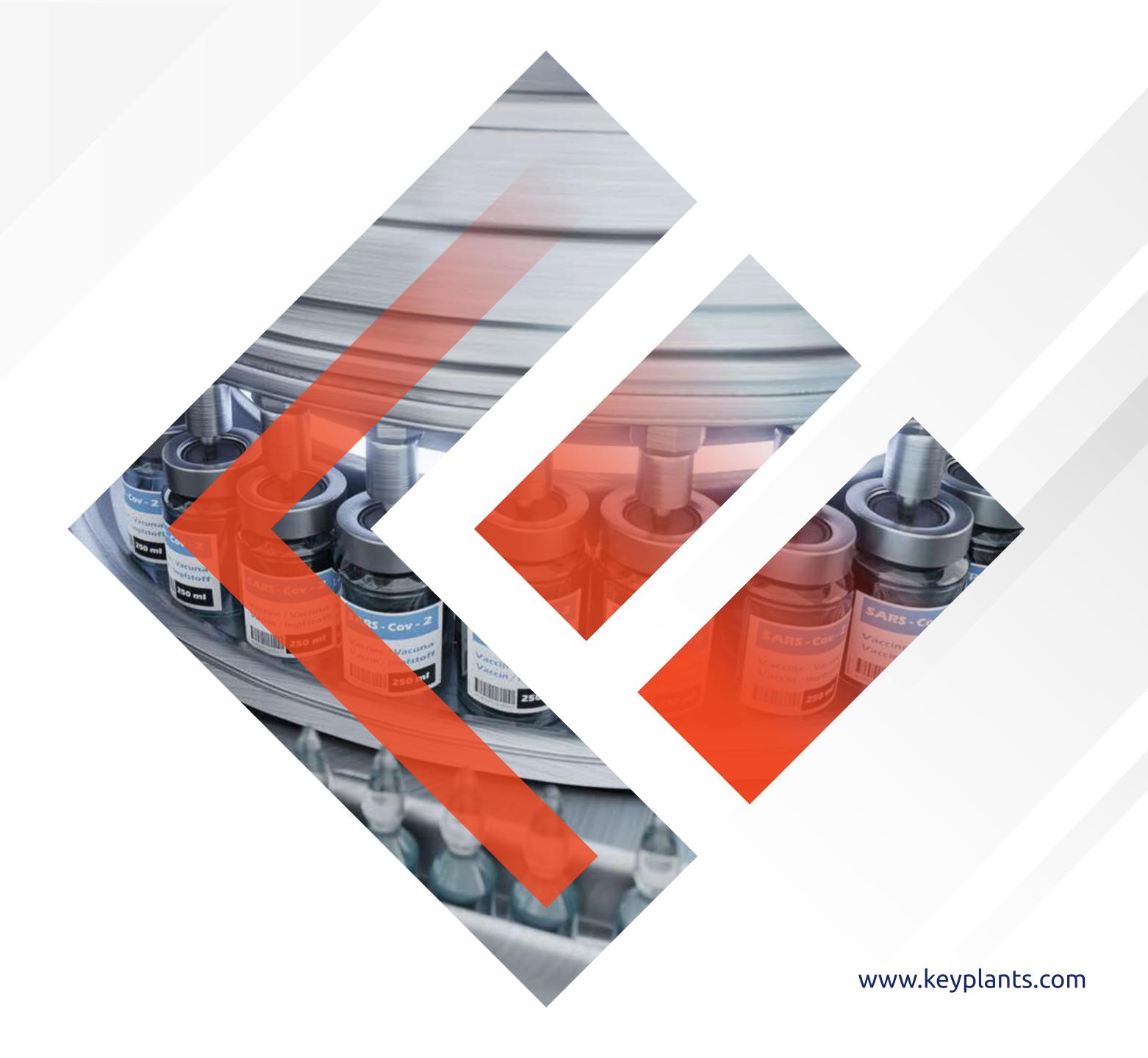


Company Profile

A leading provider of innovative life science facilities







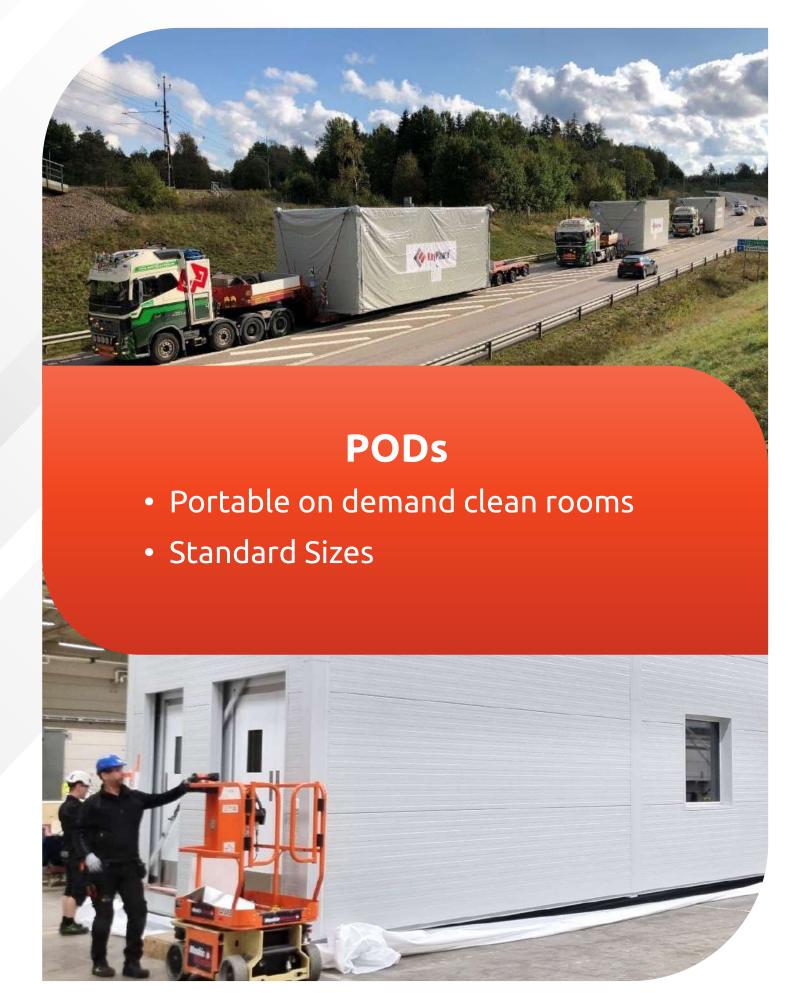
Introduction to KeyPlants

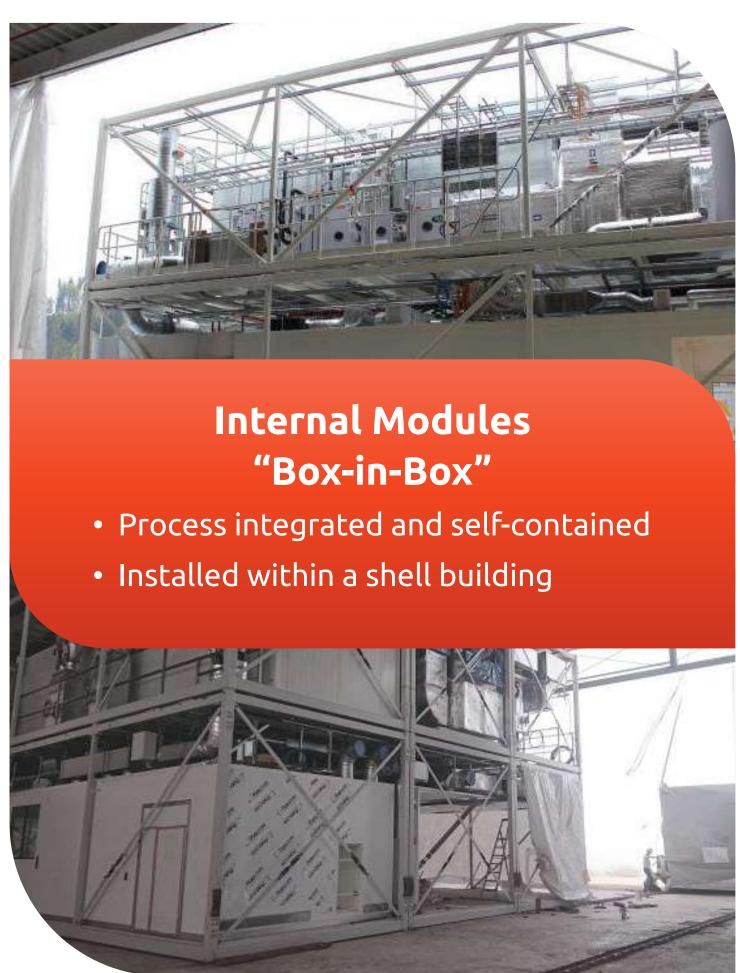
Our capabilities include full in-house design and modular fabrication as well as subject matter expertise in biologics, aseptic filling, containment and manufacturing of APIs and oral solids. We deliver turnkey facilities including process equipment, utilities and digital solutions, as well as facility upgrades and expansions.

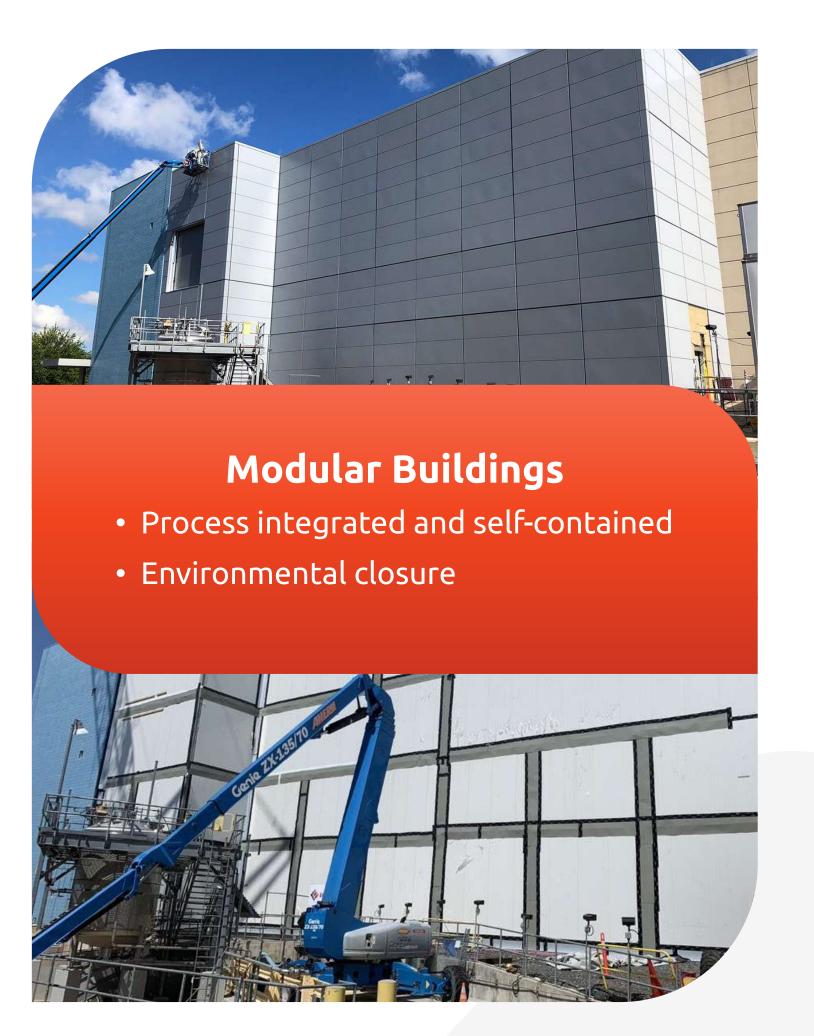




Global Modular Off Site Manufacturing Leader











Based on the tradition of industrial innovation in Sweden, KeyPlants became pioneers bringing the modular facility concept to the life science industry. We have developed our ideas and solutions over the years, in close collaboration with leading Big Pharma companies. Today, we partner with several of the top 10 Big Pharma and many regional companies in the world.









octapharma®









GALDERMA

Wvalneva







Global Experience





Historic Milestones















1990-2010

Current senior mgmt. at KeyPlants were pioneers bringing the modular facility concept to the pharmaceutical industry. 2012

Delivery of a modular OSD facility to the Middle East

2017

Delivery of a modular Aseptic Fill-Finish facility to the Kingdom of Saudi Arabia 2021

Awarded to build the first COVID-19 vaccine facility in Africa

2021

KeyPlants becomes a part of Masco Group and RSBG

2022 - 2023

