



WORLD AEROSOLS

THE VOICE OF THE AEROSOL INDUSTRY

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GLOBAL AEROSOLS EVENT 2018

Who's who at the FEA event in Düsseldorf

PERSONAL CARE

Is there still a place for aerosols in the industry?



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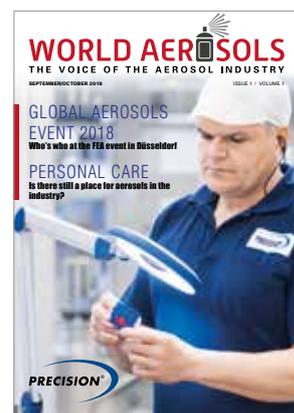
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Global Aerosols Event 2018

Who's who at the FEA event in Düsseldorf



Front cover courtesy of Precision

WINDTREE THERAPEUTICS UNVEILS NEW AEROSOL DELIVERY SYSTEM

▶ After conducting performance testing, clinical-stage biotechnology company Windtree Therapeutics (Windtree) has finalised its new proprietary aerosol delivery system (ADS) for the healthcare industry.

Focusing on the development of aerosolised KL4 surfactant therapies for respiratory diseases, Windtree's new proprietary aerosol delivery system will feature in its lead product candidate, Aerosurf.

Aerosurf, a lucinactant for inhalation, is an innovative drug/device product that utilises proprietary KL4 surfactant and aerosolisation technologies to aid in the treatment of premature infants with respiratory distress syndrome (RDS).

In previous clinical trials, Aerosurf showed how it has the

potential to lower or remove the need for endotracheal intubation and mechanical ventilation in premature infants. The ADS also has the capability to affect the long-term implications of RDS such as bronchopulmonary dysplasia (BPD).

After the prototype experienced filter clogging issues during phase two of the design development, the R&D team sought to overcome this design flaw and increase the product's reliability. After passing performance and stability testing criteria during the third phase of its

development, the company now plans to start its Aerosurf bridge study by analysing ADS in Q4 2018.

Aerosurf's drug/device combination product will use Windtree's proprietary ADS technology and a lyophilised dosage form of the Windtree's KL4 surfactant. Previously approved by the US Food and Drug Administration (FDA), the technology will use a different dosage amount for RDS.

Commenting on completing the design development of the ADS, Craig Fraser, President and Chief Executive Officer, observed: "Multiple phase

2 clinical trials suggest that Aerosurf, when dosed as intended, produces a level of efficacy and safety that gives us confidence in the drug component of Aerosurf."

The company has initiated the transfer of its medical device design and production to Mack Medical, which belongs to FDA-registered Mack Molding.

Larry Weinstein, Vice President, Medical Device Development states that the company now plans to place its focus on "manufacturing readiness and preparation" for its next Aerosurf clinical study.

KPIT MES CAPABILITIES

MES Manages All Elements Of Manufacturing Operations

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Feel free to contact Konstantin.Kirsch@kpit.com for further information around KPIT's capabilities.

KPIT

Applying MES to the aerosol packaging industry

A case study on manufacturing execution systems from KPIT

The classic factory is defined by its manufacturing of goods whose values have been measured primarily by their material components. Today, this is no longer an apt definition thanks to globalisation. This has resulted in production based on long supply chains and complexity which has triggered a paradigm shift in the concept of quality and value for the customer, with a focus on high flexibility, short delivery times, high delivery reliability, many variants, and shorter product life cycles resulting from “adaptive manufacturing”, achieved by “connecting the machines to the markets.” This is the raison d’être of manufacturing execution systems (MES).

Role of MES

The Industrial Internet of Things (IIoT) is the harbinger of the convergence of industrial systems with advanced computing, data analytics, new methods of sensing, and many possibilities of connectivity. However, today a highly, competitive, dynamic and ever-changing manufacturing environment requires operational agility like never before.

