



International Society of Automation
Delhi Section

Setting the Standard for Automation™

Pharma 4.0

By-Jacobs Solutions India(Gurgaon)-Automation

ISA-D: “Fertiliser , Food and Pharma Symposium-2023”

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Jacobs Overview

Jacobs

Challenging today.
Reinventing tomorrow.



Our values



Our values are the fundamental tenets shared across our organization and the standards we hold ourselves to.

We do things right.

We always act with integrity — taking responsibility for our work, caring for our people and staying focused on safety and sustainability. We make investments in our clients, people and communities, so we can grow together.

We challenge the accepted.

We know that to create a better future, we must ask the difficult questions. We always stay curious and are not afraid to try new things.

We aim higher.

We do not settle — always looking beyond to raise the bar and deliver with excellence. We are committed to our clients by bringing innovative solutions that lead to profitable growth and shared success.

We live inclusion.

We put people at the heart of our business. We have an unparalleled focus on inclusion with a diverse team of visionaries, thinkers and doers. We embrace all perspectives, collaborating to make a positive impact.

Jacobs at Glance

Solutions for a More Connected, Sustainable World

- A **premier global** consulting, design, engineering, construction, operations and maintenance firm **providing innovative solutions** for a more connected, sustainable world
- Serving industrial, commercial, and government clients **across multiple markets**

\$15B

ANNUAL REVENUE

40+

COUNTRIES

60K+

TALENT FORCE

400

OFFICES



We have a #1 position in...

ISPE Facility of the Year Awards



2021

Biocon,
India

2020

Sanofi , US
BMS, Ireland

2019

Pfizer, China



- Pure Designers
- Manufacturing
- Hazardous Waste
- Aerospace manufacturing
- Electronic assembly
- Industrial process
- Government offices
- Airports
- Marine & port facilities
- Site assessment & compliance
- Towers & antennae
- Water & wastewater
- Clean air compliance
- International markets



- Engineering/ Architecture
- CM Agent
- Industrial Facilities
- Data Centers
- Office Sector
- Science & Technology
- BIM
- Design-Build



#1 America's Most Admired Companies
(Engineering & Construction)

Business Sectors



Life Sciences

- Biotech Facilities
- Blood Fractionation
- API
- OSD
- Sterile Fill Finish
- Cell & Gene Therapy



Micro Electronics

- Semi-Conductors
- Display Fab.
- Wafers
- PV Solar Cells Mfg.
- Microelectronic Labs



Specialized Manufacturing

- Paints
- Pulp & Paper
- Specialty Chemicals
- Tyres
- FMCG
- Food and Beverages



Data Centers

- Hyperscale
- Co-locator
- Enterprise



Electrical Vehicles

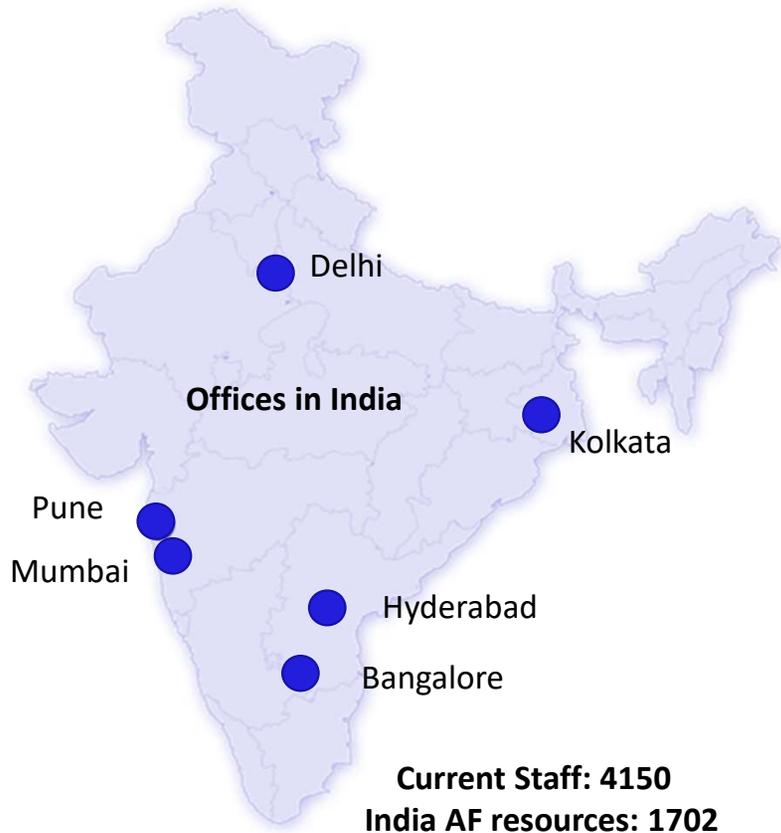
- Two Wheelers
- Four Wheelers
- Chemical for Batteries
- Batteries



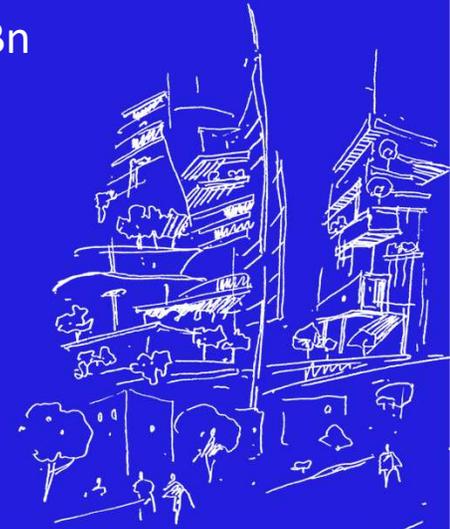
Power & Energy

- Green Ammonia
- Green Hydrogen
- Electrolysers

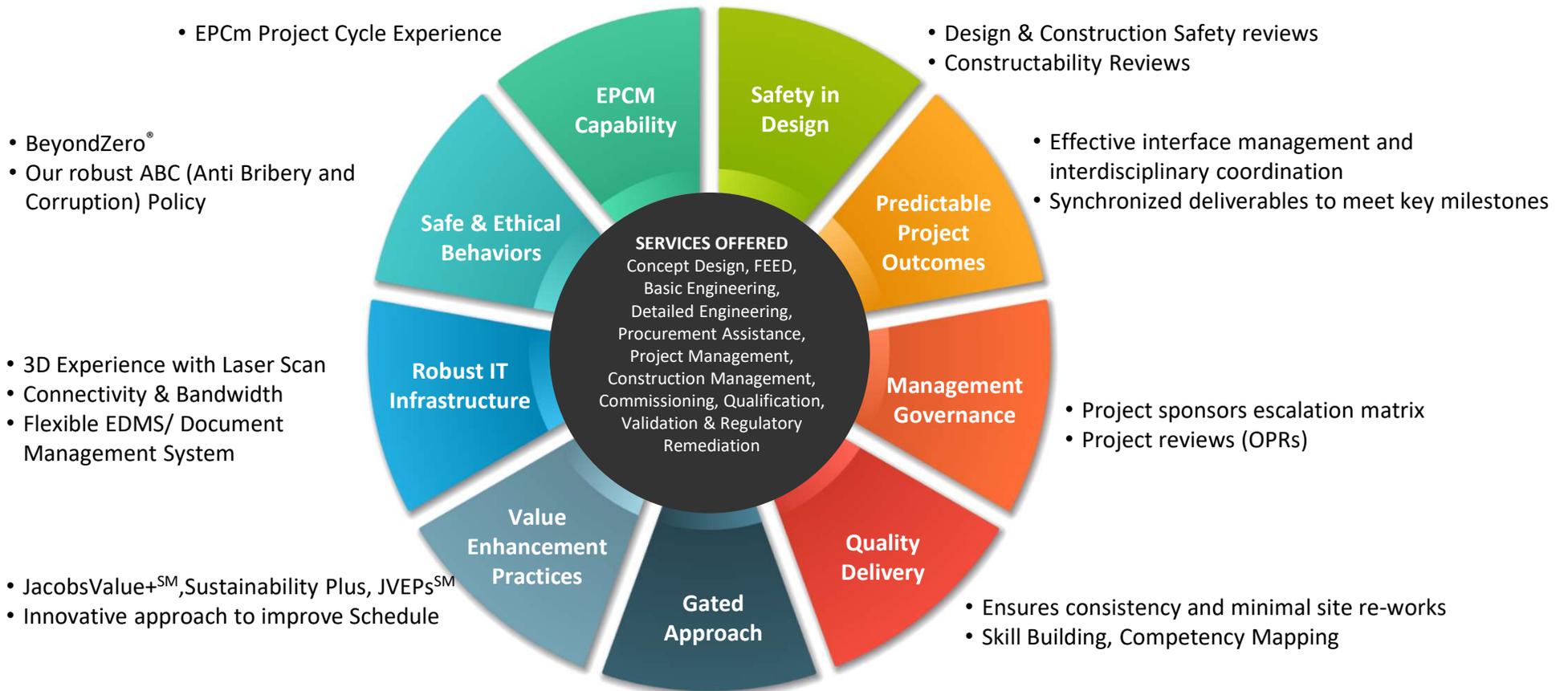
India People & Places Solutions Overview



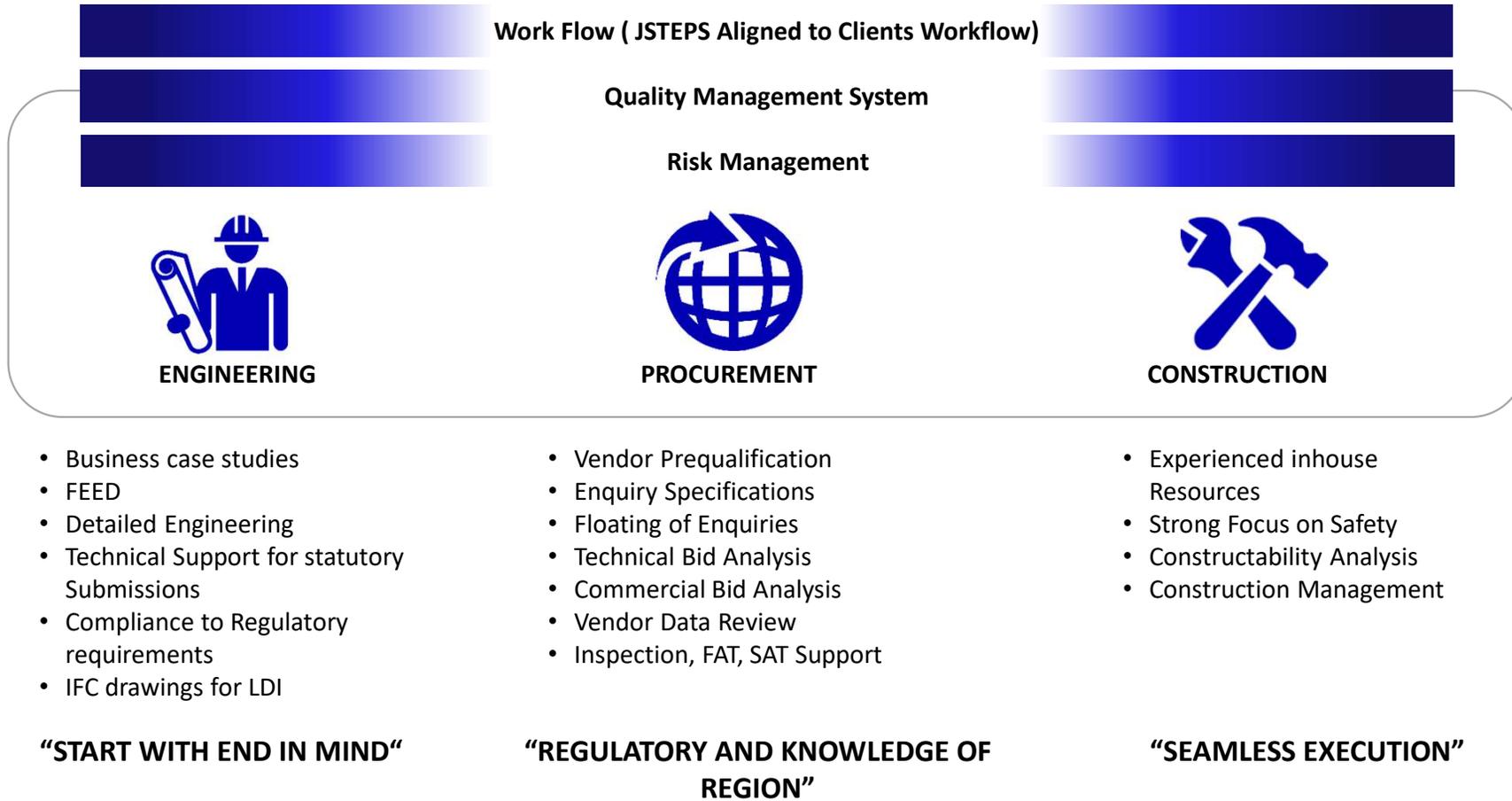
- Established in 1962 – Legacy H&G
- Jacobs One – Local delivery on Global Standards
- Full project delivery - Concept to Commissioning
- Size Matters – Flexibility to ramp up
- Projects in India & abroad Up to \$1.5 Bn and Small cap alliances.



