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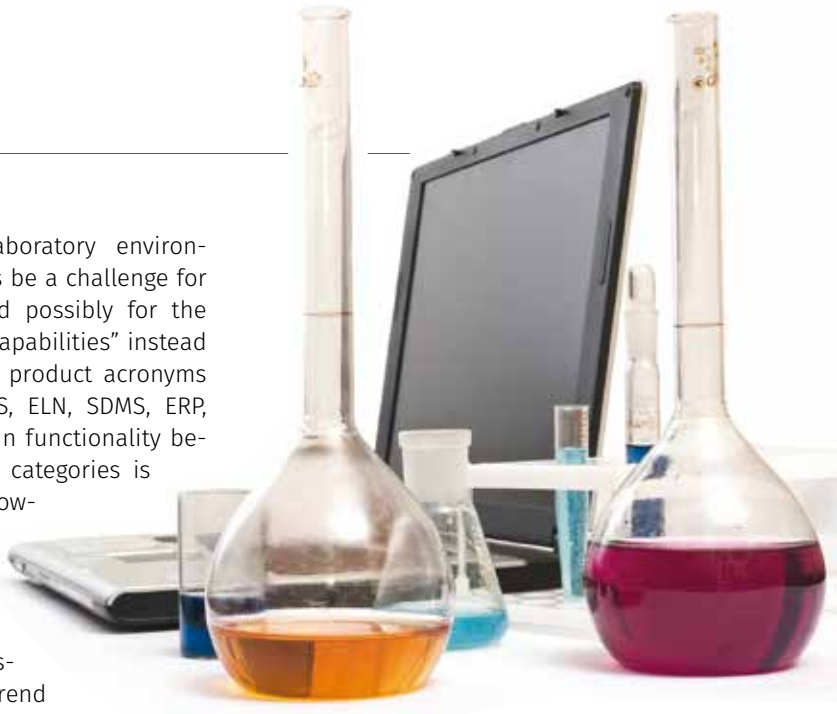
CONFERENCE REPORT

TRENDS IN LABORATORY INFORMATICS



Data-intensive science is becoming far more mainstream in our daily laboratory operations. Informatics enables organizations to create start-to-finish knowledge management repository to adopt cross functional collaboration between management, scientists and engineers responsible for products in development and manufacturing, processes, equipment and facilities. And these developments were in the centre of both the "Laboratory Informatics update" during the PharmaLab 2015 and the Computerised Systems in Analytical Labs (at PharmaLab 2016) conferences in Dusseldorf. And both specifically focused on data integrity, security and regulatory updates in both FDA 21 CFR part 11, the European Annex 11 and GAMP® guidelines. The programs included several case studies and general trends in the laboratory information.

Paperless or less Paper?

The journey to move from paper to electronic begins with the transition from paper to digital, which includes both the transfer of paper-based processes to "glass" and the identification and adoption of information to adopt process standards to harmonize data exchange. In its simplest form, an Electronic Laboratory Notebook (ELN) can be thought of as for an electronic embodiment of what is currently being done in a paper laboratory notebook. It is a tool that facilitates the workflows that play out in your particular laboratory. Having said that, Laboratory Information Management System (LIMS), Electronic Laboratory Notebook (ELN) and Lab Execution System (LES) applications all support this basic definition, to a greater or lesser extent, as they exist within various laboratory environments. It may thus be a challenge for the audience (and possibly for the reader) to think "capabilities" instead of supplier based product acronyms such as LIMS, ELS, ELN, SDMS, ERP, MES. The overlap in functionality between application categories is significant and growing. Several real-life experiences were shared during the lively discussions. Overall the trend is to consolidate existing applications rather than expanding in new potential overlapping software products. A detailed "what is needed" analysis, followed with a risk management evaluation will increase the success of a laboratory automation projects. According to Dr. Markus Dathe's (F. Hoffman-La Roche) experience there are Do's and Don'ts of going paperless. The ultimate question from his perspective is whether we can still work on paper in today's accepted QbD (Quality by Design) mindset?

While life-cycle risk management based approaches are commonly practiced in QbD and other quality processes, in our life sciences industry they seem pretty new in laboratory automation projects. So what makes the Laboratory special? Pragmatic examples were discussed during both conferences how to apply new lifecycle process validation guides to CSV and lab systems requirements and what the role of the supplier could be to reduce validation effort. For Michael Goetter from LONZA Bioscience, for instance, it is important to highlight how new regulatory guidance such as USP <1116> guidelines, argumentative in adverse trending and data integrity, will increase the demand for paperless labs. Arjan Bannink (WATERS Corp) zoomed in how Data retention, Data integrity and Traceability will address how to safeguard laboratory data. The real question is how to make it happen within our laboratories? Heiko Linde (Agilent) presented strategies to integrate multi-vendor instrument management to create an enterprise knowledge based environment.

