

## GUS-OS Audit Trail - Clarity for all Changes



### Data history – an explosive topic

Controlling and managing modern processes with computer based systems not only offers enormous information possibilities and more efficiency, it also produces an ever growing amount of data that requires ever more elaborate systems for capturing and archiving this information. Conditions regarding archiving, administrating and authenticating electronic data records have been laid down by the American health authority, the FDA (Food and Drug Administration), in the Code of Federal Regulations governing electronic records and electronic signatures (21 CFR Part 11). For this reason there is now an increased need to guarantee regulatory compliance. This is essential for Life Science companies who have GxP-compliant production environments.

To underline the importance of a process history (audit trail) here is an extract of a warning letter that the FDA sent to one company:

*“Electronic records and electronic signatures may be used to meet record and signature requirements of 21 CFR Parts 210 and 211 when part 11 requirements are met. Our inspection disclosed numerous and significant deviations from part 11. Examples include: The system does not generate an audit trail, and there is no way to determine if values have been changed on batch production records. This is important because an audit trail can be the only evidence that an electronic record has been altered.”*

### Stop anonymous and unclear Changes

In small companies it is usually not a problem to find out subsequently who carried out what data changes. However this is not the case in medium-sized and large organizations: here the manufacturing processes are often so complex that in many cases it cannot be proven who carried out which changes or what the original entries or data were. Here is where GUS-OS Audit Trail can help with the documentation of the process history.

This product offer users a modern, ergonomic desktop and is based on Java technology suitable for SMBs.

Tabellen	Benennung	Kategorie	geändert von	Datum	Info
akt	000-0	NETZB Zustand der letzten Bestellung	net	2008-02-27 13:20:08.000000	0000010
akt	000-0	NETZB Zustand der letzten Bestellung	net	2008-02-27 13:20:08.000000	0000017
akt	000-0	NETZB Zustand der letzten Bestellung	net	2008-02-27 13:20:08.000000	0000026
akt	000-0	NETZB Zustand der letzten Bestellung	net	2008-02-27 13:20:08.000000	0000121
akt	000-0	NETZB Zustand der letzten Bestellung	net	2008-02-27 13:20:08.000000	0000126
akt	000-0	NETZB Zustand der letzten Bestellung	net	2008-02-27 13:20:08.000000	0000131
akt	000-00	NETZB Zustand der letzten Bestellung	net	2008-02-27 13:20:08.000000	0000010
akt	000-00	NETZB Zustand der letzten Bestellung	net	2008-02-27 13:20:08.000000	0000019
akt	000-00	NETZB Zustand der letzten Bestellung	net	2008-02-27 13:20:08.000000	0000024

The control center gives clarity and direct handling options: create or display an Audit Trail – with one click.

