



# Biological Product Industry Prioritization Report

Detailed Project Report (DPR)



May 22, 2021



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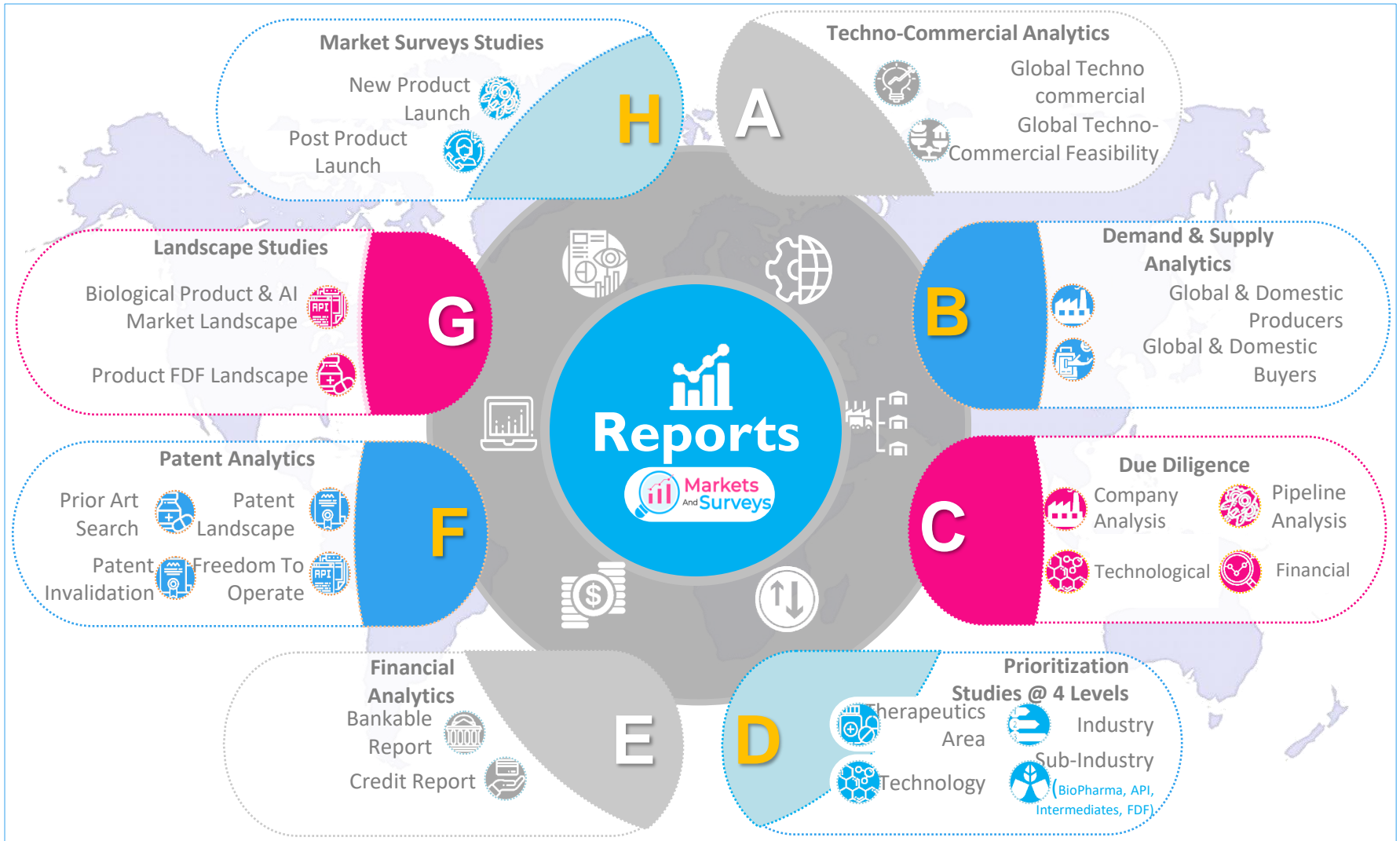


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**Market Research Reports**



## New plant set up

### A. Biosimilars Formulations plant Setup



## Sections

- A. Industry Benchmarking & 10 products selections
- B. Techno commercial feasibility
- C. Actual Technology transfer
- D. Plant setup as per guidelines





## CHAPTER 1 EXECUTIVE SUMMARY

## CHAPTER 2 BIOLOGICAL PRODUCT BENCHMARKING

### Biological Product Segmentation: By Synthesis

- a. NBE – New Biological Entity
- b. GB – Generic Biologics

### Biological Product Segmentation: By Manufacturing Complexity

- a. Easy: Fermentation biological compounds
  - b. Complex: Biological Vaccines e.g., streptokinase
  - c. R&D Intensive: Rec-DNA e.g., Monoclonal/Polyclonal
  - d. Advanced: Gene Therapy, micro RNA therapeutics, CASPR
- (Requires: Capital Intensive technology, lab and highly skilled professionals)

