

 SynergysWISSENGINEERING



# EXECUTIVE PARTNERS

The partners, complementing each other, can operate in complete synergy, thanks to their specializations which make them a point of reference for expertise and technical skills.

## RIGEL Life Sciences srl

The company is specialized in the control of air-dispersed particulate and microbial contamination and boasts important commercial relations with Climet and Biovigilant

## PATWAY srl

The company operates in the field of pharmaceutical processes and the development and execution of validation programs, process automation and DCS and MES solutions, risk assessment, PAT solutions and data integrity.

## DELIC Impianti srl

A company that is leader in the design and execution of complex high-tech industrial plants with particular reference to mechanical plants and technology

## F.lli Rossetto srl

A leading company in the design, construction and installation of GMPs in clean rooms and accessories, pass boxes, stainless steel equipment, Rabs and electronic access control systems

## Prof. Eng. Silvio Massimo Lavagna.

Professor of "Pharmaceutical Plants and Industrial Pharmacy" at "La Sapienza" University of Rome, acts as liaison between all the players involved and supervises all engineering activities

## Studio Tecnico Iorio

### GMC Impianti srl

The firm designs and constructs electrical systems, control panels, distribution substations for the chemical, pharmaceutical and biotech industry.

**Synergy Engineering** and its partners are committed to the creation of functional solutions to protect the environment and the quality of production areas, that are key points in the development of complex technological systems. The experience gained in the hospital-plant sector and the close collaboration with the academic world are the prerogatives brought to bear on the chemical-pharmaceutical and healthcare industry.

## Energy Service

Maintenance of industrial plants, on- and off-shore turbogenerators and cogeneration plants

**Traditional activities**

**Advanced activities**

## Pharming and Biotech projects

Sector dedicated to the creation and construction of technological plants for the chemical-pharmaceutical, biotech, hospital and healthcare industry.

## Civil Field

Construction of technological systems for major works.

## Pharma Field

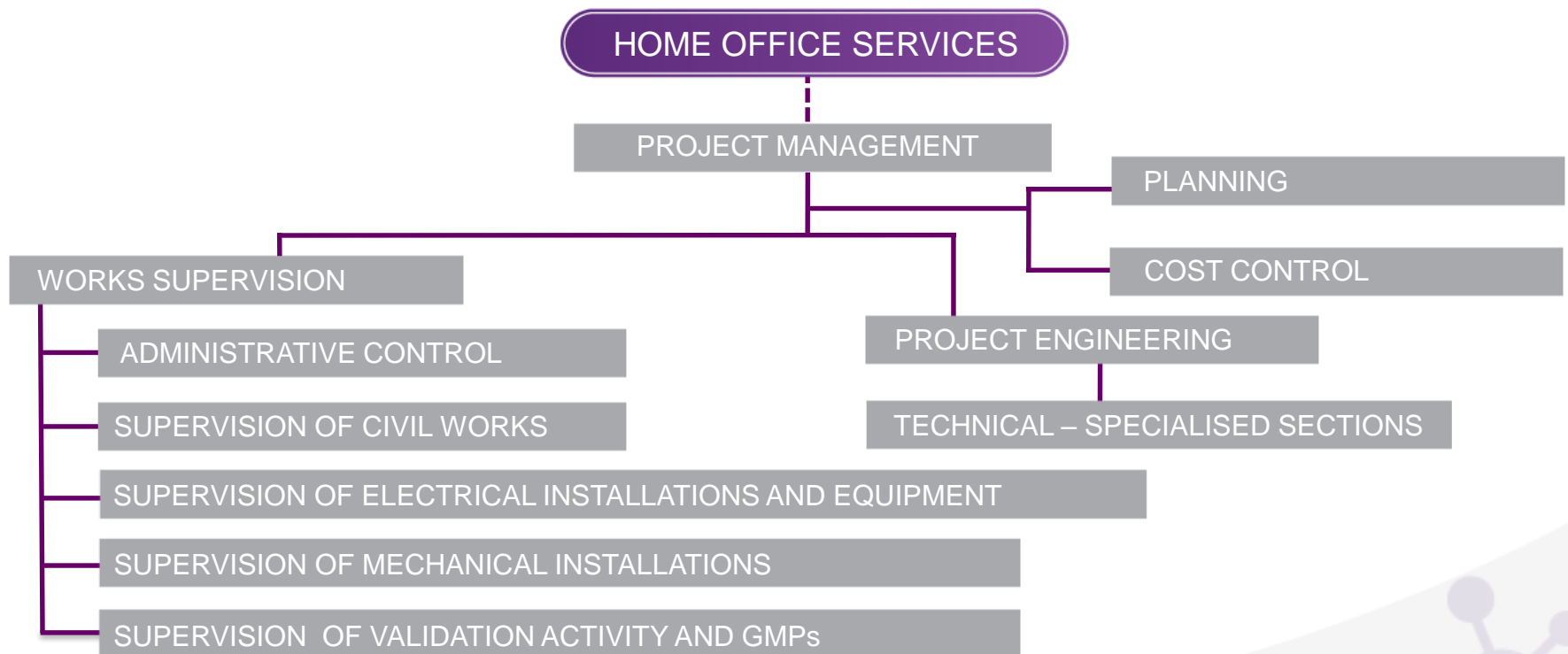
Sector dedicated to the development of the user requirements communicated by Customers and the development of a conceptual and basic design for new chemical-pharmaceutical and biotech departments and plants or their revamping.