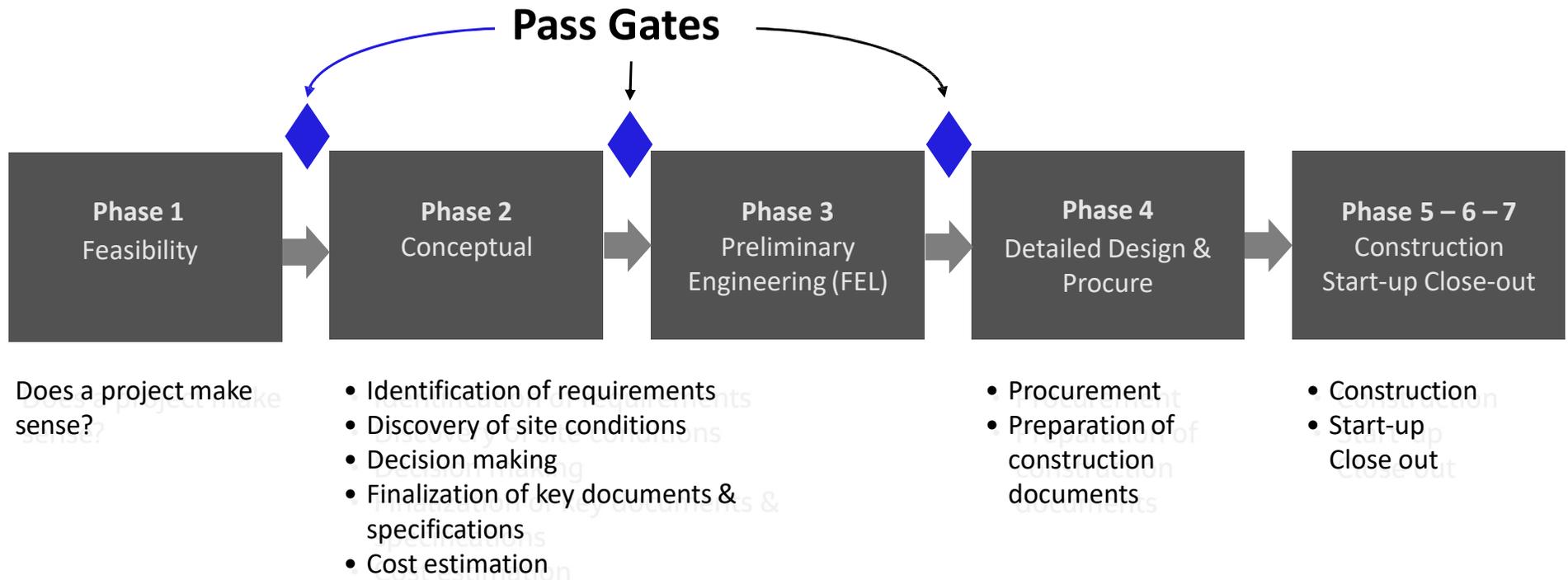
Project Life – Cycle Involvements



Execution Model - Predictable Outcomes



Stage Gate Process – JSTEPS®



Differentiators

High Performance Team

- World Class SMEs
- Local Design delivery experience
- Experience of Global projects in pharma
- Flexible and modular design concept
- Focus on Safe, Operable, maintainable, Constructible and sustainable facility
- Focus on Client's Expectation

Beyond If

- Challenging today Reinventing tomorrow
- Creative solutions
- Novel Solutions to complex problems
- New Technologies to reduce Capex and Opex
- CFD analysis
- Process simulations



Beyond Excellence

- Rigorous quality procedures and checks
- Design verification plan
- Design safety plan
- Project execution and communication producers
- 3D routine clash check mechanism
- Independent design reviews
- Inter discipline squad checks
- Constructability Review



Beyond Zero

- Culture of safety
- SbD - Safe by design
- DSP – Design Safety Plan
- HAZOP, HAZID, HASAP, SIL, HAC, LOPA.
- Relief valve calculations
- Layers of protection analysis



Our Best Benefit – Value Plus, Predictable Outcome, Less Risk

Differentiators

Optimization

Schedule

- **InterActive Planning (IAP):** An interactive platform where we list critical deliverables, ensure buy-in from each stake-holder and agree on a realistic schedule for project delivery



Project Information Systems



- JPI is a Project collaboration and electronic document management system (EDMS)
- **Bluebeam Vu** (Multi location document review platform)
- BIM 360Degree (Cloud based 3D modeling software)

Cost

- **Cost**
 - Our vast geographic experience
 - Our domain expertise
 - Our large database of similar recent project

JacobsValue+SM



- Tool to generate value-added/ cost saving ideas and innovations that can be applied to improve Return on Investment (RoI), Schedule or Safety.

Validated By: <i>AK A.L. Pannu</i>	Date: 17/10/11
Formal Estimated Value: 150,000 US\$	
Schedule Improvement:	
<input checked="" type="checkbox"/> Proceed	
<input type="checkbox"/> Do Not Proceed	
Comments:	
Note: - Client certification for cost saving may please be find in sl no-2.3.4 of MOM dt.17 th Oct-2011 minuted during MRM at site. For ready reference copy of MOM is enclosed.	
Jacobs Construction Manager: Santosh Kumar	Date: 17.10.2011
Jacobs Project Manager: K. Deshpande	Date: 17.10.2011
Client Project Manager: R.B. Singh — <i>M.S. 17/10/2011</i>	Date: 17.10.2011