### Biological Product Segmentation: By Product Type

- a. Monoclonal Antibodies
- b. Recombinant Proteins
- c. Growth Hormones
- d. Beta Interferon
- e. Therapeutic Enzymes





## Biological Product Segmentation: By Industry

- a. Hospitals
- b. Specialized Clinics
- c. Government Research Institutes

## Biological Product Segmentation: By Market Size

- a. Global Market Size
  - By Value
  - By Volume
- b. Market Trends
- c. Market Growth

## CHAPTER 3 -BIOLOGICAL PRODUCT CATEGORIZATION & SHORTLISTING BY FORMULATING ALGORITHM & SCORING METRICES USING PARAMETRS

- Technical Advantages
  - Ease of manufacturing technology
  - Patent
  - Mechanism of Action
- Market Size & Market Growth
- Global presence





- Product Segmentations

## CHAPTER 4 - SELECTION OF TOP 5 RESULTS

- Identification of relevant molecules
- Selection of the top 5 molecules
- Analysis and Reporting

## CHAPTER 5 TECHNO-COMMERCIAL FEASIBILITY OF SELECTED BIOLOGICS

### SELECTED BIOLOGICAL PRODUCTS: Basic Insights

- Product Overview
- Synonyms
- Innovator Details
- Launching date
- Priority and Patent Expiry

## CHAPTER 6 - SELECTED BIOLOGICAL PRODUCTS Categorization, FORMS, GRADES APPLICATIONS & MECHANISM OF ACTION

- Application
- Grades
- Mechanism of action



## CHAPTER 7 BIOLOGICAL PRODUCTS - CONTINENT WISE MANUFACTURERS, MANUFACTURING VOLUME & CONTACT DETAILS

- Biological Products Continent Wise Manufacturers
- Biological Products Continent Wise Manufacturing Volume
- Biological Products Continent Wise Manufacturers Relevant Contact Details
- Biological Products Country Wise Manufacturers
- Biological Products Country Wise Manufacturing Volume
- Biological Products Country Wise Manufacturers Relevant Contact Details

## CHAPTER 8 BIOLOGICAL PRODUCTS - INDIAN MANUFACTURERS, MANUFACTURING VOLUME & CONTACT DETAILS

- Biological Products Indian Manufacturers
- Biological Products Manufacturing Volume
- Biological Products Indian Manufacturers Relevant Contact Details

## CHAPTER 9 (BIOLOGICAL PRODUCTS INTERMEDIATE)-GLOBAL MARKET WITH PAST AND FUTURE PREDICTION CONTINENT WISE MANUFACTURERS, MANUFACTURING VOLUME & CONTACT DETAILS

- Biological Products Intermediate) Continent Wise Manufacturers
- (Biological Products Intermediate) Continent Wise Manufacturing Volume
- (Biological Products Intermediate) Continent Wise Manufacturers Relevant Contact Details





- (Biological Products Intermediate) Country Wise Manufacturers
- (Biological Products Intermediate) Country Wise Manufacturing Volume
- (Biological Products Intermediate) Country Wise Manufacturers Relevant Contact Details

## **CHAPTER 10 Biological Products INTERMEDIATE)- INDIAN MANUFACTURERS, MANUFACTURING VOLUME & CONTACT DETAILS**

- (Biological Products Intermediate) Indian Manufacturers
- (Biological Products Intermediate) Manufacturing Volume
- (Biological Products Intermediate) Indian Manufacturers
- Relevant Contact Details

## **CHAPTER 11 WORLDWIDE MANUFACTURING PROCESSES, RAW MATERIALS & MANUFACTURING COST**

- Manufacturing Process Analysis of Biological Products All Types Of Manufacturing
- Routes & Schematic Diagram
- Manufacturing Cost Analysis

## **CHAPTER 12 Biological Products FEASIBILITY ANALYSIS**

- Raw Material and Production capacity
- Manufacturing Process Description with comparison of various other process
- Details of Hazardous Chemicals Storage & Handling

## **CHAPTER 13 Biological Products RETURN ON INVESTMENT & BREAKEVEN ANALYSIS**



## CHAPTER 14 PRICE TREND ANALYSIS FOR 3 YEARS

- Price trend of Biological Products country wise
- Price trend of Biological Products manufacturer wise
- Price Trend of (Biological Products Intermediate) Country Wise
- Price Trend of (Biological Products Intermediate) Manufacturer Wise

## CHAPTER 15 SELECTED BIOLOGICAL PRODUCTS - GLOBAL, CONTINENT WISE MARKET SIZE & MARKET GROWTH, PRICE TREND & PRESENT & FUTURE FORECAST ANALYSIS

