



cGMP Informatics Initiatives Pave the Way for 21st Century Global Quality Data Management

The IMACS Organizing Committee is pleased to summarize the 3rd annual IMACS conference that took place on May 17-18, 2006 in Princeton, NJ. Technical and management case studies on cGMP QC/QA Lab Productivity and Compliance Automation systems were presented.

Leading advocates from the following organizations presented: AstraZeneca, Atrium Research, Avatar Pharmaceutical Services, Bristol-Myers Squibb, Bristol-Myers Squibb Imaging, Eli Lilly & Company, GlaxoSmithKline, ImClone Systems, McNeil Consumer Healthcare, MedPointe Pharmaceuticals, Purdue Pharma and Tandem Laboratories.

Some key insights from the meeting include the following:

- Thriving in the new pharmaceutical economy requires prudent infrastructure planning, with cGMP operations needing productivity improvements while maintaining compliance.
- A three-layer GMP IT architecture comprised of an ERP system at the top, a management level LIMS layer in the middle, and a chemist level LES (Lab Execution System) layer at the base can provide a cost effective and comprehensive paperless environment. This architecture encompasses all aspects of data capture, workflow and management in cGMP operations.
- Human errors, in activities such as transcription and calculations, are prevalent in a paper-based LES layer. These errors result in resource-intensive rework loops and documentation review, costing time and money. Automating the LES layer with a COTS solution can resolve these issues. One case study showed a 50%+ reduction in data review cycle times and a 35% increase in output capacity while maintaining existing headcount.
- Contract labs (CRO and CMO) have the same problems with inefficient paper-based processes. Automating these processes with an electronic system can reduce review and production cycle times, reduce compliance risks and improve quality, thereby improving performance for clients.
- Electronic Lab Notebook technology is gaining significant momentum in the life sciences. One key to adoption is the selection of application specific ELN's at the LES layer. Application verticals include Chemistry, Biology, High-Throughput Screening (HTS), Animal Studies, cGMP QC labs and Production Batch Records. Notebooks will differ from one vertical to another within the LES layer.
- A second key to adoption is rapid deployment using technology such as wizards, pre-formatted method templates, instrument libraries, and automated validation scripts. Initial target applications that are easily automated, and can be used to document efficacy metrics, include metrology and reagent preparation.
- A third key to adoption is careful consideration of integration points, including: Chromatography Data Systems (CDS), LIMS, test methods, all bench level lab instruments, and lab staff. Early communication with lab staff is critical to the adoption of an electronic system.

For program details and abstracts go to <http://www.imacs-world.com>. To be included in updates about IMACS 2007 plans, email us at <mailto:info@imacs-world.com>

IMACS 2006 sponsors included: Pharmaceutical Formulation & Quality, Pharmaceutical Technology, American Pharmaceutical Review and VelQuest Corporation.

About IMACS

IMACS (International Meeting on Automated Compliance Systems) is the definitive conference on IT-based compliance and productivity solutions, and was developed to provide a forum to outline these solutions for pharmaceutical, biotechnology and medical device laboratories in GLP Development and cGMP QC/QA operations.

The life science industry is challenged with reducing costs and improving productivity throughout the drug development and production process. IMACS is dedicated to providing an information exchange for enabling technologies designed to meet those challenges. IMACS is open to all individuals interested in advances and experiences in automating compliance and will feature implementer experiences and insights. The organizing committee will not accept commercial presentations. IMACS 2007 will take place in Princeton, NJ (USA) on May 16-17, 2007.

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