



FEXIBILITY AS DESIGN CONCEPT

Introduction to the new generation flexible, modular facilities by KeyPlants®

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80% of all conventional construction projects are delayed more than 4 months

Source: Industry Best Practise
Construction Industry Institute (CII) USA
www.constuction-institute.org

Problems: Conventional Execution

- Inefficient utilization of the facility area lay-out increase construction/operation cost (HVAC etc)
- Control of many suppliers and sub-contractors is time consuming
- Escalation (change orders 10 – 15% of conventional project cost)
- A typical cost escalation of a project is + 15 - 50%, schedule slip additional 3 – 6 months
- Quality (workmanship varies with installations companies and market)

Benefits from Modular construction

-Predictability

(comparison on one project of Stick-built versus modular: for cost, schedule, quality, and productivity)

Compliance to plan:	<u>Cost</u>	<u>Schedule (1)</u>	Quality
Stick-built (2)	+15 to 50%	+3 to 6 months	Site dependent
Modular	+5 to 10%	+1 to 2 months	Predictable

Note: (1) Does not account for the schedule gains(6 to 10months) with respect to the Stick-built delivery.
(2)Data based on large Biotech Facility; Site conditions productivity, rework...

1 Hr in a shop requires 4 hrs in the field

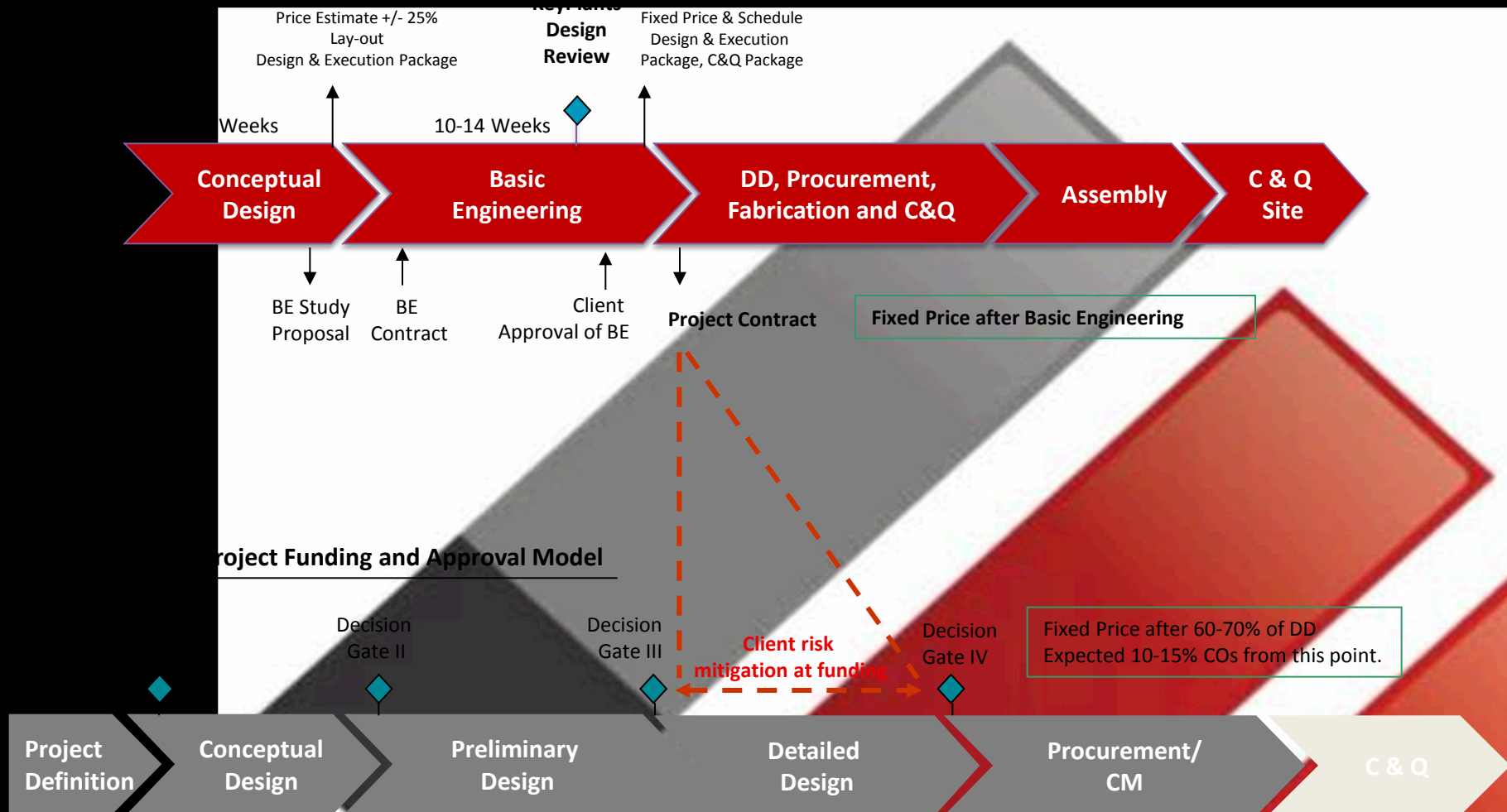
Outdoor or ...



