

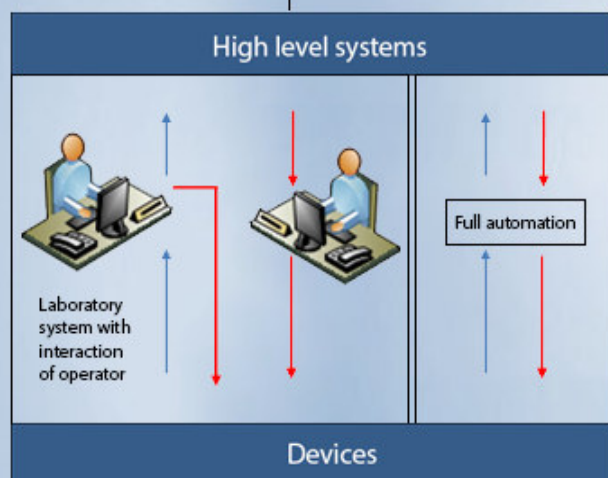
## Sm@rtline Data Cockpit

# Data Integration Solution

A laboratory middleware for central device data handling in production, development and research



One validated Interface



## Sm@rtLine Data Cockpit

A middleware for central device data handling in production, development and research.

In use at the 25 biggest pharmaceutical companies in the world.





# Sm@rtLine Data Cockpit®

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*Improve your knowledge*

*Improve your process*

*Reduce your costs*

*Improve your reaction times*



**Sm@rtLine Data Cockpit** is a unique software middleware which enables the use of sensors and analyzers for the collection, review and approval of trial results. SDC is available in the following versions:

- SDC-IS is a blackbox for the automatic transfer of data with master systems
- SDC-LS provides a comprehensive user interface for operators in the laboratory
- SDC-PS collects data from the process control systems

### closes the gap between LIMS, MES, DCS and the laboratory

SDC is placed between the sensors and the analyzers for the BIO-API processes and the interface to LIMS (laboratory information management system), MES (manufacturing execution system) or DCS (distributed control system) systems. SDC provides standardized, flexible interfaces for these systems which deliver calculated and evaluated data.

### increases your knowledge

The technician is no longer required to manually start and read measurements from the devices, but rather the measurements for these devices are reported centrally on the SDC server. SDC allows you to measure faster and more frequently and save the evaluated data in a central system. From this data, you can form a golden batch and compare your measurement and calibration curves together with multiple analyzers in a graph.

### improves your quality and QbD

SDC supports your implementation of PAT/QbD [Process Analytical Technology /Quality by Design]. These concepts strive to ensure a predefined product quality by implementing measures to improve understanding of the manufacturing process by using real-time measuring for all attributes. SDC supports these requirements by providing data transparency, reliability and traceability instead of manual measurement, where accuracy of data and precisely timed sampling cannot be guaranteed.



### reduces your costs

SDC incorporates validated interfaces which have been approved by Roche. This reduces your costs for validation and integration of the analyzers as well as reducing costs for the validation of the data handling. Overall, your costs are optimized through the improved data quality, your reaction time improves, production is streamlined and yield can be increased.

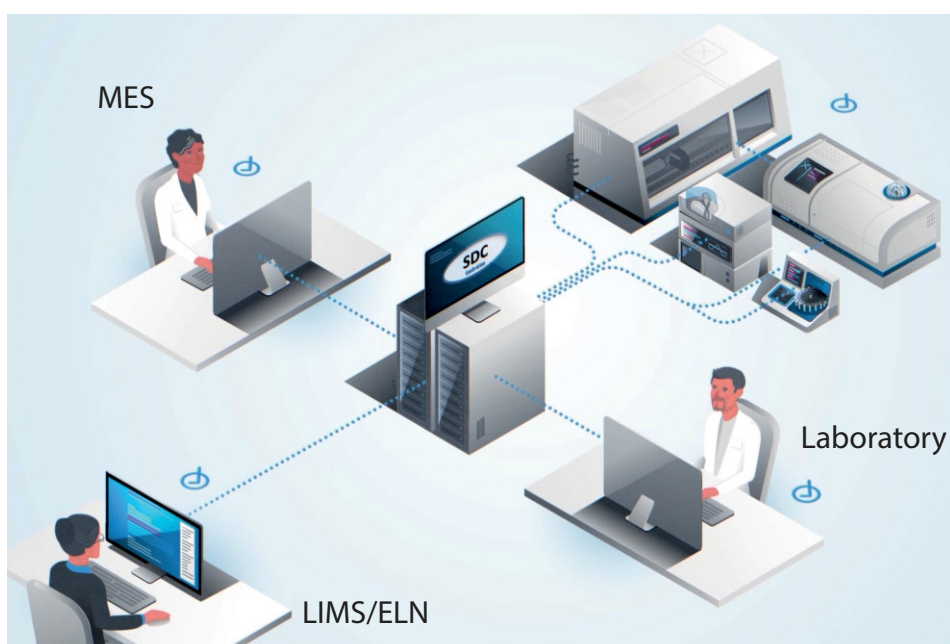


## One hub system for your success



SDC, as the most used middleware in the pharma industry, connects your instruments in the laboratory with your preferred software for higher-level systems, and, at the same time, automatizes manual processes with a bidirectional data flow.

It increases not only efficiency and data quality but reduces the overall risk of data errors at every level of your production.