# ORGANIZATION OF RESOURCES

The main objective of **Executive Synergy Engineering** is to develop the technological and processing aspects of each project, and oversee the activities of other specialists concerned with the detailed project, the **implementation** and **testing** of the plant, ensuring compliance with the specific requirements of pharmaceutical standards and GMPs.

Synergy Engineering Executive employs an **operational task force** specifically dedicated to each project based on customer needs, and an organizational chart that comprises all key players: Project manager, Process engineer, Cost control engineer, Planning engineer and Construction supervisor, etc. The task force executes the final project using the resources provided by the Synergy Engineering group and the general contractor.



## Activities

The activities carried out by Executive Synergy Engineering in the pharmaceutical sector concern the following areas:

- Production of pharmaceutical products (pharmaceutical dosage forms)
- Production of active ingredients and intermediates in bulk
- Multi-purpose facilities for bulk active synthetic ingredients
- Biotechnology
- R & D facilities: laboratories, pilot plants, research centres, etc.
- Risk Analysis
- Effluent treatment
- Building and process automation
- Computer Integrated Manufacturing (CIM)
- Validation of processes and equipment (I.Q., O.Q. and P.Q.) in accordance with European and US standards
- Support provided for ministerial and/or subcontracted auditing

## Services

The services rendered follow all the development phases, from the feasibility study to the delivery of the finished works.

- Feasibility study
- Concept design
- Process development
- Transfer of know-how
- Basic Design
- Detail engineering
- Procurement & expediting
- Project Management
- Project execution
- Training
- Validation
- Auditing



# PROJECT EXECUTION STAGES AND TECHNICAL-ECONOMIC FEASIBILITY STUDY

## PROJECT EXECUTION

1. Project conceived
2. Study of market conditions and manufacturing feasibility
3. Patents and licenses search
4. Definition of project bases
5. Designing (civil / mech. / electrical, etc.)
6. Research and procurement of materials and equipment
7. Definition and implementation of all logistics infrastructure
8. Construction and assembly
9. Staff training
10. Plant start-up, operation and validation activities
11. Product marketing



## MECHANICAL ASSEMBLY SUPERVISION

# PROJECT EXECUTION STAGES AND TECHNICAL-ECONOMIC FEASIBILITY STUDY

## The general contractor activity

1. Design
2. Procurement
3. Construction
4. Supervision
5. Commissioning and start-up
6. Industrial planning
7. Managing of external human resources
8. Managing of financial resources
9. Research, training and development of skilled personnel
10. Marketing

### The above requires:

- A valid commercial organization
- Highly professional individuals
- Flexible and dynamic groups

## External entities involved



# PROJECT EXECUTION STAGES AND TECHNICAL-ECONOMIC FEASIBILITY STUDY

01

## ESTIMATE OF ORDER OF MAGNITUDE

It is a rough estimate made using limited engineering data based on a conceptual design, on an estimate of the cost-capacity curves using scaling up/down factors and historical data.

Accuracy: (+ 50%, - 30%)

02

## PRELIMINARY BUDGET ESTIMATE

The cost estimate is developed on the basis of an in-depth feasibility study and sufficiently accurate engineering documents (basic design) such as to enable an assessment of the preliminary budget + 30%, -15%.

