

## Quality that counts

innovatis AG, headquartered in Bielefeld, Germany, is specialized on integrating lab processes and automating cell culture analysis.

Based on proven technology our specialists offer the best range of product solutions for research, pharmaceutical and biotechnology industry – all over the world. Individual service packages complete the product portfolio dedicated to future customers' needs.



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# System Suitability Test SST



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# System Suitability Test - Principle and Tools

Laboratories in the pharmaceutical industry are being held to increasingly extensive and exacting standards and requirements. It is, therefore, critical that instruments used in such labs are guaranteed and documented to meet the expected quality standards. Naturally, all systems of the same type placed in companies that are active world-wide should produce the same results – independent of location and conditions!

Therefore, all laboratory instruments need to be qualified on a regular basis. There should be an SOP for each instrument describing a qualification procedure that includes acceptance criteria as well as actions to be taken if the qualification fails. The nature and extent of a qualification will, of course, depend upon the equipment involved.

The System Suitability Test (SST) is an important process that is usually set up after the actual instrument qualification phase of a validation process is completed. The SST utilizes the experiences and results from the instrument qualification phase in order to establish a plan for verifying that the instrument is in the same condition as it was during the qualification phase. The verification should occur on a regular basis using simply executed measurements. The SST is part of the quality assurance that must be implemented in the cGMP area. In addition to the importance of the SST for routine verification of quality, the SST must also create evidence that the system complies with all of the requirements for proper operation.

innovatis offers a number of tools for its cell analysis systems in order to accomplish an SST securely and comfortably. The test is so fast and simple that daily documentation of the system integrity is child's play. The advantages are clear:

- The condition of the system can be tested before a measurement
- The validity of the measurements can be confirmed
- The results of the SST can be documented and archived
- All systems can be harmonized so that – regardless of the location – identical results are produced

The SST concept from Innovatis provides a savings in costs and resources as well as a higher increase in security! Use the possibility for creating an individually adjustable security concept to optimize the monitoring of your production process.

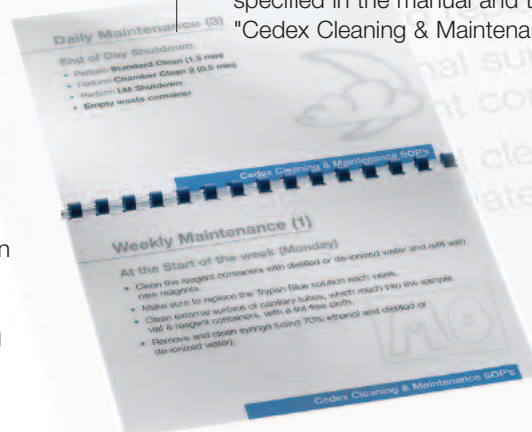
## The innovatis SST Tools

The tools that innovatis offers for the examination of system integrity should ideally be coordinated and constructed together. In combination, but also independently, they offer a high measure of security and transparency. The SST, as recommended by Innovatis, comprises five parts:

1. **Cleaning and maintenance routines** to ensure system integrity.
2. **Reagent Kits** for highest performance of Cedex cell analyzers.
3. Use of **Density Reference Standard Beads** to facilitate constant monitoring of measurement accuracy.
4. Use of **Control Beads** to check performance of measurements at regular intervals in order to detect changes in the measurement process.
5. Use of the **Chamber Monitor** for visual inspection of the flow chamber (the inlet, in particular) in order to detect impurities in the flow chamber.

## Cleaning routines

To maintain the integrity of the Cedex cell analyzers, both systems – the Cedex and the Cedex HiRes – feature on-board washing and maintenance routines as standard equipment. These programs are easy to use and almost automatic. Regular use of these routines help to maintain and secure a system's measurement precision. Recommendations regarding frequency as well as practical aspects of the procedures are specified in the manual and the laboratory textbook "Cedex Cleaning & Maintenance SOP's".



## Reagent Kits

innovatis offers Reagent Kits that contain liquids and solutions necessary for cleaning and analyzing eukaryotic cells with a Cedex system. The advantages of a ready-to-use kit are obvious:

- no handling of harmful chemicals
- no mixing and stirring of Trypan Blue
- no efforts with GMP requirements!

The Reagent Kit for the Cedex HiRes also contains a waste container that is easy to dispose securely. Reagent Kits are sufficient for 100 analyses and are – naturally – manufactured under cGMP conditions. A Certificate of Analysis is provided with every kit.

## Density Reference Standard Beads (DRSB)

are used for system calibration. This particle size standard with a defined number of particles is unique because it is traceable to a standard of the “Physikalisch-Technische Bundesanstalt” in Braunschweig/Germany – equivalent to the “National Institute of Standards and Technology” (NIST) in US.

This standard is produced according to the GMP guidelines. Equipment provided by innovatis is already calibrated and has an accuracy of > 95 %. Consequently, it is not necessary to calibrate a Cedex system prior to first use. However, the DRSB enables the user to review and record the accuracy of cell concentration measurement of the system in a highly specific way at any time. The calibration method applied is a one-point calibration using  $1 \times 10^6$  beads per mL. Typically, a five-fold repetition is used to obtain a mean value. The mean value is then compared to the nominal value listed for the test bead solution on the certificate of analysis, and the acceptance range is within 5 % maximum deviation. Calibration frequency depends strongly on throughput as well as internal calibration and QA practices. Consequently, recommendations may vary for individual customers and locations.

**Control Beads** are used to ensure the precision of cell concentration results on a daily basis. They are available in three different concentrations so that the linearity of results can also be checked. Regular use of inexpensive control beads allows for a permanent documentation of the system integrity, as well as the early initiation of prompt countermeasures, such as thorough cleaning of the system, as soon as minor deviations occur.

For control and documentation purposes, the core of each Cedex system - the flow chamber - can be optically inspected with the **Chamber Monitor**. With a keystroke, and within seconds, the user may assure himself of the integrity of chamber and inlet and, in the case of Cedex HiRes, of the complete chamber including the outlet. We designed this process to be fast and easy so that an inspection prior to every use can easily be integrated into the measurement/analysis procedure. An image of the chamber and inlet may be saved for archiving and documentation purposes.

The Cedex HiRes system is automatically equipped with this technique. The Chamber Monitor is available for Cedex standard systems as optional equipment. Naturally, existing Cedex systems on site can be upgraded quickly and in a cost-efficient manner by our service. Upgrading the Cedex Software to new Cedex 2 software makes the monitoring and inspection routines even more easy and convenient.