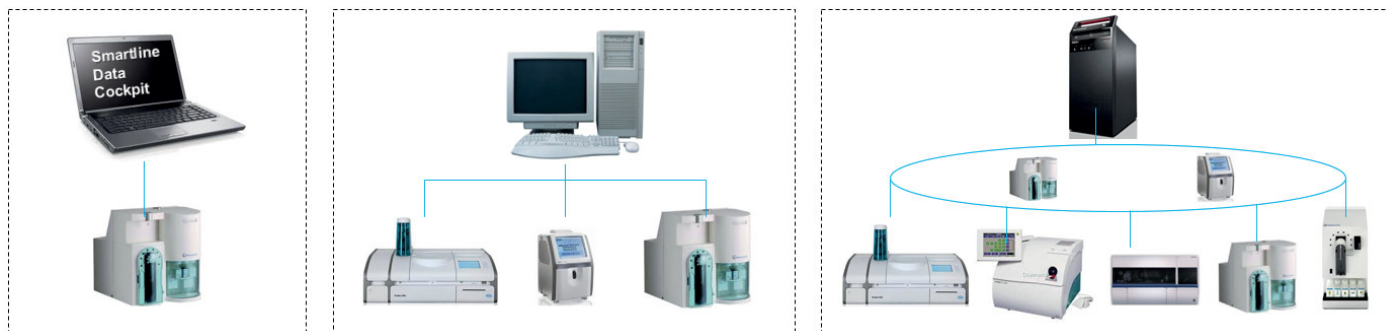




## Main features

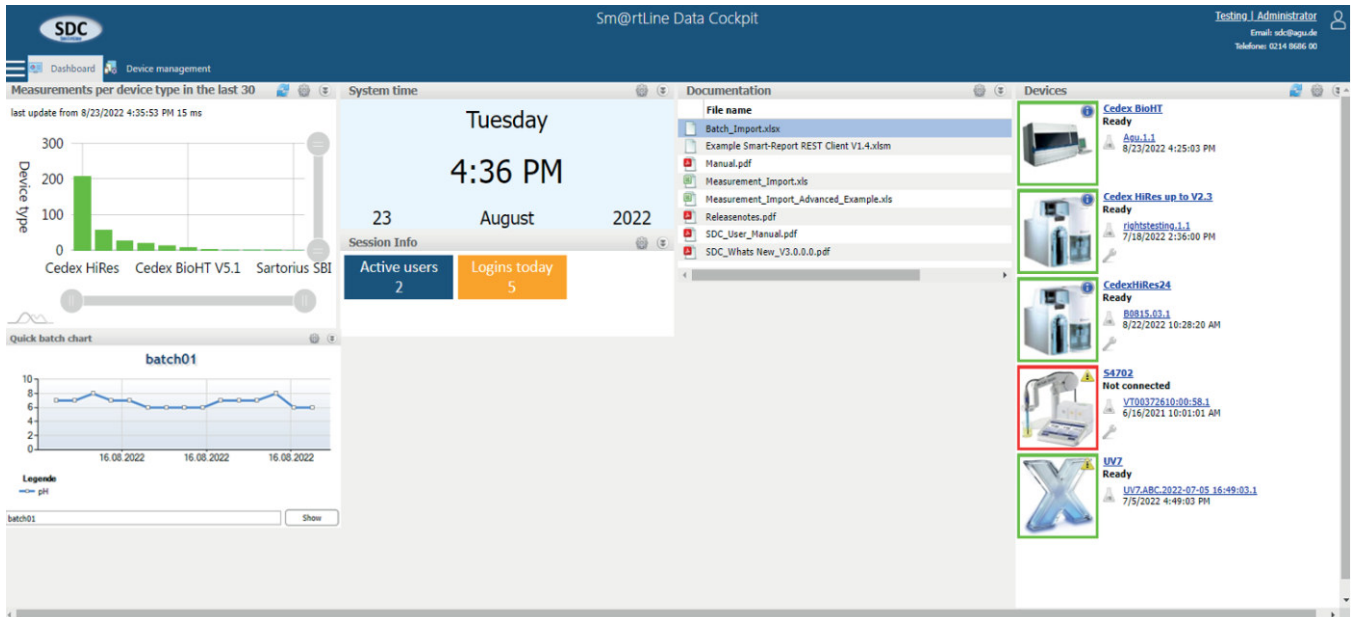
- SDC is a middleware placed between LIMS, MES and DCS systems and the laboratory areas “research”, “development” and “production”.
- SDC provides a centralized master data management of devices, samplings, samples and users.
- SDC gives you the ability to combine a multitude of analyzers and sensors to form one system and to evaluate and compare the results.
- SDC is a web- and database-based server platform that can be used from every client without special installation.
- SDC includes management of user rights, which guarantees safe access to data.
- SDC is capable of controlling analyzers remotely so that the operator is using one consistent GUI when performing his or her tasks.
- The operator can create, start and evaluate the analyzer measurements in a central system. The approved results can be uploaded to a foreign system (e.g., LIMS, ELN, MES or DCS).
- SDC offers the functionality of generating measurement results based on the data retrieved from the analyzers. Available calculation methods include averaging and trypsinization.
- SDC gives you the ability to compare measurements from research, development and production (e.g., interface calibration data) comprehensively.
- SDC can be connected to upper systems:
  - ChemLMS Persistent
  - SQL\*LIMS LabVantage
  - DASGIP Technology
  - Labware
  - Sartorius MFCS/win
  - IDBS E-WorkBook ELN (dev.)

