2ND ANNUAL

PHARMACEUTICAL MANUFACTURING EXECUTION SYSTEMS

MAY 22-23, 2017 | SAN ANTONIO, TX

Preparing for Compliance with the FDA's Data Integrity Guidance, Analysis of Efficient MES Validation Methodologies & Exploring Impactful Innovations in MES Technology & Customization

DISTINGUISHED PRESENTERS INCLUDE:

Matthew Iwema
Senior Associate, Operations Lead
ELI LILLY

Denny Catacora
Senior Engineer, Manufacturing Execution Systems
CSL BEHRING

Jordan Croteau
Senior Engineer I, Execution Systems
BIOGEN

Joe Barone
MES Program Manager
3M

James Johnson
Partner
HOGAN LOVELLS

Martin Dittmer
Product Manager
ROCKWELL AUTOMATION

Ivan Cirino
Staff Systems Engineer
ETHICON

Laura Kaplan
Associate Director, Information Technology and Solutions
SANOFI

Christian Berg
Automation Manager, Manufacturing Execution Systems
GENENTECH

Elton Ramos
Senior Manager, IT
SHIRE

Subodh Joshi
Senior Principle Engineer
SHIRE

Jerry Gonzalez, P.E., MBA, CQE, CMQ/OE, CSCP
Business Systems Manager
B.BRAUN MEDICAL, INC.

Brian DiVasta
Principal Validation Engineer
GENZYME

Baha Korkmaz
Senior VP, Operations, North America
ENTERPRISE SYSTEM PARTNERS GLOBAL CORPORATION

Frank O'Loughlin
MES Subject Matter Expert
FORMERLY WITH AMGEN

Gilad Langer
Director of Automation & MIS
NNE

Dakota White
MES Applications Engineer
ASTRAZENECA

Andy Clyne
Global Network Leader
AMGEN

Pascal Lim
Director, Operations, Business Solutions
CEPHEID

Ravikiran Medandravu, PMP
Automation Manager, Systems
GENENTECH

Jairus Martin
Senior Program Analyst
BAUSCH + LOMB

Dan Ginn
Senior Business Solutions Analyst
CEPHEID

Welf Ludwig
Sales Manager
WERUM

Josh Fritz
Programmer Analyst
SHIRE

24

DISTINGUISHED PRESENTERS
More than **24** presenters will meld industry perspectives to ensure a well-rounded platform.

UNPARALLELED NETWORKING
The program provides a matchless venue for industry peers to gather, exchange ideas and connect.

INTERACTIVITY & WORKSHOPS
The conference will feature interactive, hands-on workshops for heightened exchange of practical ideas.

PHARMACEUTICAL MANUFACTURING EXECUTION SYSTEMS

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KEY SPEAKER HIGHLIGHT:

Brian DiVasta
Principal Validation Engineer
GENZYME

SANOFI GENZYME

I am a graduate of MIT with a B.S. in Chemical Engineering and 21 years in the Pharmaceutical and Bio-tech community. The majority of that time has been spent in the realm of computer system validation, starting with my first PLC-SCADA system, progressing through increasingly complex and diverse applications and job responsibilities and culminating with my role as a Principal Validation Engineer and Manager of Computer System Validation/Compliance at Genzyme. Along the way, I have worked with PLC, BMS, DCS, LIMS, ERP (and a partridge in a pear tree), worked as a contractor, individual contributor, manager and even dabbled in Quality Assurance. I was introduced to MES in 2006 with Werum's PAS|X system and an "EBR-lite" integration with SAP. The last 5 years have seen me continue my MES journey at Genzyme, where we have successfully implemented fully integrated EBRs (shop-floor to ERP) and a very successful, though not 100%, Review-by-Exception program. We are currently developing a "Core" solution for deployment across the Genzyme network with our eyes on 2017.

Ravikiran Medandravu, PMP
Automation Manager, Systems
GENENTECH

Genentech
A Member of the Roche Group

Ravikiran Medandravu, PMP (Ravi) has 13 years of experience in Manufacturing Automation Systems. He is Project Manager & PMP certified currently a manager of Engineering (Automation Systems) in Oceanside, CA. He has Automation Technical leadership in managing Projects Portfolio managing lifecycle of MES, PCS, Applications, Infrastructure, and Manufacturing systems. He currently works for Genentech with previous experience with Sanofi Genzyme and Biogen.