Accuracy: (+ 30%, - 15%)

03

## FINAL BUDGET ESTIMATE

The cost estimate is developed based on accurate engineering documents (detailed design) such as to enable an assessment of the final budget.

Accuracy: (+ 15% - 5%)



# PROJECT EXECUTION STAGES AND TECHNICAL-ECONOMIC FEASIBILITY STUDY

## ESTIMATE OF THE ORDER OF MAGNITUDE

1. Civil works
2. Materials
3. Packaging and transport
4. Assemblies
5. Technical assistance
6. Support for assemblies
7. Home office services
8. Field office services
9. Training
10. Know-how
11. Mark-ups
12. Margin for negotiation



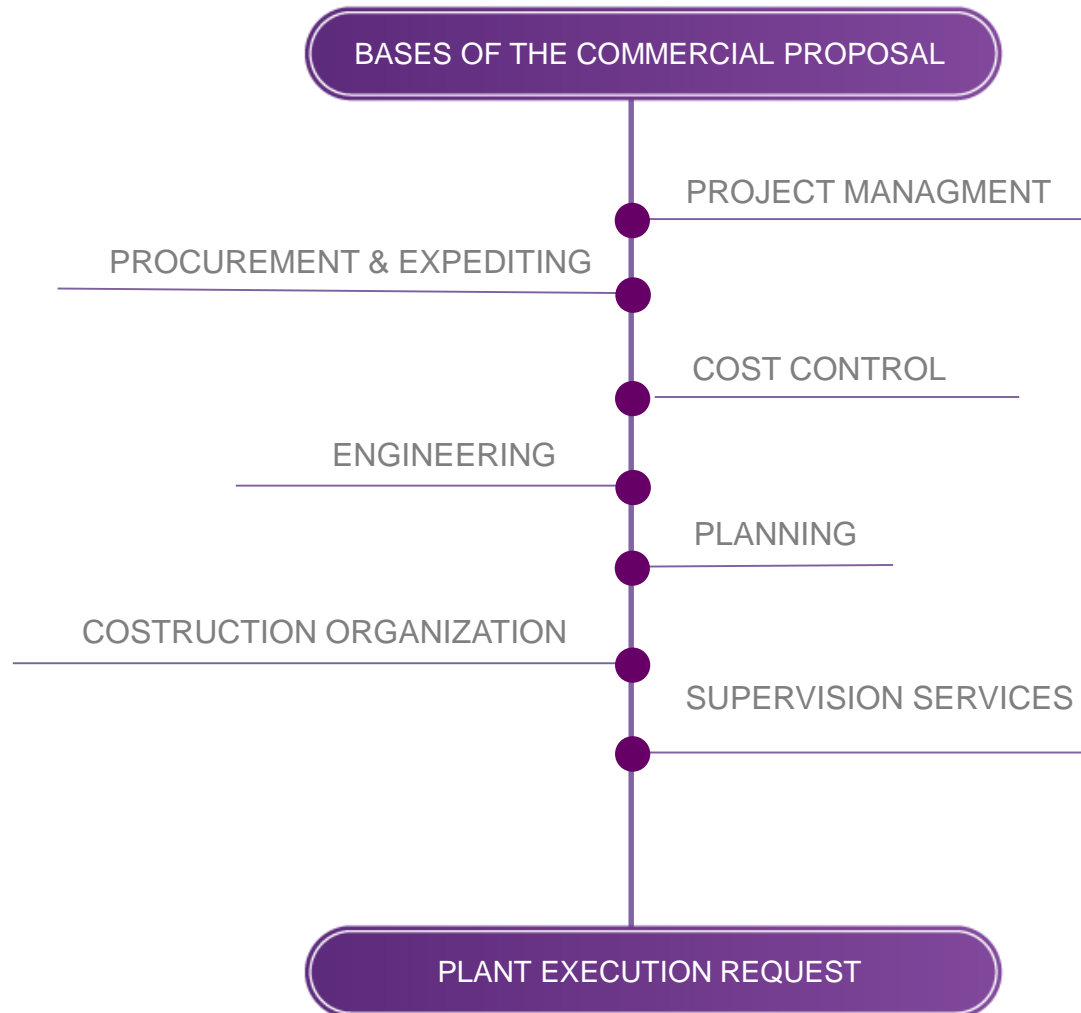
### FINAL ESTIMATE (+15%, -5%)

