ISA FPID International Automation & Control Symposium

IT/Automation for a Bio-Pharma Facility in a Green Field Site March 15th 2016





To discover, develop and deliver innovative medicines...



that help patients prevail over serious diseases.









Realizing the Transformational Potential of I-O



- First to offer melanoma patients the possibility of long-term survival
- Continued strong brand performance



- US approvals in advanced metastatic melanoma and lung
- Additional global regulatory submissions



Our new Biologics Campus @ Cruiserath





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Facility Summary

- Multi-product facility
- @ 400 Staff
- Initially producing Immuno-Oncology medicines
- Concurrent production in future after addition of 2nd purification suite
- Conformance Runs Q3 2018
- Benchmark Schedule, Project Execution and Implementation





Construction Progress







Challenge #1

Complex Automation/IT Landscape required to support delivery of business needs and objectives





Drug Substance Process influences the IT/Automation architecture

- Batches in Bioreactor > 2 weeks.
- 24/7, 365 day operation.
- Living Process need high level of process visibility.
- Notify and respond to issues in real time.



Typical DS Process

- Require robust and resilient IT/Automation architecture.
 - System Architecture Considerations:
 - DCS v PLC
 - Online upgrades
 - Redundant Controllers
 - Data Collection architecture







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Required IT/Automation Application Landscape







Challenge #2

Delivering a complex IT and Automation Landscape to support a benchmark schedule





Scope, Workstreams and Delivery Team

iT ir	frastructure, Application Hosting and Security	
1	IT Infrastructure	
2	Applications Hosting including SAN	
3	AV VC	
4	Copy Print	
5	File Print	
6	Site Services Supt / Help / laptops	
7	Network and Voice	
		🧃 Technical Lead
ME	and Detailed Scheduling	
8	MES	Boc Controller
9	Detailed Scheduling	Project Anager
_		Scheduler O S Programme Manager Management Office
Dat	a Historian, Reporting and Analytics	
10	Data Historian, Notifications	
11	Advanced Data Analytics	Technical Lead
12	Multi-Variate Analysis	Technical Lead
13	Advanced Reporting/Dashboards	Enterprise Building Automation
_		🛁 🖉 🖓 Project Manager 🖓 Applications 🔪 🔪 🖉 Project Manager
Pro	cess Automation	
14	System Integration	System Integrator
15	Control Panels	
16	Hardware and licenses	
17	Call Tracking/Issue Management	😹 Technical Lead
18	Software Management System (PLC/SCADA)	Systems Hardware
Bui	ding Automation, Environmental and Energy	Process of Data Historian,
19	BAS	Analytics
Ma	hufacturing Systems Hardware (I&C)	System Integrator
20	Process Instrumentation	Process Automation
21	Instrument installation	Project Manager 🛛
Lab	aratory Cystoms	MES & Integration Tech Lead
Lap	bratory systems	
22	Chromatography	😹 eBR Author Lead
23	Lab Execution System	MFS & Detailed
24	Data Archival	EBR Authors 🖓 🕵 Project Manager 🖉 Scheduling
25	Lab Information Management System	Renchtop Technical Lead
26	Environmental Monitoring	
E.e.t	avarian A palications	Systems 🖓 💑 Project Manager 😋 💆 Benchtop Engineer
27		
28	EKP Dee Control and Archiving	Delivery Team
29		- -
30		
31	IIN II	
32	Training	
33		
34	Drawing Management	
35		
50	Simplifient temperature monitoring	



System



Scope R&R: Design, Build and Construction

 Clearly assign design, procurement, build and construction responsibilities and reduce number of handoffs. Handoffs add complexity.







OEM Vendor Selection

- Nice to have consistent automation platforms on OEM equipment. However there are a lot of factors to consider:
 - Does it meet process requirements?
 - Is it a standard vendor offering?
 - How many instances of the vendor offering in production?
 - Vendor Support?
 - Integration with MES and data analytics strategy?
 - Platform, Operating system and Hardware lifecycle status?
 - Risk to project schedule?
 - Cost Impact?