Christian Berg
Automation Manager,
Manufacturing Execution Systems
GENENTECH

Genentech
A Member of the Roche Group

Since 2012, Christian Berg has been leading the MES engineering team at Genentech's sterile filling and packaging facility in Hillsboro, OR. Christian brings cross-functional leadership experience from manufacturing, operational excellence, and supply chain management to the world of MES. Christian has a passion for lean, quality-focused manufacturing solutions, and he emphasizes a structured approach to gathering and fulfilling user requirements in order to maximize MES benefits for all stakeholders. Christian is an ASQ Certified Six Sigma Black Belt, and he has a Bachelor of Science in Biophysics from California Lutheran University and a Master of Science in Organizational Leadership from Regis University.

Martin Dittmer
Product Manager
ROCKWELL AUTOMATION

Rockwell Automation

Martin Dittmer is head of product engineering and product management for Life Sciences MES applications at Rockwell Automation® and serves as the product manager for Rockwell Software® PharmaSuite® MES. Throughout his career, he has held multiple roles within the complete lifecycle of MES, including development, project delivery, consulting and marketing. Martin is an active member of the International Society for Pharmaceutical Engineering Community of Practice (ISPE COP) and holds a Master's degree in Electrical Engineering from Universität Karlsruhe. He has three children and in his spare time, Martin enjoys playing the electric guitar and 10K runs.

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PHARMACEUTICAL MANUFACTURING EXECUTION SYSTEMS

DAY ONE | MONDAY, MAY 22

8:00 REGISTRATION & WELCOME COFFEE

8:50 CHAIRPERSON'S OPENING REMARKS

9:00 GROUP DISCUSSION: MES 101: FIRST STEPS INTO PHARMACEUTICAL MES SYSTEM SELECTION, CUSTOMIZATION & IMPLEMENTATION

Many pharmaceutical manufacturing corporations are currently considering shifting towards the utilization of a Manufacturing Execution System (MES) to enhance production management in addition to decreasing overall production facility and processes costs. While benefits in implementing a MES are numerous, the first steps into the new structure require careful attention to many details such as which software and technological platform will best fit specific manufacturing needs, as well as how to articulate and tailor the process to guarantee maximum ROI. Further, manufacturing executives must ensure a smooth transition to the new process in 24/7 facilities, necessitating forward planning and organizing. Through experience sharing, this 101 section will provide participants interested in understanding more about the first steps into MES implementation with a unique opportunity to gain insight into varied perspectives from peers in the pharmaceutical industry who will share practical approaches for implementing MES for the first time and lessons learned.

- Selecting appropriate MES & securing corporate buy-in
- Addressing prerequisites for implementation strategy
- Outlining manufacturing system selection process
  - Appropriate tools to customize & tailor MES
  - Standardizing & deploying MES across organizations
- Practical insight into common MES implementation pitfalls

SESSION MODERATORS:

Pascal Lim, *Director Operations, Business Solutions,* **CEPHEID**

Dan Ginn, *Senior Business Solutions Analyst,* **CEPHEID**

9:45 KEYNOTE PANEL: CRITERIA FOR HIGH QUALITY MES IMPLEMENTATION

- Assessing MES readiness & plant performance strategies
- Defining & agreeing to an appropriate MES business scope
- Engaging stakeholders to define business objectives & drivers
- Planning for successful implementation & sustainment

PANELISTS:

Andy Clyne, AMGEN

Joe Barone, 3M

Laura Kaplan, SANOFI

10:30 COFFEE & NETWORKING BREAK

11:00 CLARIFYING THE FDA DATA INTEGRITY DRAFT GUIDANCE & PREPARING FOR IMPLEMENTATION

In April 2016, the FDA released a draft guidance addressing data integrity for manufacturers through the current good manufacturing practice (cGMP), in addition to providing recommendations for validating computer systems in manufacturing operations. These requirements involve developing and implementing highly technical features within the MES to validate data accuracy as well as increase data set security from one system to another. In order to proactively prepare for implementation, MES executives must ensure a thorough understanding of the guidance's requirements, and how to tailor compliance strategies specific to varying systems.

PART 1: ROAD SHOW: VENDOR PERSPECTIVE

- Remaining abreast of the FDA data integrity guidance
- Common tools used to fulfill data integrity expectations
- Upcoming technology & solutions used for data interpretation

Welf Ludwig, *Sales Manager*
WERUM

11:30 PART 2: INDUSTRY PERSPECTIVE

- Interpretation of the draft guidance & application to sites
- Identifying a clear definition of data integrity
- Interaction with FDA & lessons learned

Brian DiVasta, *Principal Validation Engineer*
GENZYME

12:00 PART 3: COMPLIANCE PERSPECTIVE:

- Analysis of the draft guidance & methods for compliance
- Identifying MES gaps in light of the draft guidance
- Practical steps & lessons learned for compliance

James Johnson, *Partner*
HOGAN LOVELLS

12:30 LUNCHEON FOR ALL ATTENDEES, SPEAKERS & SPONSORS

1:45 SYSTEM INTEGRATOR PERSPECTIVE: BEST APPROACHES & LESSONS LEARNED FOR MES INTEGRATION STRATEGIES

With the high level of costs involved in manufacturing operation systems implementation and complexity in incorporating a new process within a multiple-layered setting, pharmaceutical manufacturers must carefully plan and budget for MES integration. As a result, manufacturing teams are integrating control systems to allow for key business drivers such as reduced product cycle time and improved means of efficiency. In addition, as the architecture of a MES varies from one company to another, the industry is in need of clarification and practical insight into appropriate control systems selection criteria.