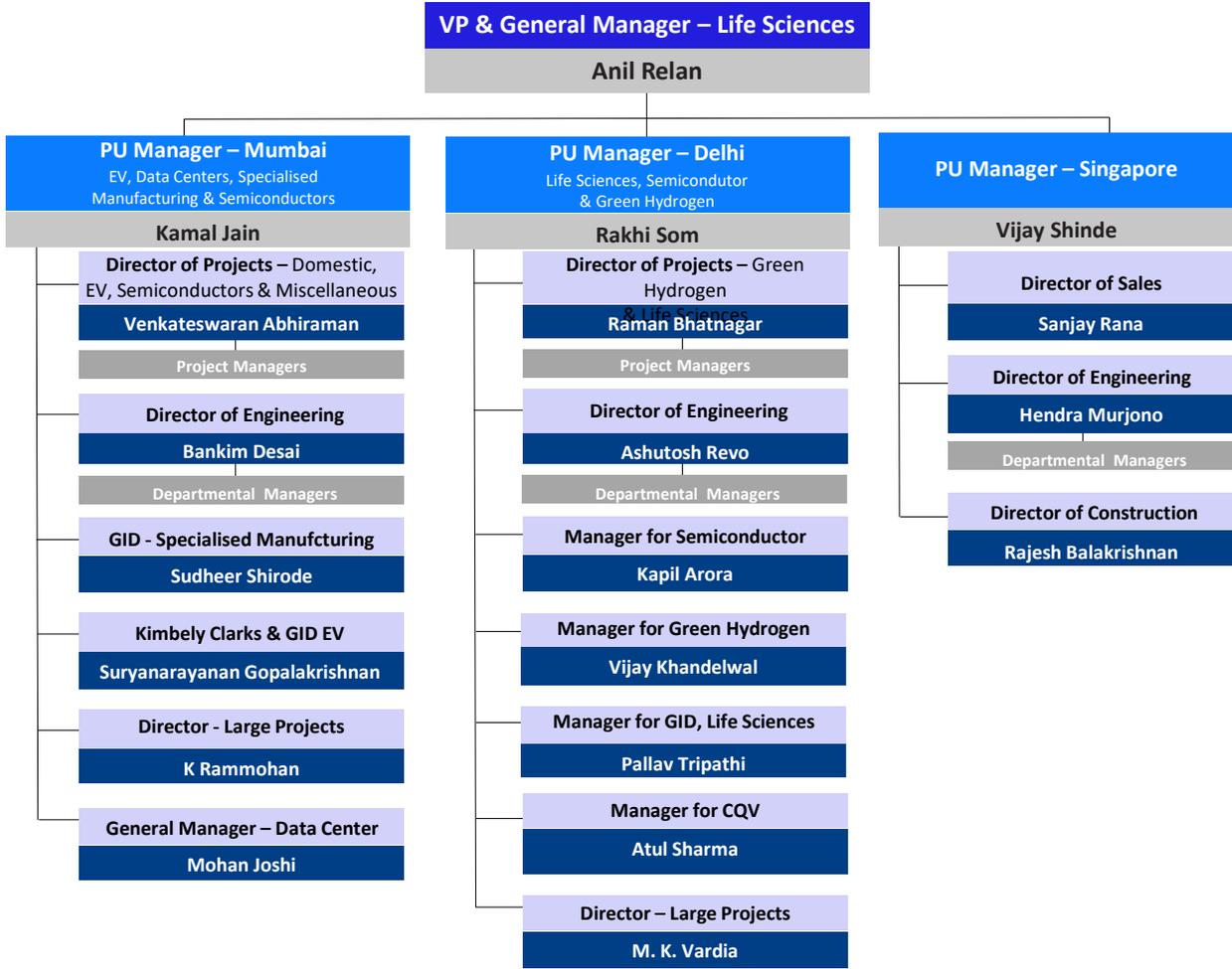
\$ 100 Mn

Savings by Jacobs India over past 5 years

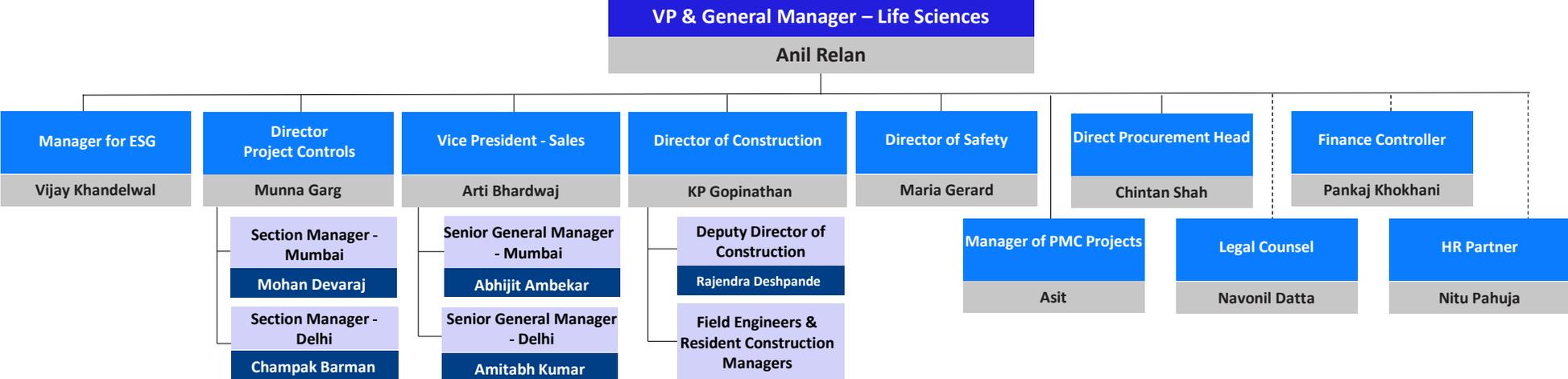
\$ 3.25 / hr

Average savings to Client

AF APAC - Organizational Chart



AF APAC - Organizational Chart



Pharma Customer List

- Pfizer
- MSD
- GSK
- Dr. Reddy's
- Biocon
- Mylan
- Sanofi
- Novo Nordisk
- Abbvie
- Ferring
- Cadila
-Almost all major pharma worldwide



Pharma Plant- Unique-Code, Standards & Requirements

Control System

Electronic Signatures and Records:

US-FDA-21CFR Part-11 (For Products to US markets)

EU-Annexure-11 (For Products to European Union)

WHO Annexure-1 : India

Piping/Material

Standard: ASME-BPE

Surface Finishes: Requirements to prevent microbial growth (Ra=Roughness Index)

Piping Connections: Clamp types for easy removal and Cleaning

Slopes – for cleanability and drain-ability

Architecture and Man material movement

Stainless Steel Clean room wall and Ceilings.

Architecture design to prevent cross contamination and gowning requirements (unidirectional movement of man and goods)

Qualification and System handover

Strict Qualification Procedure and recordkeeping

Installation Qualification(IQ): Drawings and BOQ

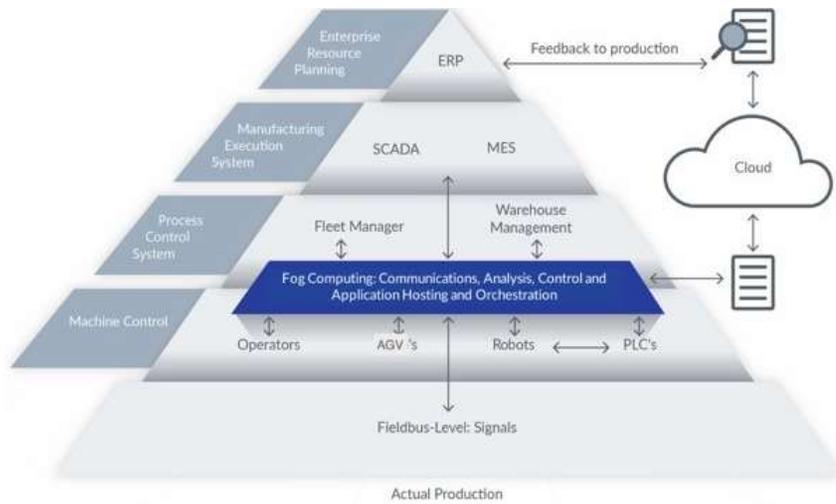
Operation Qualification(OQ): Logic and Sequence

Performance Qualification(PQ): Robustness, deviation and Repeatability

Plant can only run when PQ is handed over.

Qualification must for all-Controls, Piping, Operation

14.0 = Connected Automation from Shop floor to Enterprise



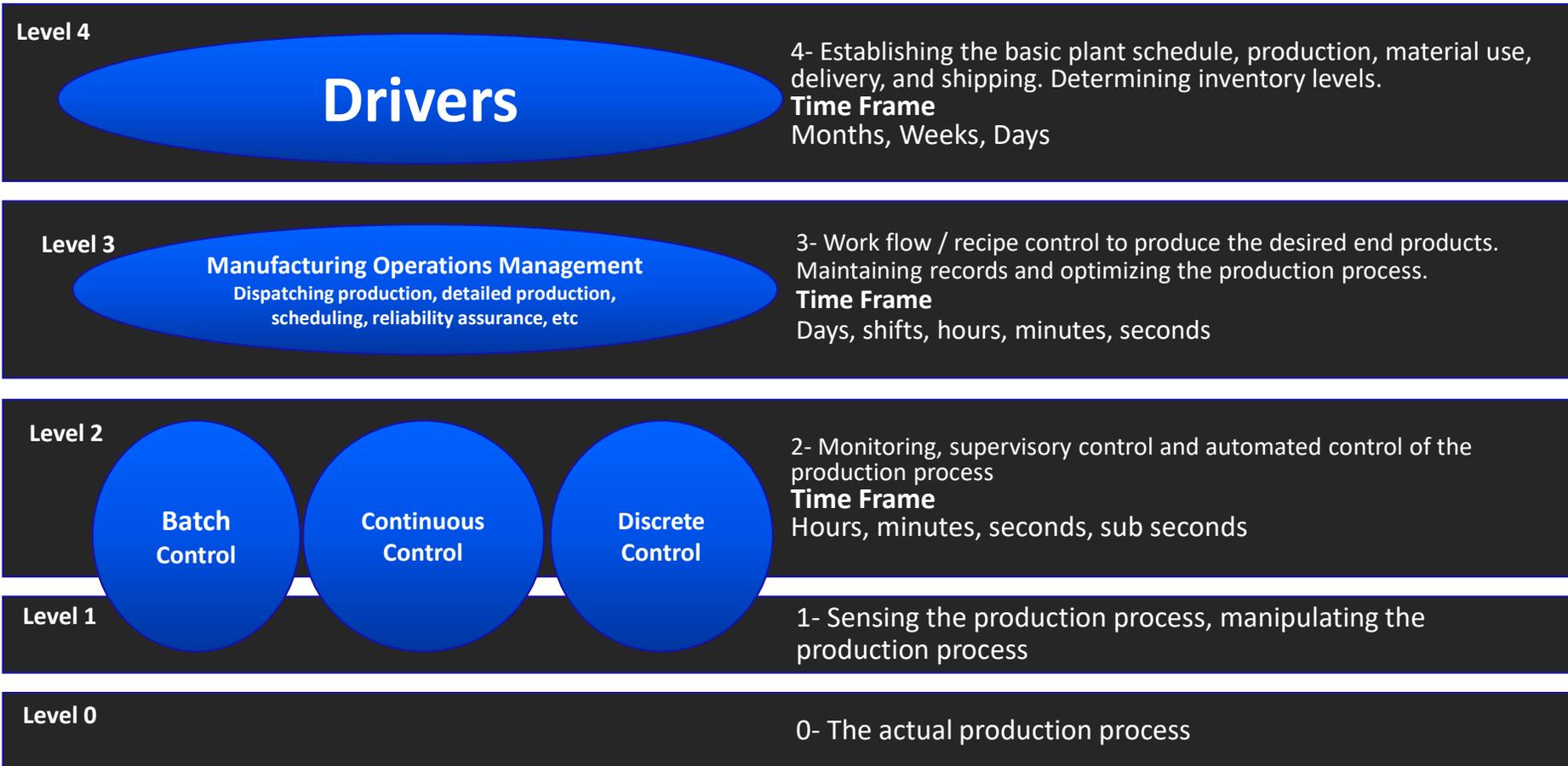
Digitalization - Refers to the integration of digital technologies and data-driven processes into various aspects of the manufacturing and process industries.

It involves technologies like Internet of Things (IoT), Artificial intelligence (AI), Big data analytics, Cloud computing and automation to transform traditional industrial processes into more efficient, flexible, and connected systems.

Industry 4.0 represents a new phase in the industrial revolution, where digital technologies play a central role in optimizing and enhancing industrial operations.



ISA 95.00.01 Manufacturing Operations and Control Functional Hierarchy



Jacobs Capability Statement

Jacobs Challenging today. Reinventing tomorrow.

Jacobs Digital Factory; your problem solving, insight building, data and development team.



Data is, and will continue to grow to be, an indispensable resource for companies. Without the expertise of **data scientists** who know how to tease actionable insights out big data, or **software developers** to automate, build, and optimise interfaces, benefits may be unrealised.



We love what we do...

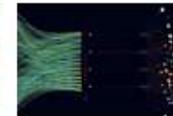
...but more importantly we are obsessed with improving things, solving hard problems and making a real impact. We are a data science and development community empowering Jacobs to deliver world class solutions in a changing and evolving data led world.

We have advanced skills in statistics, math and computer science, data visualisation, data mining, geospatial analysis, website design and build, cloud computing and information management – to name a few! We **build** software, algorithms and processes, we **run** and support the ongoing delivery of solutions and we **optimise**, enhance and evolve the customer led solution alongside sector and technology advancements.



Digital passion

We are passionate about **digital culture**, using agile ways of working to quickly scale and customise products based on **our** clients' needs. We embrace lean start-up to focus on customer first, innovating products from ideation, alpha, beta to live; delivering the highest quality to solve our clients' problems.



Turn data into decisions

Our **data scientists** and **geospatial specialists** are detectives, storytellers, and **magicians** all-in-one. We interrogate data to understand cause and effect, understanding what has happened before and how to predict the future. We bring data to life to help a client improve efficiency, streamline a process, increase revenue streams and understand where to invest.



Developing solutions

Our team of experienced **software developers** create end to end software solutions for clients. Our experience encompasses scalable enterprise applications, through to agile innovation at pace in new product development. We design, architect, automate, scale, host and govern platforms to turn the most complex challenges into opportunities.

What we can do for you



Create ingenious, relevant and competitive solutions



Make the complex easier to understand



Achieve time and cost savings through automation



Design, develop and build applications and web experiences



Manage Cloud, hosting and platform design



Deliver data monetisation

Jacobs Challenging today. Reinventing tomorrow.

