr
anzahlColli 23
defaultStorage KS
replace /expected 7.5.2015, 00:00:00
changes since last state
Letzte Änderung der Dokumentdaten
von Benutzer ogi
Änderungsdatum 7.5.2015, 11:48:23
Neu
Bearbeiten
Löschen
Probeneingang
Aktualisieren
name Absender Lagerort Zustand Erwartet
datetime Test TK 22 7.5.2015, 00:00:00
datetest2 xxxx received 7.5.2015, 00:00:00

Generic Operating Procedures



1. write generic OP's by using **<type>{<name>}**
2. assign the used values, items, etc…

Generic Calculation

Berechnungen (zusätzliche Attribute der erzeugten Laborprodukte)

Resultatname	Name	Formel
V1A	Conz	Qty(c_Vol_Konzentrat).mul(Qty('100 ug/ml')).div(Qty(c_Vol_V1)).to('ug/ml').format(toPrecision(5))
Std0	Conz	Qty('0.0 ug/ml').format(toPrecision(5))
Std9	Conz	Qty('20 ul').mul(Qty(__result__.V1A.calc.Conz)).div(Qty('2 ml')).to('pg/ml').format(toPrecision(5))
Std8	Conz	Qty('100 ul').mul(Qty(__result__.Std9.calc.Conz)).div(Qty('1 ml')).to('pg/ml').format(toPrecision(5))
Std7	Conz	Qty('60 ul').mul(Qty(__result__.Std9.calc.Conz)).div(Qty('1 ml')).to('pg/ml').format(toPrecision(5))
Std6	Conz	Qty('30 ul').mul(Qty(__result__.Std9.calc.Conz)).div(Qty('1 ml')).to('pg/ml').format(toPrecision(5))
Std5	Conz	Qty('180 ul').mul(Qty(__result__.Std8.calc.Conz)).div(Qty('1 ml')).to('pg/ml').format(toPrecision(5))
Std4	Conz	Qty('80 ul').mul(Qty(__result__.Std8.calc.Conz)).div(Qty('1 ml')).to('pg/ml').format(toPrecision(5))
Std3	Conz	Qty('54 ul').mul(Qty(__result__.Std7.calc.Conz)).div(Qty('1.0125 ml')).to('pg/ml').format(toPrecision(5))
Std2	Conz	Qty('150 ul').mul(Qty(__result__.Std4.calc.Conz)).div(Qty('1.5 ml')).to('pg/ml').format(toPrecision(5))
Std1	Conz	Qty('50 ul').mul(Qty(__result__.Std4.calc.Conz)).div(Qty('1 ml')).to('pg/ml').format(toPrecision(5))