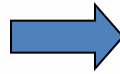
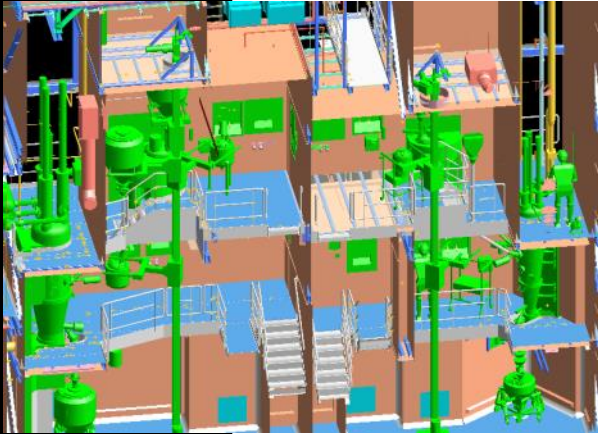
Indoor modules



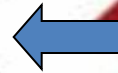
Project Execution Model



Modular Project Execution



Transport

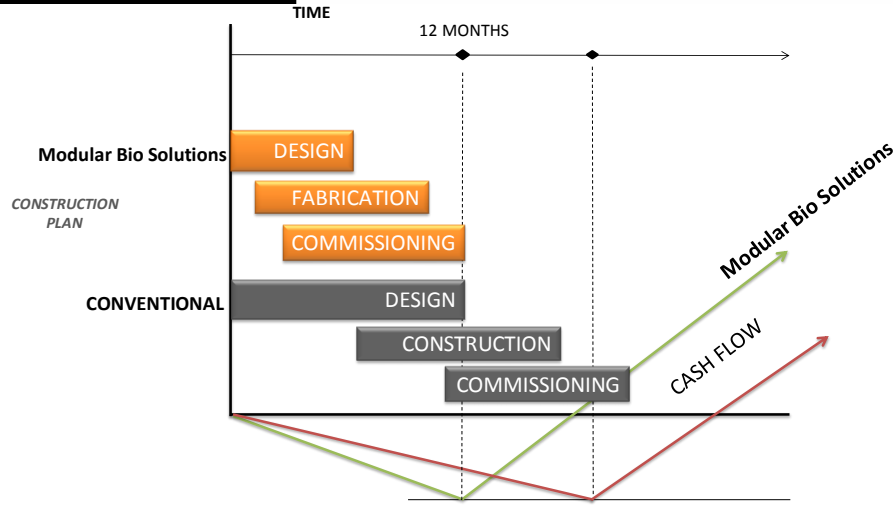


Modular Assembly at Site

The Genentech Example



Enhanced financial performance



- **Enhanced Cash Flow**
Enhances cash flow due to shorter implementation schedule

- **Higher Project Net Present Value**
Increases net present value of the investment in real terms



