

## Weighing highly active substances

### Roche is going 100% paperless with LabX

#### The handling of highly active substances is strictly controlled

Pharmaceutical companies classify active substances within 4 categories depending on their activity. Category 4 substances are highly active and have been proven to be effective against diseases such as cancer. Inhalation or skin contact must be avoided for lab personnel. At Roche, the IOEL (Internal Occupational Exposure Limit) must be inferior to 50 ng/m<sup>3</sup> for Category 4 solids substances.

The weighing process is especially critical because the substances are used in their pure form. The handling of these substances is strictly controlled by external regulations and company dependant standard operating procedures.



#### Traceable weighing in the Highly Active Substance lab has been the challenge of Roche

At Roche Pharma Development Center in Basel (Switzerland), a brand new HAS lab (Highly Active Substances lab) has been constructed to handle Category 4 active substances. This lab fully complies with the

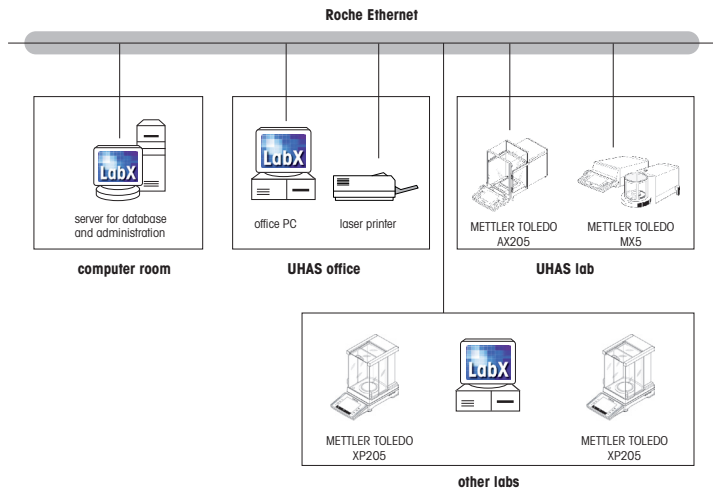
“LabX combined with the large XP display is the perfect solution for supporting both the weighing process and the strict requirements of a traceable documentation system”

The METTLER TOLEDO balances operate under stringent conditions in ventilated cabinets.

applicable regulations. Among the list of many requirements, the most relevant include:

a permanently filtered atmosphere, ventilated cabinets, dedicated analytical equipment, easy to clean surfaces, validated software installations, carefully trained personnel, special clothes and limited time spent in the lab...

Additionally, it has been established that paper can easily be contaminated. In principle, paper has to be avoided or must be thrown away in the HAS lab and destroyed according to special procedures. Moreover, the HAS lab is a regulated area. Consequently, the data



The flexible software architecture allows installation on multiple computers in different rooms. LabX controls multiple balances directly over the network.

produced must be fully traceable and the electronic records generated in the lab fall under FDA 21 CFR Part 11. The installation and use of a data capture system must be validated.

Therefore the task of Roche became challenging to find ways to completely abolish paper documentation in the HAS lab and keep total traceability of all weighing and analytical data. Roche was confronted with the unique chance to enforce a 100% paperless policy!

#### The METTLER TOLEDO weighing solution and its benefits

- For weighing in the HAS lab, Roche uses one AX205DR and one MX5. Both balances are connected to the company network with the METTLER TOLEDO e-Link RS-Ethernet converter. No PC is required for the LabX application in the HAS lab. The operator logs-in on the balance display and is guided through the weighing procedure, step by step. Data is collected automatically, thanks to the LabX PC software controlling the balance in the background. The weighing procedures are purposely kept simple, including back weighing.
- In 2 other labs, several of the latest generation of Excellence Plus XP balances are linked to LabX. They are connected directly to the company network with a simple Ethernet plug-in option, which means less cable. The balance and its immediate environment become extremely easy to clean. Additionally, the

large XP display is very easy to use and gives clear instructions to the user to guide him/her through the defined procedures.

- The LabX server and 4 Client PCs are located in several offices. From any office, the users can access reports or administrate methods, depending on their rights defined in the user manager. Both software architecture and use of the balance display as a terminal limit the time spent in the HAS lab to the weighing tasks only. All data is securely kept in an SQL database and changes can only be carried out by defined users. The LabX system supports Roche Pharma in their regulatory requirements – 21 CFR Part 11 and GMP and was validated by METTLER TOLEDO validation specialists using the LabX Validation Manuals.

**“Electronic weighing data contributes to both employee safety and data security”**

All managers, lab assistants and technicians who work in the HAS environment have been trained on the LabX system. The system is periodically extended to add new balances or to accommodate new customer applications. Following this successful pilot installation, LabX balance is currently under evaluation in several other Roche Pharma departments.



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