- Biological Products Present & Future Global Market Size In Terms Volume
- Biological Products Present & Future Global Market Size In Terms Value
- Biological Products Present & Future Global Market Growth In Terms Volume
- Biological Products Present & Future Global Market Growth In Terms Value
- Biological Products Present & Future Asian Market Size In Terms Volume
- Biological Products Present & Future Asian Market Size In Terms Value
- Biological Products Present & Future Asian Market Growth In Terms Of Volume
- Biological Products Present & Future Asian Market Growth In Terms Of Value
- Biological Products Present & Future Europe Market Size In Terms Of Volume
- Biological Products Present & Future Europe Market Size In Terms Of Value
- Biological Products Present & Future Europe Market Growth In Terms Of Volume
- Biological Products Present & Future Europe Market Growth In Terms Of Value



- Biological Products Present & Future South America Market Size In Terms Of Volume
- Biological Products Present & Future South America Market Size In Terms of Value
- Biological Products Present & Future South America Market Growth In Terms of Volume
- Biological Products Present & Future South America Market Growth In terms of Value

## **CHAPTER 15 SELECTED BIOLOGICAL PRODUCTS - CUSTOMER WISE CONSUMPTION, QUANTITY & CONTACT INFORMATION INSIGHTS**

- Biological Products Global Buyers
- Biological Products Global Buyers As Per Buying Quantity
- Biological Products Continent Wise Buyers
- Biological Products Continent Wise Buyers As Per Buying Quantity
- Biological Products Country Wise Buyers
- Biological Products Country Wise Buyers As Per Buying Quantity

## **CHAPTER 112 SELECTED BIOLOGICAL PRODUCTS WORLDWIDE PATENT & REGULATORY AS**

- Total Patent Filed With Details
- Country Wise Product Registration
- Import Policy- Anti Dumping
- Import Duty
- Export Benefits



- REACH Status
- License Required For Trade
- Regulatory Status

**CHAPTER 17 SELECTED BIOLOGICAL PRODUCTS CONTINENT WISE EXPORT/ IMPORT STATISTICS**

- Biological Products Continent Wise Import Statistics
- Biological Products Continent Wise Export Statistics

**CHAPTER 18 (SELECTED BIOLOGICAL PRODUCTS INTERMEDIATE) CONTINENT WISE IMPORT STATISTICS**

- Biological Products Continent Wise Import Statistics

**CHAPTER 19 SELECTED BIOLOGICAL PRODUCTS WORLDWIDE SWOT ANALYSIS & BUSINESS RECOMMENDATION**

- Biological Products SWOT Analysis (Strength, Weakness, Opportunities & Threat)
- Biological Products Business Prospects & Our Recommendation



## CHAPTER 21 TECHNOLOGY TRANSFER INCLUDING PATENTS & LICENSING

- Patent Portfolio Analysis
  - Identification of key takeaway
  - Key statistics for the portfolio
  - Trends in patent filings and grants
  - Technical focus of patent filings
  - Technology trends over time
  - Summary of recent inventions
- Identification of licensing opportunities
- White-space analysis
- Technology Transfer Services
  - Transfers of late stage R&D
  - Transfers of dedicated operations (large and small scale)
  - Transfers of niche processes
  - Transfers to Pharma Tech's vertically integrated capabilities
- Deal closures



## CHAPTER 22 PLANT SETUP MANUFACTURING BLUEPRINT

### Environmental Scan

- External Analysis
- Internal Analysis

### Sub-sector Assessment

### Identification of Value Added Services

- Supply Chain Issues

### Financial Analysis

- Infrastructure
  - CAPEX
  - Equipment Cost
  - OPEX
  - Annual Utilities Usage
- Legal/ Statutory Fees
- Investment Summary

### Human Resources

### Organisation Chart

- Job Descriptions for Key Positions
- Labour Availability
- Location



## CHAPTER 23 PLANT SETUP DESIGN

- Plant Set-up Design
- Business Objective
- Pre-requisite-understand
- Market The Product & Requirements
- Process
- Layout Planning Parameters
- Basic Design
- Risk Based & Life Cycle Qualification







**SAMPLE**

**2019**

**Global Biological Product Market**



by Value  
2019

**\$255B**

by Value  
2024

**\$390B**

Growth rate  
2019-2024

**8%**

**Selected Biological Product Market**



by Value  
2019

**\$\*\*B**

by Value  
2019

**\$\*\*B**

Growth rate  
2018-2023

**\*\*%**

**Global Manufacturers Market share by Geography & Regional Growth Rate**



**Key Global Manufacturers**

Amgen



Roche



J&J



Merck



Pfizer



## SAMPLE

LSIP will create a metric system to score all APIs on the basis of various parameters.