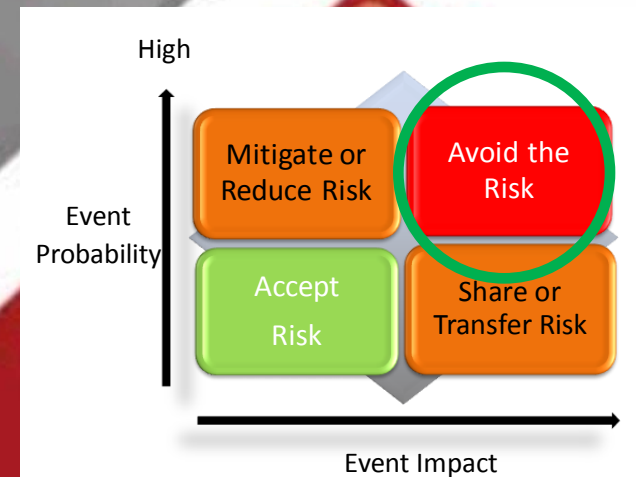
$$[\text{NPV} = -3 + 20/1 \text{ R}]$$

This significantly raises the **NET PRESENT VALUE**

Risk Mitigation



- ❖ 3D modular design, process design and execution experience
- ❖ Faster and predictable execution
- ❖ Fixed price offering after Basic Engineering
- ❖ Pre-IQ and pre-testing
- ❖ Movable asset
- ❖ Off site construction in ISO 9001 certified factory
- ❖ Standardized, pre-engineered platforms

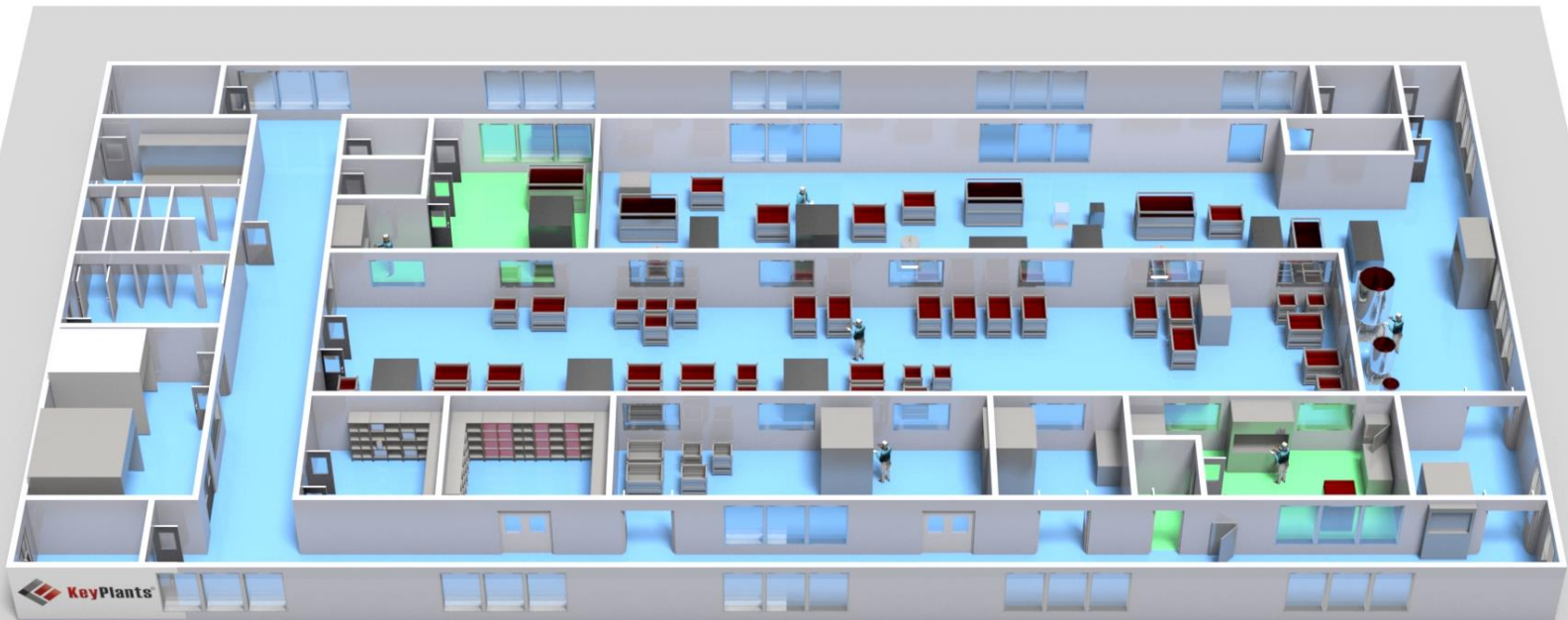


The Flexible MBS™ Platform



Complete building with fixed installations, process equipment and clean utility generation.

