ISPE SINGAPORE VIRTUAL HACKATHON 2020

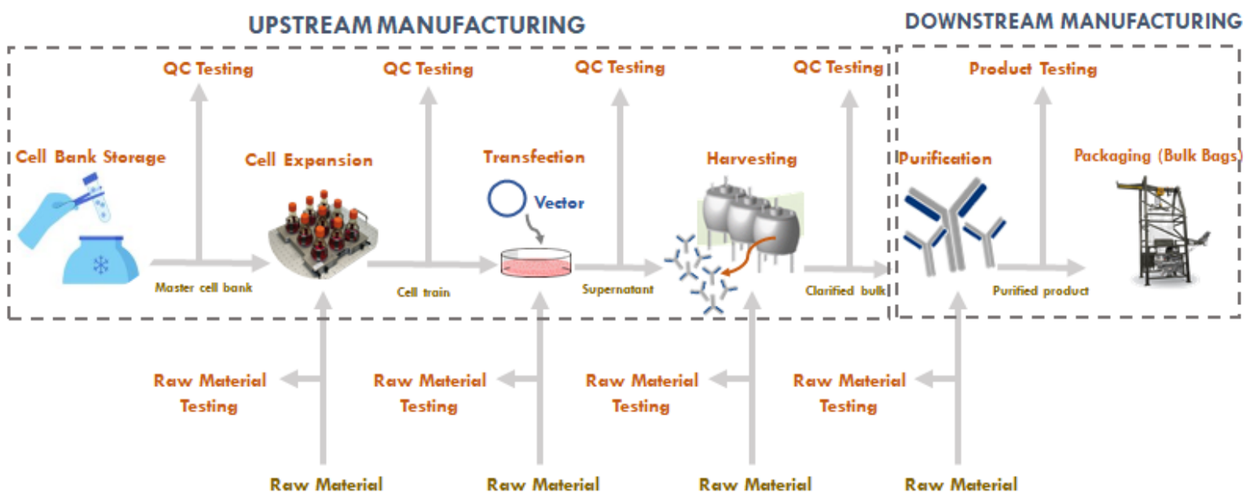
DIGITALIZATION OF PRODUCTION PROCESS AND PHARMA 4.0

BY ALDRIAN JERRIKO, FORTUNA OKTAVILINA, MONEEM AHMED, NAWAT KAWKEEREE, YEO SHAO JIE, SITI AISYAH

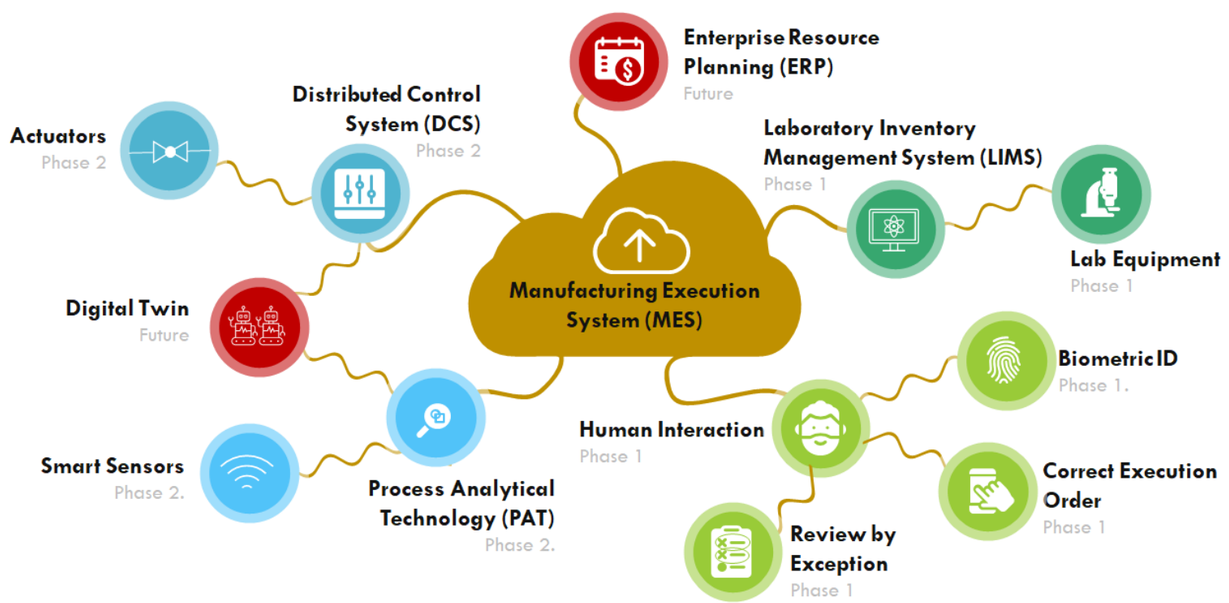
INTRODUCTION

The team was tasked to carry the role of cGMP consultant to help a company identify the weakness in the quality system. CAPA and FMEA analyses were used to identify risks and dangers of the current paper-based system.

Furthermore, the team also proposed long term solutions for a modern data acquisition system. The business case and project plan was built for the company to transition into Pharma 4.0 at a reasonable time frame and affordable cost.