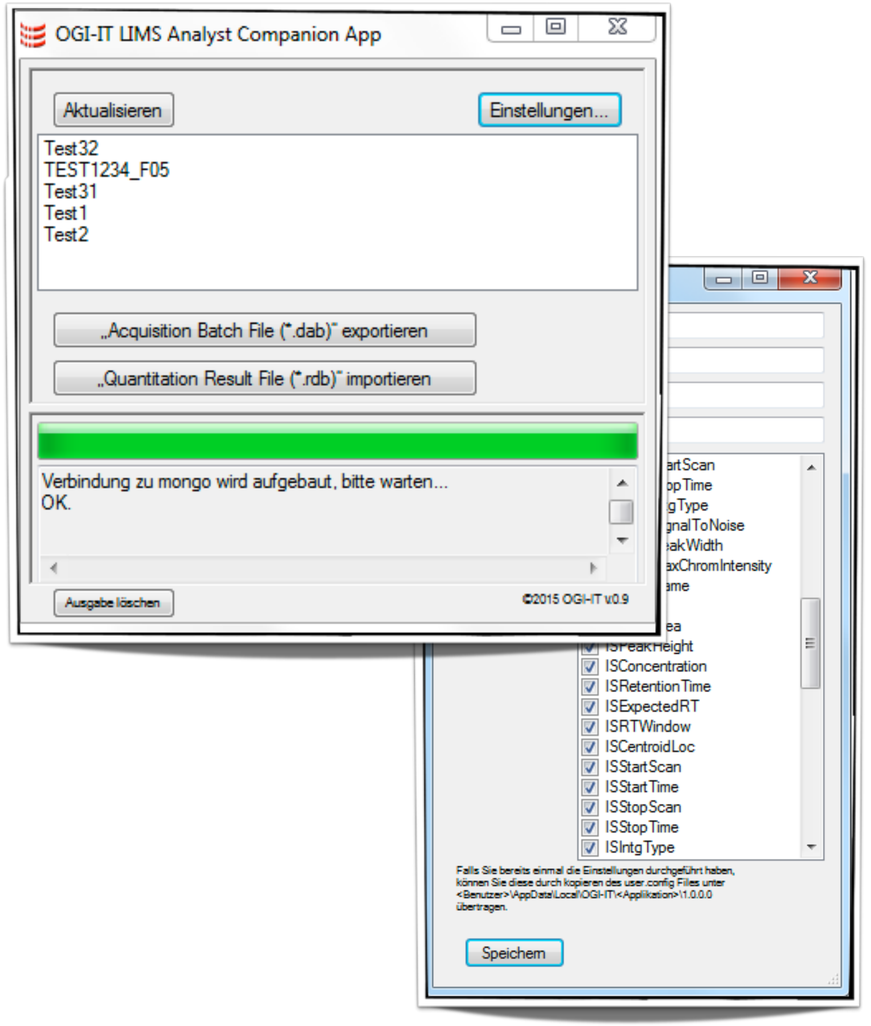
Zu generierende Laborprodukte

Name	enstanden aus	Kurzname	Etikett	Berechnung Werte		definiert via	
Std0::S12		Std0	Std0A-762	Name	Wert	Name	Std0
				Conz	0.0000 ug/ml		
		Std1	Std1A-762	Name	Wert	Name	Std1
				Conz	1.0000 pg/ml		
		Std2	Std2A-762	Name	Wert	Name	Std2
				Conz	2.0000 pg/ml		
		Std3	Std3A-762	Name	Wert	Name	Std3
				Conz	8.0000 pg/ml		
		Std4	Std4A-762	Name	Wert	Name	Std4
				Conz	20.000 pg/ml		
[illegible]::S12		Std5	Std5A-762	Name	Wert	Name	Std5
				Conz	45.000 pg/ml		
Std6::S12		Std6	Std6A-762	Name	Wert	Name	Std6
				Conz	75.000 pg/ml		
7::S12		Std7	Std7A-762	Name	Wert	Name	Std7
				Conz	150.00 pg/ml		
Std8::S12		Std8	Std8A-762	Name	Wert	Name	Std8
				Conz	250.00 pg/ml		
Std9::S12		Std9	Std9A-762	Name	Wert	Name	Std9
				Conz	2500.0 pg/ml		
V1A::S12		V1A	V1A-762	Name	Wert	Name	V1A
				Conz	0.25000 ug/ml		