Optimized flexibility by allowing easy re-configuration

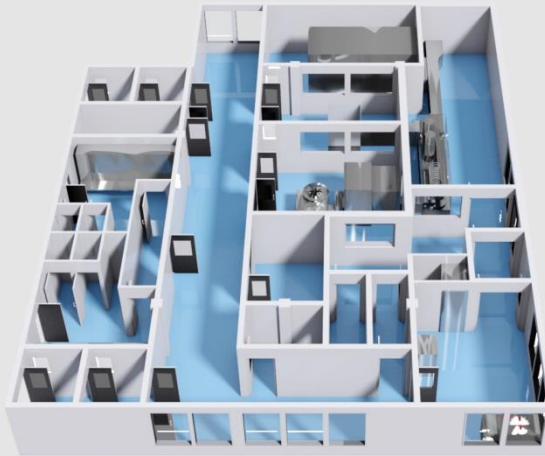


Scalable capacity, 500, 1 000 to $X * 2\,000$ L SUB:s

The Flexible MAS™ Platform



Complete building with fixed installations, process equipment and clean utility generation.



RABS

Container: 2- 2

Capacity: 100/min 10

Isolator

2- 20 ml vials

200/min 10 ml vials

PFS

0,5 – 10 ml

200/min 1 ml

All these platforms can be modified to fit the required capacity

Flexibility – Single use or SS



Independent of any vendor or process – gives the client flexibility to stay with current vendor or possibilities to negotiate best price



100 % single-use ↔ 100 % stainless steel



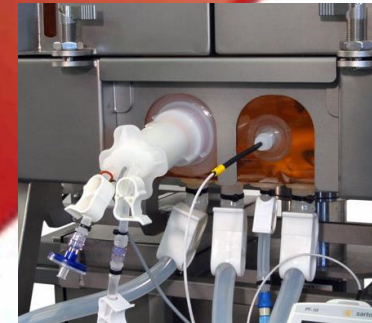
Design with maximized use of single-use equipment → 100 %

Healthcare

Millipore

Sher Scientific-

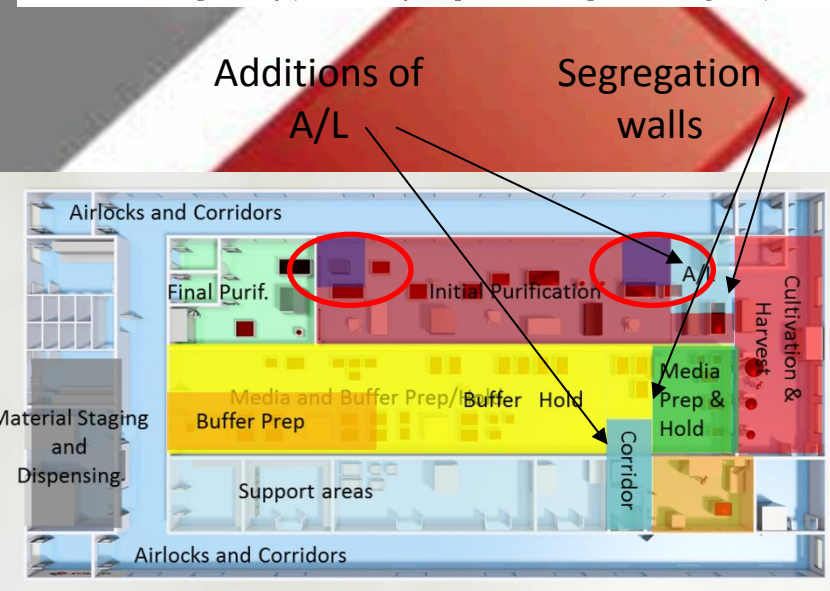
ers



Healthcare Life Sciences



- 



Flexibility – Full Integration



A fully integrated facility through easy expansion and connections according to needs – a hybrid

- Add on for MAS (Modular Aseptic Solutions™)
- Add on for Utilities
- Connection to Conventionally Constructed Warehouse
- Connection to Conventional Laboratory
- Connection to Conventional Administration