- Process flow charts: drafting
- Piping and tool diagrams
- Civil works: define the basic data for metric calculations and specifications
- Equipment and machinery
- Piping: define piping classes and Material Take Off (MTO)
- Steel structures: metric calculations and specifications
- Electrical system: metric calculations and specifications
- Instrumentation: metric calculations and specifications
- Insulations and coatings: metric calculations and specifications
- Fire protection and insulation: metric calculations and specifications
- Validations



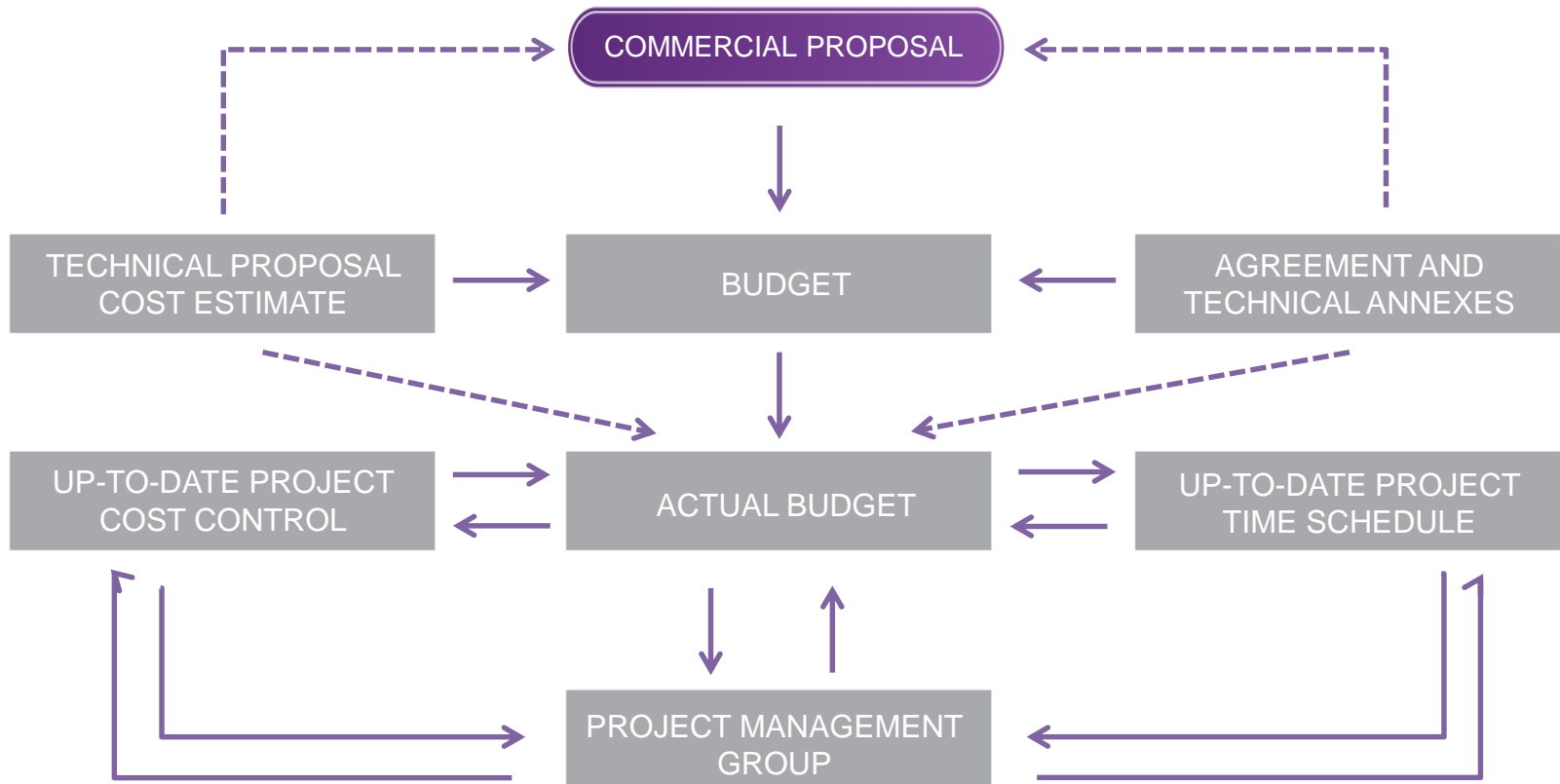
# PROJECT EXECUTION STAGES AND TECHNICAL-ECONOMIC FEASIBILITY STUDY

## COMMERCIAL OFFER



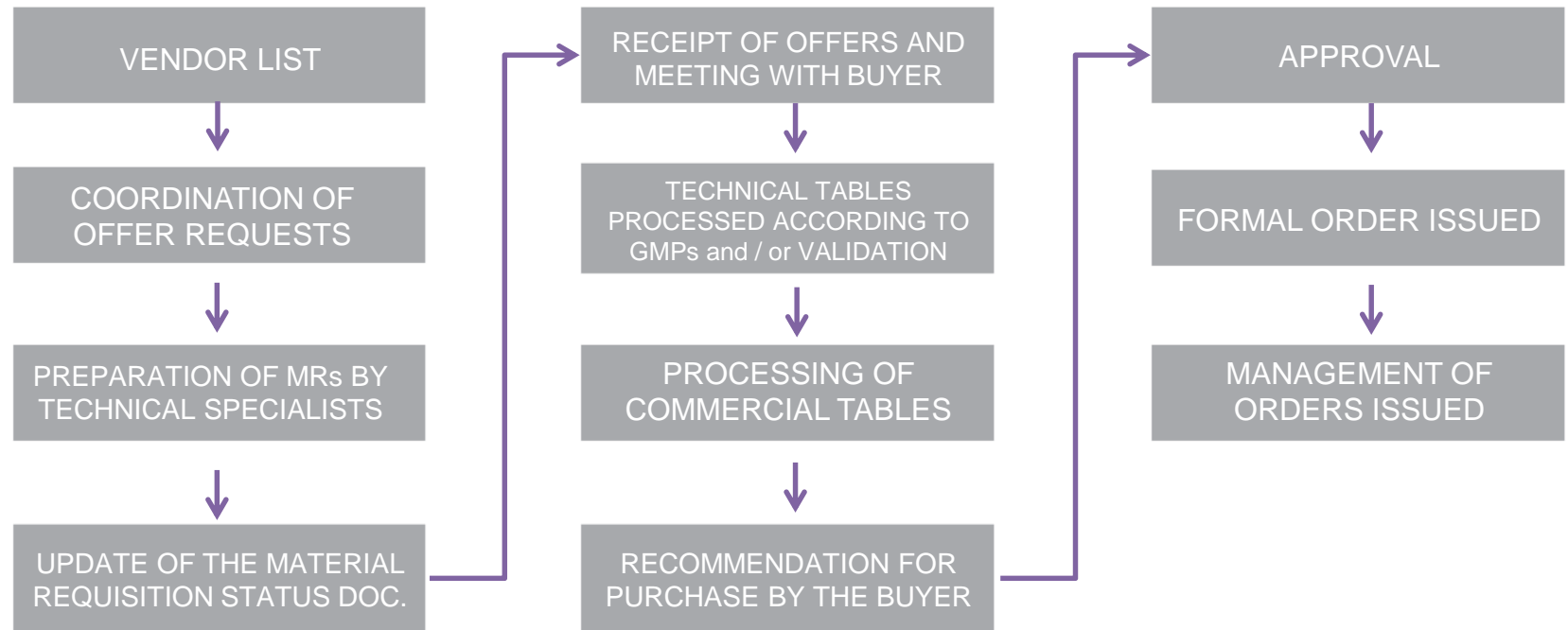
# PROJECT EXECUTION STAGES AND TECHNICAL-ECONOMIC FEASIBILITY STUDY

## BUDGETING PROCESS



# PURCHASING COORDINATION PROCEDURE

## PURCHASING AND AUDITING





# COST CONTROL

## Main objectives

## Cost control activities

PROMPTLY HIGHLIGHT ANY UNWARRANTED CAUSE OF COST INCREASE OR ADDITIONAL COSTS



CONTROL OF THE COST OF SERVICES PERFORMED BY G. C. (CONTRACTOR'S SERVICE)