Manufacturers must constantly endeavour to strike a balance between production speed to reduce missed delivery penalties, without compromising product safety and quality. This requires rapid response to changing conditions in production activities across the factory and supply chain, making use of manufacturing intelligence, analytics, and control imperative to drive performance improvements to reduce costs, improve quality, and accelerate production with optimised manufacturing performance from the plant floor to the enterprise, to get ahead of the competition.

A study conducted by the Manufacturing Enterprise Solutions Association International (MESA) industry group and the Industry Directions Inc. analyst firm, which encompassed 150 manufacturers, found that there is clear relationship between the use of MES and improvements in business

results. In a number of areas, such as on-time delivery, manufacturing cycle times and labour and inventory costs, companies using MES were significantly more likely than those not using MES to report annual increases in performance.

It is important to understand the challenges that plant managers are facing to offer solutions that encompass all aspects. Here are some of the key issues:

- How accurate and reliable is the actual data feedback from the shop floor (up-times, down-times, yield, scrap, reasons for scrap, utilisation, efficiency, effectiveness, etc.)?
- What is the time lag between the actual occurrence of shop floor data and its recognition in the ERP-system at the management level?
- What is the actual cost of time and effort required to capture all the data manually, process it, and ultimately provide it to the upper management level (ERP-system)?
- What causes delivery time problems, when are we not running at full capacity?

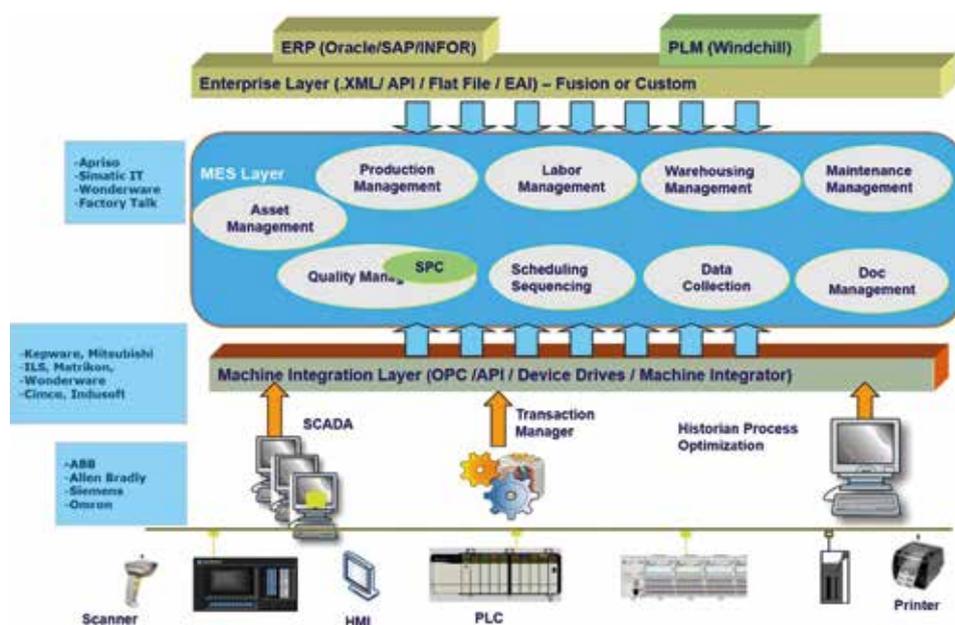
- Why don't our profit margins reflect our production output?
- Where and what are the most common reasons for scrap?
- Where and what are the most common reasons for machine downtimes?
- Where do most common material idle times occur (WIPWork in Process that is not moving)?

KPIT's Case Study: MES Implementation for a Global Leader in Packaging Solutions

This solution features real time machine and business application integration

for a global leader in Packaging Solutions. A global manufacturing and packaging giant with presence across different verticals and multiple geographies wanted a dynamic MES solution that would provide them with real time shop floor visibility as well as reporting and monitoring capabilities, features that were lacking in their current system. The solution had to

be scalable so that it could be rolled out



Typical architecture for shop to top connectivity

across their plants, locally and globally, at a short notice.