Established US organization, new projects in Sweden, Europe and Middle East

1986

First modular life science facility delivered from Emtunga Workshop 2010

KeyPlants founded

2013

First Big Pharma order. Delivered an indoor modular facility to Switzerland in 6 months. 2018

Awarded a €80M modular facility to Latin America. Biologics bulk manufacturing and aseptic filling of mAbs.

2021

KeyPlants acquires Emtunga Workshop 2021

Modular extension to a vaccine facility for Big Pharma. Delivered to the USA in 13 months during the COVID19 restrictions.













KeyPlants is part of Life Sciences Division of Masco Group

RSBG SE is the future-oriented, reliable and strong investment partner for innovative and successful medium-sized companies.

RAGSTIFTUNG

RAG-Foundation funds the long-term obligations of the closed German hard-coal mining industry towards environmental protection, socio-economic development and responsible governance. RAG-foundation has in total over EUR 20B in capital

RSBG SE

We foster innovation.

RSBG Infrastructure Technologies GmbH

Information & Communication **Technologies**

Automation & Robotic Technologies

Advanced Manufacturing **Solutions**

Life Sciences

Alfa Tech (US)

RGBG UK



MascoGroup

KeyPlants®

Market-leading individual technologies, as well as integrated projects.

Our Value Proposition

KeyPlants is best in rapidly providing sustainable and high-quality turnkey design and modular projects for the life science industry by breaking down complexities into standardised solutions that deliver flexibility and safety for its clients.



