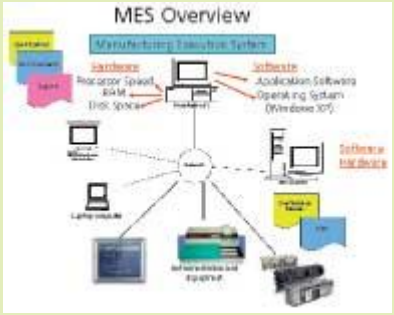
IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY
UBM A division of UBM Americas
Published on *IVT Network* (http://www.ivtnetwork.com)

On the Horizon: MES for the Medical Device and Diagnostic Industry

Feb 8, 2013 9:49 am PST



Over the past decade, manufacturing execution systems have become increasingly commonplace in pharmaceutical manufacturing. However, as computer systems and software continue to evolve and improve, validating MES and remaining compliant with regulations becomes increasing more difficult.

MES systems are some of the most complex aspects of a manufacturing plant. They incorporate hardware, software, employee computers, equipment and instruments, and relevant documentation. Validating MES and adhering to FDA, ISPE, and EU regulations requires a comprehensive change and configuration management, risk assessment, vendor qualification, and training program. This year's Forum on Manufacturing Execution Systems (MES) for the Medical Device and Diagnostic Industry discusses current problems and innovative solutions for MES implementation, validation, and compliance.

Last year, Thomas Quinn discussed 21 CFR Part 11 and other global regulations that involve MES. Despite being well-known and frequently referenced documents, there are numerous complexities of the regulations that often go overlooked. Quinn makes it very clear that both 21 CFR Part 11 and Annex 11 of the Eudralex applies to all electronic records, not only records that have been signed. There is an explanation of other global guidances to assist compliance, such as the US Food and Cosmetic Act and The Electronic Signatures in Global and National Commerce Act. Quinn also discussed the very real threat of security breaches, citing a 2011 arrest of a New Jersey-based pharmaceutical employee who intentionally damaged his companies computers.