**Step 1 : Biological Product Landscape :** To Identify key Biological Product (600+) across the industry

**Step 2: Biological Product Benchmarking:**

- By Synthesis
- By Manufacturing Complexity
- By Product Type
- By Industry
- By Market Size

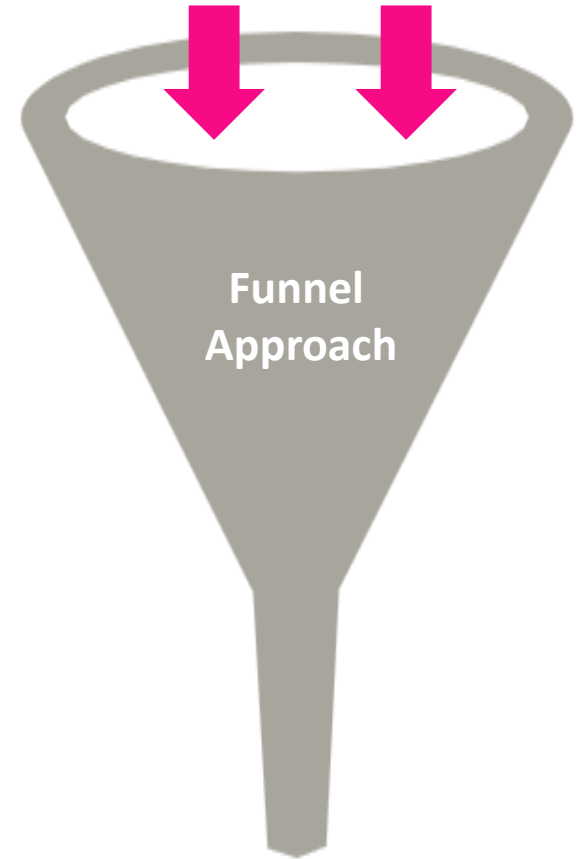
**Step 3: Top 5 Biological Product Selection By Formulating Algorithm &**

**Scoring Matrices**

- Technical Advantages
  - Ease of manufacturing technology
  - Patent
  - Mechanism of Action
- Market Size & Market Growth
- Global presence