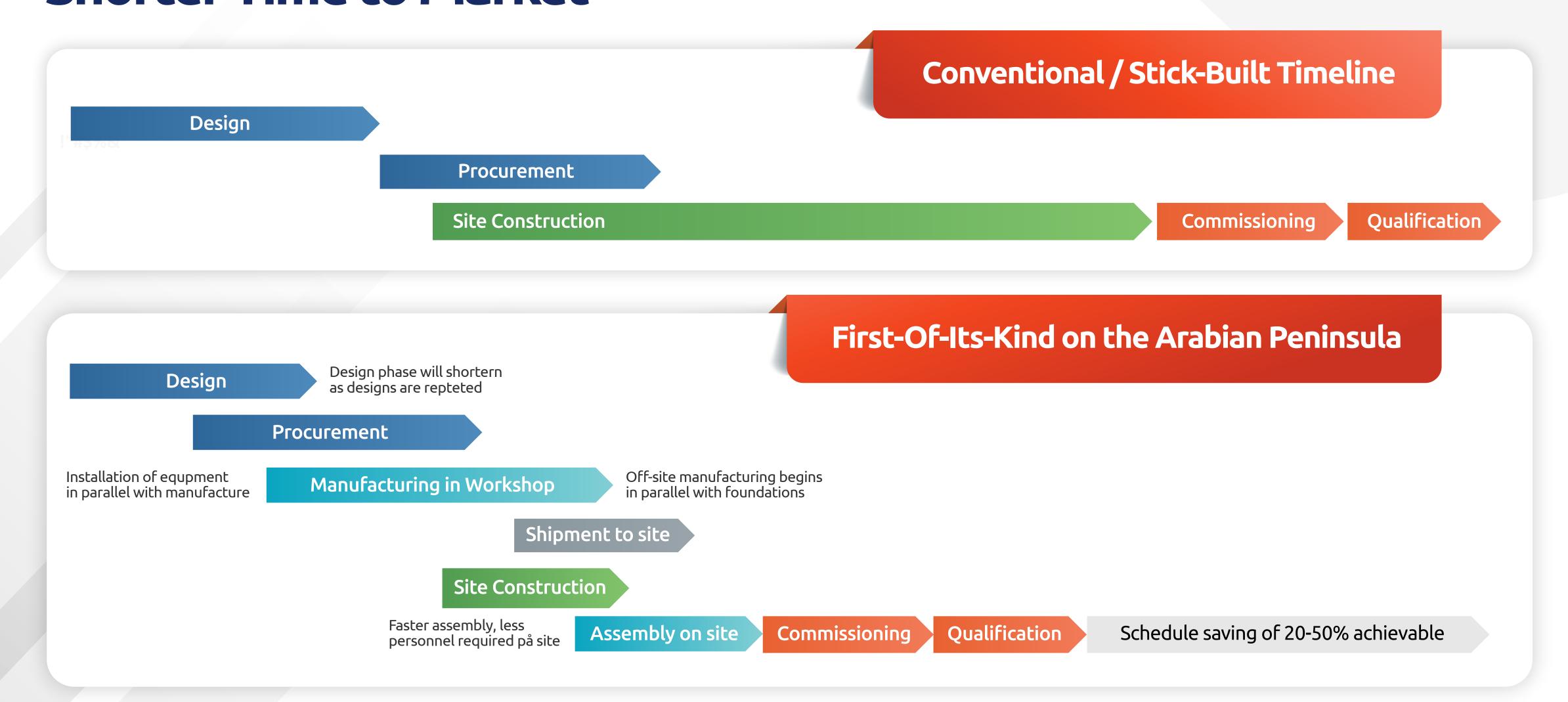
Advantages of Modular Off-Site Manufacturing

- Shorter time to market
- Manufacturing under controlled conditions
- Increased safety and sustainability
- Less disturbance of site operations
- Increased predictability in cost, schedule & quality
- The facility can easily be expanded and moved





Modular Off-Site Manufacturing Shorter Time to Market



Why KeyPlants

Modular Off-Site Construction Advantages



Global Modular Off Site Manufacturing Leader unrivalled modular design and execution experience and capability



One-Stop-Shop

enhanced value with full in-house design and construction capability and use of subject matter experts in containment, oral solid dosage, aseptic and biotech processing and modular process plant design.



Vast Experience

we have executed a substantial number of projects to highest quality leading to expedient FDA and EMA approval.



Fixed price based on BOD with culture of "No Change"



Modular projects have a probability to be executed 10-20 % more cost efficient and up to 12 months faster.



Adopting modular or modular hybrid to a project reduces the project risk both on cost and schedule.



Increased Safety

Outstanding safety records with 85%+ of your facility built in our workshop.



Presence in the region and experience of GCC countries



Turnkey delivery of a modular Aseptic Fill-Finish facility to Saudi Bio, the Kingdom of Saudi Arabia



VACCINE CO is the first and only company aiming to set up state of art Vaccines manufacturing facility in Saudi Arabia.



Local Partners In Saudi Arabia & Other GCC



Selected Design **Projects:**



- Aseptic Fill-Finish facility for FDM Vaccines
- Dubai, UAE, 2018



E20 INVESTMENT LTD.

- Packaging of vials, PFS and cartridges
- ♦ KSA, 2020



- Veterinary Vaccine Fill-Finish Facility
- ♦ Abu Dhabi, UAE, 2022

Full-Service Turnkey Capital Assets



Full-Service Turnkey **Capital Assets**

Develop the scope for the selected concept

Prepare and plan the project for execution

Site construction, deliver the modular facility and make site installations

Verify and record all agreed requirements

Hand over to the client's operations organization.

Objectives >>>>

Concept Design

Basic Design Detailed Design, 2 **Fabrication**

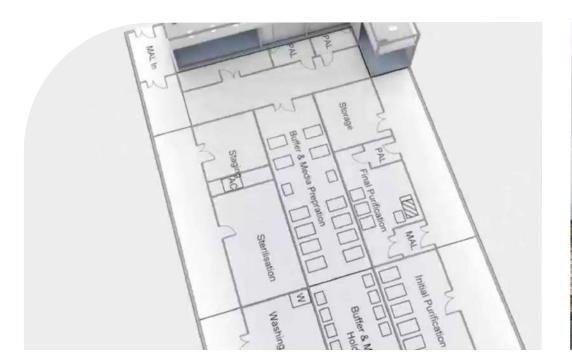
Delivery, Site Construction & Installation, Commissioning and Qualification

Develop concept that addresses the client requirements

Budget and schedule according to the client's business case

Complete the Detailed Design and procure materials

Pre-fabricate in workshop







Recent Projects



Project

Bulk and Aseptic Filling Facility, Latin America

Aseptic Filling Facility, Middle East

Vaccine Filling Facility, Senegal, Africa

Expansion of Vaccine Filling Facility, Big Pharma, The Netherlands

Large Syringe Filling Facility, Big Pharma USA

Aseptic processing

Formulation, liquid and lyo vials, powder-filling in vials and two-chamber syringes

Formulation, vial, syringe and cartridge filling

Formulation, pouch and vial filling

Formulation and filling of vials with VHP

Syringe filling

KeyPlants Delivery

From concept design to operational facility

Facility with Equipment











Timing

2020

2021

2022

2023

Galderma, Sweden, Uppsala

The largest Life Science facility ever built in Europe using modular off-site manufacturing





Keyplants is responsible for the complete project, including detail design, ground works and construction on-site, installation of all equipment, as well as qualification. The floor area of the new facility is around 13 000 m2 and will be located in direct connection to Galderma's current Uppsala plant.



Off-site construction of the new facility for manufacturing of products in aesthetic treatment has started in January 2023.











Scope:

Facility extension with a modular building to increase vaccine manufacturing capacity. A 4-story extension to an existing building with integrated cold rooms and buffer preparation process areas. Façade and roof installed on site to match the adjacent building.



13 months including Basic Design.





Expansion of Vaccine Filling Facility, Big Pharma, Europe



Scope:

Turnkey delivery of two story 1,300 m2, BSL2 class modular facility for vaccine formulation and filling. Complex design with meeting requirements acc. to BSL2, Air tightness VDI class 1 and FM global requirements on safety systems. The biggest challenges came from the advanced automated Hydrogen Peroxide Vapor (HPV) decontamination system. Site with limited space close to residential district: just 20 meters away from the neighboring buildings.



