

Beamex Case Story

AstraZeneca Sweden Operations
Sweden



Introducing an automated
and validated calibration system.

beamex

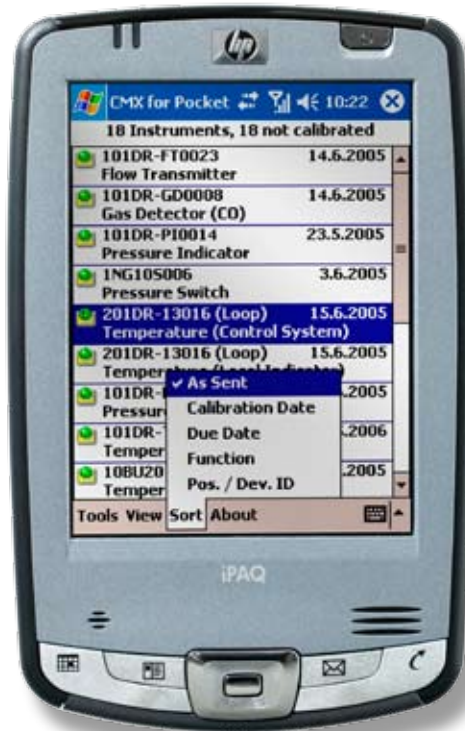
AstraZeneca is one of the world's leading pharmaceutical companies.

AstraZeneca is one of the world's leading pharmaceutical companies with 30 manufacturing sites in 20 countries. The company has over 64,000 employees worldwide and sales in 2004 totalled \$21.4 billion. Their products are available in more than 100 countries. Beamex made a corporate agreement with AstraZeneca Sweden Operations, which means that eventually every production site in Sweden will be using CMX for calibration management. The contract includes Beamex's CMX calibration management software licenses, training and software support. AstraZeneca made the internal, green-light decision for implementing a new calibration system in June 2004. In March 2005, the validation process began and by October 2005 the first calibrations were made. Recently, AstraZeneca Sweden Operations also made a contract with Beamex regarding the procurement of equipment and calibration service.

Anders Ånlind is a Calibration Manager at AstraZeneca Sweden Operations and his responsibility was to manage, co-ordinate and implement the new calibration management system at AstraZeneca Sweden Operations.

The situation

The starting situation at AstraZeneca Sweden Operations was challenging and the company had many demanding requirements for a calibration system. First of all, a calibration system should save money for the company by reducing the time it takes to perform calibration and the time production lines are shut down due to calibration. Secondly, the amount of calibrations was huge. Approximately 21,000 calibration certificates are made in total on a yearly basis. This is both expensive and time-consuming. "We needed to reduce the time from start to finish", Anders Ånlind begins. There were also other requirements for the new calibration system. "We needed a tool that would highlight adverse trends in calibration," Anders continues.



AstraZeneca Sweden Operations uses CMX's Pocket PC option for manual data entry of calibration results, checking the Calibration Master Schedule (CMS) and for uploading all test results and notes to their central database.

Items should be identified before they are out of tolerance. Likewise, if the item delivers good performance, it is justified to reduce the calibration frequency. Finally, the system should provide quick and easy access to data. Data should be available through any desktop computer within AstraZeneca. Going through huge certificate archives is difficult. Furthermore, AstraZeneca Sweden Operations wanted to get rid of all typing errors related to hand-written calibration certificates.

These were the factors behind AstraZeneca Sweden Operations decision to choose Beamex's CMX for their calibration management software. "According to suppliers of maintenance systems, we introduced the most effective, automated and validated calibration process known in the pharmaceutical industry", Anders states.

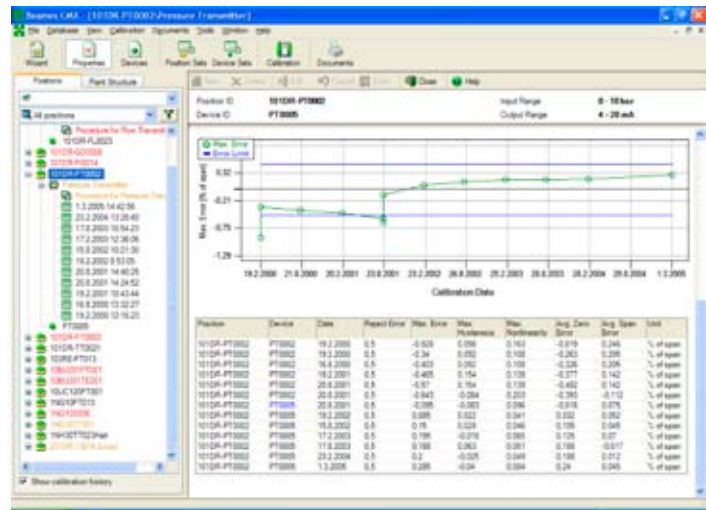
“According to suppliers of maintenance systems, we introduced the most effective, automated and validated calibration process known in the pharmaceutical industry,” states Anders Ånlind, Calibration Manager at AstraZeneca.