MAS



MBS



Flexibility- Relocation of Facility



1. Disassembly at first site



2. New site in preparation during disassembly



3. Reassembly at new site







5. Reassembly gain?, same site



4. Facility in operation at new site

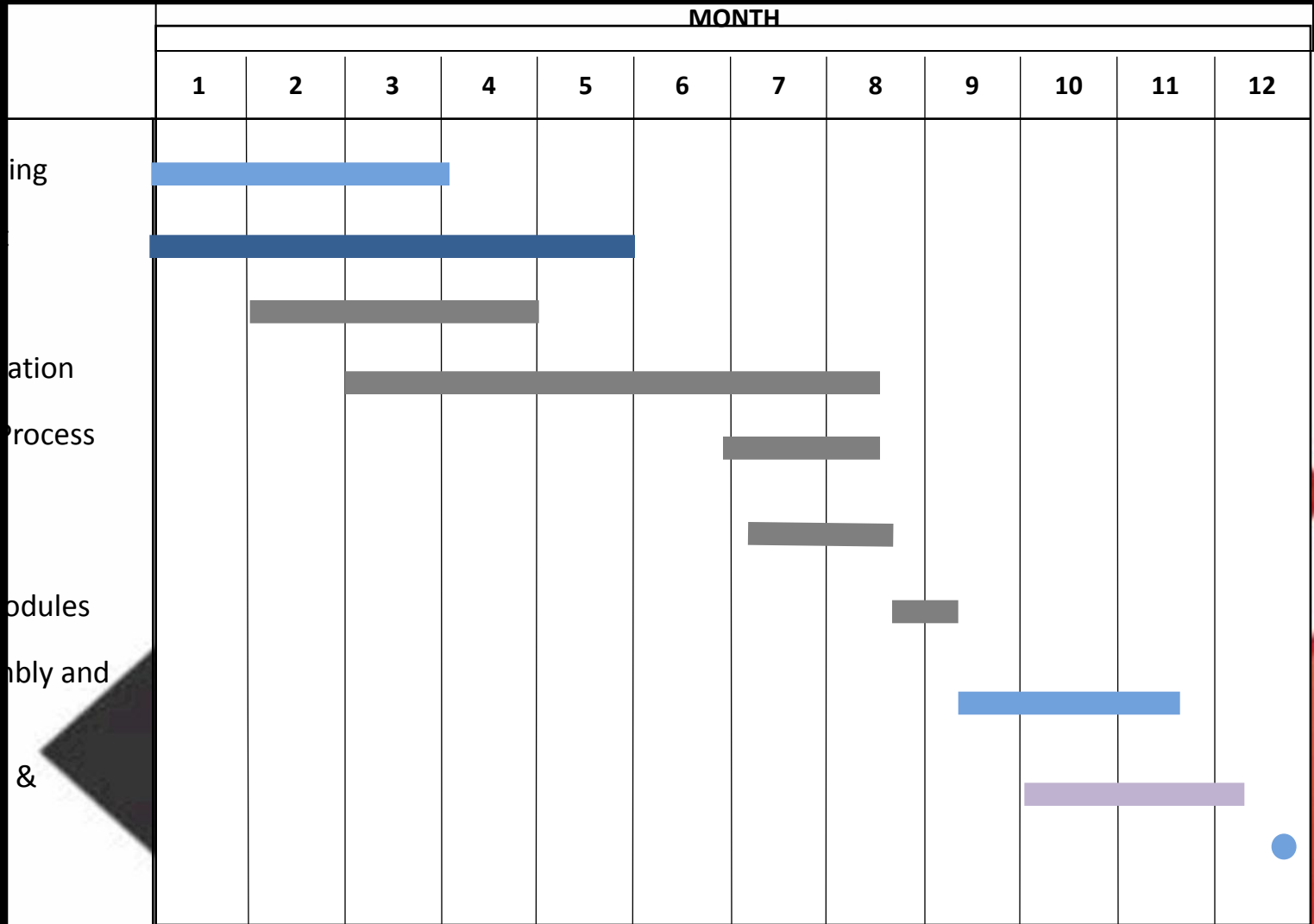
Flexible Scope



-  Standard covers the manufacturing process from seed cultivation, harvest, purification to filled bulk in cold storage (optional MAS aseptic filling)
-  Engineering Management System and the support functions including cleaning and sterilization, weigh and dispense, in process control and disposable waste
-  Mechanical installations on level 2
-  Design incorporated