Solution:

KPIT acted as strategic partner for implementing the MES solution. This included selecting the MES platform and designing a solution that would meet the following business objectives:

- KPI configuration and monitoring at global and local levels
- Configured high availability
- Alarms for failures to provide accurate
- Real time data Global core model with regional and plant specific configurations
- Centre of Excellence configuration for Global and Local Visibility

Outcome:

- Improved manufacturing efficiency by reducing rework and scrap
- Improved throughput and synchronized production plans
- Flexible manufacturing process with reusable templates
- Systematic and on-demand quality planning and execution
- Sustained continuous quality improvement plan across the enterprise

Modules developed:

Shift Book

The plant uses this module to keep track and maintain an electronic copy of shop floor activities, Manager and operator workplace has been designed to display the current and the last 72 hours of machine and line production count. One can get production count, spoilage and break-down through machine data. End of shift production reporting with OEE per line is generated & circulated via emails. KPI monitoring, central management reporting, logbook reporting, and morning meeting reports etc are also possible.

Maintenance

All plant maintenance activities are carried out using the maintenance module, with work order created for corrective and preventative maintenance. The maintainer can see a precise list of items to be acted daily and their status, can record repair and downtime, entire machine and maintenance history, order workflow, auto-closure and spare part management which is fully integrated with SAP.

Tool handling

All tool room activities are recorded and



Manufacturers must constantly endeavour to strike a balance between production speed to reduce missed delivery penalties, without compromising product safety and quality

managed through this module. This includes the tool lifecycle, from ordering new tools, to tool pack creation, and tool status whether on-machine or off-machine.

Now the tool room can easily handle ring and punch diameter combinations with high precision. The system proposes the tool pack based on potential improved tool change time on machine. Also, one can get pieces produced by each tool.

Shim handling

This module is specifically designed to manage the plant's tooling requirement. It supports and maintains shim life, starting from ordering new tools through to tool pack creation. Tool status, whether on-machine/off-machine, or sent for different operation, is recorded and the entire history is maintained.

Fault catalogue

Faults across various departments are created at a central server, synced up and sent to each plant. This module allows a unique combination of fault code generation, activation & de-activation, maintenance revision etc. This is required for common reporting and various central reporting needs. Faults are used across and by departments such as Maintenance, Production, Quality.

PLC (Machine Integrator)

Machine and equipment raw data is collected, processed for data to action and used for dash boarding and reporting. Near real time data is sent to visualisation, which is a display on a big screen in the plant. The

dashboard also uses this data for reporting and monitoring, Production reporting is done using data collected from the machine.

PDS (Pallet Data System)

This is the core module of APRISO for handling high volume data and information. Labels are printed within one second, and the transaction posted in ERP and third party system simultaneously. Products, BOM, and production order are downloaded from ERP, auto assigned to each workstation: label printing, visual inspection and sorting, pallet scanning, and quality inspection. SAP receives updates and stock information accordingly. Each Pallet production genealogy is maintained, with part pallet and rework supported.

CDS (Coil Data System)

Coils are received from vendors according to purchase order and scheduling agreement, and POs are raised in SAP and downloaded automatically in APRISO, with all steps performed and usage history loading/unloading, inspection and production count updated at each stage of Coil. Complete Coil tracking and weighing information is captured, maintained and synced up with SAP. Automatic month end reporting to SAP that includes Coil status on each machine, Coil usage, scrap and remaining weight which is updated in SAP directly

Conclusion

KPIT has supported a global giant in packaging for the aerosol industry to successfully implement MES and rollout in different geographies seamlessly, not only enhancing the operational efficiency but also helping to enhance the manufacturing process and, reduce cost without compromising safety and quality.

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For more information:

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