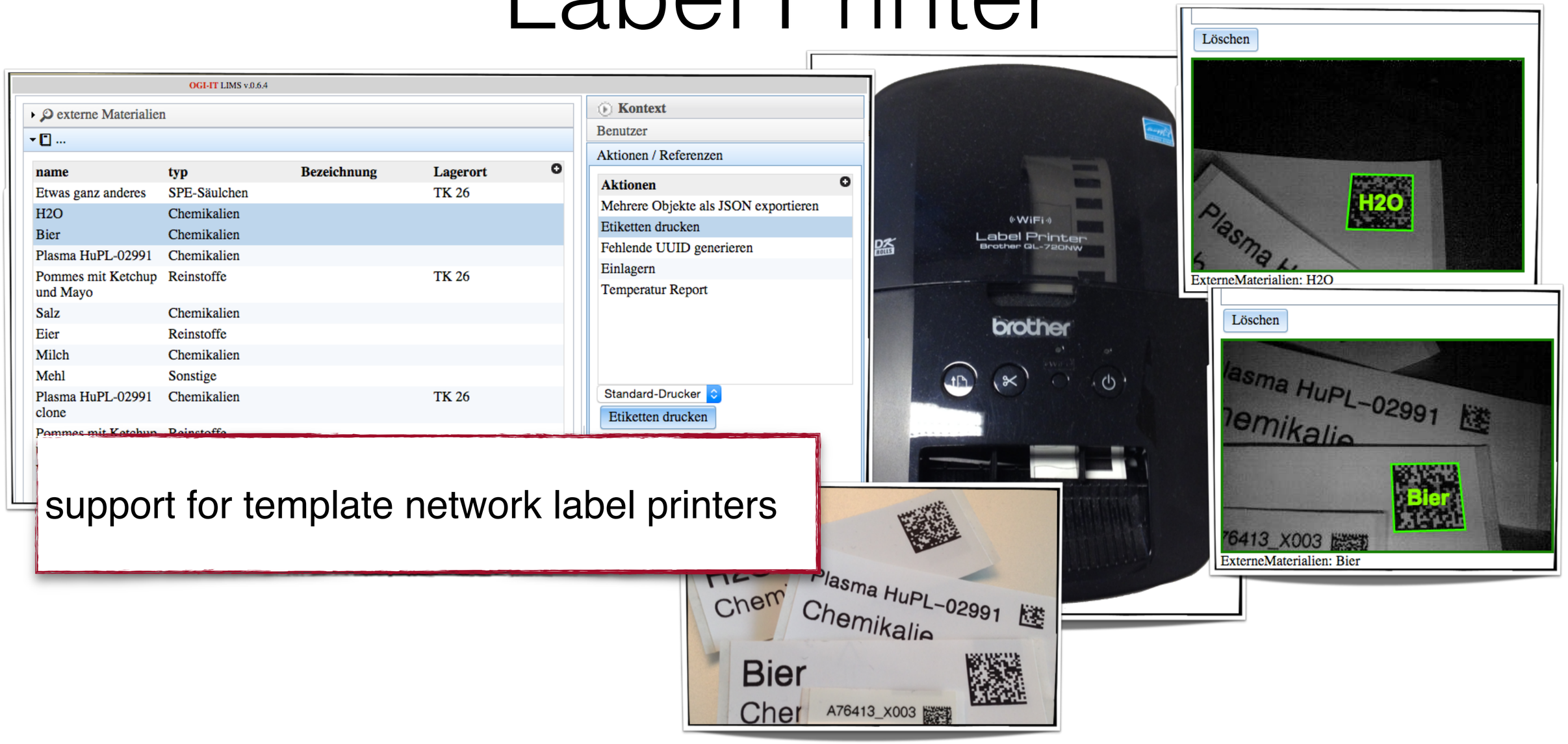
properties of derived probes are calculated automatically

Analyst Companion App

The OGI-IT LIMS Companion App is started inside of the SCIEX Analyst Software , a widely used LC/MS/MS (Liquid chromatography–mass spectrometry/ mass spectrometry) instrument control software. It allows both import of „Acquisition Batches“ from the LIMS and export of „Quantitation Results“ back into the LIMS.



