Case study: Upgrading of the existing production line with the system of electronic records and electronic signatures

Problem case

There are many existing pharmaceutical production lines, where the recipes and reports are stored on the off-line graphic OP terminals. Unfortunately, these systems lack compliance with higher levels of the FDA requirements (e.g. CFR 21 part 11). Therefore, the production companies shall choose to upgrade the existing systems or to buy the new ones to be compliant with the required standards and norms.

Milestones

- the biggest challenge is how to upgrade the system without changing the validated program core; we are able to upgrade it in a way that the program core remains unchanged and we add the recipe and report data, which can be uploaded and downloaded, to the system,.
- there is a service routine that runs in-parallel with the process; this routine intercepts the user actions on the terminal and forwards them to the process in case of sufficient user rights
- we built in a completely new Recipe, Reporting and Event management system – the so called PDBM
- every action and every event is stored in the Audit Trail table, which can be reviewed at any time by an inspector or in case of a deficiency

TRAC solution

TRAC successfully implemented the remediation project based on the following main outputs:

- the program's core remained unchanged, resulted in the commissioning and the qualification time minimization –
- we have upgraded several machines with only one central SQL database system
- the PDBM application runs on a special PC computer; this application is used to create the production recipes, printing of the reports and to store various events
- the user management system, together with the comprehensive access rights, is run centrally from one location
- our concept can be easily upgraded with new systems within the same application