## Scalable: from a single system to large laboratories

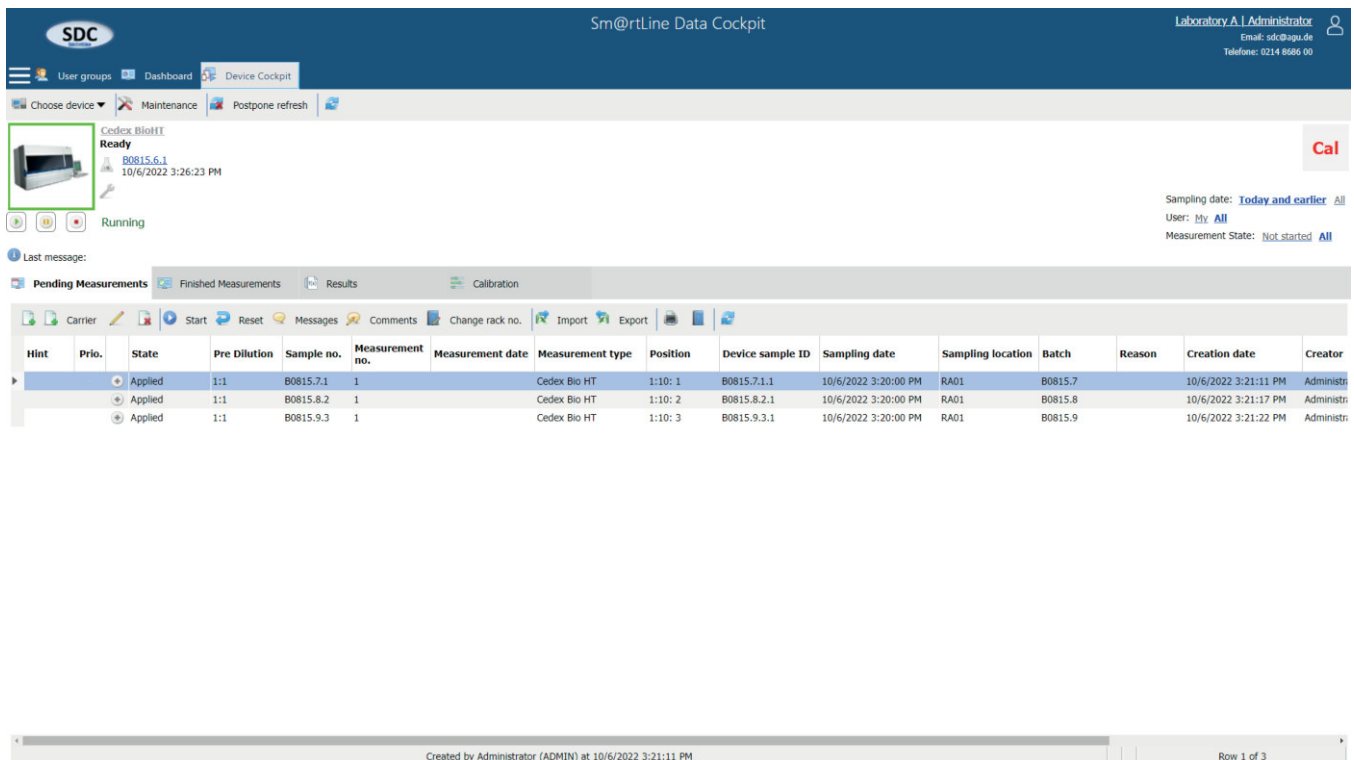


SDC can be set up as a single station, local network or company-wide server solution.

SDC is a web-based, easy-to-learn software solution. Great importance was placed on developing an intuitive operating concept and a perfect overview. The department-oriented dashboard provides the individual operators with a simplified view of the analyzers important to them.



The consistency of operation is apparent in the recurring buttons and graphical elements for all analyzers. Information is displayed uniformly, creating data transparency.



The compilation and depiction of the measurement results of a batch makes SDC an efficient tool. Batch results can be compared and exported to Excel for additional evaluation.

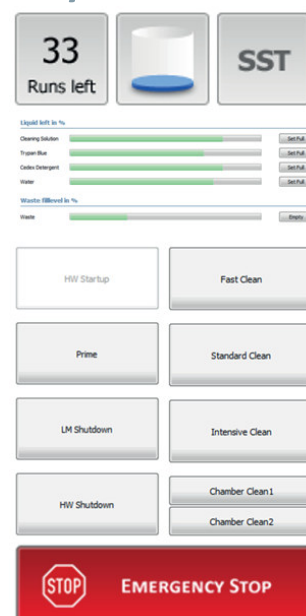


## Extended interface functions for the Cedex® HiRes Analyzer

SDC supports the operators and laboratory personnel when performing tasks in the areas of maintenance management, lifecycle management and consumption management.

The interface to the Cedex® HiRes Analyzer offers multiple functions which can be performed directly from SDC.

- Liquid management, e.g., resetting liquid and waste levels
- Hardware control, e.g., cleaning and emergency stop
- Cedex® database storage optimization
- SST: performing System Suitability Tests
- Display of the runs-left counter