KEEP THE CUSTOMER AND THE GENERAL CONTRACTOR CONSTANTLY INFORMED AND UPDATED ON THE FINANCIAL PERFORMANCE OF THE PROJECT



CONTROL OF THE COST OF MATERIALS and EQUIPMENT

ASSESS THE COST OF ALTERNATIVE SOLUTIONS DURING THE COURSE OF THE PROJECT



CONTROL OF THE COST OF CONSTRUCTION AND ASSEMBLY ACTIVITIES

ASSESS, IN COOPERATION WITH THE PROJECT GROUP AND SPECIALISTS, THE COST OF ANY AMENDMENTS AND CHANGES IN THE OBJECTIVE OF THE WORK



DRAWING UP OF "CLAIMS" AND "CHANGE ORDERS"

ENSURE PROPER USE OF THE CODES FOR CHARGING COSTS TO PROJECTS AND OF ACCOUNTING PROCEDURES



PREPARATION AND COMPLETION OF MONTHLY COST CONTROL "REPORTS"

# COST CONTROL

## 01

### CONTROL OF SERVICE COSTS

+ The use of resources, the hourly base cost, fringe benefits and OHDs referred to a given date, subdivided per person

+ Direct costs statement:

- Travels
- Communication
- IT
- Reproduction and photocopies
- Model
- Living allowances

+ The complete budget of in-house hours required to complete the project

## 02

### CONTROL OF COST OF MATERIALS

+ Analysis of "Bid Tables" and their update for the calculation of "estimates to completion"

+ Inputting orders issued in cost control analytical accounting

## CONTRACTOR SERVICES

## 03

### CONSTRUCTION AND ASSEMBLY

+ The "final estimated cost" is defined on the basis of the following criteria:

- More accurate cost information obtained from the quotations received from subcontractors
- Trend in labour costs (hourly) and other associated costs (using newsletters, A.NI.MA tables, etc.)
- More detailed information (coming from engineering) regarding the quantity of materials to be assembled)

## 04

### CONTROL OF WORK-SITE COSTS

+ The construction phase is carried out under the constant supervision of the C.S. (Construction Superintendent)

+ The report with "up to date" data and the forecast are analyzed by the C.C.E. (Cost Control Engineer )

+ The report follows the route below:

- It is approved by the P.M.(Project Manager)
- It is included in the monthly cost control report of the entire project