Level-1&2 Control Systems in Pharma

Type of Plant	Active Pharma Ingredient (API)	Biotech Upstream and Downstream	Fill and Finish	Oral Solid Dosage(OSD)
Description	API plant process are characterized by usage of large number of reactors, heat exchangers, condensers, Vent control, handling hazardous solvents. These plants are majorly batch operated.	Plant process are characterized by usage of Bioreactors in upward scaling, Media, Buffer, Harvest vessels and specialized equipment such as chromatographs, Filtration skids.	Plant process are characterized by usage of Formulation vessels, specialized Filling machines, Water for Injection(WIP) systems. These plants mainly have vendor skids for process control.	Plant process are characterized by usage of Formulation vessels, Fluid bed dryers, milling, sieving, Tablet pressing machines. All these are specialized machines. These plants mainly have vendor skids for process control.
Preferred Control System	DCS-Plant operation SIS-Plant safety	DCS-Plant operation & Skid integration. Validated system	DCS-Mainly for Vendor Skid integration and centralized monitoring and Reporting. Validated System	Further important factor is Biotech, Fill-Finish and OSD plants are Clean in place(CIP)Systems and Clean utilities Generation and distribution. These Process are handled in strict environmental control inside Clean rooms maintained by specialized Air handling units(HVAC) . These plants process and products are validated through international regulations such as WHO, US-FDA, EU and are mandatory auditable .
	BMS-For HVAC and Black utilities	EMS-For Clean room Area monitoring-Validated System Clean Utilities SCADA-Validated System		

Current State in Most of the Companies:

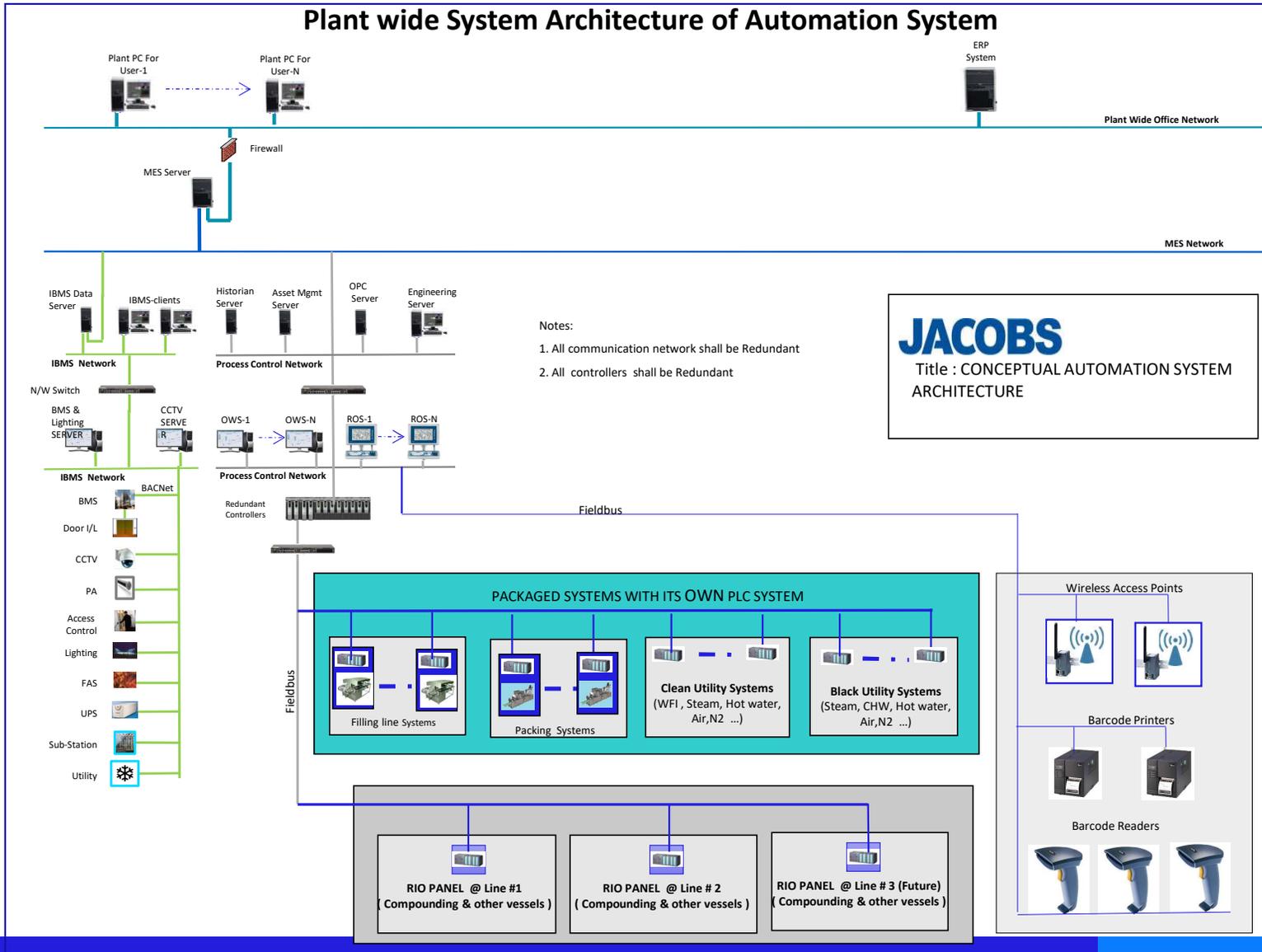
1. Combination of manual and auto batch report in PCS system, leading to paper trails, time lost in analysing, errors in manual entries, inconsistency in final products
2. MES understanding and partial implementation
3. Understanding of Pharma 4.0

What Are The Challenges of Pharma 4.0 ?

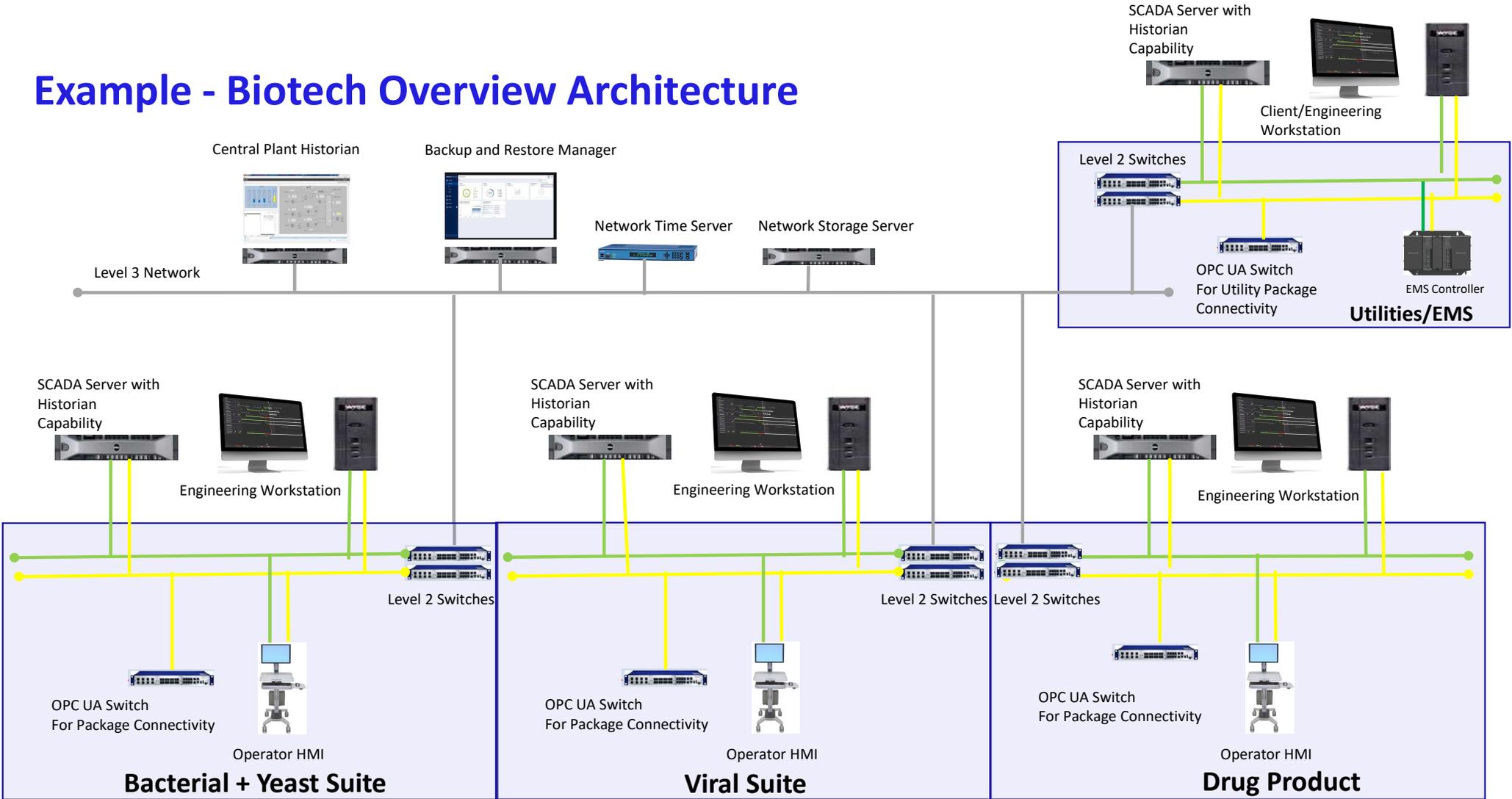
- Integration of data from disparate sources in order to enable industry 4.0
- Transformation of data into information from multiple data structures
- Lack of clear business case that justifies investment in the underlying IT architecture
- System Integrators with Industry 4.0 & ICH Guideline skills
- Difficulty in coordinating actions across different organisational units

Control System Architectures-- Examples

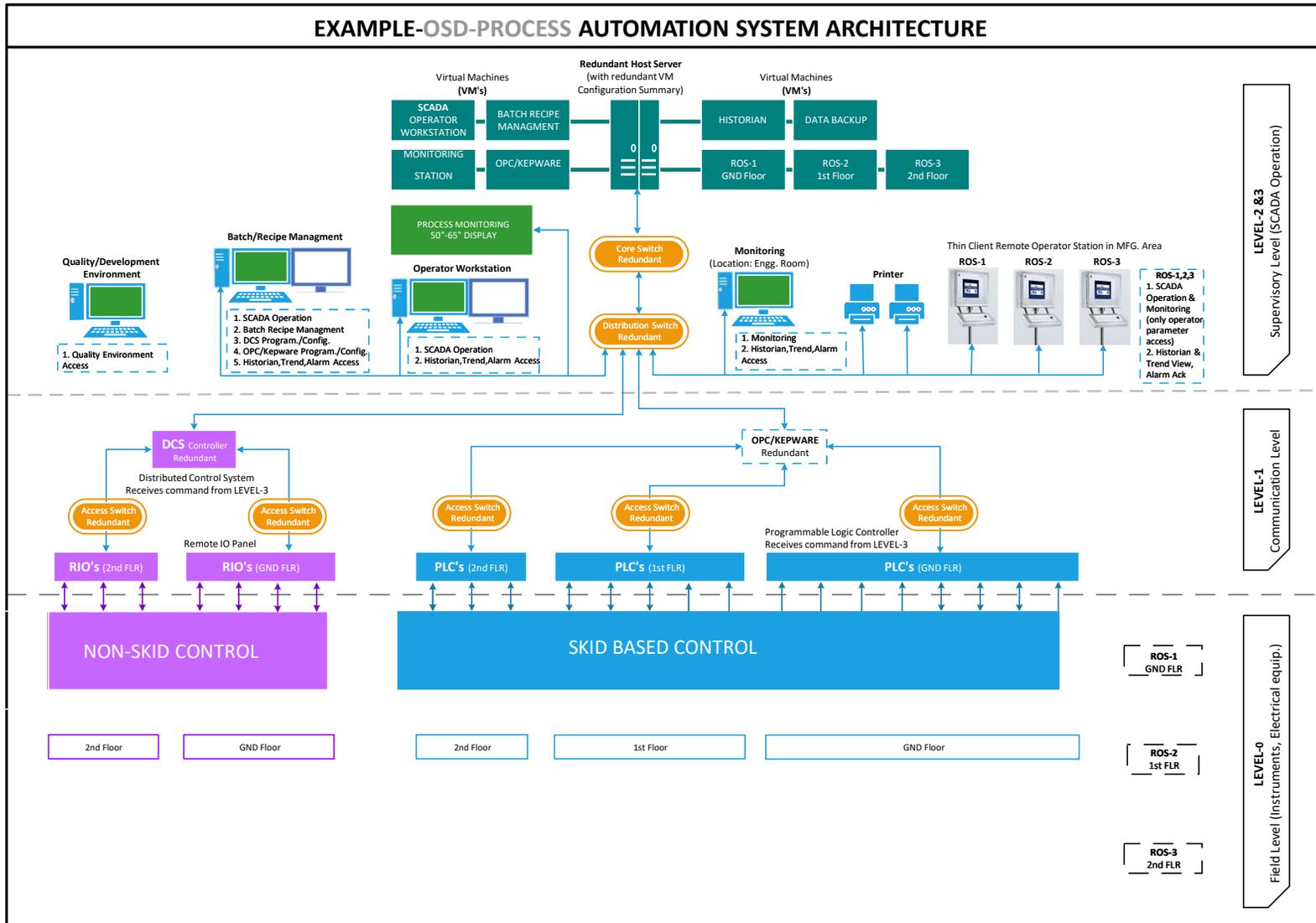
Plant wide System Architecture of Automation System



