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MES Software to Improve Manufacturing Performance...STAY IN THE RACE

Agenda

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- ↔ Cloud Overview
- ↔ Cloud Based MES
- ↔ Benefits
- ↔ Challenges:
 - ↔ Slow Adoption
 - ↔ Security
 - ↔ Data Integrity
 - ↔ Validation
 - ↔ Availability
 - ↔ Integration
- ↔ Shopfloor-Online MES
- ↔ Conclusion

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Cloud Market



- Private Market (Source: Forrester Research):
 - ↔ 2016: \$20B
 - ↔ 2020: \$64B
- Public Market (Source: Forrester Research)
 - ↔ 2016: ~\$60B
 - ↔ 2020: ~\$190B
 - Numbers have entered hypergrowth
- Most successful company:
 - ↔ Salesforce
 - ↔ Multi-tenancy
- salesforce



- - new infrastructure.
 - ✤ 2016: Cloud DB: 6% of cloud market
 - ✤ 2020: Cloud DB: 30% of cloud market



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What does "Cloud MES" Involve?

↔ MES built as a web application

- ✤ No thick client deployment: just use a web browser
 - Browser based application, web server and databases installed on scalable infrastructure and platform

Hosted remotely (not at the plant, but often within the country):

- Third-party Private Cloud Provider Leaders (Source: Gartner):
 - ✤ Amazon Web Services (AWS)
 - ↔ Microsoft (Azure)
- ↔ Single Tenancy:
 - ↔ The MES application manages data associated for 1 client
 - Dedicated (virtual) server space
- ↔ Licensing:
 - Subscription model (recurring expense) SaaS
 - ↔ May include an initial setup fee / commitment

What does "Cloud MES" Involve?

↔ Maintenance:

- ↔ Standardisation of processes
- ↔ All users rely on the same version of the software
- ✤ Software updates, upgrades are handled in the background
- ✤ Scalability:
 - Process is available to scale the application on demand or based on some performance measure (load balancing, traffic management)
 - Elastic computing
 - ✤ Local Site Buffering / queuing for OPC/Data Transfer
- ✤ Platform: robust management tools
 - Scaling, performance monitoring, security, single sign-on, analytics, load balancing

Benefits of Deploying in the Cloud

- ✤ No upfront capital investments
 - ✤ Think: Hardware / Support personnel / Training Support Team
 - ✤ Instant access to server capabilities
 - ✤ Subscription model (SaaS / BPaaS): recurring expense
- ↔ On demand scalability:
 - ↔ On demand ("Elastic") sizing
 - ↔ You only pay for what you need
 - ↔ New users/data: add as the need arises
- ✤ Provides unprecedented agility & flexibility:
 - Section 5 Construction Section 5 Construction Section 5 Construction 5 Constru
 - ↔ Easy to try things out
- ↔ More reliable infrastructure:
 - Proven track record
 - ✤ Fast Solution Delivery bottom line benefit sooner

Benefits of Deploying in the Cloud

- ↔ Better business continuity:
 - Many redundancies built-in to maintain the agreed Service Level Agreement (SLA)
 - ✤ Replication of client data to multiple locations
 - ✤ No on-going maintenance headaches (backups / archives)
 - Suppliers can do that admin in a much more cost effective manner by sharing costs across all their clients
- ✤ Sharing of information across the organization
 - ✤ Anybody can be given access
 - No need to migrate batch records to Document Management System (Archive to long term storage)
- ✤ Faster solution deployment:
 - No upfront IT infrastructure build
 - ↔ Less desire to customize solution
- ↔ Device independence
 - ↔ Particularly with HTML5 support
 - ✤ Still need to configure solution web



Cloud Services





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Challenges Summary



✓ Slow Adoption (until recently)

↔ Security:

- Proprietary data is not deemed to be as secure: third party sites are being hacked (mostly Public Cloud)
- ✤ Data Integrity:
 - ✤ Unclear who my be accessing my data?
 - ↔ Is anybody else owning my data?
 - ↔ Can I get my data back?
- ↔ Validation:
 - ✤ No established guidelines to properly validate software in the cloud
- ↔ Availability:
 - ✤ Infrastructure adds failure points: broadband communication link
 - ✤ Communication bandwidth is not available
 - ↔ Support is not available
- ✤ Integration
 - ↔ How do we connect other solutions / many devices in the plant?

Challenges: Slow Adoption

- Lack of guidance for deploying solutions in the cloud:
 GAMP: Cloud Special Interest Group (SIG)
 Lack of industry "GxP certification" model, similar to ISO
 Pharma market for cloud suppliers is limited
- ✤ Innovation vs compliance:
 - ↔ Compliance is key
 - Technology adoption is second
- Risk averse culture
 Does "different" mean "inferior"?

Why are other industries adopting the cloud faster?

- ↔ "Local control" mindset
 - Resistance towards delegation of responsibilities & control (particularly when it's your data)

Challenges: Security

- Who do you trust more: Amazon cyber security experts or your own experts to create a secure environment?
 - So where is the safest place to store data?
- ✤ Technology is available:
 - ら VPN
 - Second Encryption
 - ↔ Firewalls
 - ✤ SSL (Secure Sockets Layer)
 - Traditional Endpoint Security

Combining: • Tor (Web privacy tool)

- VPN
- Strong encryption Then NSA says: "Virtually impossible to break"

- Breaches are often the result of improper human behaviour (not failing / weak technologies and in the Public Cloud):
 - ↔ Failure to patch / upgrade software
 - Sharing of passwords
 - Accessing unknown sites with viruses
 - Casual approach to connecting devices
 - Inability to detect intrusion in a timely fashion

Mark Zuckerberg's Twitter & Pinterest accounts hacked because he re-used his 'dadada' LinkedIn password!