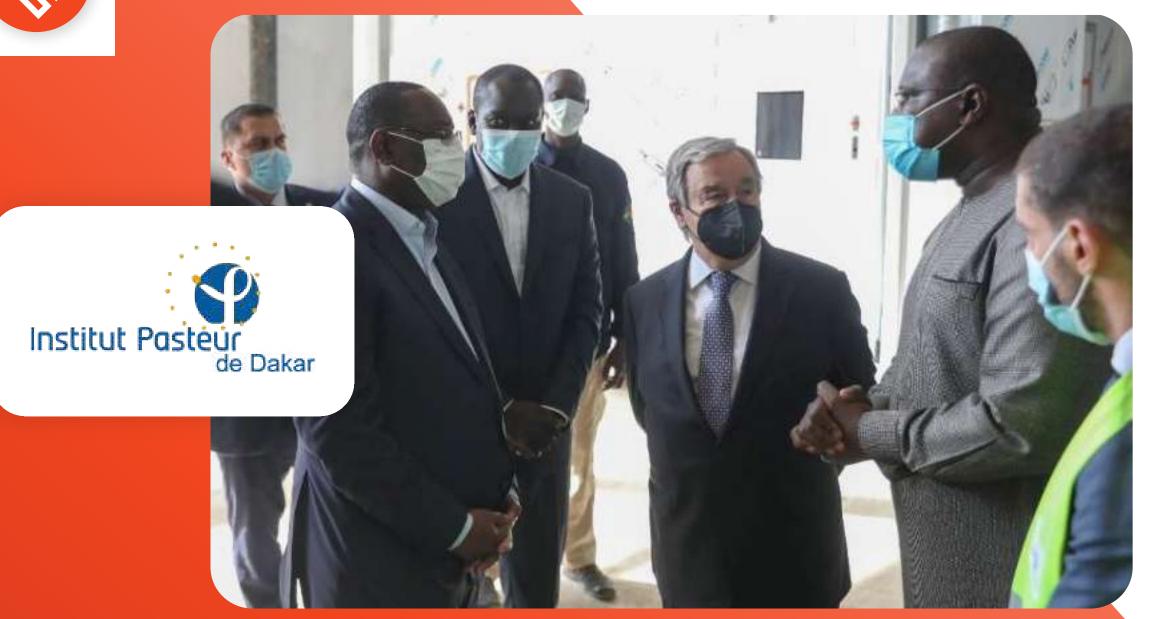
Delivery:

Design, procurement and off-site fabrication of complete production building with all process equipment and automation. Site installation and commissioning on client existing site including integration to existing production facility. Delivery time from Basic Design to Finalized off site fabrication of building – 13 months. Site Installation 3 months.











COVID-19 Vaccine Filling Facility, Senegal, Africa

Scope:

Turnkey delivery of a modular aseptic filling facility to Institut Pastur de Dakar (IPD) in Senegal, Africa. The first target will be COVID-19 vaccine production, with the flexibility to adapt to future needs.

O Delivery:

Design, procurement, off-site fabrication and commissioning of a complete facility. This fully customized facility was delivered in less than a year after starting the design work.



Modular Movable Facility, Ferring, Germany and Indonesia



Scope:

This aseptic filling facility was designed and manufactured by KeyPlants in Sweden, shipped to Kiel (Germany) for Tech Transfer, production trials and process validation and finally shipped to Indonesia for validation batches, commercial production and launch. The newly formed production team from Indonesia travelled to Kiel for training, to take over and qualify the new modular units.



A complete manufacturing facility built in one location, further equipped, tested and qualified in another location and then moved again to a final site to begin production.







Bulk Manufacturing and Aseptic Filling Facility, Latin America

Scope:

Turnkey delivery of two modular facilities for bulk manufacturing and aseptic filling. Based on KeyPlants' design platforms MBSTM and MASTM. Outdoor integrated process buildings. Bacterial fermentation with UF and chromatography purification. Liquid and lyo vials, powder-filling in vials and two-chamber syringes.

O Delivery:

Complete modular buildings including all process equipment.



Aseptic Filling Facility, The Kingdom of Saudi Arabia



Scope:

Turnkey delivery of a modular Fill Finish facility based on KeyPlants design platform Modular Aseptic Solutions (MASTM) from concept design to handover. Indoor "Box-in-Box" integrated process buildings. Combi-filler for vials, syringes and cartridges. Pre-sterilized RTU containers in nests. Formulation instainless steel tanks and disposables.



Delivery:

Complete modular facility with equipment was delivered in 16 months + lyophilization addition

First-Of-Its-Kind on the Arabian Peninsula.

Reference project



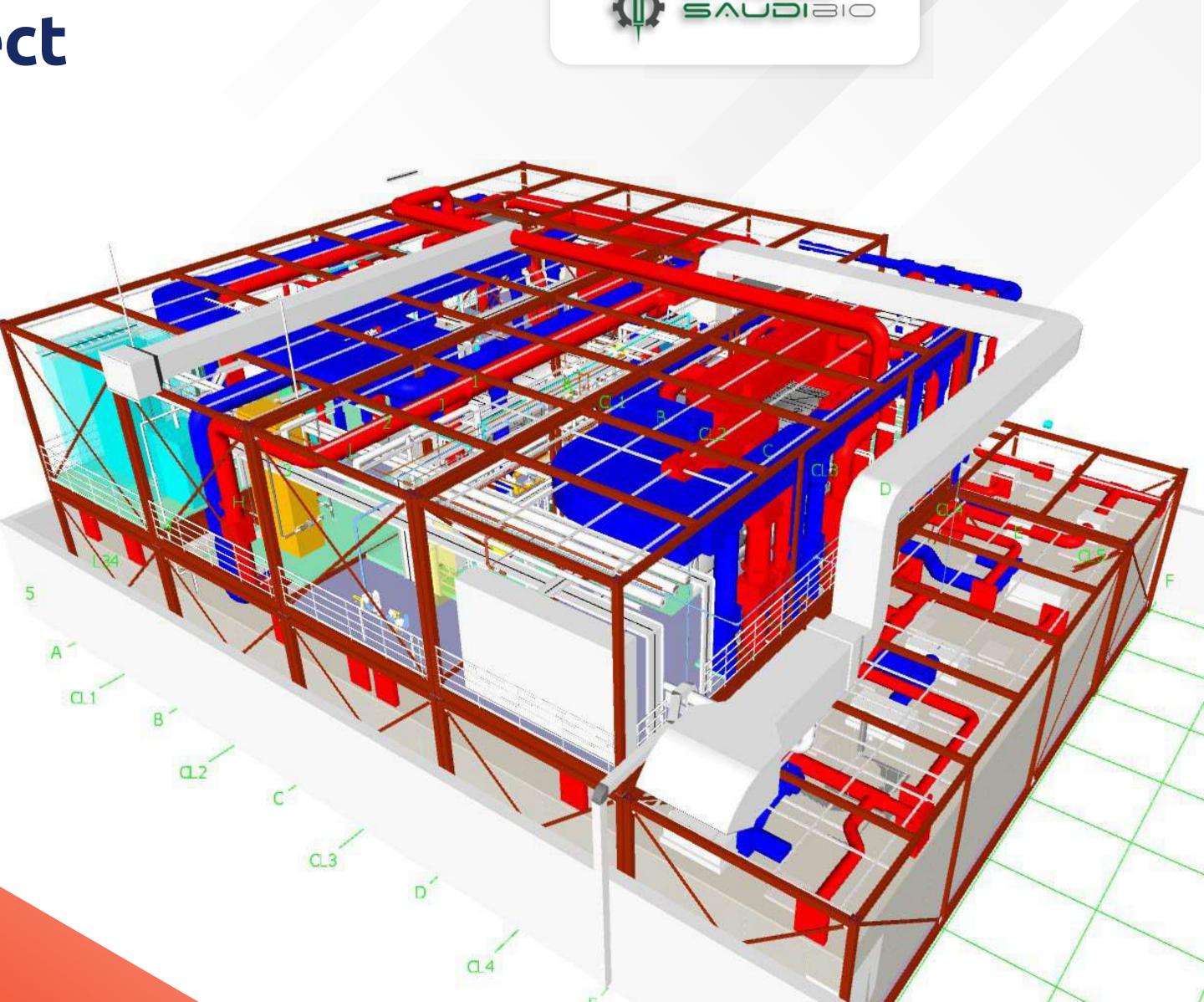


Saudi Biotech Manuafacturing Co. Project

- A facility for rapid deployment globally
- Relocation possibility
- Designed for compliance with requirements of