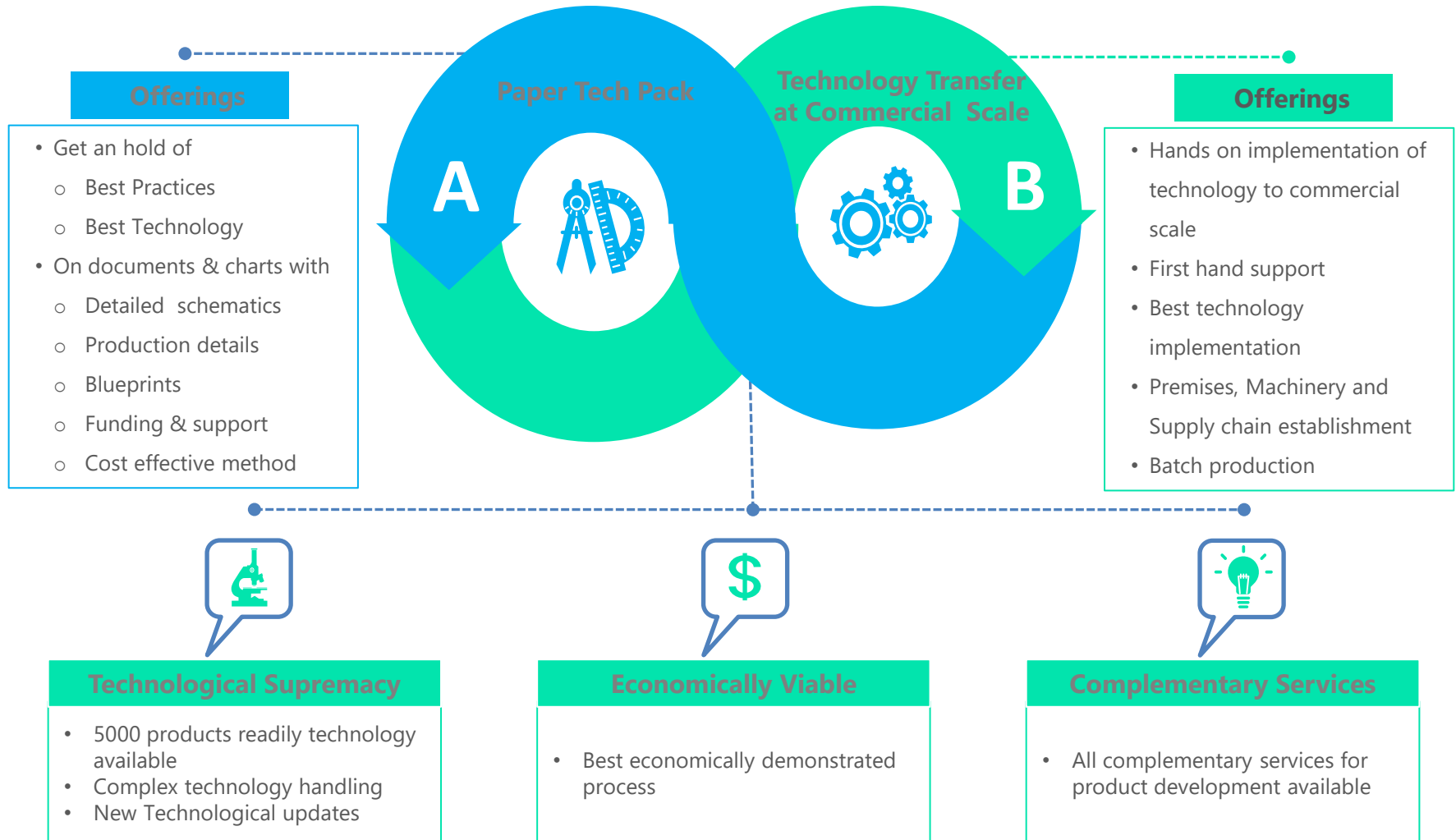
**Step 4: Reporting and Analysis**

Biologics (600+)



Top 5 Biologics

## SAMPLE



## SAMPLE

### Objective

### Work Flow

To establish new pharmaceutical manufacturing facility for pharmaceutical formulation

Yes

No

Client's bare land

Facility Improvement

Old facility provided by the client

Bare Land

Premise construction by client

Feasibility & Gap analysis by LSIP

Parameters

Area

Product type (Dosage Form)

Compliance (cGMP, WHO)

Batch Size

Average: 50x40 m<sup>2</sup>

Tablets, Capsule, Syrups, injections etc.

Compliance Audit

Lab & Commercial Scale

Schedule M

Cost Analysis

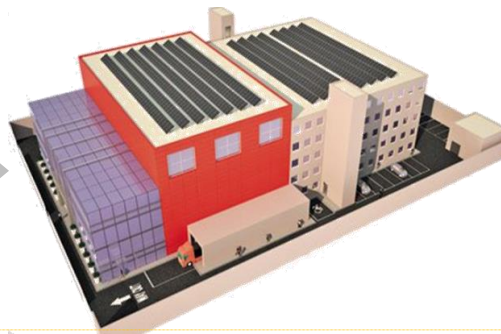
Analysis of fixed cost (Machines, Equipment, Premises etc.) and variable cost (Raw Materials, Logistics etc.)

By LSIP

By Client

Consulting i.e., Engineering, Compliances & Project Management cost (soft work)

