

Autoscribe News Release – PR0511

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Delivering the Power of a Truly Configurable COTS LIMS

Autoscribe's Matrix LIMS GAMP COTS Category

Autoscribe's Matrix LIMS is a GAMP Category 4 Configurable Software Package. The hidden value and true benefit of Matrix LIMS lies in the power of its unique configuration tools. These tools enable us to fully meet your user requirements without the need for custom programming or esoteric, proprietary scripting languages.

Your LIMS requirements and business needs change throughout the long life-time of the system and Matrix LIMS is designed for change.

Matrix LIMS and Configuration Tools – So Why configuration?

Matrix LIMS is fully configurable, but based on a standard product core. Matrix LIMS comprises of an elegant suite of LIMS configuration tools designed to facilitate the smooth, fast implementation of a LIMS completely designed to meet your current and future user requirements. This suite of tools can also be used to modify the LIMS as business and/or laboratory needs evolve. A “wizard” style interface and use of a LIMS configuration knowledgebase helps the vendor, and later the system administrator, create and/or modify end-user screens. Other tools facilitate documenting the configuration and providing configuration control.

Successful LIMS do not stand still and our unique next generation suite of LIMS configuration tools deliver significant business benefits throughout the lifetime of the system.

Autoscribe designed Matrix Plus LIMS to be built your way, not our way, and any way you like it, whenever you want to.....

So what is a COTS LIMS package?

COTS is a term used to describe “Commercial Off-The-Shelf” software packages and some hardware systems. COTS systems are manufactured commercially and are then tailored / configured for specific uses. Almost all software fits into the COTS category such as operating systems, word processors, office products and email programs. Such software applications are configured for use for a specific function without altering the basic program.

COTS packages were further categorized by GAMP in the Good Automated Manufacturing Practices guide for Validation of Automated Systems see www.ispe.org . GAMP was started in 1991 by a group of UK pharmaceutical experts who subsequently partnered with ISPE (the International Society for Pharmaceutical Engineering) in 1994 to publish the first GAMP guidelines and to run training seminars.

GAMP Software & Hardware Categories

Category 1 Operating Systems

Category 1 covers established, commercially available operating systems. They are currently considered to be validated by use for any project in e.g. a pharmaceutical manufacturing environment. Upgrades to the operating system could potentially lead to retesting of applications run on the operating system.

Category 2 Standard Instruments, Micro-controllers, Smart Instrumentation

Category 2 covers instrumentation that is driven by non user-programmable firmware such as some standalone laboratory instrumentation, barcode scanners and weighing scales. Such systems may be configurable and the configuration is usually recorded in the equipment IQ. The IQ needs updating if the revision of firmware is changed.

Category 3 Standard Software Packages

Category 3 covers 'canned', out of the box, widely commercially available configurable packages such as Microsoft Excel, Lotus 1-2-3 and other spreadsheet packages. Such packages have usually been installed in multiple industries / environments and their sales run into 100's of thousands if not millions of copies. There is currently no requirement to validate such software packages, however new versions are usually treated 'carefully' and risk assessment should be performed prior to upgrades being performed. Validation effort is typically focused on the application of the spreadsheet package eg to perform specific calculations such as those used in Impurities Analysis, Dissolution Testing, Bioassay Method Validation, Calibration Bracketing etc.

Category 4 Configurable Software Packages

Category 4 covers configurable packages and includes some LIMS products and Chromatography Data System (CDS) products, Data Acquisition packages (SCADA), Manufacturing Execution Systems and MRP packages. The system and platform should be well known and mature before being considered as Category 4 otherwise Category 5 applies.

Category 5 Custom or Bespoke Systems

A complete life-cycle model approach for the development, testing and validation must always be completed for all custom built or bespoke systems.

Autoscribe - The Winning Formula!

About Autoscribe

Autoscribe Limited is a world leader in the development and supply of successful software solutions for LIMS (Laboratory Information Management Systems) and the scientific laboratory and business markets.

Autoscribe pioneered the use of innovative configuration tools within the LIMS market and today our Matrix Plus LIMS software is seen as the industry standard to which others aspire.

Autoscribe offers a wide portfolio of products and services including systems for LIMS, sample tracking, instrument calibration and maintenance, stability testing, customer complaints management, support management system, ISO9000 protocol driven training records management and resource planning.

Founded in 1981, Autoscribe is a privately owned UK company. Worldwide we are represented by a network of business partners in regions including the USA, Canada, France, Benelux, Germany, Indonesia, Switzerland, Scandinavia and Australia.

Our organisation includes a dedicated team of developers, technical support specialists and sales & marketing professionals.

Our customers include leading analytical, oil, pharmaceutical, biotechnology, chemical, and consumer products companies as well as academic research institutes, hospitals and many others.

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Reader Enquiries

Please send reader enquiries from this news release directly to matrix@autoscribe.co.uk