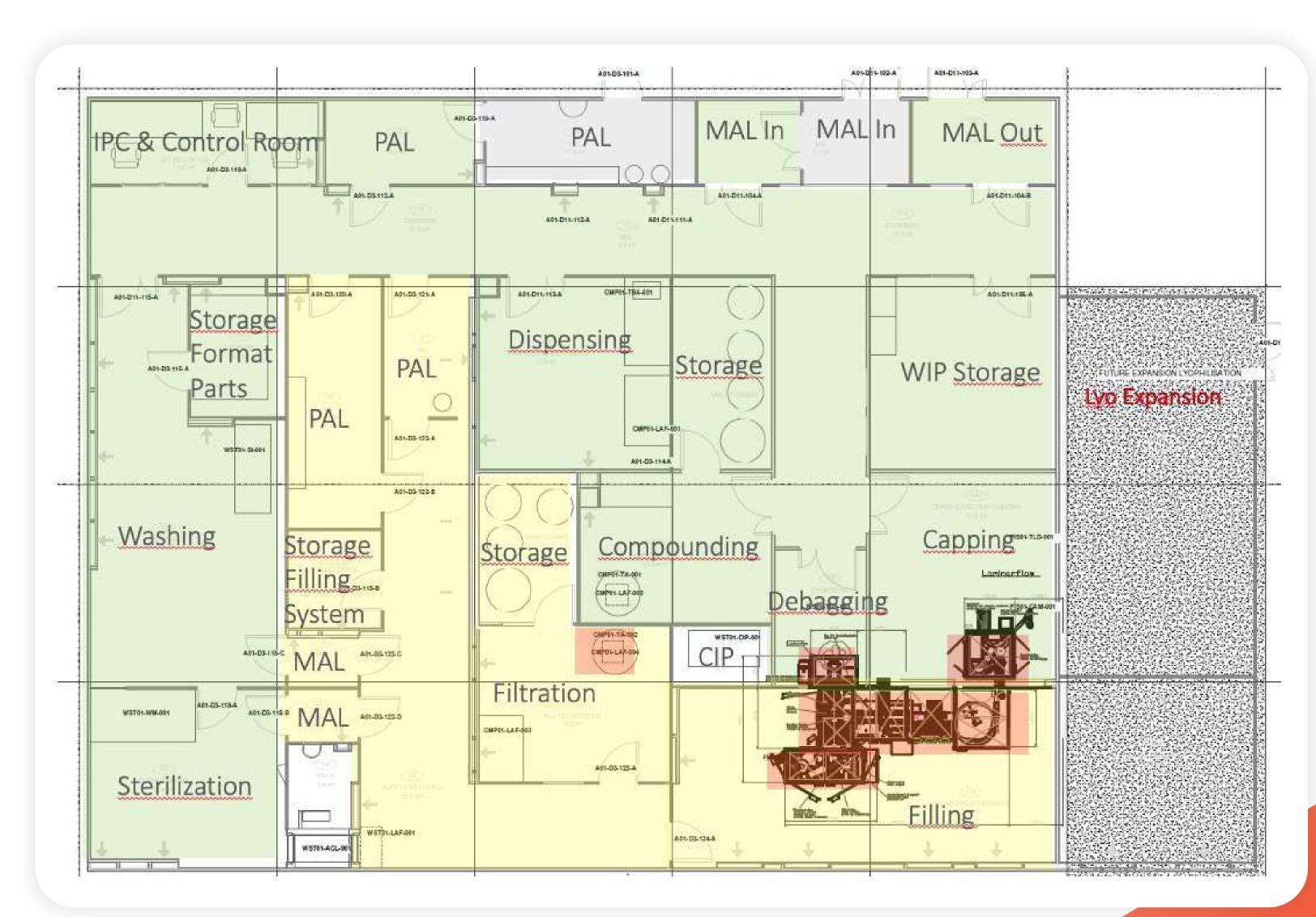






Modular Layout with LYO Expansion





- Combi Filler for Vials, Syringes & Cartridges
- Disposable Fill System Pre-sterilised RTU
- Containers in Nests Stainless Steel or
- Disposable formulation system
- Expanded with a LYO module at a later project stage



Fabrication in KeyPlants workshop in Sweden

- Fabrication of modules
- Installation of clean rooms, process equipment, utilities and piping
- Testing (IQ)
- Preparations for Transport & Site Assembly







Transportation Route



- Modular facilities can be shipped anywhere in the world
- Modules are shipped below deck to guarantee environmental conditions
- For Saudi Arabia, Dammam on the east-coast or Jeddah on the west coast are harbours options
- For KeyPlants' project to Saudi Bio in Sudair, the harbour in Jeddah was selected



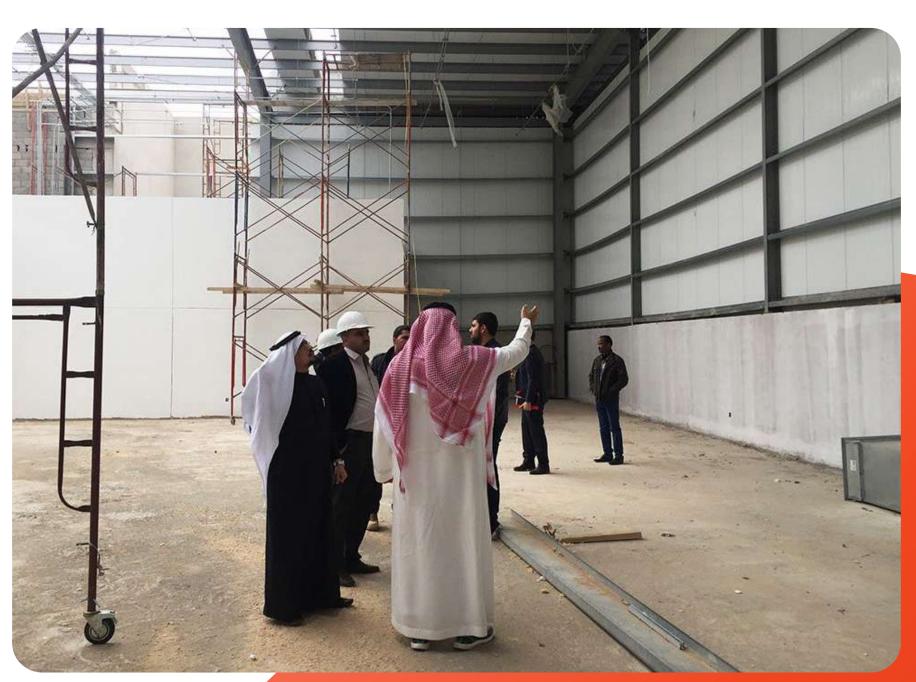




Site Preparations



- KeyPlants assisted the client in sourcing qualified local contractors for installations
- Local constructed building with offices and warehouses and a prepared open space for installation of the modular plant inside the shell-building
- KeyPlants and Saudi Bio checked interfaces between the modular facility and the conventional constructions and local installations