Example - Biotech Overview Architecture



EXAMPLE-OSD-PROCESS AUTOMATION SYSTEM ARCHITECTURE



Automation Technologies: Level-0 to 4

Automation technologies for Level 0

- SMART sensors
- Wireless sensors
- Robots/robotic arms
- Machine monitoring(Vibration analysis)
- Analyzers Smart
- Final control elements, mainly valves
- Fieldbus technologies
 - FF
 - Profibus
 - Asi etc
 - PSVBs
 - FF JBs

Automation technologies for Level 1

- Control Systems
 - DCS
 - PLC
 - SCADA
- Fieldbus technologies
 - FF
 - Profibus
 - Asi etc
 - Ethernet
- Thin Clients(Virtualization)
- Control systems on Open communication protocols such as OPC, MQTT for seamless parallel and upward integration

Automation Concepts for Level 2

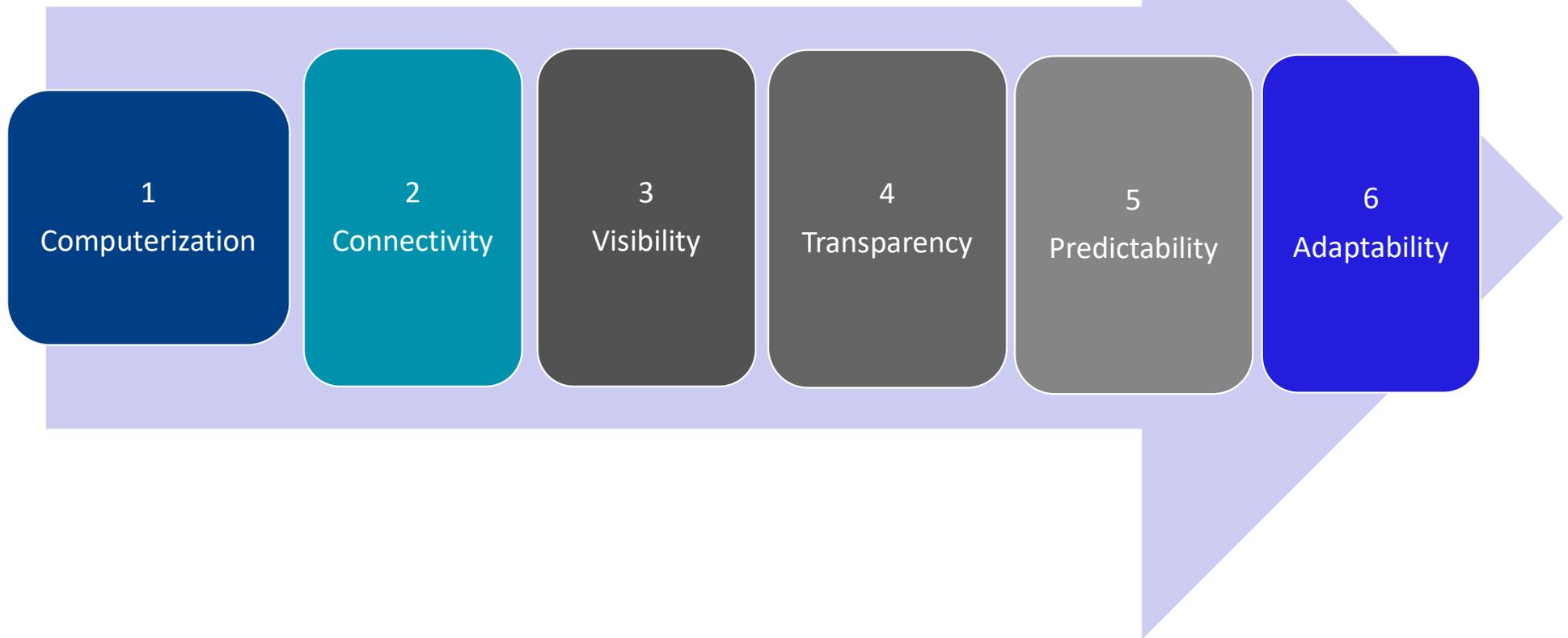
- Server Virtualization
- Thin Clients concept
- Asset management systems
- Historians
- Batch servers

Automation technologies Level 3 and 4

- MES
 - **Pharma-based MES solutions** optimize the pharma supply chain by lowering manufacturing costs and increasing efficiency. This is achieved through capabilities like comprehensive data monitoring, whereby recipe management and electronic batch processing occur in real time.
 - **Benefits MES solutions offer pharma companies:**
 - Real-time data accessibility
 - Improved operating efficiency
 - Faster lead times for materials
 - Equipment and material suitability checks
 - Right first time (RFT) manufacturing
 - Training verification
 - Improved compliance

Pharma 4.0

Digital Maturity Stages



Digitalization

- The global economy has experienced numerous industrial revolutions that have fundamentally changed the way business is conducted.
- Today, we are in the midst of a 4th industrial revolution: a digital revolution that seeks to integrate physical systems to cyber networks, unlocking the insight and power inherent in the “connectedness” of the resulting systems.
- With each industrial revolution, market leaders faced a choice: to embrace the revolution and be a disrupter in their industry or ignore the revolution and wait to be disrupted. Jacobs embraced it, to deliver new kinds of solutions that better solve our clients’ most difficult problems.



Digitalization

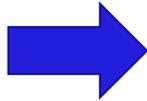
- Increased efficiency and productivity
- Data Driven Insights
- Operational Excellence
- Asset optimization
- Predictive Maintenance
- Flexibility and customization
- Supply chain optimization
- Remote monitoring and control
- Cost Reduction
- Innovations and new Business Models
- Environmental Sustainability



Pharma-4.0 Simple Implementation Example

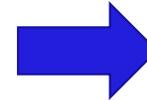
Smart Plan Goal Setting-What we want to achieve

- Energy Optimization
- Process Optimization
- Asset Optimization
- Overall Plant Visualization and Enterprise control
- Man less and paperless facility



Smart Plant

- Smart Sensors that can provide data over IIOT network/cloud
- Servers on Virtualization :
 - Virtualization is the process of running a virtual instance of a computer system in a layer abstracted from the actual hardware.
 - In absence of real hardware incorporating various plant servers such as Engineering, OPC, Historian, Asset management can greatly reduce the time, efforts and cost required for Future upgradation
- Process Control systems on open communication protocols such as OPC/ MQTT for seamless upward and parallel integration between different Vendors and Supervisory systems



Future Proof IT-OT network

- Internet Speed and Bandwidth is the backbone to achieve industry 4.0 requirement and seamless real time data integration across all platform.
- The enterprise network and hardware should be aligned for future bandwidth and speeds.
- Close integration of IT and OT systems for maximum reliability. Dedicated Data Center shall be required for Process Automation Servers and Networks with backup from a second Data Center at an alternate location for disaster recovery. All the Network cabling shall redundant.
- Client IT and network philosophy shall support OT reliability and recovery requirement

Jacobs Approach: Digital Master Plan.....

A Digitalization project is an interactive process.

An effective Digital Master Plan requires coordinated and increasing maturity in adopting digital technologies across four domains: resources, organization, culture and information systems.

Companies must mature across all domains to realize the benefits promised in digitalization.

Jacobs facilitate interactive workshop sessions to define your **Operational Capabilities Visioning**. [Jacobs established a class of plant tool in the 1990's which has been enhanced and modernized to reflect the latest ISPE Pharma 4.0 concepts against a rich set of benchmark data gained through hundreds of applications.]

We will define the desired end-state for the Factory of the Future environment that enables accomplishing your overall business strategy ("what **core activities and value chains** can be improved through digital tools and new ways of working?" and "what actions does the company need to take to fully benefit from digitalization in its business operations and functions?")

The team then develops the **Digitalization Solution Strategy**.

- Identify the required technology solutions to achieve your operational capabilities
- Assess the technology gap between the your "As-Is infrastructure" standard and the required or To Be

architecture and infrastructure to close capability/cultural gaps

- Determine the workflow gaps that restrict adopting digitalization workflows
- Introduction strategies to migrate from computer supported to digital operations

Jacobs Approach: Digital Master Plan.....

Main activities to achieve this step will be technical investigation, market survey, pros & cons analysis to identify the set of suitable solutions to cope with the desired innovation target.

