DEBRIEF 1st Pharma-Lab – Laboratory informatics Update -Düsseldorf NOV 13-14 - 2013

Held in Dusseldorf for the first time, the PharmaLab 2014 2 day conference I had the opportunity to chair the laboratory Informatics update stream. Over 60 delegates participated in the full day program, which included 7 presentations and great opportunities to network during the breaks in the exhibition hall. I shared my experience on the functionality overlap of the different laboratory informatics applications including LIMS, ELS, ELN, SDMS, ERP, MES and PLM. A special focus was given towards how these overlapping applications would be positioned with the end user in mind. Instead of looking it from the technology or IT perspective, an end-user centric view was presented with a focus of usability. Overall the program included several case studies and general trends in the laboratory information, but there were three particular topics that triggered attention.

At first, despite the fact that paper is familiar and comforting, paperless technologies such as barcode technology and automated instrument interfacing are becoming more accepted in laboratories. Michael Goetter (LONZA), Dirk Badura (Carbogen), Ralf Schroder (WATERS) and Peter Boogaard (Industrial Lab Automation) showed several applications, to significant reduce transcription errors and validation efforts by implementing these enabling technologies. Despite what some vendors want you to believe; moving toward a paperless lab is not about gimmicks, new instrumentations or other (fancy) software platforms. The power of a paperless laboratory is the ability to enable organizations to implement self-documenting processes that produce both non-and GxP-compliant documentation that eliminates unnecessary tasks from the workflow to result in significant re-use of knowledge in research, as well as a reduction of cost to support corporate cost of goods sold (COGS) targets. It was concluded that paper is not likely to disappear (Less paper vs. Paperless); what will change is the way, how and when we will use paper.

Second, the need for the industry and regulatory bodies to accelerate joined discussions how new informatics technologies can benefit both worlds. While the main roles of the EMA is to assure central coordination of scientific evaluation of quality, safety and efficacy and verification of compliance with GMP principles, a lively discussion with Karl Heinz Menges (Regional Council inspector) showed the need for good guidelines to comply with these new chapter 6 guidelines.

At last, the acceptance to adopt industry best practices across industries. To enable harmonization, integration and consolidation of business processes in the Life Science development and manufacturing, requires corporate commitment. Peter highlighted that ICH Q10 guideline describes a comprehensive model for an effective risk-based pharmaceutical quality system that is based on International Organization for Standardization (ISO) quality concepts. Good examples include increased acceptance of QbD (Quality by Design) in these processes, however in our laboratories this process is not always well known. Ulla Bondegaard (NOVO Nordisk), shared how a life cycle, risk based, approach utilizing guidelines from GAMP5, EU GMP Annex 11, ISPE guidelines can be successfully expanded towards the Commercial Of The Shelf (COTS) software in the laboratory. Typical COTS applications include LIMS, ELN, SDMS and LES software.

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. Laboratory information is critical since it will provide significant detail for the overall process. Wasn't that the devil is in the details? I myself certainly look forward to next year's meeting and hereby thank the organizers for a well-organized event.

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