

Compliance Newsletter

Issue August 2008

Page 1/1

General Comments

There's a lot of confusion about customizing. Even the word is confusing. Customizing in SAP-lingo means configuring the system. Customizing in common US-lingo means enhancing a product, (developing). GAMP5 uses the term custom applications to label category 5 (bespoke) software. Our SAP template includes customizing documentation, which is intended to cover SAP customizing, i.e. configuration of SAP. GAMP 5 has some new requirements for this documentation, but SAP has some old functionalities which support this. That will be the focus of this issue.

For those new to the newsletter, it is built from hyperlinks. You can view the linked documents when you are on-line.

Customizing Documentation

As commented upon in the May issue of the newsletter, GAMP5 calls for a new level of specification and testing for category 4 software, e.g SAP. This new level is placed directly below the functional specification layer, and includes configuration specifications and tests. Configuration testing is not functional testing, but rather confirmation that the specifications have been transferred to the configuration.

Category 4 software, because of its definition, is almost always OTS (off-the-shelf) software. That means usually, that functional specifications can be obtained from the vendor. So, we are back again to the same number of specification levels which must be specially prepared by the owner, 2 (User Requirements and now Configuration Specifications). Past interpretations of CSV used the functional specification layer to prescribe the configuration. For example, SAP blueprints were put in the form of functional specifications.

Compliance Newsletter

Issue August 2008

Page 2/2

Our customizing documentation template was intended to address the concerns of GAMP4 for configuration management. The documentation is intended to allow management of the configuration, as this system changes during its productive life. It can now be interpreted as configuration test documentation, since it both records the current configuration and is used to review and approve it (based upon the blueprints).

As most of us know, customizing documentation of an SAP installation can be quite extensive and expensive to maintain, if paper is relied upon. The March issue of this newsletter pointed to the advantage of the Solution Manager, an add-on to SAP, that make maintenance of Customizing Documentation easier.

SAP (and probably most other configurable OTS products) offer supportive tools for configuration management. These tools should be used if at all possible for specifying and verifying the configuration, just as our Customizing Template relies upon IMG within SAP.

Other SAP tools worth mentioning are the internal change management, transport management, and the Business Configuration Sets. These tools, when used alone, do not meet CSV expectations for at least one of the following reasons: there is not an integrated review and approval step; there is insufficient traceability to requirements; there is no audit trail or version history. It is not difficult to add organizational measures or other software tools to overcome these limitations however, and the resulting documentation of configuration is then largely paperless. At least one of our clients has taken this approach.

Interestingly, GAMP5 did not take on the subject of transport management within CSV, although most larger applications now have an architecture of multiple systems and are maintained via transports of programs and configurations between them. Transport records provide a history of how the system was built and how it is maintained, and should be explicitly included in your change control procedures (and customizing documentation). The BC Sets within SAP rely upon Transport Requests for definition of the configuration.

Compliance Newsletter

Issue August 2008

Page 3/3

Compliance News from the USA

GMP issues have not been getting many headlines lately, but business compliance has. Hardly a week goes by without news of another lawsuit or settlement involving charges that prices for drugs charged to the local health authorities are too high.

Typically, false claims acts form the basis for the lawsuit. As a refresher, False Claims Acts allow American citizens, whether affiliated with the government or not, to file actions against contractors claiming fraud against the government. The laws can come to bear when a health care provider charges such government programs as Medicaid or Medicare for products or services. The most frequent cases involve overcharging, but also ineffective or defective products can be the basis for fraud. The situation will get even more difficult when the flock of pending revisions to these laws at both the state and national levels get approved.

Keep in mind that persons filing under a false claims act (whistleblowers) are allotted a sizeable portion of any recovered damages, thus lengthening the enforcement arm of the government substantially. Pharma must reckon with more litigation costs for its drugs and medical devices in the USA.

More on MUDs

You've probably forgotten my report in the Dec. 2006 issue about the [FDA's offensive against MUDs](#) (Marketed Unapproved Drugs). It has come back in the news in the form of a major seizure of [drugs from KV Pharmaceuticals](#). Trouble at KV Pharmaceuticals started when the FDA started clamping down on marketers of MUDs containing guaifenesin (an ingredient of cough syrups) in May 2007. KV was inspected at the start of this year and was found to be still producing such products. No Warning Letter was issued, and it is unclear in the press release why the seizure and destruction occurred now. However, the FDA's position is, "When a company does not heed a cessation date relating to a specific product, the FDA will take enforcement action relating to the company's other unapproved drugs." So, the FDA destroyed all of the MUDs, that it could get its hands on.

Compliance Newsletter

Issue August 2008

Page 4/4

EU's REACH Implementation affecting Chemical Trade

REACH stands for: Registration, Evaluation, Authorization, and Restriction of Chemicals; a regulation in effect since June, 2007, which is supposed to establish a uniform system for assessing the risk posed by new and existing chemicals. This cross-industry topic (affecting API trade) has hit the news, as the American SOCMA (Synthetic Organic Chemical Manufacturers Association) protests the costs of the program and its ineffectiveness.

In any case, the chemical industry has a new compliance cost position for trade with or within the EU. You need to have an European-based representative to submit and maintain the registrations, and you need plenty of data, including toxicology studies.

Contributing Author:
Dr. Paul Thomas Noble
Mobile: +49 172 6868 591
Email: PaulThomas.Noble@ids-scheer.com
www.ids-scheer.com

If you have any further questions or comments, please don't hesitate to contact me directly via phone or email!