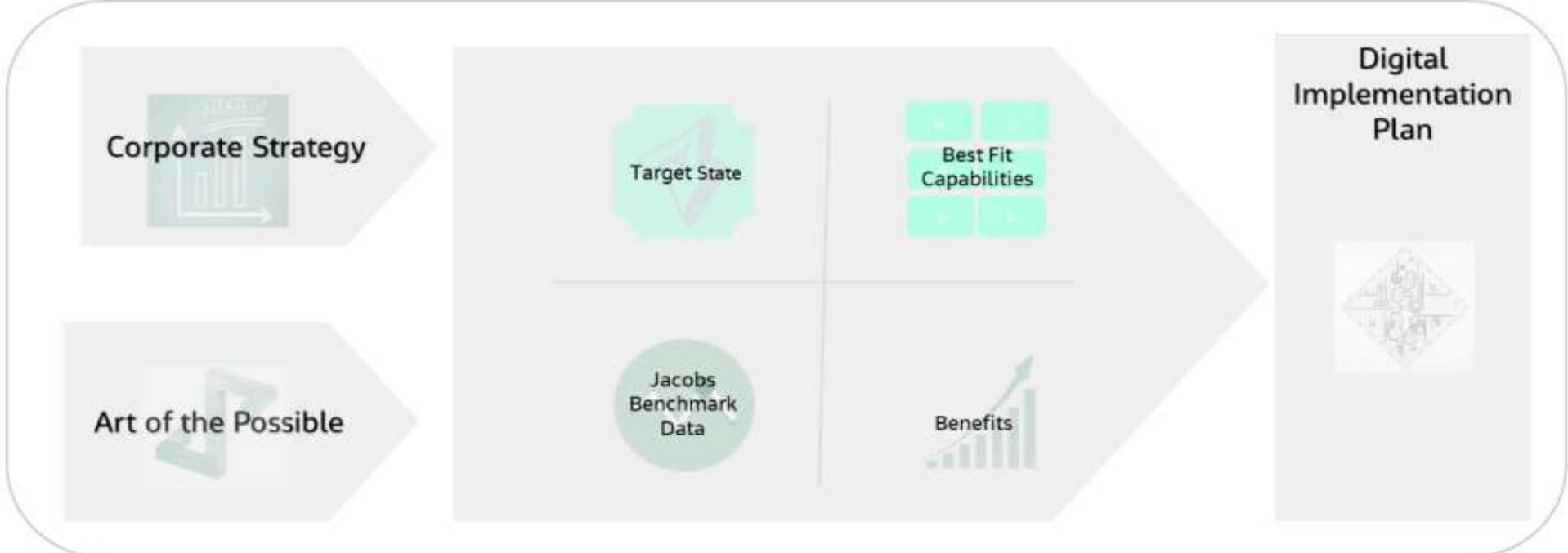
The Digital Master Planning is the Technology Blueprint for the comprehensive adoption of digital work strategies. This will include developing a prioritized (organization, cultural, processes, and technology) blueprint for building the new infrastructure that combines IT and OT frameworks.

The Final step is the Technology Roadmap Development. This will include developing a prioritized (people, processes, and technology) Roadmap.

The roadmap will take into account project execution constraints, will focus on enabling technologies, which shall be deployed across the facility with the right phasing,

It will take advantage from synergy among different solutions, will take care about change management, consider the needed resources and skills to successfully pace across the roadmap.

Our Approach: Digital Master Plan



Finally, we will have a Digital Strategy and Roadmap that will ensure that all the data collected from the OT (e.g., PLC, DCS, MES) and the IT systems is consolidated and transformed into asset intelligence to support effective decision making so that objectives are achieved in a manner consistent with the planned digital transformation/ digitalization strategy.

Jacobs Approach: Digital Master Plan: Case Study



Jacobs has developed and deployed artificial intelligence to predict equipment failure. Through combination of conventional sensors, maintenance data, health sensors and synthetic data the model predicted the future failure of equipment.



Jacobs combined operational data from several sources such as personnel flows, process area heat maps, and thermal imaging for early identification that operations were deviating from normal and assisted with identifying the root cause that allowed a return to normal operations.



Predictive Analytics (PA) is the process of using current and extensive objective, empirical and quantitative data to predict future need and guide project investment and design decisions.



Discrete event simulation tools create a digital representation of all the work that occurs within and around a facility and are used to review and rank order hundreds of design alternatives to maximize the entire solution space.



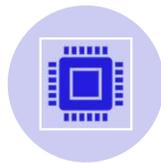
The simulation includes data relating to physical space, materials management and transport systems, equipment, IT and communication technologies, staffing models, scheduling and arrivals protocols, and every step of every process related to production.



ROBOT and COBOT



ROBOT and COBOT. Jacobs has provided throughput and logistics consultation expertise to a myriad of clients for complex decision making. Jacobs has supported automation endeavors for companies such as



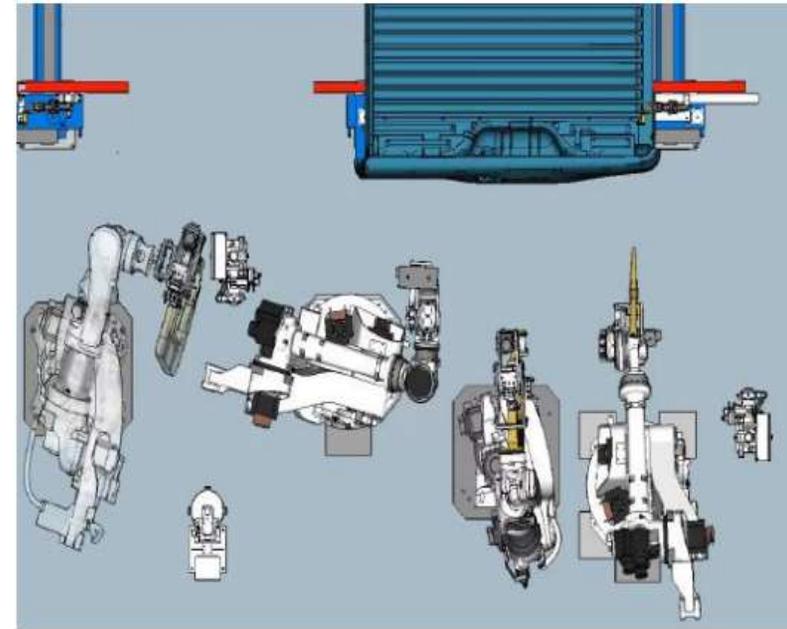
Throughput simulation enables virtual analysis of a system



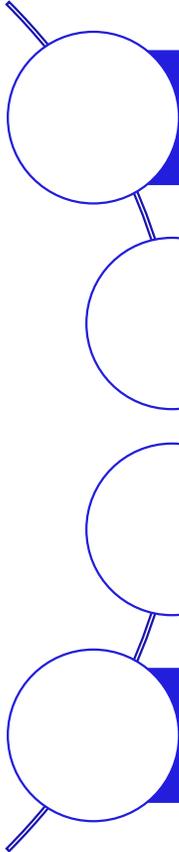
Throughput analyses are useful independently, but most effective in collaboration with site selection and project operations as a full-service solution.



Evaluate responsiveness to vulnerabilities and interruptions, considering Workforce skill, environmental risks, layout restrictions, resource constraints



ROBOT and COBOT.....



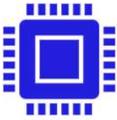
Quantify sensitivity to variability, changes, and failures (including machine failures, supply chain disruptions, labor interruptions, surge limitations)

Material Handling (Robots and AGVs), Dispensing/Sealing, Scanning, Stamping, Robot Vision and Cobots. Jacobs supported the first-gen Tesla Model 3 Underbody Mainline which consisted of 50+ robots with rivet guns working in tandem with 50+ material handling and spot-welding robots

Jacobs being contacted to assist in bringing large-scale, ambitious projects to life is our support for a Gigafactory in Texas. Jacobs was tasked with the concurrent assembly facility and assembly system design to optimize the facility. The goal was to optimize the facility in order to enable the design of a “smart” complex that ultimately will encompass 22 million square feet.

Jacobs AMS also boasts a very rare capability in our knowledge of programming vision robotics. Vision is currently only used in specific applications, but it is becoming more prevalent as customers realize the benefits of robots being able to see and analyze for themselves.

Digital Twins



Digital Twins or Digital Replicas are sophisticated models that run in parallel with the actual system being modeled. The difference being the degree of integration between the actual and the model.

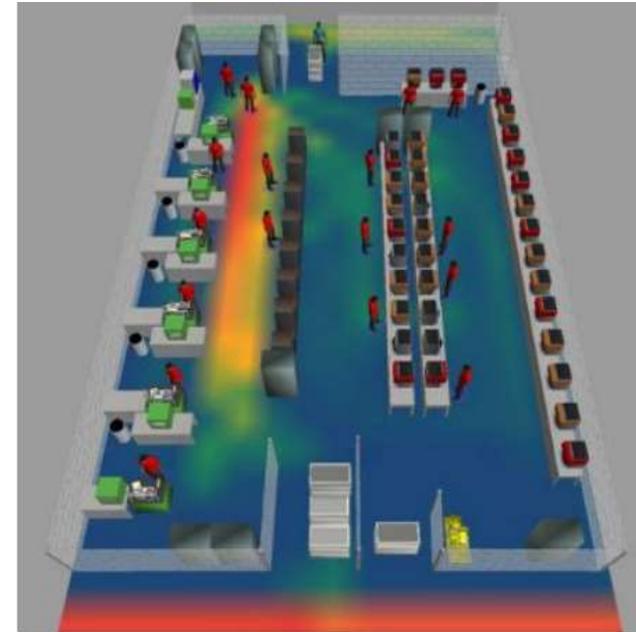


The system can be anything from a single phase of one operation, such as the growth phase in a bioreactor or the loading step in chromatography column, or it may be vastly greater such as the entire supply chain providing a key raw material. The benefits of a digital twin implementation are correspondingly varied and can contribute meaningfully both financially and to productivity. Some examples:

Real time monitoring and parallel simulation of a bioreactor. Take corrective action (manually or automated) to bring back an errant batch. Or perhaps end the batch early to avoid unnecessary processing, wasted materials and get started on a good batch sooner.

Use process data to optimize equipment performance or indicate preventive maintenance. Replace resin in a chromatography column. Change depth filters only when needed.

Predict, and avoid, conflicts with shared equipment increasing overall productivity.



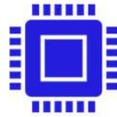
Digital Twins: Benefits



Optimize staffing. Redirect staff to respond quickly when and where needed or escalate less critical tasks when the workload is predicted to be low.



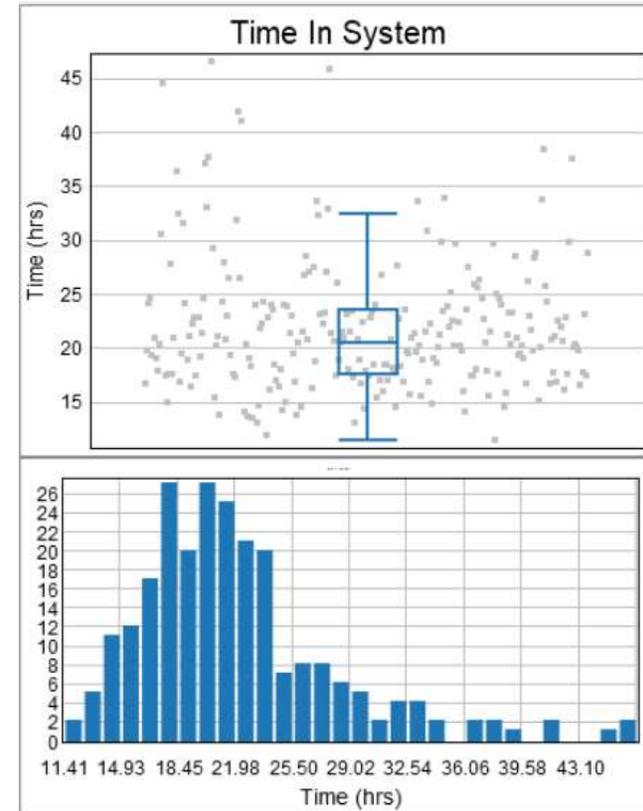
With more knowledge of the supply chain, enabled by an appropriate digital twin, production planning can be improved. Inventories of raw materials and supplies can be safely reduced. In many cases, these inventories are kept high to respond to unexpected disruptions in the supply chain.



As the disruptive events become less frequent and more predictable, the inventories can be safely reduced, allow a leaner manufacturing process. This saves operating costs while lowering risk. The space which would otherwise be used for raw materials and WIP can be repurposed to be more productive.



Jacobs teamed with our partner network and developed advanced network detection to support cyber security. Using neural networks and advanced machine learning Jacobs developed an advanced warning detection of abnormal and suspicious network traffic on client networks.