Logistics i.e., Civil, Material & Equipment procurement & installment



SAMPLE

# Plant Set-up Design

Guidelines based entire plant setup of Biosimilars



SAMPLE

# Business Objective

- 1) Project variable prioritization
  - Compliance ( )
  - Cost
  - Schedule
- 2) Design as per Compliance.
- 3) Design for handling multi product



SAMPLE

# Pre-requisite-Understand the Product & Market Requirements

Knowledge about the particular products to be processed within the facility fundamental to complete system design

- Product type Liquid Juices and Tablets production

**SAMPLE**

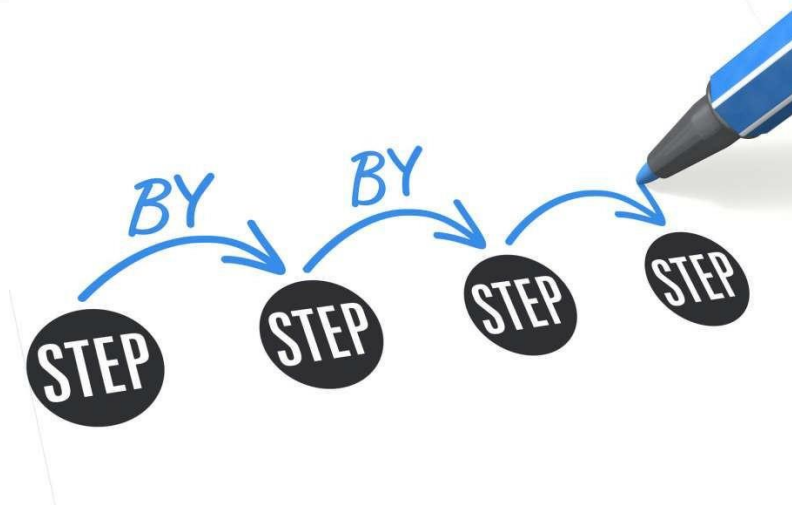
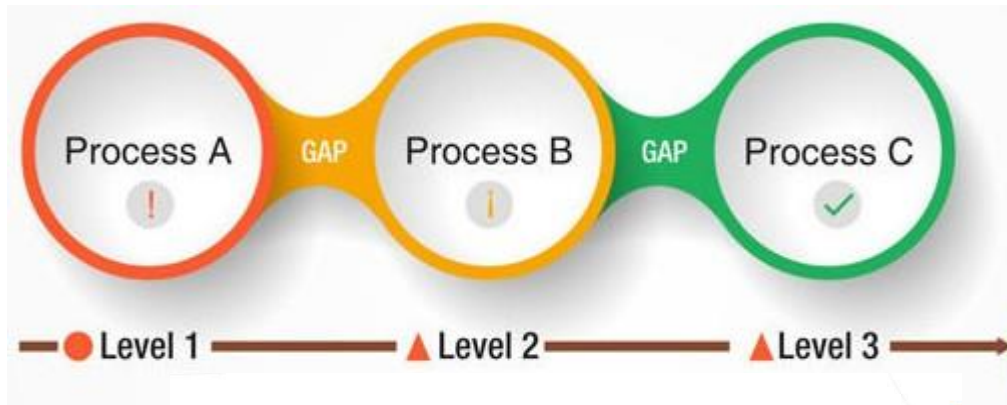
Pre-requisite-We Understand the Process Knowledge of the critical step for Manufacturing Process and facility design to overcome the damage of the materials or Hazards