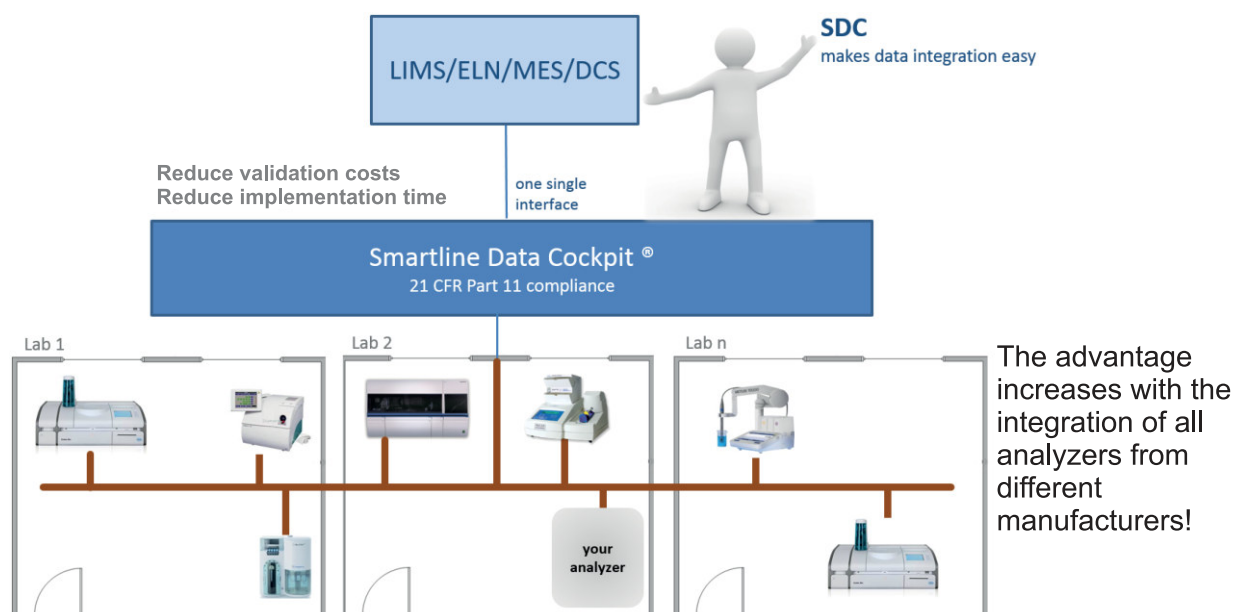


Tasks performed manually, such as specifying the measurement parameters and recording the result data from the analyzers, make extra organizational measures necessary in order to monitor and verify these steps. This leads to high costs and additional risks due to faulty entries.



SDC simplifies the processes, increases flexibility and secures data quality.

The implementation of SDC to connect the analyzer level to a higher system saves substantial costs because it is only necessary to take one interface into consideration.



## SDC-IS [interface system]

SDC-IS controls the gateway between the analyzers and MES or DCS systems.

The analyzer data is read into SDC and saved. The interfaces to the analyzers are monitored and displayed in the status manager. The analyzer data is managed, displayed and made available to MES and DCS systems.

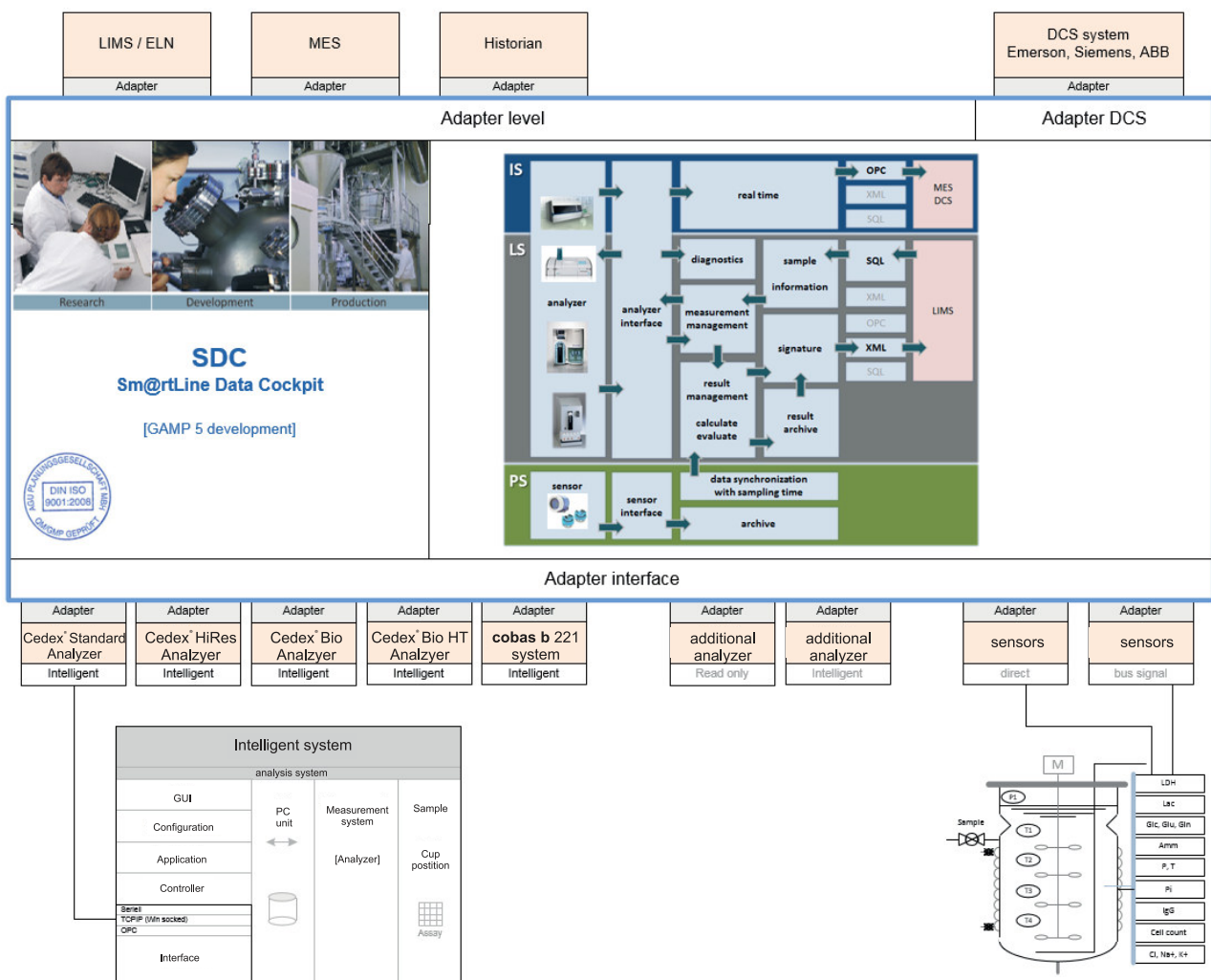
## SDC-LS [laboratory system]