Challenges: Security





Challenges: Security - Audit Suppliers

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Full Reports under NDA Disclosures



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Challenges: Data Integrity

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- ✤ Data integrity is key focus of FDA audits:
 - Typical: "Company failed to ensure appropriate controls are in place to prevent unauthorised changes to data"
- ✤ Data integrity must be maintained:
 - Data is correct and in context -> relational model
 - Data cannot be falsified -> controlled access
 - Data is available -> backups, archive, restore disaster recovery
 - No loss of data due to availability
- ✤ Data transfer needs to be managed:
 - Can the data be moved across servers or outside current hosting location?
 - Stablish "Data Transfer Agreement"

Application



Infrastructure





- Regulatory requirements still apply with the cloud:
 - Regulated companies are responsible for compliance
 - Applications need to be validated (risk-based approach): V-model, OQ/PQ

- ✤ In outsourced environment...
- ✤ No substitute for robust quality mindset:
 - Supplier defines procedures
 - Supplier demonstrates compliance with them
 - Supplier keeps improving



✤ Risks need to be properly evaluated:

- ✤ Understanding of risks (basis for testing) is more difficult
- ✤ Needs to audit supplier to understand their processes & the risks
 - Define responsibilities for risk management carefully and enforce through solid contracts & SLAs
 - ↔ Who is responsible for application performance?
 - ↔ Who is responsible for security?
 - ✤ Who is responsible for upgrades?
 - What does Service Level Agreement mean?
 - ✤ Who is responsible for what in the event of business failure?
 - How is data segregation ensured?
 - ↔ How supplier access to client data restricted?

GAMP Cloud SIG:

Concept paper that list risks

Key perceived risks areas:

- Security
- Change Control
- Availability / data integrity





↔ IT Environment needs to be qualified:

- Do dynamically allocated resources belong to a pool of prequalified resources?
- What is a pre-qualified resource (disk space, CPUs, web server)?
- ✤ Do I get a certificate for new resources in the pool?
- ↔ Should I test backups / disaster recovery more regularly?



Business

Processes

- ↔ Availability cannot be taken for granted:
 - ✤ Particularly with the increase of major weather events
 - ✓ Needs to have a disaster recovery plan (to maintain data)
 - ↔ But reliability of electronic devices is very good (MTBF)
 - ✤ Local buffering/queuing of interface data in the event of an outage
- Service Level Agreements ("Service Level Agreement", "Quality Agreement", "Master Service Agreement") are key:
 - Incident Management
 - Disaster Recovery (Event Management)
 - ↔ Audit Support
 - ↔ Change Process to upgrade software / notification process
 - Issue investigation Problem Management
 - Key Performance Indicators: incident resolution duration, uptime etc.

Challenges: Integration

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Challenges: What's left on site?

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Introducing Shopfloor-Online MES

Vision Systems ERP Badges/Cards Desktop PC Laptop Tablet Device Gauges Machine Controllers ShopfloorOnline Lifescience Edition SFOL Website UDI PLCs/DCS **IIS Web Server** Local Buffering Devices OPC Client Plant Database RFID 🛑 kepware[.] OPC DA / UA Weigh Scales

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- Central Database per Plant
 - All data in one location (SQL Server or Oracle)
- Web-Based User Interface
 - Access from any network PC / Laptop
 - Browser only no client installation
 - Supports mobile devices with Windows
 Mobile/ Avalanche browser

• Easy Integration

- From process equipment with OPC
- From other systems via Universal Data Interface (UDI) C# scripts
- IT Friendly/ Approved Architecture
 - Server-based or fully Cloud-based
 - Various hardware types; not prescribed
 - Standard Microsoft Platforms
 - Virtualisation (HyperV or VMWare ESX)



Deployment Options

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Example

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Client development:

- Test & Quality environments are in the cloud (Azure)
- Not the Production system (data volume high speed and huge)
- LZ Lifescience offers remote access to its solution:
 - Client is not involved in setting up the SFOL system: DB / Application / OPC
 - Client can be involved in providing/using qualified environment image
 - The system is ready to be configured from a user point of view when it is made available



About Us: Current Projects

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On Demand Integration





- Enables connectivity between cloud applications, & cloud to plant
- Focus: Master data management / Data Modelling Unification
- Needs to share data model



- Develop comprehensive cloud strategy that accounts for:
 - Cost reductions, data integrity, validation, security, availability, scalability, education & training, SLA based on ITIL, auditing, integration, etc.
 - ✤ FDA: understand, assess & mitigate risks
- Be prepared to delegate control & responsibility while maintaining accountability (from regulatory perspective):
 - ↔ Audit suppliers
 - ↔ Establish strong service agreements and ITIL Processes (visible)
 - Test business continuity
- Industry would benefit from a set of guidelines to deploy cloud solutions:
 - ↔ Ex: auditing check lists / best practices
 - ↔ Ex: relevance of certifications to GxP requirements

✓ ISPE GAMP Cloud SIG Concept Papers (July 2016):

- SaaS in a Regulated Environment The impact of multi-tenancy and subcontracting
- Using SaaS in a Regulated Environment A Life Cycle Approach to Risk Management
- Evolution of the Cloud: A Risk- Based Perspective on Leveraging PaaS within a Regulated Life Science Company
- ↔ ISPE GAMP Cloud SIG:
 - ↔ Mike Rutherford (Lilly / USA)
 - ↔ Kathy Gniecko (Roche / Switzerland)
- ↔ Forrester Research
- ↔ Gartner Magic Quadrant
- ✓ Microsoft Security Intelligence Report Data (2016)