Arrival to the Site in KSA and Site Assembly

- Total transport time from workshop to the site approx. 6 w depending on timing of connecting boat of re-loading
- As arrived and unloaded the modules are lifted on top of each other and winched into the shell building
- As the modules are placed into their final location the structural hook-up of architectural, Piping, E&I and HVAC interfaces are finalized











- Building IQ/OQ executed by KeyPlants
- Main equipment IQ/OQ executed by vendors
- KeyPlants staff and equipment vendors trained clients personnel in operating the facility









ISO Certified Manufacturing Workshop

160 modules indoor and 160 modules in expanded workshop on yard

♦ 50.000m² area













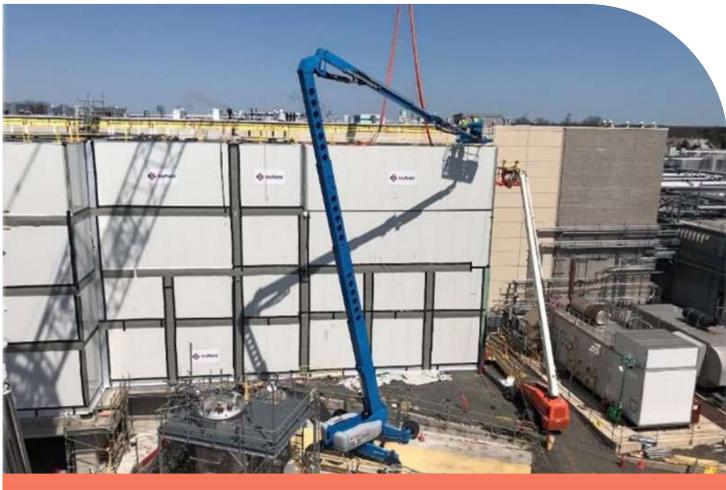


Modular Offering for the Life Science Industry



PODs

- Portable on demand clean rooms
- Standard Sizes
- Process Tech Agnostic
- Installed within a shell



Modular Facilities

Complete Process & Infrastructure integrated and self-contained



Internal Modules

- Process integrated and self-contained
- Single level or multi-level
- Installed within a shell building or warehouse





KeyPlants PODs

Expandable, express PODs from the experts



Your Project Partner



Leading provider of innovative life science facilities

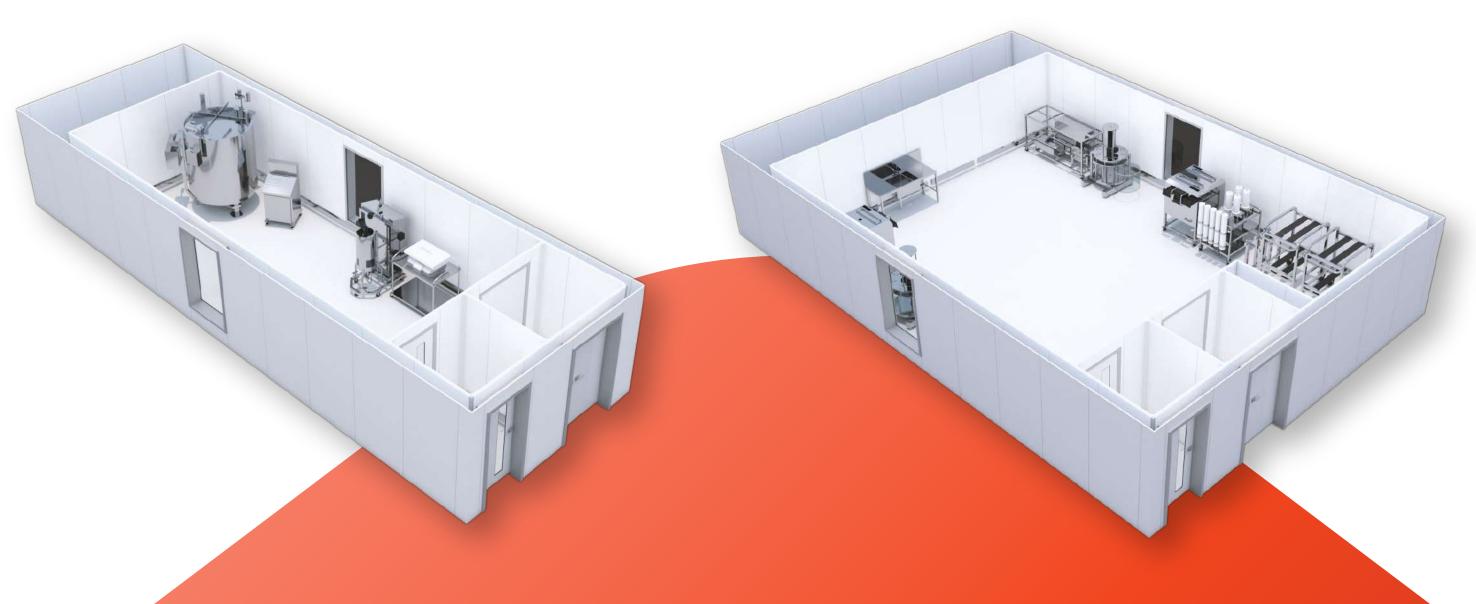


- Portable, on-demand cleanrooms for development, clinical and manufacturing
- Self-contained GMP environment
- Installed within larger conditioned building (Gray Space/CNC/Grade D)
- Equipped with dedicated air handling, building management system (BMS), fire protection, and electrical and process utility distribution
- Designed with minimal connections to wider facilities (power, condensate, make up air)
- Personnel/material link on one end and utility access/ connects on other end and process suite in middle



Single wide





Single POD Dimensions

Length: ~ 15 m / ~ 50 ft Height: ~ 4 m (3 m interior) Width ~ 4.5 m / ~ 15 ft Area: ~ 70 sqm (per POD)

With airlocks for personnel and material respectively **HVAC** control & door interlocks Superior operator visibility with viewing window

Single point of interfaces (utilities, HVAC, electrical)

Removable skin for service access to void between clean room and external skins. Allows for service and reconfigure installations with minimum disturbance from clean room side.

No-ramp entrance

Grid-based ceiling & floor track system for ease of future reconfiguration

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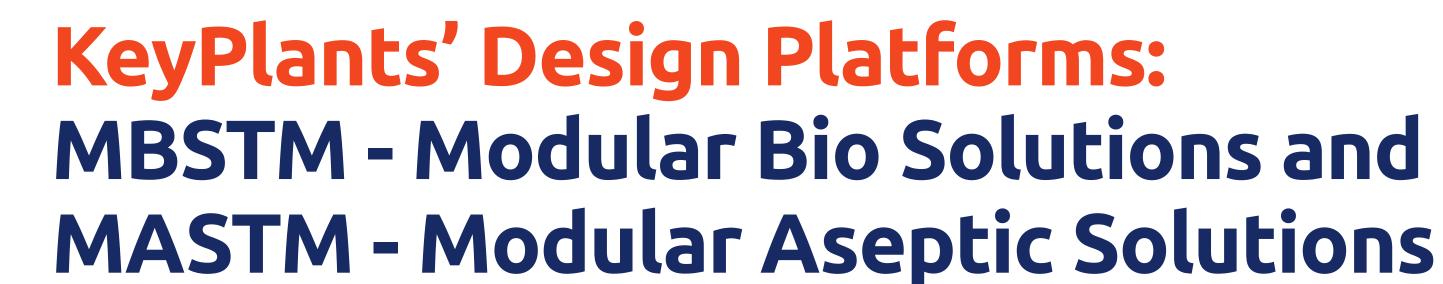
Robust design with steel frame Stackable Easy to move with equipment installed

Design prepared for global deployment

areas access from ground floor

Mechanical

Secondary Air **Handling Units with** sufficient cooling power



KeyPlants' design platforms have been developed to simplify the construction of turnkey biopharmaceutical and aseptic filling pharmaceutical facilities. A flexible facility solution for rapid deployment of new biomanufacturing and aseptic filling facilities.