- Product limits(temperature & humidity)
- Product form (liquid, powder etc)
- Process step-Granulation,Dispensing,coating,secondary packing and the applicable hygiene zone(LEVEL-I,II,III For oral application and ISO-5,7,8 for parenterals
- Handling of equipments and tablets manufacturing section



SAMPLE

# Process



- Production Planning
- Production equipment sizing
- Equipment URS
- Process flow diagrams
- P & ID's
- Utility estimation
- CIP/SIP Scheme
- Gowing Philosophies.

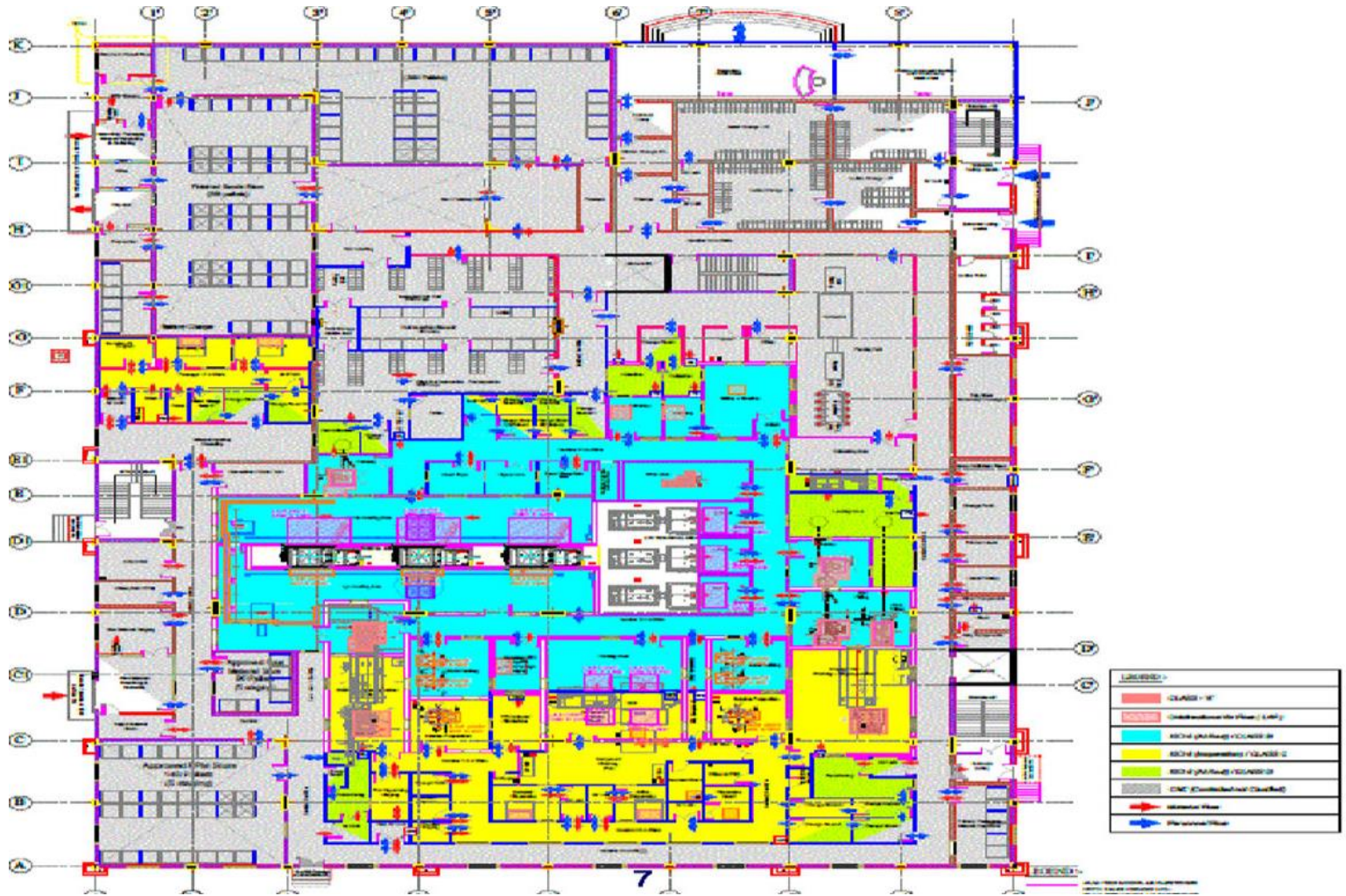
SAMPLE

# Layout planning parameters

- Man material from unclassified to classified areas)
- Proper equipment placements & operational spaces.
- GMP view (Classification, cross contamination)
- HAZOP & Other safety view.
- Production planning & operation (Sampling, dispensing, washing & quarantine requirements)
- Storage of RM, PPM, SPM & FG
- PD lab, QC Labs etc for testing.
- Future area planning

# Typical Layout

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# Site Master Planning

Allocation of required spaces & best location for each of following blocks :

- Main production blocks
- QA/QC Areas.
- Utility block (boiler, DG, Compressed air, chiller, pumps etc)
- Water system area
- Technical area for AHU/process equipments.
- Material, personnel guard house.
- Parking space, green belts, cable trench, plumbing, HT panel,
- transformer location etc.
- Fire house
- Effluent treatment

# Typical SMP

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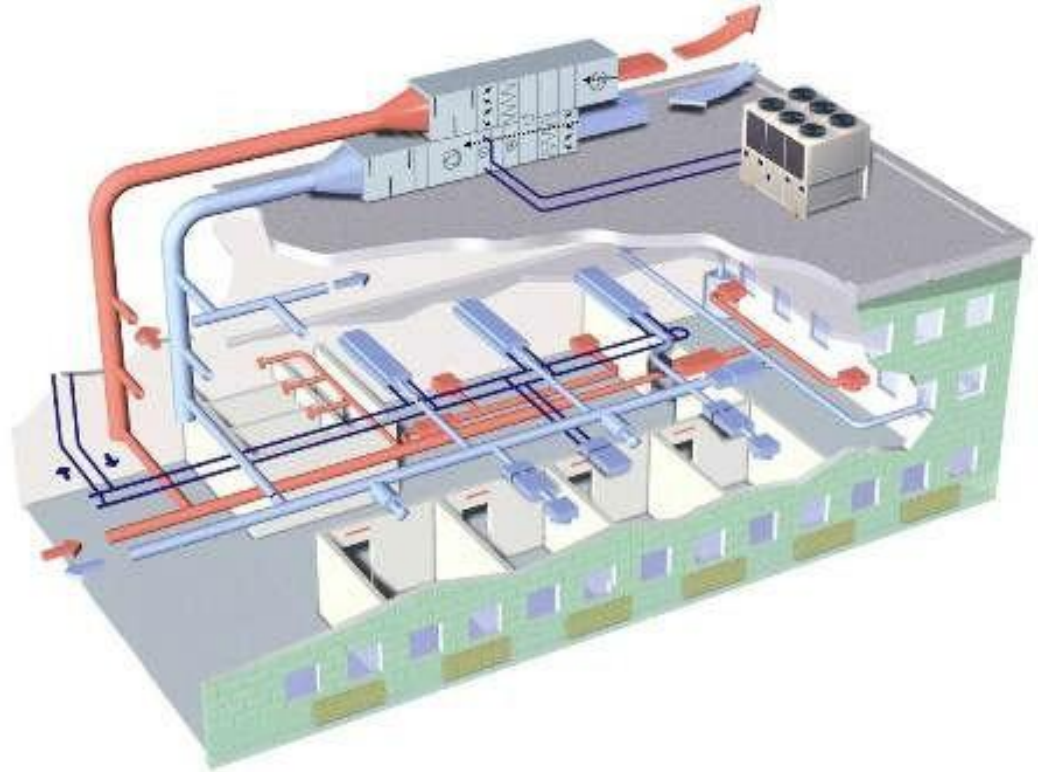


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# Basic Design

Design philosophies for:

- HVAC Systems
- Civil structural engineering
- BMS
- Mechanical & piping
- Modular panels
- Electrical systems