The solution and main benefits

At the moment, AstraZeneca Sweden Operations is utilizing Beamex’s CMX calibration management software (CMX for server) with the Pocket PC option, as well Beamex’s documenting MC5 Multifunction Calibrators. Using the CMX with the Pocket PC option allows AstraZeneca Sweden Operations to extensively utilize PDAs (Personal Digital Assistant) for manual data entry on site. The server version of CMX makes it possible for several plants within the corporation to use and share the same database.

The implementation of CMX introduced many new benefits in the workflow of performing and managing calibrations and it also solved the problems that were related to the former calibration system. They had multiple calibration processes within Sweden Operations due to 12 different databases and 4 to 5 different workflows. AstraZeneca Sweden Operations now has a new uniform calibration process. In addition, the new calibration process has proved to be very cost-effective. It has replaced manual verifications and approval of results after performed calibration with an automated and validated process. The History Trend function also allows AstraZeneca to use the CMX as a tool for identifying adverse trends and good performance. Paper documentation is being replaced with Electronic Record data, which is stored in the CMX database. However, the system also provides the possibility to print calibration certificates, in case they are needed.

Even though the new CMX system has proven to be much more efficient and cost-effective, it is still compliant to regulatory requirements. This was an essential requirement when AstraZeneca began looking for a new calibration system. With CMX, AstraZeneca Sweden Operations has a validated calibration system with full Audit Trail, which is compliant with 21 CFR Part 11.



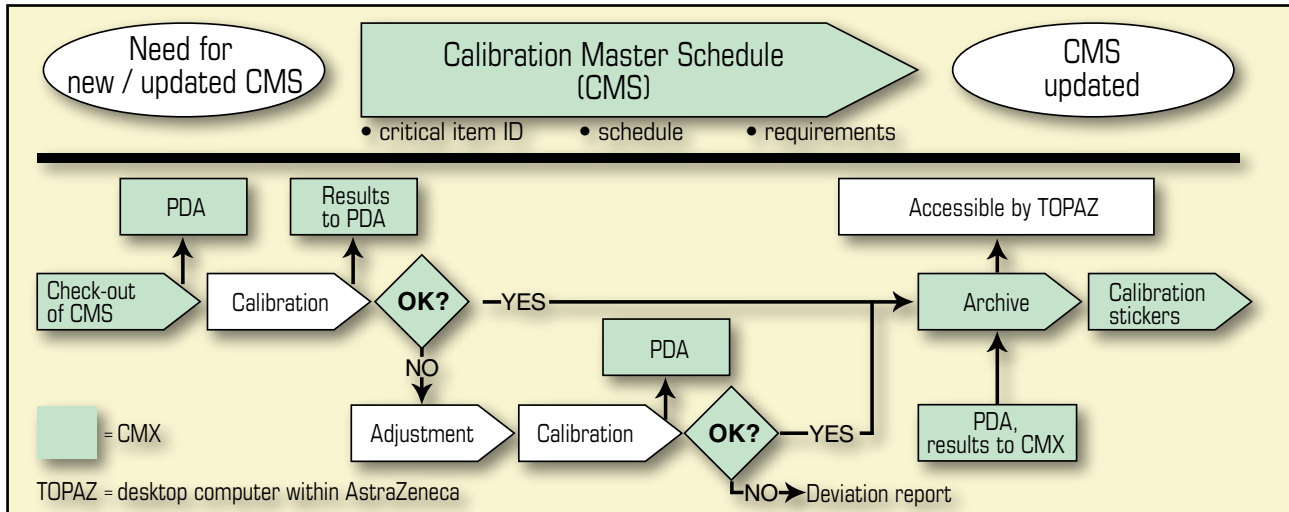
At AstraZeneca’s Sweden Operations, CMX, with its History Trend function, is being used as a calibration management tool to identify adverse trends and good performance.



Using the CMX, AstraZeneca Sweden Operations is able to automatically produce fully auditable and traceable calibration certificates.

CASE STORY IN BRIEF

Customer profile AstraZeneca Sweden Operations Sweden



AstraZeneca Sweden Operations - new calibration process with CMX calibration management software.

Business Situation

AstraZeneca Sweden Operations was looking for a new calibration system. The starting situation was challenging and the company had many demanding requirements for the new calibration system. First of all, a calibration system should save money for the company by reducing the time it takes to perform calibration and the time production lines are shut down due to calibration. Multiple calibration processes existed due to 12 different databases and 4 to 5 different workflows. The amount of calibrations was extensive. AstraZeneca Sweden Operations made more than 21,000 calibration certificates in total on a yearly basis. They needed to reduce the time from start to finish. There was also a need for a tool that would highlight adverse trends in calibration. Likewise, if the item delivers good performance, it is justified to reduce the calibration

frequency. Finally, the system should provide quick and easy access to data.

Solution description

- CMX calibration management software
 - CMX for server with Pocket PC Option
- MC5 Multifunction Calibrators

Main benefits

- Calibration process now more efficient and cost-effective
- Ability to automatically produce fully auditable and traceable calibration certificates
- 21 CFR Part 11 compliant calibration system with full Audit Trail
- Short pay off on the project.

Beamex representative in Sweden:

JMEX AB
Box 2093
S-650 02 Karlstad
SWEDEN

Phone: +46-54-561010
Fax: +46-54-560785
E-mail: info@jmex.se
Web: www.jmex.se

For more information

Please visit
www.beamex.com

or contact
info@beamex.com