

## **Positive sample tracking in a SAP QM environment under 21 CFR Part 11 conditions using barcode identification**

Sample tracking in a chemical or pharmaceutical production/QC environment is mission critical. Different containers with sample material must be identified and traced from the warehouse via a sample distribution organization to the various instruments in the laboratories. Identification and material transfer is often done manually. Economic and regulatory requirements, e.g. 21 CFR Part 11, are pushing towards higher efficiency and security. Throughput has to be increased, and access to all relevant information always has to be provided. Security implies the correctness of information and prevention of manipulation.

Our project deals with a SAP/MM material management environment and SAP/QM as LIMS. Sampling is triggered by SAP/MM. The samples are distributed in several steps to the laboratories. The results are then shipped back to SAP/QM where they are documented.

All different containers carry unique positive identifications with Data Matrix barcodes. At all transfer points these container IDs are chained using a 2D barcode scanner and an underlying database. Barcoding even is used for random arrangement of sample vials in sampler rotors. The vial identifications are used also as result IDs transferred back to SAP/QM together with the results. On the way through the system we provide electronic signatures and data encryption for security purposes.

With the poster we present a software simulation of all features mentioned above. It especially supports the closed chain between production and quality control using a graphical user interface, a HPLC rotor simulator, and barcode chaining dialogs in different locations within the company. Identifications and results may be manipulated on purpose via special dialogs to show the proper processing of the electronic signature and data encryption methods.