The main area of use for SDC-LS is in the laboratory. SDC-LS supports the laboratory personnel in carrying out efficient, paperless measurements.

The integrated interface to a LIMS system makes the data handling simple and error-free. With SDC-LS, measurements can be entered and started. The results can be calculated, checked and, after approval, sent to the LIMS system. SDC takes into account the GMP requirements of 21 CFR Part 11.

## SDC-PS [process system]

SDC-PS makes it possible to assign sensor data from the BIO API process to the sample-oriented data. As is the case with all other data, the sensor data can be graphically depicted, exported and made available in interfaces.

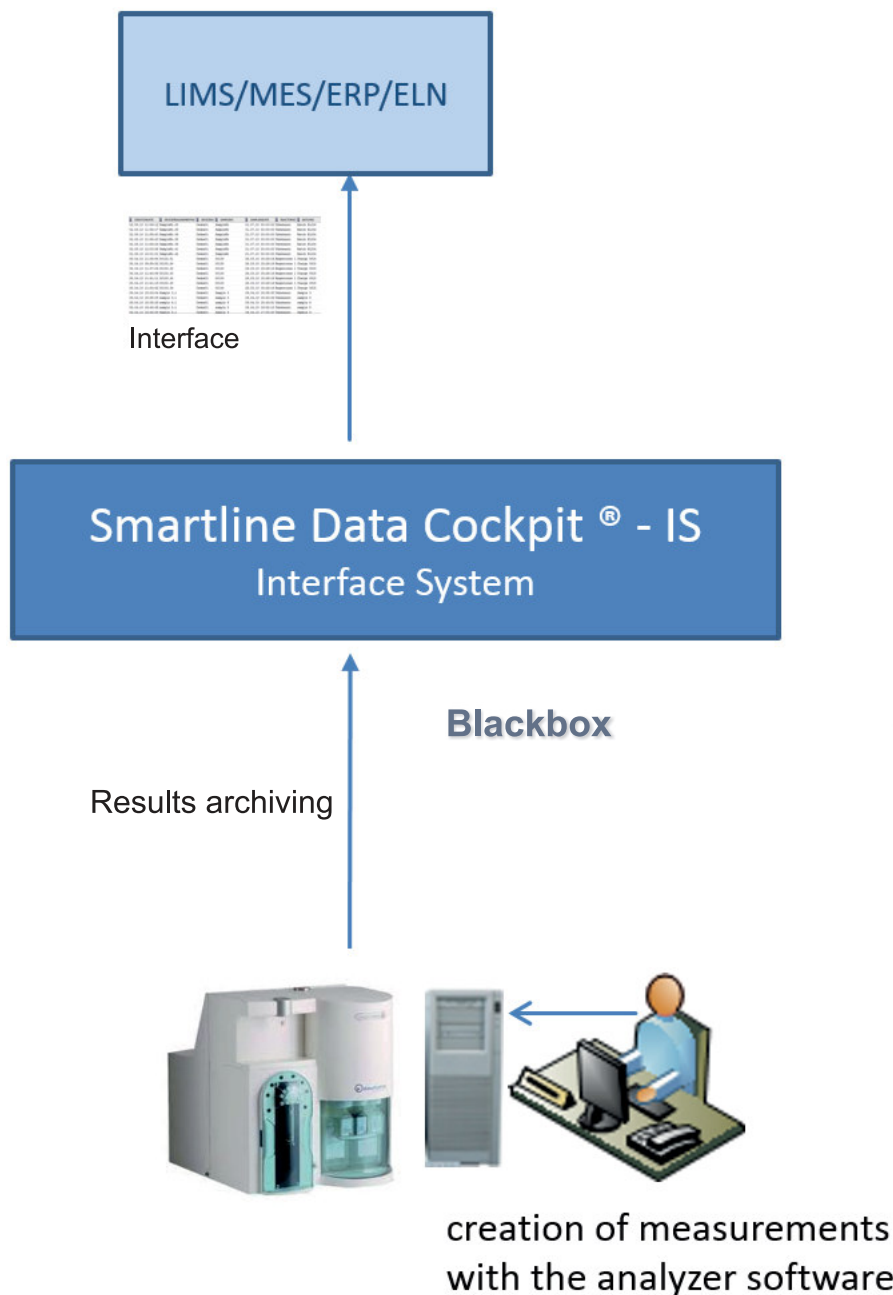


## SDC interface system (SDC-IS)

- ☐ Blackbox for automatic data transfer.

Measurement jobs can be received automatically from the upper system and transferred to the analyzers. Measurement results from the analyzers are received and measurement results are archived. All data can be transferred automatically to the upper system (e.g., ERP, MES, LIMS, DCS).