Speed

- Less design efforts an Alignment Study saves time for Engineering
- 4 months delivery time for prefabricated clean rooms
- 12 months delivery time for a complete facility for commercial production

Flexibility

- Configurable to any biomanufacturing or aseptic filling process
- Ability to add on unit operations such as fill finish
- Expandable to manage increased demand forecast
- Mobile to enable re-location



Predictability

- Fabrication in workshop secures predictable quality and timeline
- Fixed price on fixed scope after Basic Design

Modular Bio Solutions

- Pre-Engineered design platforms to reduce time to market
- Turnkey delivery including in-house bioprocessing expertise ensure industry standards are met
- Optimised layout and equipment positioning for reduced footprint and savings in utility and energy consumption, operations costs and maintenance







Modular Bio Solutions

The MBSTM Design Platform is available for the following biomanufacturing processes

- Therapeutic Proteins
- Monoclonal Antibodies
- Viral Vectors (vaccines and gene therapies)
- Microbial Vaccines



Layout Example

Washing, Preparation and Storage



Final Filtration & Formulation

Virus Inactivation

Virus Infection, **Harvest & Purification** BSL2 or BSL3

With airlocks for personnel and material respectively

No-ramp entrance

HVAC control & door interlocks Superior operator visibility with viewing window

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Client	Business Case	Financing	Product Licencing
	Organization and Human Resources	Quality System and Training	Regulatory
	Design	Production Facility Build	Site Infrastructure
KeyPlants	 Concept Design Basic Design Detailed Design 	 Building Utilities Process Equipment Automation 	 ❖ Infrastructure ❖ Warehouse ❖ QC Lab ❖ Office and Admin
	Technology Transfer	Process Validation	Maintenance

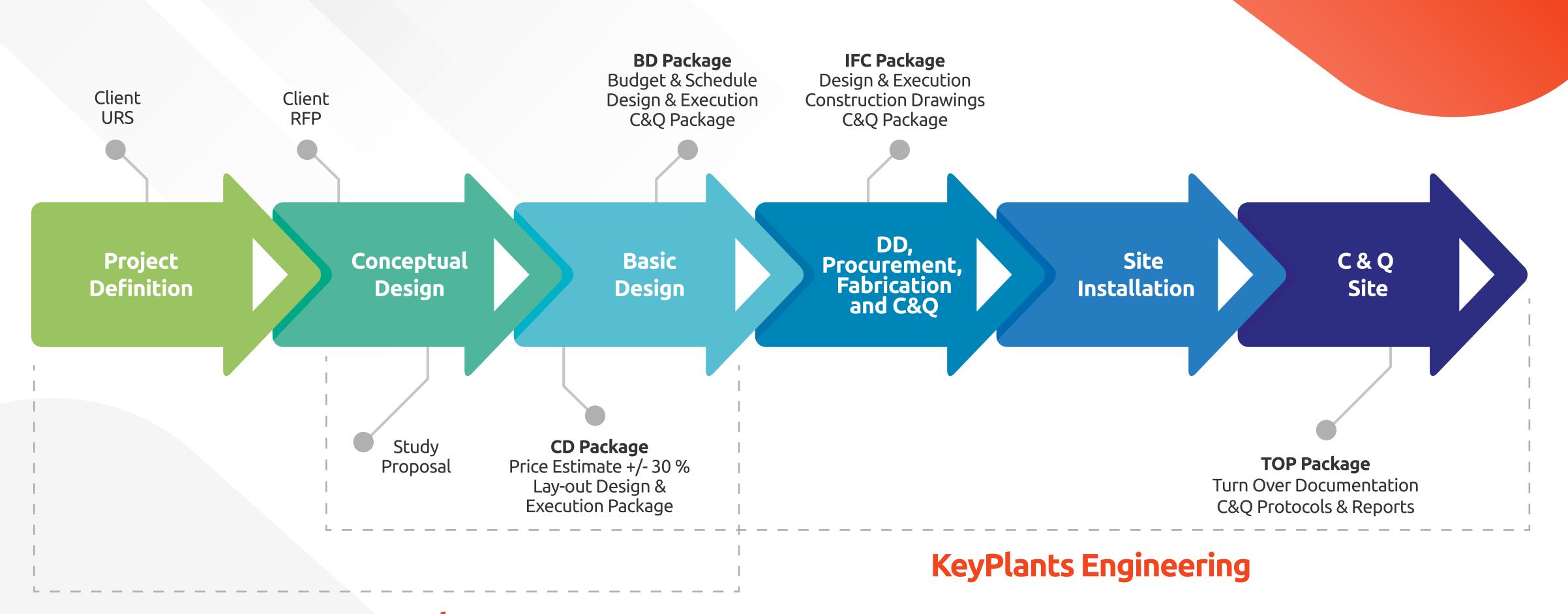
Project Execution Model Overiew



Project Phase	Conceptual Design	Basic Engineering G2	Detailed Design + Fabrication + Commissioning, EXW	Delivery + Construction/ Installation + C&Q
Objectives	 Develop various alternatives that addresses the client opportunity Select the preferred concept and define the conceptual scope Budget and schedule according to the client's business case and as agreed in the CD contract 	Develop the scope and complete the basic design as agreed with the client for the selected concept Align, prepare and plan the project for the execution as agreed with the client and according to the client's business case	Complete the Detailed Design and procure materials Pre-fabricate as applicable regarding scope and according to the approved and contracted scope, cost and schedule.	Deliver, construct/install the scope of works Verify and record all agreed requirements in the contract. Hand over to the client's operations organization.
Key Input	 Client URS or similar document Client Project drivers and business needs Target value design cost 	CD Report and updated URS's by client Client insurance and EHS req. Lessons learned Client stakeholders, drivers, decision roadmap and target value	Agreed contract with client Incl. KeyPlants' Basic Design or (client design if bid or similar)	Construction/Installations drawings C&Q protocols Site Execution Plan
Key Deliverables	 Project Estimate Draft Project Schedule Concept and execution strategy Scope Description Risk assessment QEHS strategy Constructability & Permitting strategy IT and Automation Strategy CD Report with process description CD Design Deliverables 	 Price, Estimate and schedule Scope, requirements & VE Agreed vendor list Interfaces & responsibilities Risk assessment's Quality plan with procedures Execution plan with procedures Contract for execution Constructability and permitting Codes, regulations compliance report Agreed documents review & approval 	MTO's and procurement packages Construction drawings and specifications C&Q plans Test protocols EHS Plan TOP	As-builts Executed test protocols and reports Final and complete TOP
Typical Commercial Terms	T&M	T&M	Fixed price if risk can be absorbed	T&M
Accuracy Project Budget	+/- 30%	Fixed price or T&M +/- 10%, firm schedule	Fixed price for Ex works parts, cost plus for equipment, firm schedule	T&M budget
Gate	Technical and commercial review CD Submittal. Commercial roadmap	Technical and commercial review BD Submittal, project ready for contract.	Project ready for delivery	Project Closing check list Client take over

