



## Computer Compliance Made Easier for SAP

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Record integrity is a central tenet of computer compliance for SAP owners. There are many threats to SAP records that pose potential integrity problems in the eyes of outside auditors and regulators such as the Food and Drug Administration (FDA), or the Securities Exchange Commission (SEC), or possibly even the Department of Justice (DOJ). These threats include record loss and/or corruption from the following events:

- Inaccurate change to software programs, configuration, or data
- Ineffective testing of changes which does not discover hidden defects
- Inability to identify alterations to records, either intentional or inadvertent
- Inability to verify the authenticity of an in-bound or out-bound record after it has been copied, transferred, migrated or reformatted
- Security breaches, both internal or external, and both human and electronic (e.g. viruses)
- Record falsification or record repudiation – denying accountability to a record because of the fact that the lack of existing controls offers the potential for falsification by anyone (e.g. inadequate controls over system/data access including the ability to change the system clock)

A complete governance program is crucial to defending against and managing these threats and should include organizational controls following the DEAR model:

- **D**efined rules stipulated in policies and procedures
- **E**ducation and training of the rules; and
- **A**udit activities of
- **R**eliable records which demonstrate compliance with the rules

To illustrate the DEAR concepts, let's take a look at a critical function: SAP change control. Depending on the organization, the frequency of changes to the SAP environment can be happening on a monthly, weekly, daily, or continual basis. The changes can be happening proactively because of changing market conditions or reactively because of discovered instabilities within the system. Most SAP change programs consist of a number of "engagements" between appropriate stakeholders (e.g. SAP Technical Operations, Business Analysts, Business Unit System Owners, Quality Assurance, Computer Validation, and User Support, etc.). Representatives from these stakeholders may make up a change control board (CCB) which is responsible for the evaluation, authorization, implementation, and final approval of changes before they are moved through to production.

The problem with many SAP change control systems is that they lack one or more critical components which hampers the efficiency of one or more stakeholders and may pose an unnecessary threat to record integrity. These critical components include:

- Defined workflow options which are appropriate for different categories of change
- Enforcement of the workflow sequencing
- Traffic cop coordinating multiple change implementations that could interfere with each other
- Visibility and metrics of the change status and accomplishments aggregated by different variables (e.g. team member, SAP module, etc.)
- Ready access to change documentation for re-use and investigative purposes

Without one or more of these components, many stakeholders succumb to the effect of the “80/80 Rule” whereby 80% of our system downtime is caused by uncontrolled change and then 80% of the time needed to fix the problem is spent on trying to determine what changed. These effects are mostly realized because the change system in place is based entirely on paper or is a hybrid system where some of the workflow is electronic, but the resulting change documentation must be printed, signed and archived. Both of these systems do not lend themselves to rapidly determining who did what/when when something has gone wrong in production. The question is: *How can we stop self-inflicted work and how much extra work could be avoided?*

In addition, these systems can tend to be overly complicated: asking for people to review and approve deliverables for which they add no value (which causes natural hesitancy and delay) and produces lots of documentation (having a “thud factor”) but not really contributing to the efficiency of change implementation and then post-change impact analysis. And the fact is, the more complicated the change process is, the less likely it is going to be fully and consistently followed by the change staff. The question is: *Can we reduce the number of steps in the process and at the same time easily respond to compliance audits?*

One product that can contribute to positive answers to the above questions is Rev-Trac, developed and supported by Revelation Software Concepts. Rev-Trac is an end-to-end SAP change management solution which controls changes from initial request to automated delivery of the transports. The solution offers the following benefits:

- Permits you to easily define different change processes which are appropriate for the type of change (e.g. upgrade, patch, regulated versus non-regulated, emergency). Having the flexibility to utilize the right process based on risk can reduce overall change costs.
- Provides an automated “traffic cop” which prevents changes from entering production until the change has successfully progressed through your defined process with all applicable electronic signatures.
- Provides a complete audit trail, on-line at your fingertips, to view the history of changes. Knowing who did what, when, can dramatically reduce the investigation time needed to correct emergent errors. This gives you one version of the truth and also helps to reduce the time to investigate and recover from a production problem that may have been caused by a change. It also provides readily accessible and reliable change records which facilitates inspections with auditors.
- Prevents transport errors because of human error of improper sequencing in TMS and also prevents errors resulting from parallel development of identical objects (e.g. avoids accidental overwrites and overtakes).
- Provides valuable “dash board” metric information on the state and rate of progress for changes in queue and completed. The change process becomes more visible and this data can be used to identify bottlenecks and introduce process improvements.

- Provides easier to administer security because Rev-Trac is integrated within SAP and utilizes logon SAP security versus other solutions that reside outside of SAP.
- The security, audit trail, protection of records, and electronic signature functionality has been tested to show full compliance with the technical controls of FDA's rule 21 CFR Part 11 covering Electronic Records and Electronic Signatures. Thus, regulatory (**FDA/SOX**) compliance becomes unobtrusive, repeatable and easily explainable.

It is a fact, which is often taken for granted, that maintaining and defending the institutional records of the company is one of several critical factors which have a positive impact on the organization's future profitability longevity. Critical to the success of Rev-Trac, or any other SAP change control system, will be the institutionalized cultural value system (spirit or ethos) within whereby employees and management are following the DEAR model, not for compliance sake, but because it benefits the stakeholders and contributes to the longevity of the organization itself. It's good to know that Rev-Trac helps enable this spirit and ultimately makes computer compliance easier for SAP.

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### **About QA Edge**

QA Edge, Inc., headquartered in Wilmington, DE provides its customers with real-world strategies to avoid costly mistakes through a diverse range of Computer Validation and Part 11 training and services, "Making Computer Compliance Easy." The company's knowledgeable and experienced professionals provide clients the advantage needed in meeting today's regulatory requirements. Recognized in 2005 with a coveted Philadelphia 100 Award as one of the fastest-growing, privately held companies in the Philadelphia region, the individualized solutions crafted for clients by QA Edge carry the industry's only ironclad corporate guarantee: Documents authored by QA Edge staff will pass any FDA inspection. In the unlikely event the FDA has an issue, the document is corrected immediately at no charge. More about QA Edge, its products and services can be found on the web at <http://www.QAedge.com>.