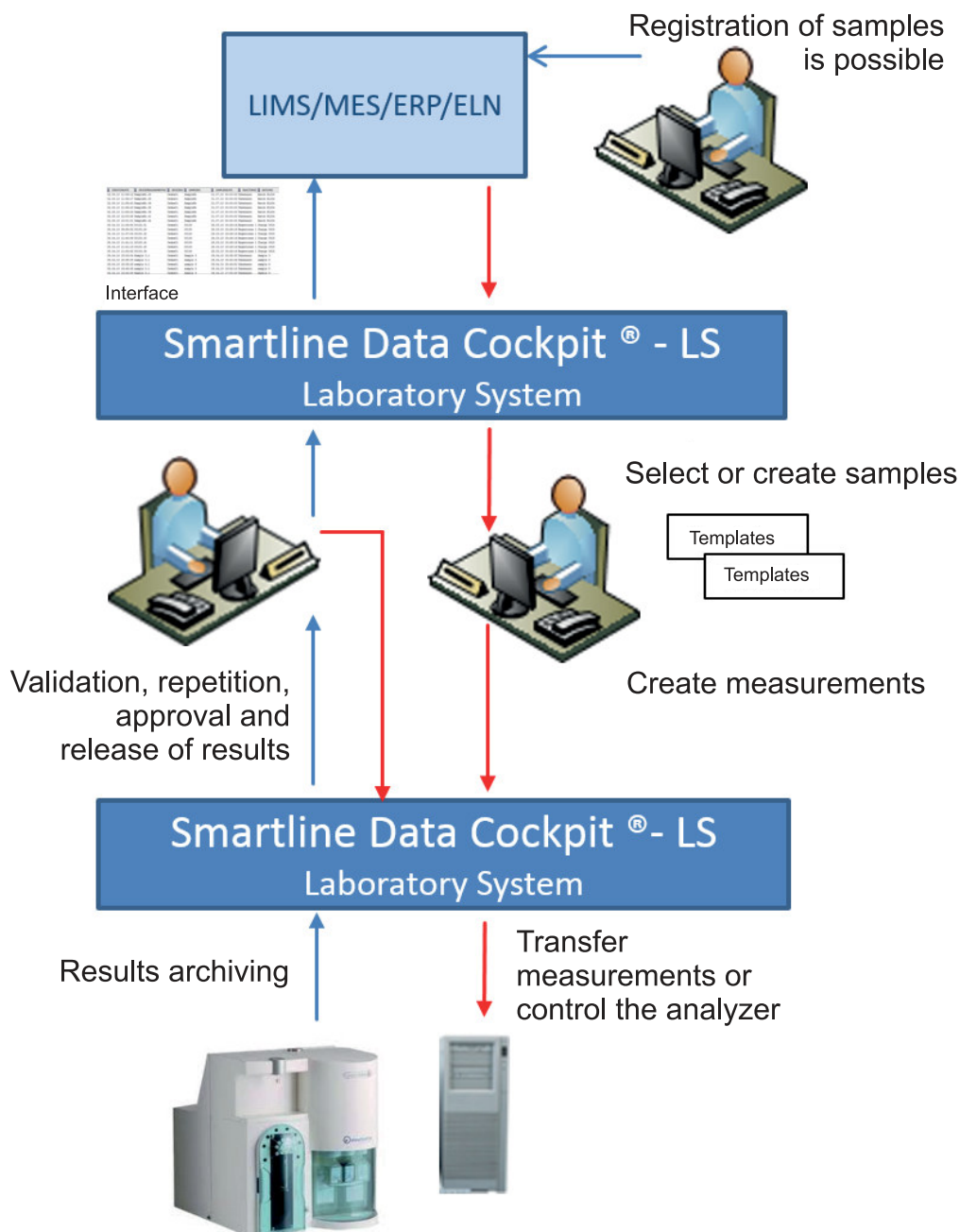
- ☐ The administration and configuration of the system with a web application is possible.
- ☐ User interface for device diagnostics and monitoring
- ☐ Minimal effort needed for validation
- ☐ Validated standard interfaces
- ☐ Supports the standard interfaces TCP/IP, OPC, XML, SQL, ODBC, *etc.*