SAMPLE

## Detailed Design

- Design tenders for all the items used
- Specification of all the items used
- BOQ of the items detail  
GFC drawing will proceed after tender award to various contractors.
- Terms & Condition of execution for contractors
- Specified Drawings

SAMPLE

# Civil & Architecture

- False ceiling drawings, Modular panels, road.
- Door window schedule
- Civil finishing schedule , epoxy flooring etc.
- Beam layout, plumbing drawings, Hume pipe, chamber, plinth
- Various sections for building & staircases,  
protection, foundation layouts etc.
- Various Architectural views preparation



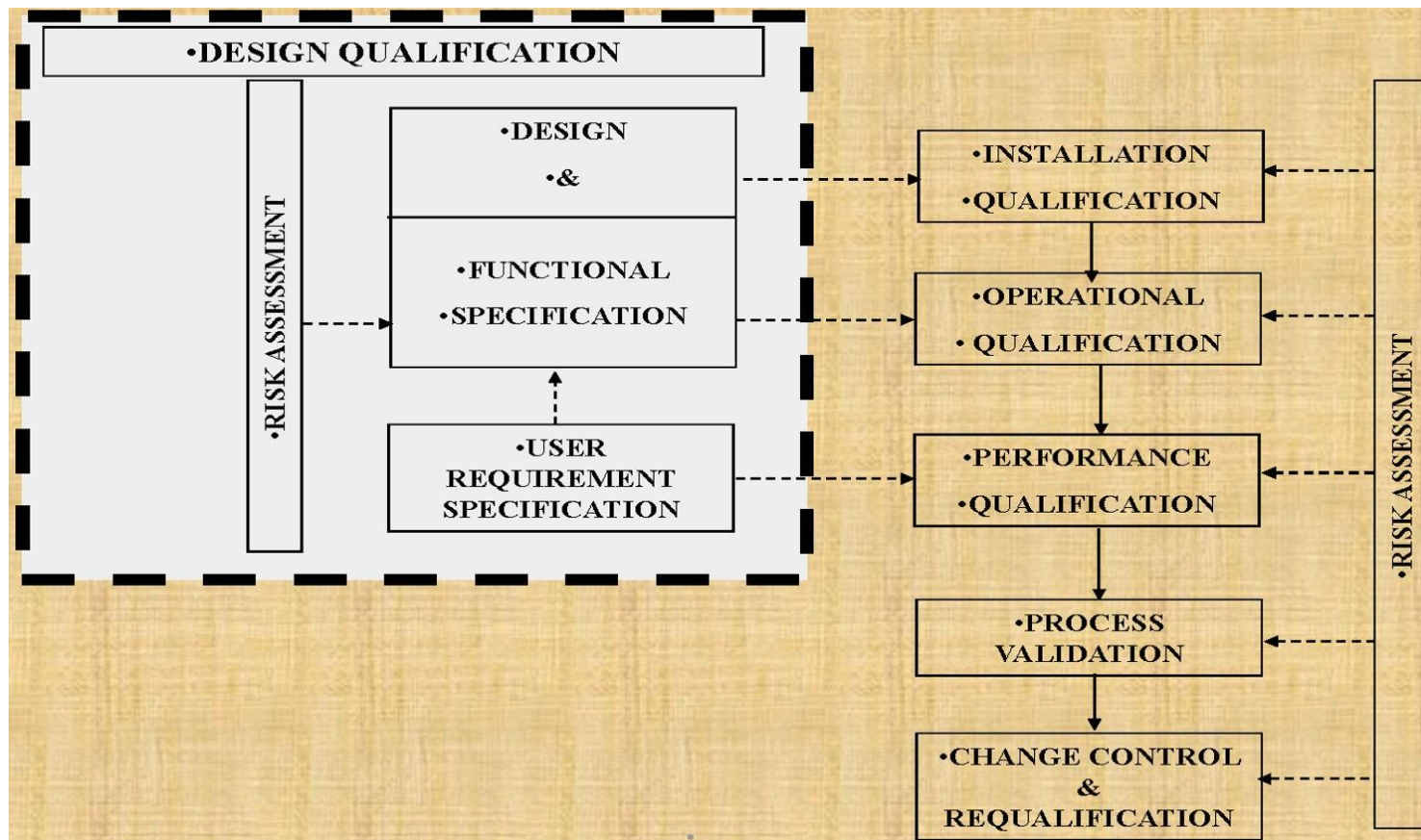
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# Electrical Design

- Overall plant load sheet
- Transformer, DG, UPS System Calculations & specification.
- Power socket layout, earthing, overall plant lighting, cable tray design.
- Design & BOQ for HT & LT panels.
- CCTV, Access control, LAN Telephone data and fire detection system design.

SAMPLE

# Risk Based & Life Cycle Qualification Approach





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