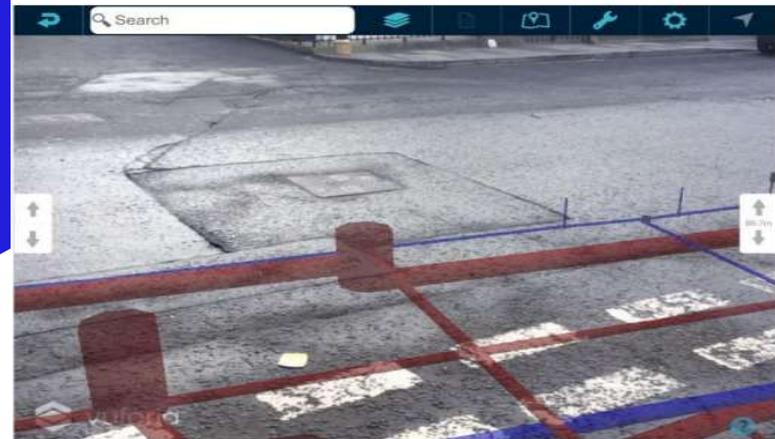
Augmented Reality and Virtual Reality

Augmented reality and virtual reality helps to improve the training efficiency in a safer environment, to guide users in operations and maintenance, to visualize buried infrastructure.

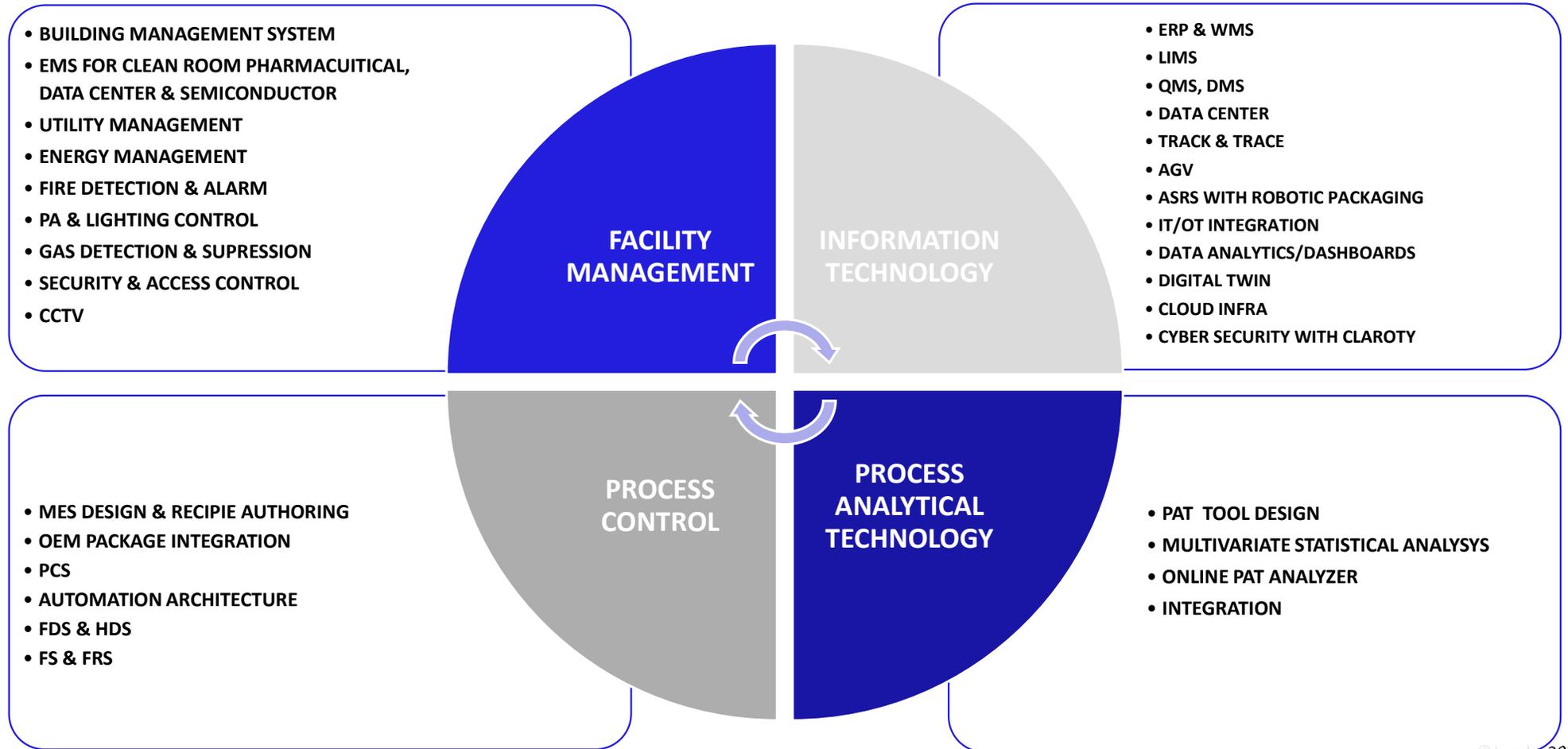
Recently Jacobs conducted a contractor bid walk through utilizing virtual model. This was enabled by the development of a common data environment that brought design, supplier, and architecture models together. Allowed contractors to visualize the client desires and end goals prior to bidding.

AugView app on tablets/phones helps to "see" buried pipelines in the field. The app is loaded with the GIS map for the utility network and uses its own antennae to locate and orient the user's perspective in the system.

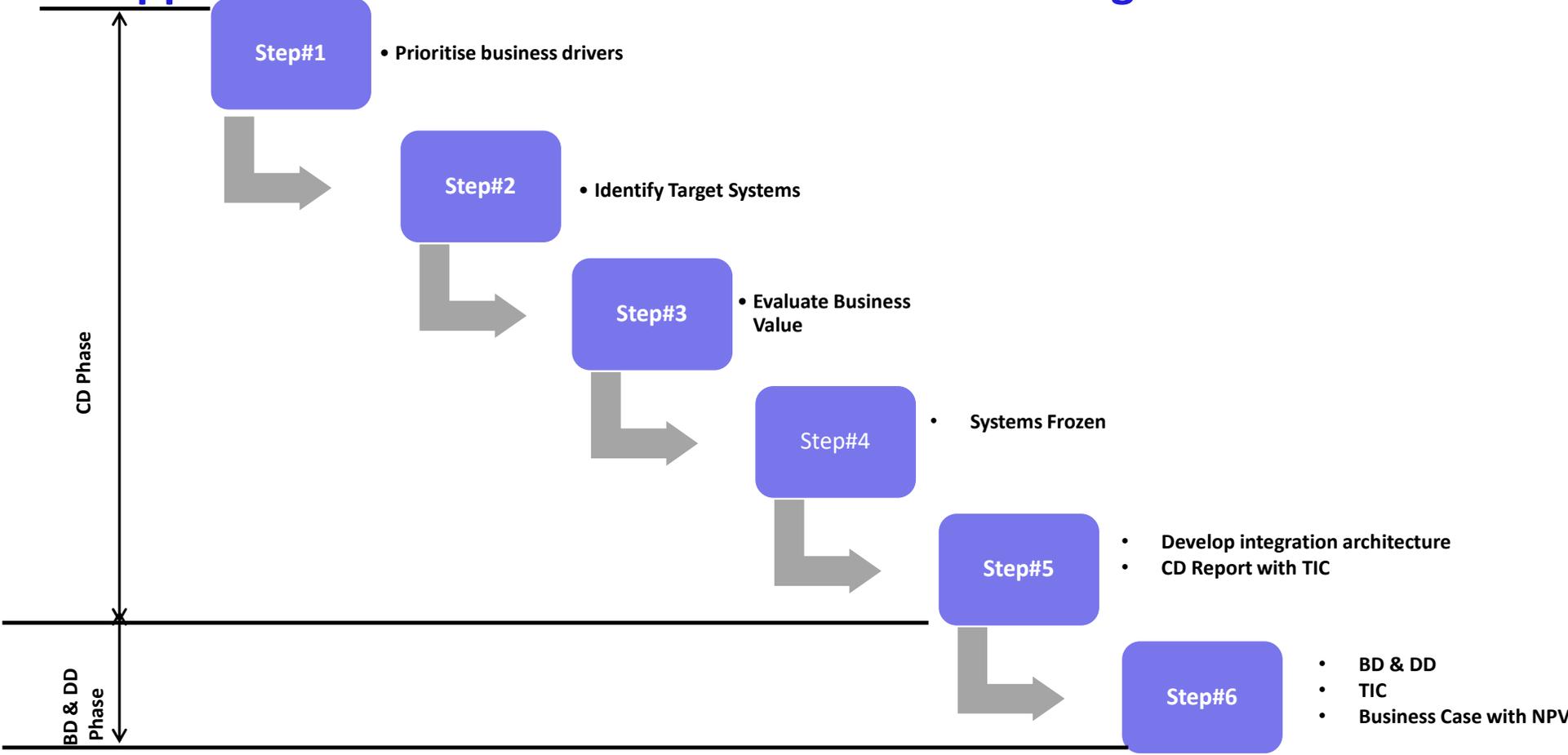
Wearable technology offers multiple methods of improving the relationship between people and machines. Jacobs has adopted wearables to establish a contact tracing and social distance monitoring application that has been deployed on both construction sites and pharmaceutical operations



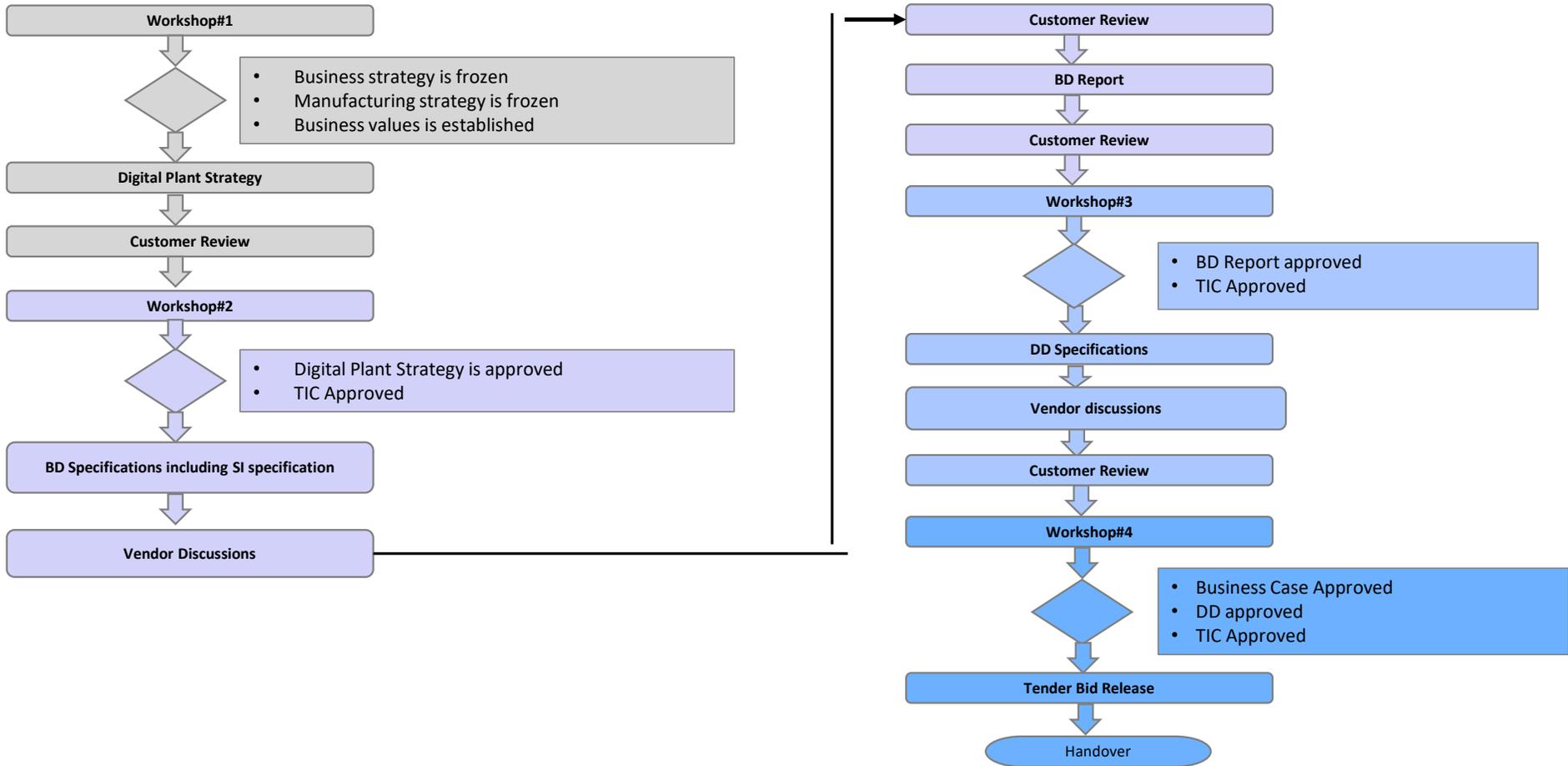
Integrated Automation Solution by JACOBS