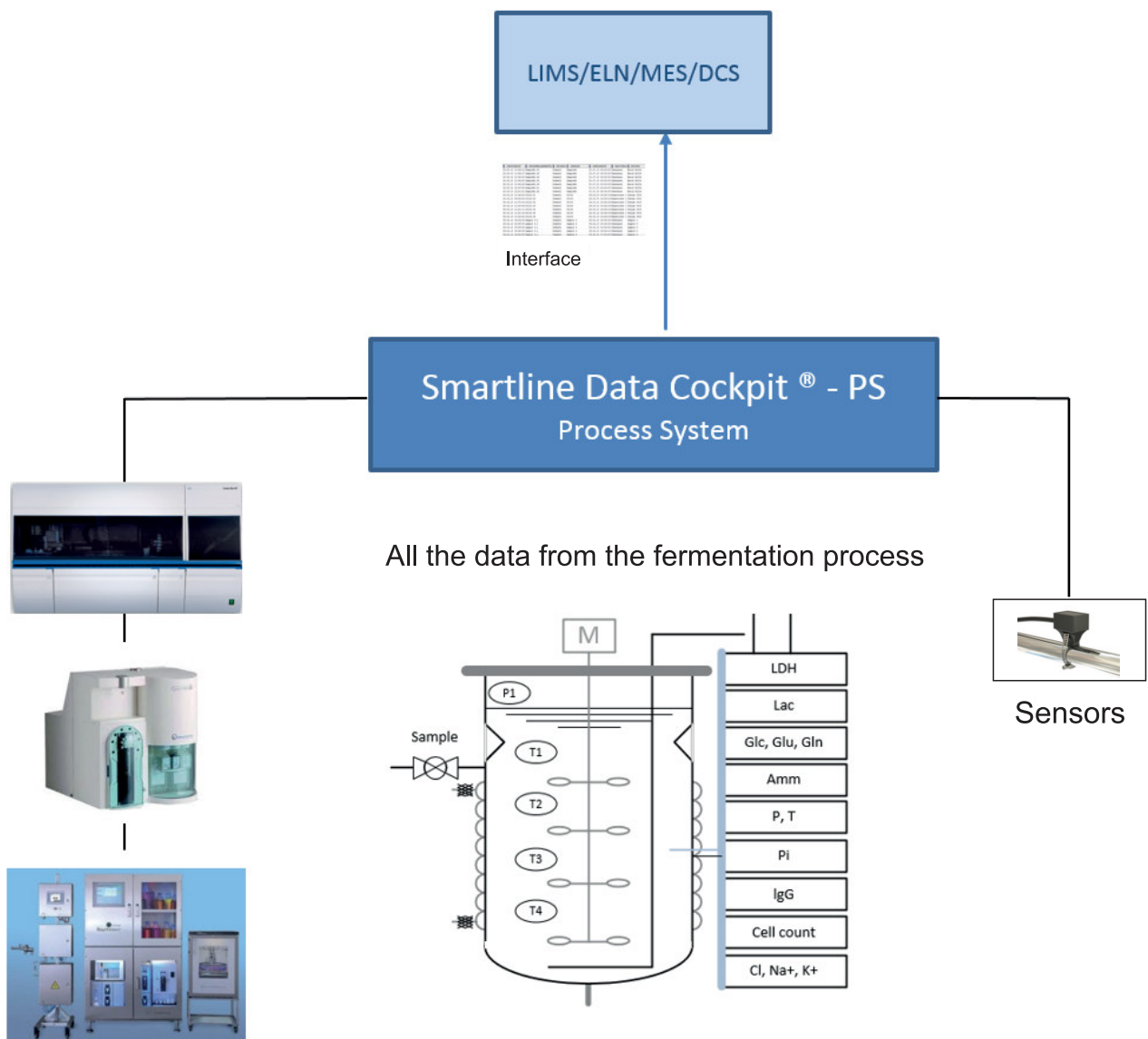
## SDC laboratory system (SDC-LS)

- ☐ SDC-LS includes all functions included in the SDC-IS system.
- ☐ The implementation of SDC makes it possible to combine SDC-IS, SDC-LS and SDC-PS in one environment.
- ☐ Central user interface for all analyzers to support the operator in the laboratories.
- ☐ The operator can request the context data from the master system using the sample number, enter measurement jobs and send these to the analyzer. If the analyzer supports remote control, the measurement jobs can be started using SDC.
- ☐ Measurement results are received from the analyzers and the measurement jobs and measurement results are archived.
- ☐ The operator can evaluate, calculate and release the measurement results.
- ☐ The released measurement results are transferred to the master system.



## SDC process system (SDC-PS)

- SDC-PS includes all functions included in the SDC-IS and SDC-LS systems.
- The implementation of SDC makes it possible to combine SDC-IS, SDC-LS and SDC-PS in one environment.
- SDC-PS enables the continuous read-in of measurements from sensors which are implemented in the process control or other systems. Together with the intermittent, sample-oriented analyzer values, these values can be displayed, saved as a batch and compared.



With SDC, it is possible to connect the following systems:

### Analyzers

Advanced Instruments - Model 2020  
 Advanced Instruments - Model 3320 Micro-Osmometer  
 Advanced Instruments - Model A20  
 Advanced Instruments - Model 3250  
 Advanced Instruments - Model OsmoPro  
 Advanced Instruments - Model OsmoTech  
 Advanced Instruments - Model OsmoTech Pro  
 Advanced Instruments - Model OsmoTech HT  
 Advanced Instruments - Model OsmoTech XT  
 BeckmanCoulter - Vi-Cell Blu  
 BeckmanCoulter - Vi-Cell XR  
 C Technologies, Inc. - SoloVPE  
 CAS - CI 153 CLiMET partice counter  
 Chemometec - NucleoCounter NC-202  
 Gonotec - Osmomat 030 RS/D  
 Gonotec - Osmomat 3000  
 Gonotec - Osmomat auto  
 Hach Lange - DR 2800 photo meter  
 Hach Lange - DR 3800 photo meter  
 Hach Lange - TL2350  
 Heidolph - Overhead Stirrer Hei-TORQUE  
 Knick - Portavo 907 pH, conductivity, O2  
 Mettler Toledo - Compact Titration G20 / G20 S  
 Mettler Toledo - Compact Titration V20 / V30 / C20 / C30  
 Mettler Toledo - D4 / D5 / D6 / R4 / R5 / RX4 / RX5  
 Mettler Toledo - DM40 / DM45 / DM50 / RM40 / RM50  
 Mettler Toledo - DX40 / DX45 / DX50 / RX40 / RX50  
 Mettler Toledo - Excellence balances XP / XS / XPE / XSE - LabX  
 Mettler Toledo - Excellence balances XPR / XSR - LabX  
 Mettler Toledo - MP70 / MP80 / MP90  
 Mettler Toledo - Quantos automatic dosing systems: XP/XS/XPE  
 Mettler Toledo - SevenExcellence  
 Mettler Toledo - Titration Excellence T5 / T7 / T9  
 Mettler Toledo - Titration Excellence T50 / T70 / T90  
 Mettler Toledo - UV7/UV5/UV5Nano/UV5Bio  
 Nova Biomedical - BioProfile FLEX  
 Nova Biomedical - BioProfile FLEX 2  
 Nova Biomedical - BioProfile pHox  
 Pall - Palltronic® Flowstar IV  
 Perkin Elmer - Lambda 25 Spectrometer  
 Radiometer - ABL 805  
 Rapid Micro Biosystems - Growth Direct