Manufacturing process flow for the production of mAb



Cloud Based MES acts as a platform to enable Pharma 4.0

CAPA ANALYSIS

A. Corrective Action

Data Verification

Conduct Internal Audit

B. Preventive Action

Computer Based System
Data record, Audit trail, data retention

User Administration
Limited access for authorised user

Automation
Automated data processing and reporting

FMEA ANALYSIS

A. Failure

Possibility of tampering the data due to presence of human interaction

B. Effect

Affect product's quality if no mistakes are alerted

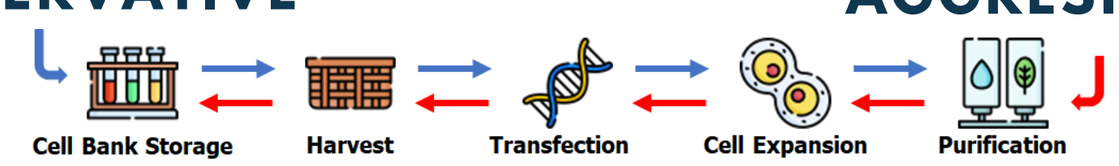
C. Countermeasure

Plant manager is to develop a new business plan by transiting into Pharma 4.0

CONSERVATIVE

Piloting starts from the simplest unit

AGGRESIVE

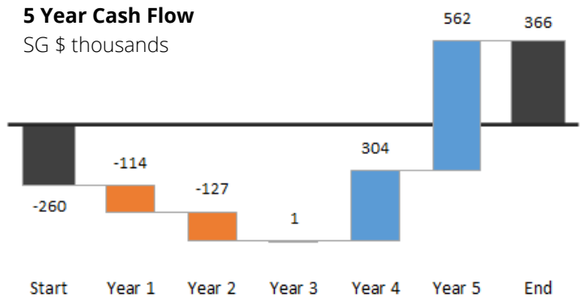


Piloting starts from the most critical unit

Cost: $1.4M
Benefit: $1.8M
NPV: $89k

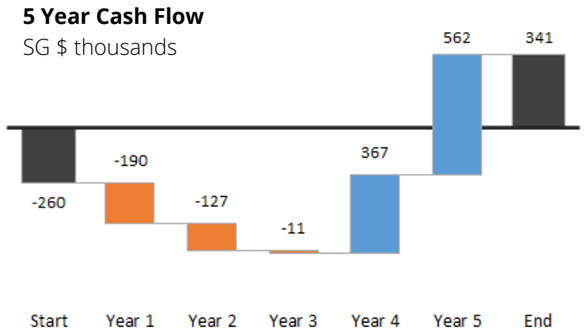
go

RECOMMENDED



Benefits

- *Lower Cost of Pilot*
- *Less Disruptive*
- *Lesser Time to Implement and to See Positive Cash Flow*



Benefits

- *Greater Cost of Quality Savings*
- *Higher ROI*
- *Faster Positive Impact on Product Quality*

Cost: $1.4M
Benefit: $1.8M
NPV: $53k

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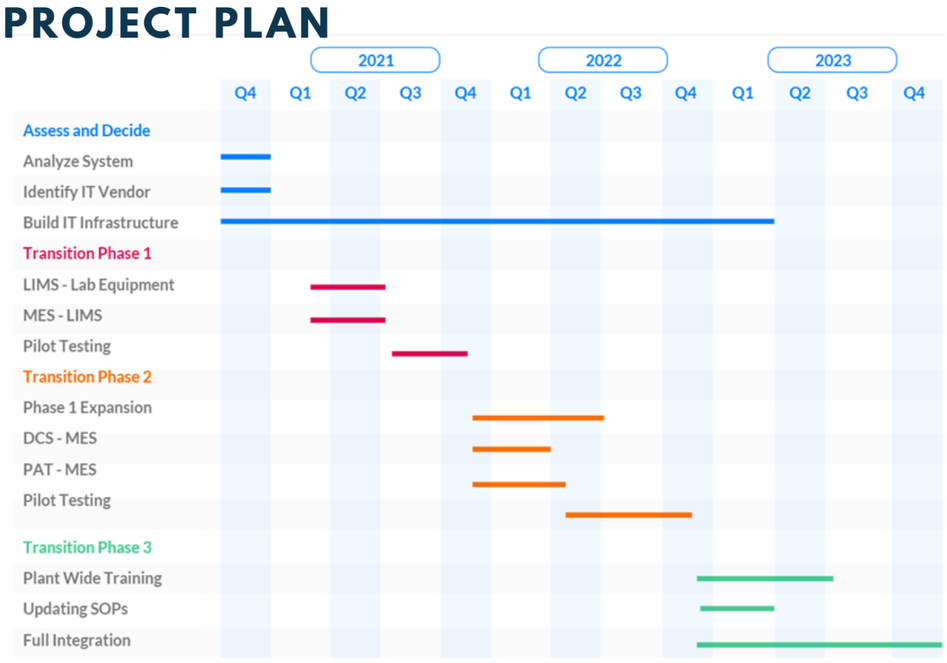
PROJECT PLAN



PHASE 1 TRANSITION

Integrating lab equipments to LIMS

- *For automated collection of data*
- *Help to maintain accurate and timely reporting*

Integrating LIMS to MES

- *Enables efficient and relevant data transfer from LIMS to other departments*

Conducting pilot test to a single production unit

PHASE 2 TRANSITION

Integrating MES to DCS and PAT

- *For automated process control*
- *Provide up to date analytical and preventive maintenance*

Easy to Use · Smart Workflows · Technology & Integration · Easy to Configure & Support

PHASE 3 TRANSITION

- Incorporating old system with computerised system
- Tools for measuring raw data into computerised system
  - *Integration of system with in-line testing for live updates*
- SOPs converted to procedural enforcement operations for new system, to eliminate errors, omissions and rework
- Plant wide training of labour to use computerised system
  - *Use of pilot system to train*

SWOT ANALYSIS

STRENGTH	WEAKNESS
Scalable Increase yield Increase safety	High upfront cost Time for integration
OPPORTUNITY	**THREATS**
Data lake for integrated IIOT devices	Risk of cyber attack

4.0

ISPE Singapore Affiliate