Label Printer

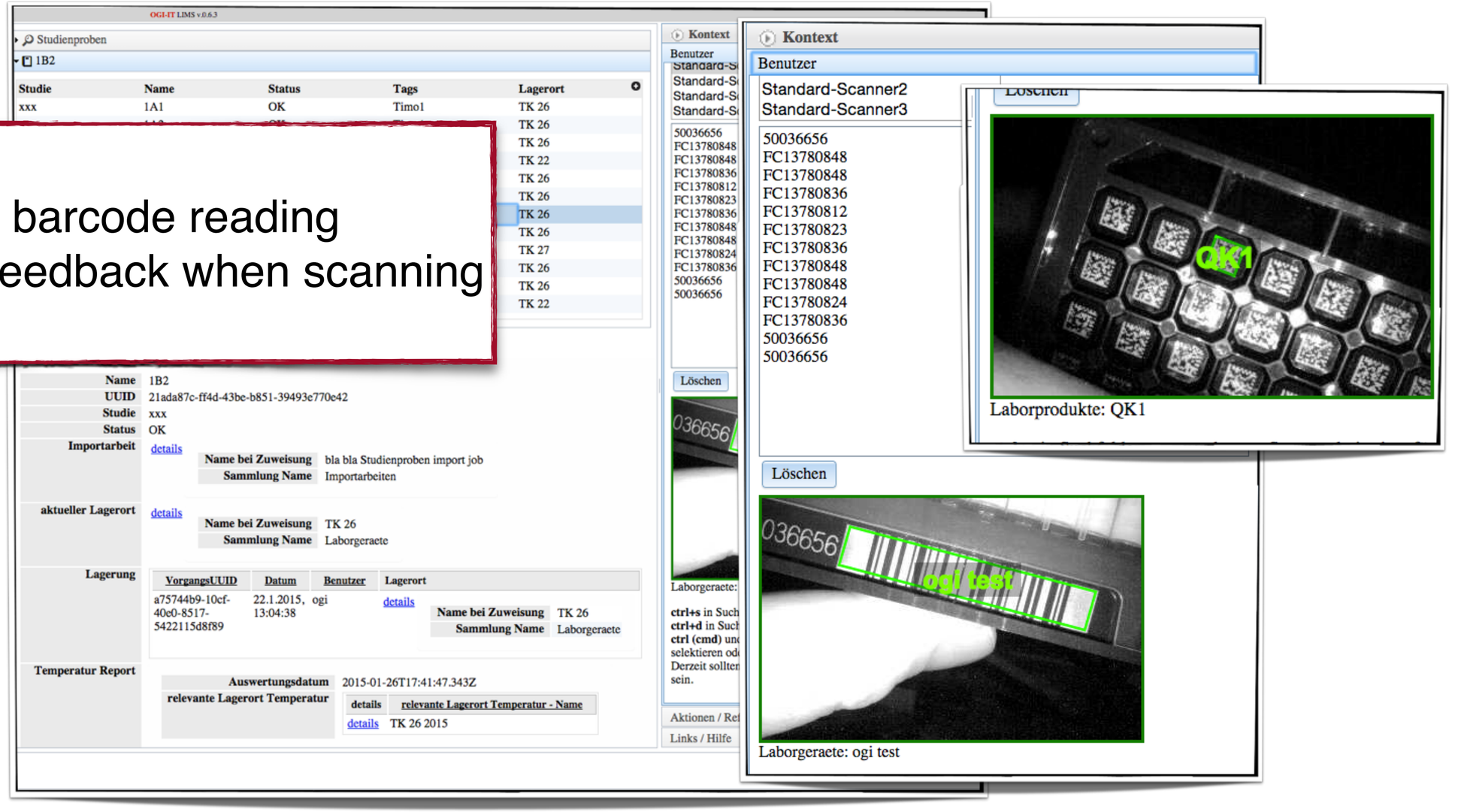


support for template network label printers

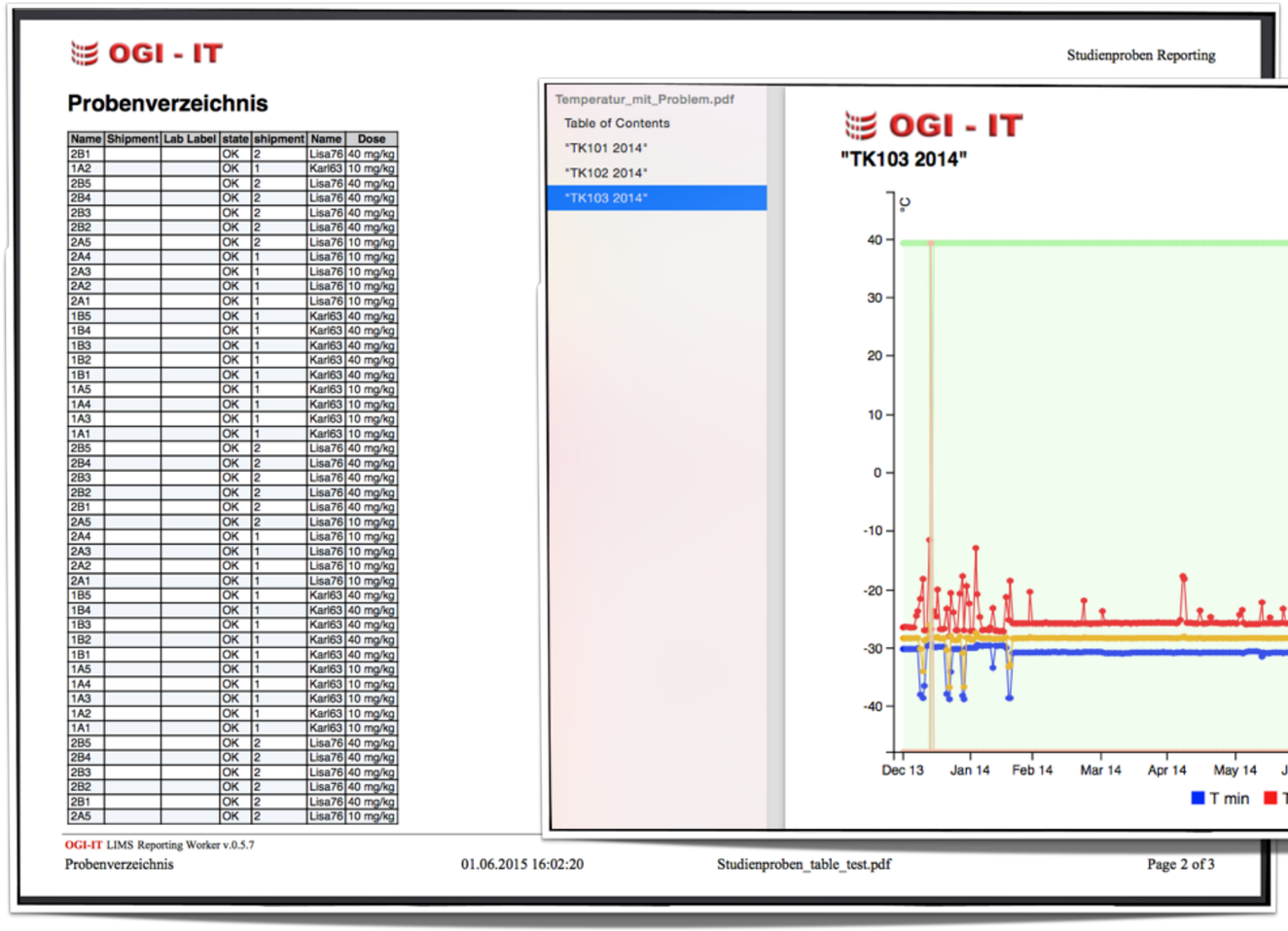
Visual Feedback

image-based barcode reading

- get visual feedback when scanning



Reporting



template based Reporting

- PDF
- CSV
- JSON

Quality

General

- **ISO-9000 ff** - http://en.wikipedia.org/wiki/ISO_9000 family of quality management systems standards is designed to help organizations ensure that they meet the needs of customers and other stakeholders while meeting statutory and regulatory requirements related to a product

Specific to Laboratory

designed with this in mind

- **ISO-15189** - http://en.wikipedia.org/wiki/ISO_15189 based on ISO/IEC 17025 (General requirements for the competence of testing and calibration laboratories) and ISO 9001, it is a unique document that takes into consideration the specific requirements of the medical environment and the importance of the medical laboratory to patient care

- **GAMP 5** - http://en.wikipedia.org/wiki/Good_Automated_Manufacturing_Practice a set of guidelines for manufacturers and users of automated systems in the pharmaceutical industry (ISPE - International - EU)

- **CFR Part 11**- http://en.wikipedia.org/wiki/Title_21_CFR_Part_11 defines the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable and equivalent to paper records (FDA -US)

Thank you!