Roche Diagnostics - Cedex Bio  
 Roche Diagnostics - Cedex Bio HT  
 Roche Diagnostics - Cedex HiRes  
 Roche Diagnostics - cobas b 123  
 Roche Diagnostics - cobas b 221  
 Roche Diagnostics - cobas e 411  
 Sartorius - ambr 15  
 Sartorius - ambr 250  
 Sartorius - Sartocheck 5 Plus  
 Sartorius - Scales  
 Siemens - RAPIDLab 1200  
 Siemens - RAPIDLab 248  
 Siemens - RAPIDLab 348  
 Siemens - RAPIDLab 348 EX  
 Siemens - RAPIDPoint 500  
 TECAN - EVO  
 TECAN - Fluent  
 TECAN - Infinite M200

### Bioreactor systems

Sartorius ambr® 15  
 Sartorius ambr® 250  
 Sartorius BioPAT® MFCS/win  
 DASGIP  
 Finesse TruBio

### ELN/LIMS systems

Labware LIMS  
 Persistent LIMS  
 LABVANTAGE LIMS  
 IDBS E-WorkBook ELN

### Historian systems

OSIsoft-PI  
 Generic OPC DA

**You can view the current list of supported instruments here:**

<https://www.agu.de/de/SDC/AnalyzersDevices>



Your analyzer isn't listed?

No problem. SDC's development framework makes the integration of new interfaces a snap.

Contact us with your lab requirements.

[sdc@agu.de](mailto:sdc@agu.de)



## General benefits

- 01 Reliability of data:** SDC shortens measurement times, which leads to more frequent data and therefore to more knowledge about correlations between critical parameters. Reproducible and automated cell culture analysis improves the reliability of data.
- 02 Central database:** The central database provides a unique point of information. Data analysis occurs within ONE database and not in many different databases. Efficient data evaluation occurs in ONE system for flexible data analysis and reporting.
- 03 Global visibility:** Global data collection increases the visibility of different processes. Global task-sharing is facilitated.
- 04 Data availability:** SDC delivers the data simply and transparently. The operator saves valuable time on the preparation of measurements and data transfer.
- 05 Transparency and traceability:** SDC makes a comprehensive correlation of analyzer and sensor measurements in research, development and production possible and creates transparency and traceability.
- 06 Calibration data:** Calibration data during a product lifecycle (research, development and production) can be compared and contrasted regardless of the device used.

## User benefits

- 01 Sample handling:** Measurements can be repeated easily and they can be prepared while the analyzers are still working. It is possible to monitor measurement progress from anywhere within the company's network, including status observation of devices and calculation of time remaining. The measuring procedures of the analyzers are controlled without further user action.
- 02 Data evaluation/calculation:** Individual measurement results of the analyzers and sensors can be evaluated and calculated into a single result (e.g., mean value, trypsinization). Measurement results can be evaluated/calculated according to batch ID and then displayed graphically in a "time cultivation chart". The integrated batch comparison enables comparison with the golden batch.
- 03 Intuitive system:** SDC's modern and intuitive operating concept is grounded in practical experience, resulting in wide acceptance and minimizing need for on-the-job training.
- 04 Validation effort:** SDC reduces the validation efforts tremendously by replacing the manual transaction and processing of data by the user.
- 05 GMP conforming data handling:** Paperless data handling of measurements and data transfer to foreign systems (LIMS, MES, ERP) occurs with electronic signatures and change logs in consideration of 21 CFR Part 11. This ensures the data integrity of all measurements and further parameters. The operator can transfer data for special reports or evaluations easily to Excel.

## IT benefits

- 01 Remote solution:** SDC can be used as a remote solution for facilities regardless of location. Due to its integrated web technology, SDC can be used within the complete network centrally or remotely. Due to modern web technology, no additional installation work is necessary at the client site.
- 02 Interfaces:** SDC has an open interface concept that enables the connection of LIMS, MES and ERP through XML, SQL and OPC.
- 03 New analyzer:** The adapter concept for the connection of analyzers and sensors allows for a continual expansion of the system.
- 04 Administration:** User administration (user- and rights-management) can be linked to the active directory.
- 05 Backup:** SDC supports the central data backup of results and images.
- 06 Setup:** A setup oriented toward master data enables conformity and expandability.
- 07 IT concept:** SDC is a fully developed *.NET* technology with an Ajax GUI framework and MVP architecture.

## Production benefits

- 01 Real time:** Real-time data leads to more accurate process adjustment. Real-time monitoring increases process understanding.
- 02 Ready for automation:** SDC creates the basis for future automated processes. The development data can be compared to the production data and all process information (sensors and analyzers) can be viewed on a common timeline. The golden batch can be formed through real-time monitoring for “Closing the Loop” (QbD = Quality by Design).
- 03 Boost of quality and yield:** More effective and faster processing time of trials makes more frequent measuring possible, optimizes process monitoring and boosts both quality and yield.
- 04 Consolidation:** With SDC, the user can consolidate all sensors and analyzers used in fermentation research, development and production into a single system. This method makes the work easier and safer.

## How to get in contact with us:



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