

Earning money every day thanks to the Beamex Integrated Calibration Solution



AstraZeneca Ab, Sweden

BEAMEX
CASE
STORY

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beamex
WORLD-CLASS CALIBRATION SOLUTIONS

AstraZeneca is one of the world's leading biopharmaceutical companies with 30 manufacturing sites in 20 countries. The company has over 62,000 employees worldwide and sales in 2009 totalled \$32.8 billion. Their products are available in more than 100 countries. In 2004, Beamex made a corporate agreement with AstraZeneca Sweden Operations. They decided to implement a completely new calibration system including Beamex's CMX calibration management software licenses, training and software support. The goal was to integrate every production site in Sweden in this project. 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.

The situation

Sweden Operations is AstraZeneca's largest production and product support unit, and the majority of production facilities are located in Södertälje. The largest tablet factory in the world is located here. The pharmaceutical industry is strictly controlled by institutions and regulations, such as the Food and Drug Administration's (FDA) Good Manufacturing Practice requirements (GMP). Calibration is one of the fields fenced by very strict regulations. The GMP requirement 21 CFR Part 11, which regulates how the calibration certificate is documented and signed electronically, is essential to the working process.

All equipment and instruments in the production process must be calibrated regularly to ensure they function as they should and, for example, give the correct dosing of all the various substances. This involves testing if a sensor gives the correct measurement result in various conditions, such as temperature, atmospheric pressure, air humidity, and so on. It's vital that the instrument stays within the acceptable tolerances and that their readouts give correct measurement values, otherwise the final products may be faulty. Calibrating the instruments and devices is of great importance to avoid this type of risk altogether.

The solution and main benefits

Anders Rackow, Global Project Manager and Tomas Wahlgren, System Owner, at Global Operation Information (GOI) were responsible for managing, co-ordinating and implementing the new calibration management system at AstraZeneca Sweden Operations. They also introduced the computerised system Beamex CMX to support it.

"Previously, the calibration was primarily done with manual- and paper-based processes. The certificate was on paper, which was signed and stored in binders. After implementing the new calibration management process, the entire process takes place digitally, from measurement to signing and archiving. We perform about 22,000 calibrations annually, which previously engaged 50 employees. Today, the same work can be accomplished with only 15 people", Tomas Wahlgren says. "The number of calibrations is continuously diminishing as calibration history-trend analysis allows us to identify instruments and sensors that remain stable over a long time, which means that the calibration interval for

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them can be extended without having an impact on production or quality", Anders Rackow points out.

There were a lot of challenges when introducing both the new calibration management process as well as the system to support it. The process and system needed to be able to reduce time and costs for the calibration itself, as well as for the line down period in production. With 22,000 calibration certificates to be made, the reduction of time and being able to identify adverse trends justifying a reduction in the calibration frequency were crucial. The system should also provide quick and easy access to data available through any desktop computer within AstraZeneca. With Sweden Operations having 12 different databases and several different workflows, unifying the entire organisation around a new uniform calibration process was a huge challenge.

AstraZeneca Sweden Operations ended up procuring Beamex's CMX calibration management software (CMX for server) with the Pocket PC option and documenting Beamex MC5 Multifunction Calibrators. The use of CMX with the Pocket PC option allowed AstraZeneca Sweden Operations to extensively utilize PDAs (Personal Digital Assistant) for manual data entry on site. The server version of CMX made it possible for several plants within the corporation to use and share the same database. Being compliant to regulatory requirements, CMX was also very essential to AstraZeneca. With CMX, AstraZeneca Sweden Operations has a validated calibration system with full Audit Trail compliant with 21 CFR Part 11. "According to suppliers of maintenance systems, we have introduced the most effective, automated and validated calibration process known in the pharmaceutical industry. Furthermore, purchasing the Beamex calibration management system has added functionality to our business as we are now able to calibrate weighing instruments as well", Anders Rackow states.

The total investment for the new uniform calibration process and all the mobility supporting it amounted to \$600,000. The calibration process proved to be very cost-effective. The pay-off time was one year. "The greatest profit was made during 2005 and 2007 when the work process was made more efficient through automation and increased mobility with calibrator MC5 and the CMX support system. The calibration management process became simple and completely electronic, which resulted in a decreased number of performers. The implementation of this uniform system has created a "best practice" for the entire AstraZeneca", Anders and Tomas say.



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DESCRIPTION

- Beamex CMX calibration software
- Beamex MC5 multifunction calibrators

MAIN BENEFITS

- 1 year pay-off
- The number of databases has been reduced from 12 to 1
- All paperwork has been replaced by an electronic calibration process
- Less frequent calibration intervals
- Less labor intense
- The overall quality of the calibration process has improved.

CASE STORY IN BRIEF

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“When the toughest work with unifying the entire Sweden Operations around one uniform calibration management system was done, we settled down and started gathering and analysing data. Thanks to this data cleaning process, we have become more and more aware of how to optimize the amount of data, which data to keep and which to dispose of”, Anders and Tomas add. This

process was stabilized in 2010 and then AstraZeneca, based on the gathered data, started reducing the calibration frequency on certain devices and instruments.

This customer specific calibration management software solution was named Beamex CMX193. AstraZeneca's upcoming project is to integrate Sweden Operations CM X193 in the upcoming European SAP installation (Sweden, UK, Germany and France). This will provide the possibility for other sites to take advantage of this new, easier way of working as well.

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