Scoring Vendors - KT Analysis Example

- Pre-Qualify suitable vendors early to assess strength and weaknesses.
- Perform detailed vendor analysis and scoring process to select the right vendor.

Weight	Sub- Weight	Metrics
A%		VENDOR
	x%	Track Record in Delivering multiple similiar or larger Fixed Fee Projects
	x%	Vendor Capability Delivering Multi-product batch systems using an ISA88 approach.
	x%	Experience with implementing ProductX based systems
	x%	Experience with implementing Data Historian and Reports
	x%	Strength of the formal vendor relationship with SupplierA for product support
	x%	Ability of the organisation to support the site beyond the LSCC project (Managed services)
	x%	Strength of the formal vendor relationship with SupplierB for product support
	x%	Potential of the Vendor project workload/backlog to impact the LSCC project
B%		PROJECT TEAM
	x%	Technical experience of the proposed DCS Team
	x%	Technical experience of the Proposed Data Historian Team
	x%	Technical experience of the Proposed OEM Management Team
	x%	Technical experience of the Proposed CSV Team
	x%	Technical MES and Process Integration Experience
	x%	Management experience of the Proposed Project Management Team
	x%	Ability to work with the proposed team and organisation
	x%	Ability to understand and successfully leverage SiteA standards
С%		EXECUTION STRATEGY
	x%	Understanding of the project Scope and Requirements
	x%	Strength of the Execution strategy for the project including innovative recommendations
	x%	Alignment between development standards, locations and software version management
	x%	Likelihood of meeting the Project Schedule
	x%	Proximity of the System Integration Team to Cruiserath during design, development and testing
	x%	Mix of long term resources versus 'new hires' to resource the project
	x%	Vendor Local Presence for Commissioning and Operations support including call out
	x%	Dependency and track record with sub-suppliers
	x%	Impact of exceptions to the RFP
D%		PRICING
	x%	Fixed Fee Cost (incl BMS costs)
	x%	Unit Rates for Site Works
	x%	Cost Accuracy Likelihood (potential for change orders)
	x%	Current Vendor Financial Stability
	x%	Compliance with BMS Terms & Conditions





Challenge #3

Ensuring Flawless Execution



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Project Management: Schedule Integration

- On the Project there are 3 main schedulers.
- All schedulers use the same scheduling tool.
- This allow tight integration of schedules.







Project Management: Strong Governance

- Extremely important to have strong governance processes in place.
- Escalation Triggers:
 - Scope change request
 - Issues/risks requiring sponsorship support
 - Project delays
 - Projected budget over-run







Alignment of MES and Automation Design

- Traditionally Automation design starts first and MES follows.
- Align the function design of the Automation and MES systems.
- Agree guiding principles early.
- Conduct lessons learned from other facilities.
- Keep it Simple !







Importance of Process Engineering Input

- Automation Engineers are not Process Engineers.
- Need strong process engineering support to define process descriptions and review automation area functional design.
- Hire Process Engineers and Operations personnel with strong appreciation of Automation and MES systems.
- Process engineers are very busy at the start of the project – P&ID's, HAZOPS, etc. Communicate resource support required to support automation early.



Validation

- Conduct interactive "Design Reviews" prior to FAT Run the process with Operations and Process Engineering. Allows identification of required process changes early.
- Follow a sensible approach to leveraging FAT'd software. Test Functional Design thoroughly at FAT. Cannot emphasis enough the importance of testing phase synchronisation scenarios, especially recovery from hold.

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• Test Functional Design meets the process requirements at site.



Finally, Create the right team environment

- Communicate, Communicate, Communicate
- Create an environment that allows issues to be comfortably raised and resolved
- Be inclusive, open to different viewpoints
- Focus on delivery "Perfection is the enemy of good enough"
- Have fun