- Outlining S95's control systems hierarchy & applications
- Interpretation of the 4 levels for system controls
  - Defining the high functionality of level 2 process control
  - Methods & analytics for connecting to an ERP system
- Selecting a control system best suited for specific MES

Baha Korkmaz, *Senior VP, Operations, North America*
ENTERPRISE SYSTEM PARTNERS GLOBAL CORPORATION

2:30 PANEL DISCUSSION: PROS & CONS OF INTEGRATING MES IN EXISTING CONTROL SYSTEMS

- Approaches for developing & designing system architecture
- Utilizing technology & data to integrate control systems
- Overview of successful end to end ERP, MES & PCS implementations
- Corporate challenges faced with integration strategies

PANELISTS:

Elton Ramos, SHIRE

Ravikiran Medandravu, PMP, GENENTECH

Dakota White, ASTRAZENECA

3:15 COFFEE & NETWORKING BREAK

3:45 ALIGNING CUSTOMER EXPECTATIONS TO DELIVER SUCCESSFUL MES

Organizations are always chasing process improvement. Internal customers have an insatiable appetite for continuous optimization of process control systems under ever shortening timelines. Unrealistic customer demands place a crushing burden on system administrators, creating an environment of unfulfilled expectations, cross-functional distrust, and weariness to pursue change. Genentech's Hillsboro facility has successfully used a simple framework for aligning customer expectations and priorities in order to deliver meaningful changes in a way that fosters trust and creates a sustainable environment for process improvement.

- Align expectations regarding time, resources, and effort
- Implement robust problem solving and options analysis.
- Keeping system administrators and system users aligned

Christian Berg, *Automation Manager, Manufacturing Execution Systems*
GENENTECH

4:30 INTEGRATING PRINCIPLE SYSTEM WITH MANUFACTURING EXECUTION SYSTEM

- Best approaches for developing system architecture
- Recognizing integration challenges & approaches for overcoming challenges
- Optimizing MES with principle system & corporate challenges faced with integration

Subodh Joshi, *Senior Principle Engineer*
SHIRE

5:15 CLOSING REMARKS & DAY 1 CONCLUSION

PHARMACEUTICAL MANUFACTURING EXECUTION SYSTEMS

DAY TWO | TUESDAY, MAY 23

7:30 REGISTRATION & WELCOME COFFEE

7:50 CHAIRPERSON'S OPENING REMARKS

Baha Korkmaz, *Senior VP, Operations, North America*
ENTERPRISE SYSTEM PARTNERS GLOBAL CORPORATION

8:00 DEPLOYMENT METHODOLOGIES FOR LAUNCHING A SUCCESSFUL MANUFACTURING EXECUTION SYSTEM

- Utilizing the concept of core solution
- Expanding system functionality based on best practice and operational excellence
- Use of standards & EBR deployment for centralized recipes
- Connectivity to DCS/Automation
- Evergreen strategy

Martin Dittmer, *Product Manager,* **ROCKWELL AUTOMATION**

8:45 GROUP DISCUSSION: APPROACHES TO EFFECTIVELY MANAGE MANUFACTURING EXECUTION SYSTEM LIFE CYCLE

- Recognizing the MES's lifespan
- Handling multiple lifecycles in a single MES
  - MES software
  - MES equipment
  - MES vendor tools
- MES lifecycle management costs

SESSION MODERATOR:

Jairus Martin, *Senior Program Analyst,* **BAUSCH + LOMB**

9:30 COFFEE & NETWORKING BREAK

10:00 GROUP DISCUSSION: VALIDATION PROCESS & CRITERIA FOR PHARMACEUTICAL MANUFACTURING EXECUTION SYSTEMS

When implementing and upgrading a MES, manufacturers must validate the overall system itself, in addition to on-going control strategies to meet compliance with authority requirements and prepare for manufacturing facility inspections. To ensure the most appropriate validation of a MES design, it is essential to have a well-defined strategy, based on quality standard operating procedures (SOPs) and further detailed in an approved quality assurance plan (QAP). Understanding the technological complexity of MES increases the need for more rigorous review, testing, and oversight of the MES validation process.