KeyPlants Project Execution





Front End



Front End Design and Process Simulation Services

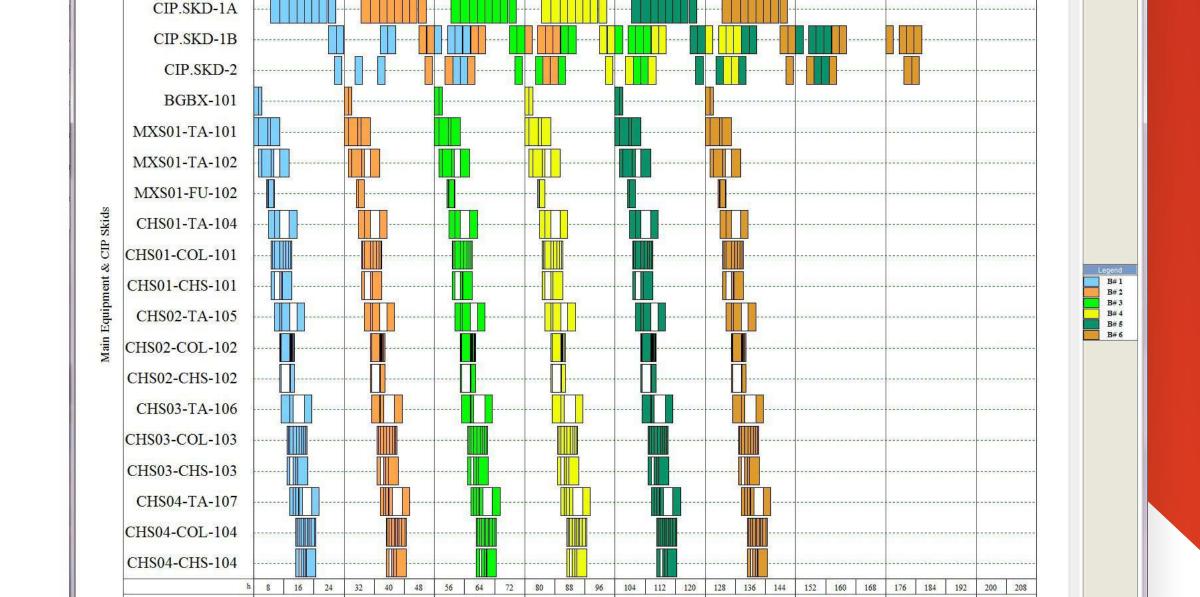
- Site Master Planning
- Process Architecture

Adjacency Studies Facility Layouts (Floor Plans, Equipment Layouts, Zoning) Flow Layouts (Product, Material, Personnel)

- Process Simulations and Production Scheduling
- Process Design

Process Flow Diagrams Design of production systems for biopharmaceutical and aseptic manufacturing

- Containment Strategies
- Technical Audits
- Subject Matter Experts Biotech / API / Fill & Finish



Process Simulation and Production Scheduling

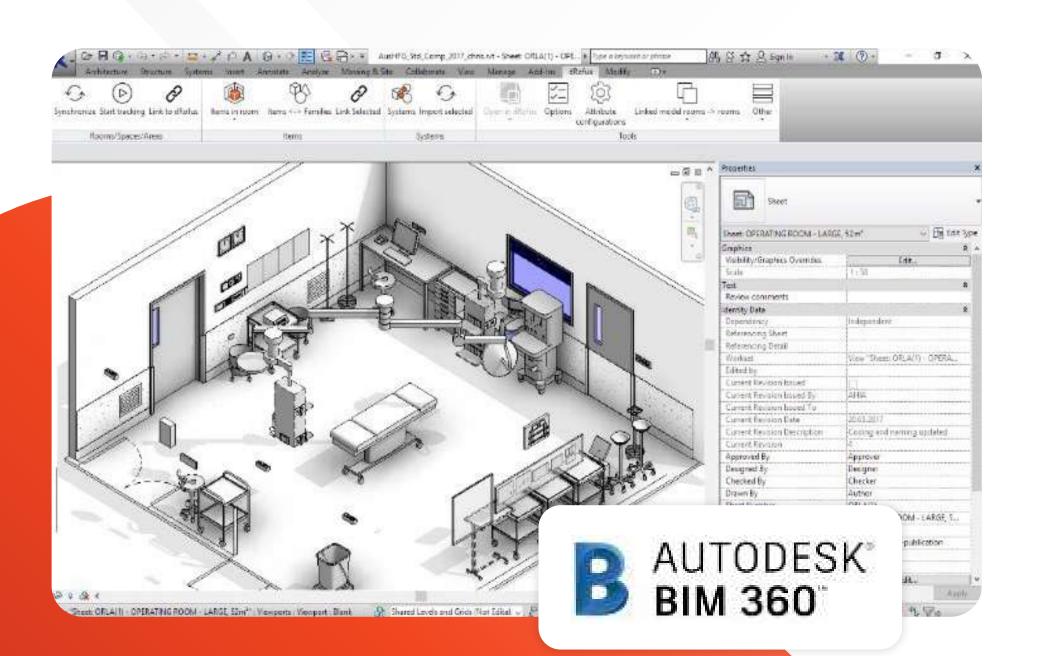
- Simulation of batch and continuous processes
- Scheduling of batch operations
- Throughput analysis
- Cycle time reduction and debottlenecking
- Equipment occupancy

- Sensitivity analysis
- Clean utility consumption
- Utility consumption
- CIP/SIP system set-up
- Drain system simulations

Design and Engineering

State of the art data-based design and design management tools for efficient design and communication with client and project partners.

- BIM Model with one source of data
- Navisworks as coordination and client review tool
- Design Integration of process equipment with vendors



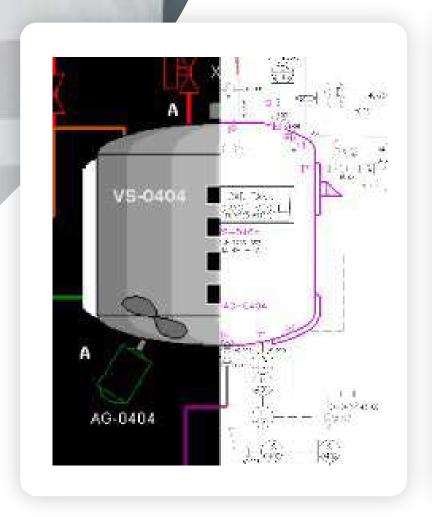








- Established Siemens solution partner for PCS7 and Tia Portal with extensive execution experience on the Simatic platforms.
- Proven project experience from conceptual design to full engineering, installation and qualification.
- Specialists in automation for regulated industries such Biopharma and Synthetic Pharmaceuticals with dedicated automation CSV resources.



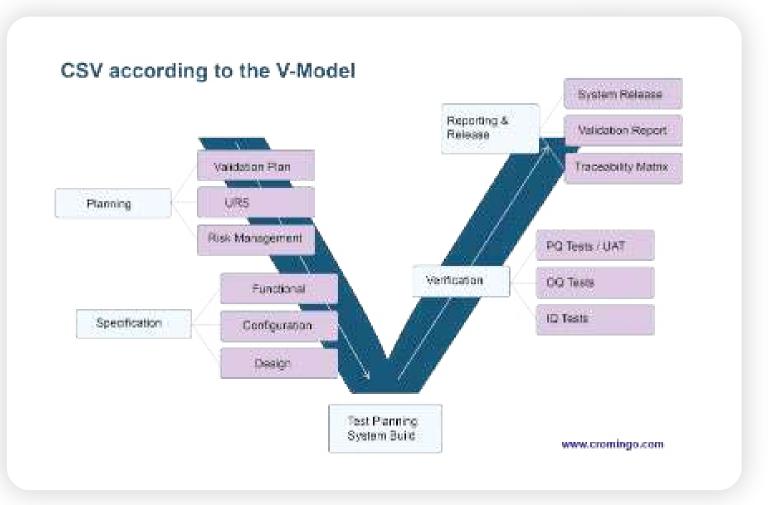
Solution

Partner

Drives

Automation

SIEMENS







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