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Pharmaceutical Automation Roundtable (PAR) - Part 1 - MES Benchmarking Survey Results

This is the first article in a series that are the result of the annual Pharmaceutical Automation Roundtable (PAR). The individual PAR group members have a wealth of practical knowledge and knowhow to share with other participants, truly learning from each other.

I had the privilege of attending the Pharmaceutical Automation Roundtable as an observer this last November at Pfizer's Andover, Massachusetts biotech facility. The PAR was co-hosted by Jim LaBonty and James Galloway, both from Pfizer's central engineering group. Over 30 automation lead engineers from various parts of the world attended the invitation-only, two-day event. In my opinion, this was likely the most knowledgeable group of automation professionals gathered in one place at any one time focused on discussing automation issues. Life Science companies represented in the PAR include Abbott, Alcon Labs, Allerga, Amgen, Bayer, Biogen Idec, BMS, Boehringer Ingelheim, Centocor, Cook Pharmica, Dow, Genentech, GenMab, Genzyme, GSK, Imclone, J&J, Eli Lilly, Lonza, Merck, NNE Pharmaplan, Novartis, Novo Nordisk, Pfizer, Roche, Sanofi-Aventis, Schering Plough, Talecris, and UniLife.

The PAR was founded about 15 years ago by Dave Adler and John Krenzke, both with Eli Lilly and Company at the time, as a means of benchmarking and sharing best practices for automation groups among peer pharmaceutical companies. The group specifically does not discuss confidential or proprietary information, cost or price of products, price or other terms of supply contracts, plans to do business or not do business with specific suppliers, contractors, or other companies.

This year's PAR topics covered the following items:

- Manufacturing Execution System Projects - Benchmarking
- Control System Virtualization Approaches
- Governance Organizational Structures
- Software Development Environment & Configuration Management
- Control System – Automation Lifecycle Management and Long Range Planning
- Electronic Testing Tools & Validation
- Wireless Networks
- Disposable Technology and Automation Implications
- Control Loop Operating Modes – Operator use of Auto & Manual modes relative to Safety

In opening remarks during keynote address, a key point made by George Skillin of Pfizer was that in these days of shrinking investment when capital spending is down, the goal is to do more with less and take full advantage of what is already in place. By using the systems and platforms in place, learning more about processes, and using data to solve problems, automation engineers are really good at process optimization. By working hand in hand with production, manufacturing, and process engineering groups, the automation people can optimize processes and squeeze out costs to lower the overall cost of medicine for all.

The structure of PAR is to discuss a topic and then attendees respond to 3 - 5 questions.

MES Benchmarking Survey Results

Dave Adler (dave.adler@brilligsys.com) conducted and presented the results of the PAR MES Benchmarking survey completed by the group prior to the PAR meeting. Based on the discussion, it appears that the long standing tension between IT and automation had gone down significantly in the last five years. The survey asked what technologies were implemented in an MES. The top three new functions added or improved with the installation of MES are paperless tickets, product tracking and paperless logbooks. The next level of significant items includes quality, dispatching, manufacturing intelligence, and resource allocation. The MES survey also indicted that bar codes are the dominant data collection method, instead of RFID.

Average MES project cost in the survey was $7 million, with average annual support cost of $0.5 million or 7% of initial cost. In contrast, average automation projects cost $11 million based on last year's PAR benchmarking survey. The cost of instrumentation for automation projects is a big part of the difference. MES functionality drives the systems cost and appears independent of facility size. Forty percent of MES projects reported took an average of 18-24 months to complete.

On average, doing an MES project with a DCS is significantly lower cost than with a PLC based system. The discussion on this point indicated that the information needed to deploy an MES was already easily available in a DCS.

The primary MES project drivers are cost reduction and compliance. In general, MES implementations for cost reduction were more expensive, require more customization, but the return on investment was higher.

Comments from the PAR group…
MES requires more engineering than automation and this may be due to the fact that automation has long established standards that do not exist for MES.

Shop floor devices such as analytic instruments, scales, and bar code devices are interfaced much easier directly to the MES without going through the DCS or PLC.

The level of replication is often higher in automation systems vs. MES when configuring the systems. The view is that automation has long established standards enabling replication and MES doesn't have well established standards.

Some feel that creating software components is the best way to gain efficiency when building MES applications. Components provide a level of standardization and maintain flexibility as opposed to replication of big parts of the application.

MES projects are many times run by three groups - making them more challenging. Many agree there is a need to educate management on how to justify MES projects. High level management commitment to force compliance to standards helps make an MES project successful.

My Observations…
MES is still relatively new and in this group they see a positive value to implementing it. Today we take ERP systems for granted but they went though evolutionary steps including MRP, MRP II, and ERP. MES has been going through a similar evolution.

Summary
The Pharmaceutical Automation Roundtable is a terrific event and I am sure attendees gained a number of ideas. The next article in this PAR series will cover the group's thoughts on Virtualization & Software Configuration Management.