- Considerations & controls necessary for validation & compliance
- Determining standards for testing external systems for potential integration
- Validation of batch records for new manufacturing areas

SESSION MODERATORS:

Denny Catacora, *Senior Engineer, Manufacturing Execution Systems*
CSL BEHRING

Josh Fritz, *Programmer Analyst,* **SHIRE**

11:00 MES PREPARATION IS THE KEY TO SUCCESS

Learn about a proven and mature methodology to develop a conceptual solution architecture designed to meet the business objectives of the pharma/biotech manufacturing business. Our approach involves a strategy development methodology that brings focus and enables superior solution architecture tailored for Manufacturing Systems solutions, S95, and S88 standards. The key benefit of this methodology is effective alignment of business and technology.

- Develop a prioritized capital project planning roadmap to meet business objectives.
- Strategic Technology Management process for MES Applications for IT Enterprise Architecture.
- Discover a holistic visual tool that enables harmony between all departments stakeholders.

Gilad Langer, *Director of Automation & MIS,* **NNE**

WHO SHOULD ATTEND:

Executives that will find this program of greatest relevance are those currently leading the manufacturing arm of pharmaceutical corporations. Job titles of those executives that will find this program to be most applicable to their job functions include:

- Manufacturing Execution Systems/MES
- Manufacturing IT
- Process Engineering
- Automation Engineer
- Validation Engineer

11:45 PANEL DISCUSSION: DETERMINING THE VALUE & NEED FOR CONTINUOUS MES UPGRADES

With the plethora of MES-related software and IT tool upgrades released every month, manufacturing executives are required to determine the need for an upgrade as well as carefully supervise the shift through change control procedures. In theory, operations must not slow down and furthermore, the MES must remain compliant and efficient during the transition period. Manufacturing executives are at times unsure whether to launch an upgrade to a system all while maintaining high production rates of pristine quality or determine if the system can remain in current form.

- Benefits in staying up to date vs. stable in systems versions
- Approaches for effectively managing IT software upgrades
  - Lifecycle of the equipment itself
  - Incentives in changing software versions
- Upgrading legacy systems to new systems
- Cost-benefit analysis for upgrading MES

SESSION MODERATOR:

Martin Dittmer, ROCKWELL AUTOMATION

PANELISTS:

Jerry Gonzalez, BBRAUN

Ivan Cirino, ETHICON

Elton Ramos, SHIRE

12:30 LUNCHEON FOR ALL ATTENDEES, SPEAKERS & SPONSORS

1:45 CASE STUDY: OPERATING A MES ROLLOUT AT MULTIPLE SITES & LOCATIONS

- Identifying unique organizational challenges from site to site
- Standardizing multiple implementations on different platforms
- Simplify operations to be designed & re-used without modifications

Frank O'Loughlin, *MES Subject Matter Expert,* **Formerly with AMGEN**

2:30 PANEL DISCUSSION: BUILDING A SUPPORT MODEL FOR MES LARGE SCALE INVESTMENTS

- Importance of support model design in a 24/7 operating system
- Debating cost-efficiency in MES support models
- Balance between outsourcing & employee workforce
- Analysis of common support model pitfalls & lessons learned

PANELISTS:

Matthew Iwema, ELI LILLY

Christian Berg, GENENTECH

Jerry Gonzalez, B.BRAUN

3:15 MINIMIZING RECIPES REQUIRED FOR MANUFACTURING EXECUTION SYSTEMS

- Defining the value of recipe parameters for different systems
- Utilizing MES system recipes for product variations
- Comprehending the concept around object based recipes
- Managing data to minimize appropriate recipes required

Jordan Croteau, *Senior Engineer I, Execution Systems*
BIOGEN

4:00 CLOSING REMARKS & CONFERENCE CONCLUSION

SPONSORSHIP OPPORTUNITIES:

At this time, there are a variety of sponsorship and exhibition opportunities available for companies wishing to increase their visibility and participation in the program, ranging from keynote speaking opportunities through to exhibitor and documentation sponsors. Organizations most suitable for this type of exposure provide services and solutions including:

- Contract Manufacturing
- Manufacturing Software Validation & Execution Systems
- Scheduling & Resource Allocation, Automated Workflow Solutions
- Quality Management Solutions & Supplier Quality Assurance
- Facilities Management Solutions
- Validation & Batching Software
- Product Testing Services
- Quality Management Software
- Regulatory Compliance Consultants & Experts
- Clean Air Solutions & Sterilization Systems
- Supply Chain Engineering & Integrity, UDI, Track & Trace
- Streamlined Packaging & Labeling Systems