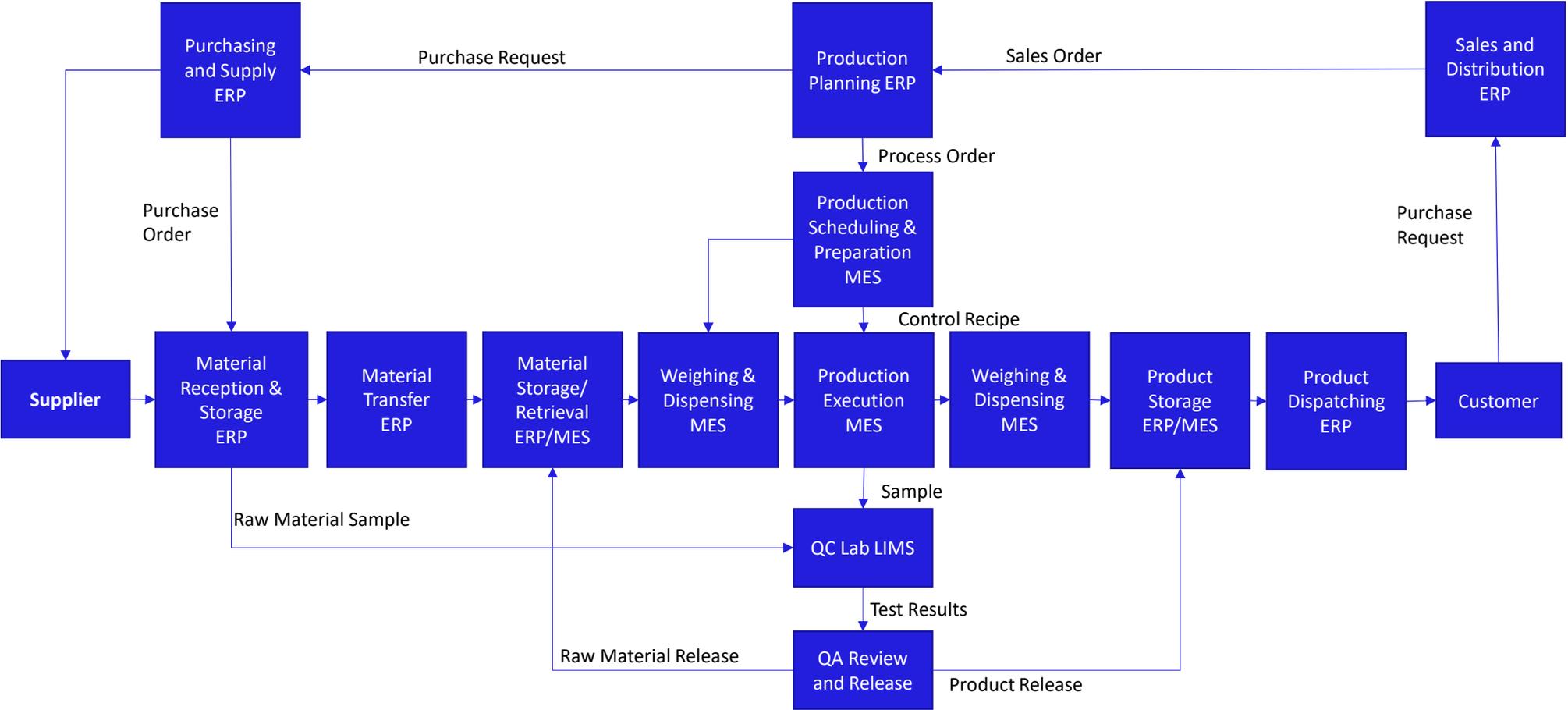
Jacobs Approach To Address Your Business Case Challenges



Design Execution Approach



Typical Business Work Flow



Jacobs Core Capabilities: Digital roadmap

Backbone of the Industrial IoT

- Reliable
- Connectivity
- Gateways / Message Ques

BIM®

- Data-Centric Models
- Collaborative Process
- Connected Information
- Need to start during early design phase

MES + eBR

- Electronic Data Capture
- Automated Procedural Controls
- Paperless workflow

Cybersecurity

- Address Cybersecurity as a System following ISO 27001 standard
- Continuous protection

Dashboard

- User friendly interface
- Support data driven decision
- Support smart working
- Intelligent Asset Management (energy savings, comfort, space optimization etc.)



Jacobs Core Capabilities: Digital roadmap

AR and VR

- Facilitate design reviews
- Effective training
- Operational Support

Big Data Analytics

- Data driven decision
- Contextual Democratic Data

Digital Twin

- Understand, predict, and optimize performance in order to achieve improved business outcomes

Robot and Cobot

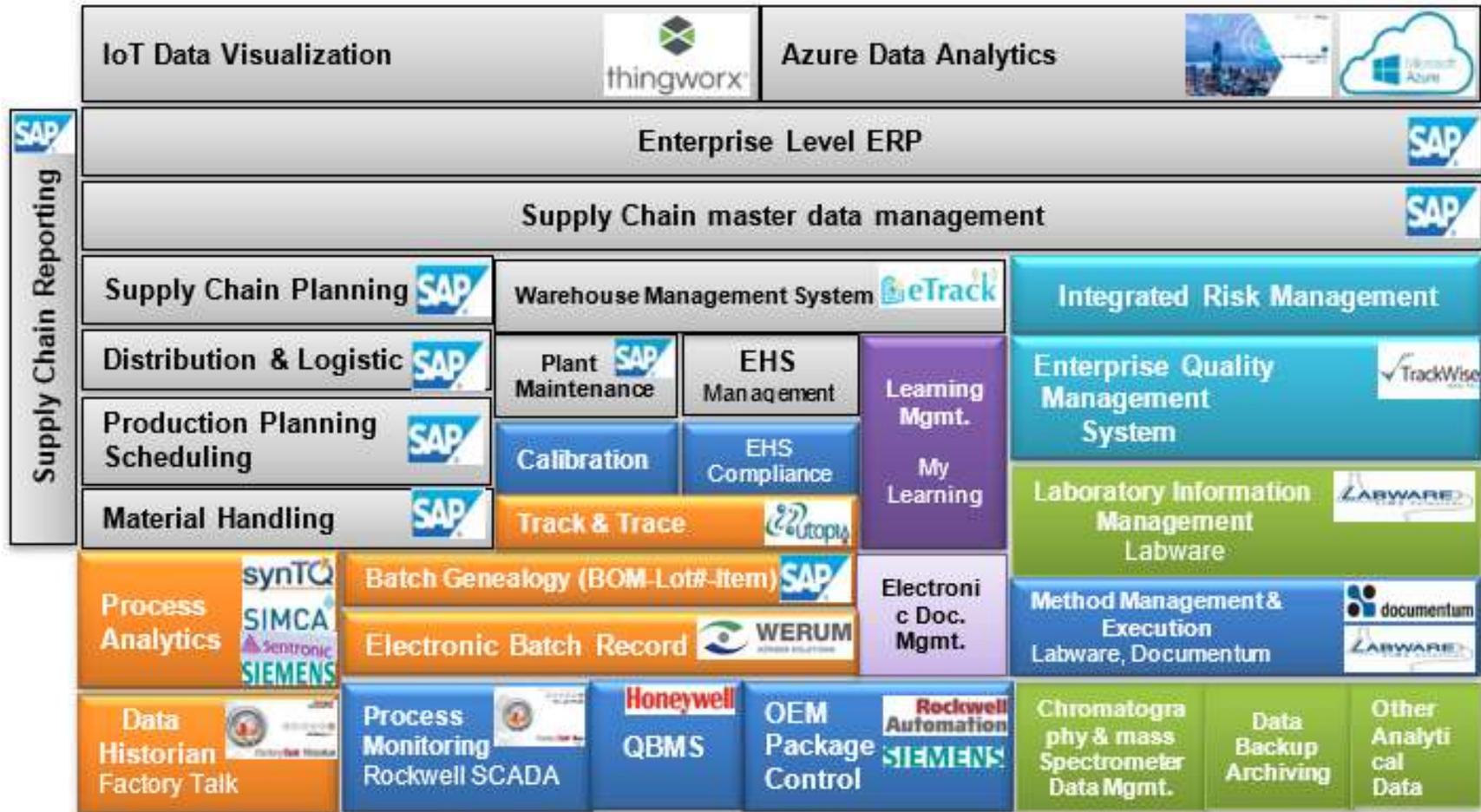
- Able to work alongside and interact with people to boost efficiency and productivity

AI

- Predicting Treatment Results
- Drug Design
- Data Preprocessing
- Predictive Maintenance



Industry 4.0 Automation Model



Jacobs USP – Automation Solution Provider

■ Cyber Physical Systems

- A virtual representation of a physical product or process, used to understand and predict the physical counterpart’s performance characteristics
- Typical design goal: a digital platform that dynamically mimic operation to provide
 - Predicted Yield performance
 - Operational scenario performance
 - Predictive future performance
 - Capacity Performance



■ Digital Transformation

- Industry 4.0 / Pharma 4.0 /
 - Namur Module Type Package – Data structure as interface, state model, defined services – Process Industry Focus
 - ISPE Plug & Produce – Data storage, Data Integrity, Time Synchronization, User Management – Pharmaceutical Industry Focus
 - BioPhorum Plug & Play – Define profiles and function for Biological processing equipment – Bulk Biological Industry Focus
- “Factory within a Factory” autonomous operations not “Islands of Automation”
- Focus on data, data management, operational integration

Thank You