Accelerated Schedule, Overlapping



CONCEPTUAL LAYOUTS

1. Microbial Vaccines MV
2. Therapeutic Proteins TP
3. Live Viral Vaccines LVV, BSL3 containment
4. CMO Multipurpose

1. MICROBIAL VACCINE, MV

Conceptual Layout

Configurations MV



g minor configurations to the pre-engineered flexible platform Modular Bio Solutions™ have been made:



SIP added since there are stainless steel process component



mn packing area added



storage added

2. THERAPEUTIC PROTEINS, TP

Conceptual Layout

Configurations TP



ing minor configurations of the pre-engineered design
n Modular Bio Solutions™ have been made:



Increased Media and Buffer prep/hold area



Increased Cultivation and Initial purification area



The addition of CIP/SIP, Column Packing and Cold
Storage as for the process MV

3. LIVE VIRAL VACCINE, LVV

Conceptual Layout

Configurations LVV



g minor configurations of the pre-engineered design
Modular Bio Solutions™ have been made:



ased the level of segregation to meet the
rements of BSL3 and handling of Live Virus by
g airlocks in to the live area.



area also includes a Virus seed lab in Grade C



disposeable






4. CMO MULTIPURPOSE

Conceptual Layout

Configurations MP

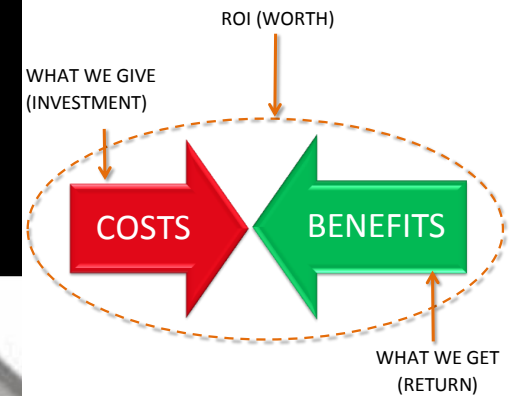


g configurations of the pre-engineered design
n Modular Bio Solutions™ have been made:

-  to limited area on site a CMO requested a two storey
figuration based on the MBS platform
-  disposables (as in the original design)
-  segregation between cultivation and initial
ification
-  ough the floor segregation to final purification
-  er/Media carts by elevator to Buffer/Media hold.

Why Modular Platforms?

- ❖ Schedule within one year – shorter time to market
- ❖ Improved flexibility to produce several vaccines
- ❖ Enhanced value with integrated design and construction capability
- ❖ Subject Matter Experts in Aseptic and Biotech Processing
- ❖ Higher quality with off-site fabrication workshop ISO 9001 and OHSAS 18001 certified, with only specialized labour for all disciplines
- ❖ 3D modeling for efficient client and discipline coordination
- ❖ Standard business model to offer fixed price (ex works) after completed and accepted Basic Engineering
- ❖ Standard design concepts for shorter implementation at reduced cost. Cost of operations reduced through savings in labor, QA cost, validation, maintenance, utility and energy



KeyPlants Globally



Global capabilities in Life Sciences and Process Manufacturing Industries



Part of Telstar/Azbil Group with > 2 Billion Euro in turnover and 9 000 employees whereof + 900 pharma specialists

Our Services



Services

- Conceptual Design
- Basic Engineering
- Detailed Engineering and Execution
- EPCM contracts
- Turn-Key Delivery
- Consultancy (Feasibility studies etc.)

Project Types

- Green field/Brown field
- Upgrades, Expansions and Renovations

Standard Facilities

- MAS (Modular Aseptic Solutions)
- MBS (Modular Bio Solutions)

Complete Range of Modular Solutions

- Building Modules
- Indoor Modules
- Process Modules/Super Skids



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Vaccines

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KeyPlants' & Big Pharma



Experience with Big Pharma:

- Over 20 years on average of working biotech and pharma projects for the big 30



GlaxoSmithKline



Lonza



Johnson & Johnson



MERCK



Genentech
A Member of the Roche Group



Baxter