Methods to increase data integrity in the laboratory

Data Integrity is not a new requirement. For years, the basic principles have been described in several international good manufacturing practice (GMP) guidelines. Nevertheless, data integrity is currently one of the highest cited areas in regulatory observations. An FDA observation summary report shows that laboratory processes and deficiencies associated with laboratory controls are ranked in the top 3!

Automate scientific instrument data capture will have a significant impact

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Laboratory data integrity observations
Alteration of raw, original data and records
Multiple analyses of assay with the same sample **without adequate justification**
Manipulation of a **poorly defined analytical procedure** and associated data analysis in order to obtain passing results
Backdating stability test results to meet the required commitments
Creating acceptable test results **without performing** the test
Using test results from previous batches to substitute testing for another batch

Source: US FDA - CHAPTER 46- NEW DRUG EVALUATION Compliance Program Guidance Manual

on the overall quality of the data. The following case illustrates the potential impact when we allow ourselves to think with a different mind-set. Over 75 percent of a laboratory experiment or analysis starts with some kind of manual process, such as weighing. The majority of the results of these measurements are still written down manually on a piece of paper or re-typed into a computer or tablet. The market perception is ELN Electronic Lab Notebook software and mobile devices like tablets are married to each other. However, to connect a balance to such device, you need to be an IT professor. Complex network protocols, corporate IT involvement, non-standard instrument protocols and data formats are resulting in complex validation and non-standard IT processes.

While many modern LIMS, ELN and LES software do allow electronic connection using traditional network protocols, it is recommended that we adopt simpler processes. To integrate simple instruments like a pH, balance, titration and Karl-Fischer should be as simple as it is to connect a smartphone from almost any brand to almost any car manufactured around the world – without the need to consult a specialist. There should be no difference between securely pairing a Bluetooth device to a car and a computer and pairing a balance to an ELN or LIMS application on a tablet or computer. It is time to rethink how we operate these devices – a statement stimulating lively discussions. However, overall it may be convincing, that adopting these processes in conjunction with LIMS, ELN, SDMS or LES, will significantly decrease the Data Integrity observations as identified by the FDA in the laboratory and create a modern mindset.

Dr. Markus Dathe shared an interesting insight how to expand the usability of audit trails. While the audit trail capability initially was used to log records to prove for regulators a full trail of the lifecycle of computer record, he indicated that the reviewing of the audit trail could also be mined in the context of data integrity. Audit trail datasets and other event logs are becoming valuable resources to also optimize the overall lab processes. While CAPA focuses on the systematic investigation of the root causes of identified problems or identified risks in an attempt to prevent their recurrence for corrective action, we may change this paradigm into a PACA mindset, focusing on the preventing element first. The information stored in these datasets may significantly reduce potential CAPA's and therefore contribute to systematic continuous improvement process, resulting in optimizing analytical methods and workflow optimization.

New trends

There are several new trends impacting the laboratory automation industry. At first, the power of life cycle process improvement. The scientist is no longer in the laboratory, but integrated in the overall quality process. Quality should be built into the design throughout the specification, design, and verification process. Performance metrics on non-conformance tracking are mandated and monitored by regulatory authorities. An example was presented that established HPLC technology and which can be deployed outside the lab in real-time manufacturing processes. Integrating more scientifically based laboratory technology will add significant value. Secondly, new budgeting and licencing models will create a new challenge. It is expected that managing operating budgets will be redefined in the next decade. The days to purchase software as a capital investment (CAPEX) is changing to a new model based upon a "pay-as-you-go" philosophy (OPEX). CRM applications such as SalesForce.com started this business model in the traditional enterprise business software segment. Popular applications such as Photoshop and Microsoft Office 365 and Amazon are following these trends rapidly. It is expected that scientific software suppliers will be forced to follow the same model in the years to come. Community collaboration and social networking is changing the value of traditional vendor helpdesks. At last, consolidation, simplification and harmonisation of systems is a hot item within many corporate organisations. Most laboratories already depend on an informatics hub comprising one or more of the major tools: laboratory information management systems (LIMS); electronic laboratory notebooks (ELN); scientific data management systems (SDMS); Chromatography Data-handling Systems (CDS) and laboratory execution systems (LES). The trend over recent years has been towards convergence, applying best practice industry standard processes to harmonize multisite deployments. Cost reduction to interface harmonized processes to ERP (SAP), MES and CAPA result in lower maintenance and validation costs with a significant overall higher system availability for end-users.

As mentioned in the beginning, informatics enables organizations to create start-to-finish knowledge management repository to adopt cross functional collaboration between management, scientists and engineers responsible for products in development and manufacturing, processes, equipment and facilities. It is therefore essential to raise the awareness for laboratory information. After all, it is critical for many organizations since it provides significant context for the overall business process.