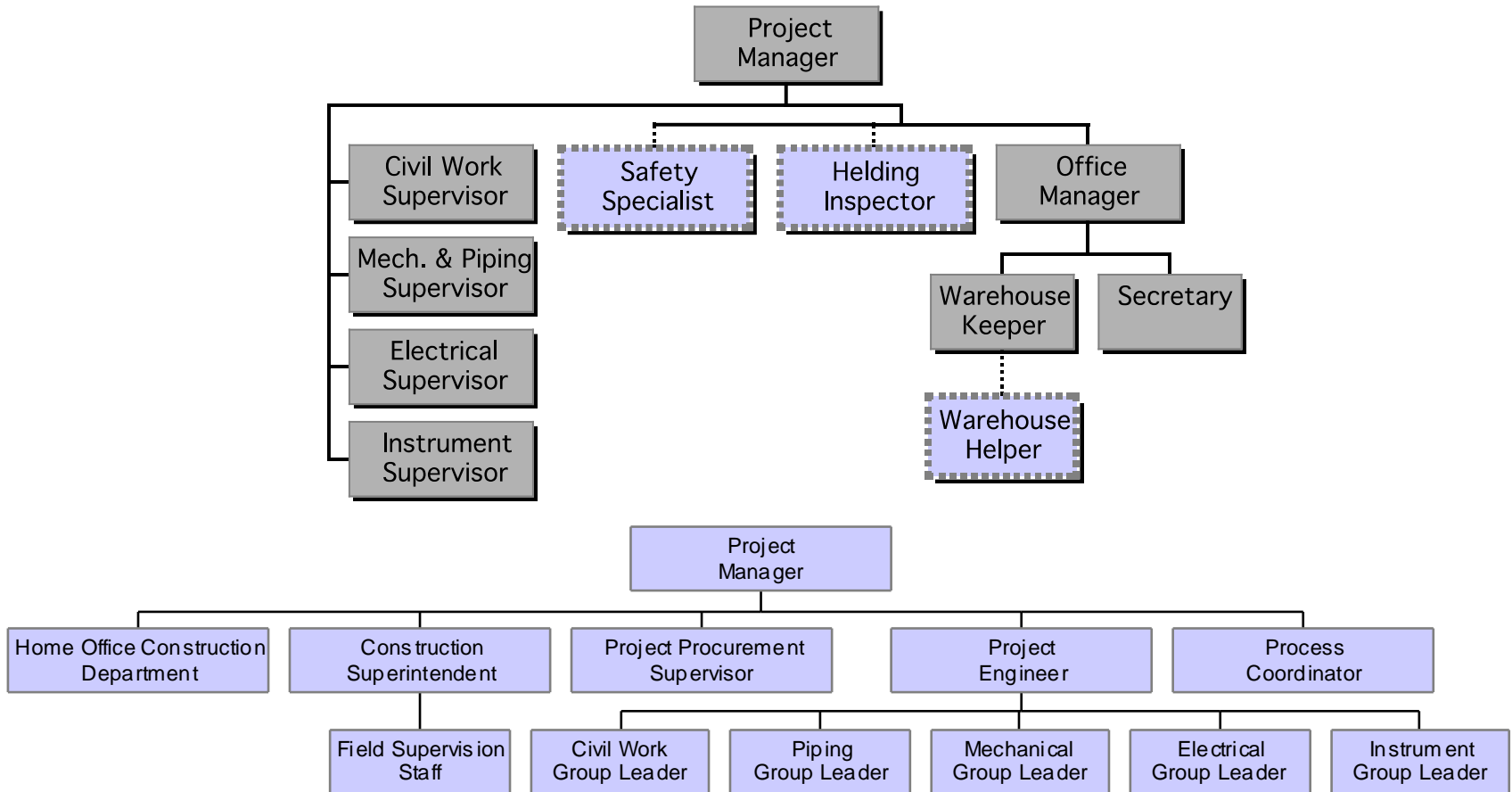
## 05

### CONTROL OF COST OF MATERIALS

+ It describes the overall progress of the project in economic terms with the following assessments:

- Progress and analysis of major deviations (over / underrun) compared to the budget.
- Analytical summary by categories and items of the comparison of the updated budget with the final cost estimate

# PROJECT ORGANIZATION



# BASIC ENGINEERING

## CIVIL ENGINEERING AND STRUCTURES

A<sub>1</sub>

1. Soil analysis 2. Foundations layout 3. Drawings of foundations layout 4. Layout of underground piping 5. Architectural drawings of buildings 6. Metal structure drawings

## MECHANICAL DESIGN FOR PIPELINES AND EQUIPMENT

A<sub>2</sub>

1. Time schedules 2. General map 3. Map of the area 4. Key map 5. Piping routes 6. Piping maps 7. Area views 8. Axonometric drawings 9. Piping classes 10. Piping material survey 11. Mechanical specifications for containers, columns and exchangers 12. Model

## ELECTRICAL DESIGN

A<sub>3</sub>

1. Area classification 2. List of electrical loads 3. Single-line wiring plan 4. Electrical cable path 5. Identification of material for electrical cables

## INSTRUMENT DESIGN

A<sub>4</sub>

1. Tool specifications 2. Control panel drawings 3. Control panel maps 4. List of cables and instrument air tubes 5. CFR 21 annex 11, GAMP, and TEMA, when required



# DETAILED ENGINEERING

## CIVIL WORK PLANNING

B<sub>1</sub>

1. Drawings and load diagrams for the final layout of the foundations as well as main and secondary structures
2. Sizing of works in reinforced concrete and construction drawings
3. Listed maps for sewers and floored areas
4. Construction and sizing of metal structures
5. Specifications for construction contracts for piling, reinforced concrete works, buildings, roads, excavations and fire-fighting works, etc.

## MECHANICAL PLANNING

B<sub>2</sub>

1. Piping support drawings
  2. Stress Analysis
  3. Drawings of stairs and walkways
  4. Insulation specifications
  5. Final survey of piping material
  6. Drawings of pressurized tanks and exchangers
  7. Construction drawings of containers and storage tanks
  8. Dishes and interiors
  9. Completion of process specifications for machinery, ancillary services and packaging units
  10. Pipe-fitting drawings
  11. List and data for line assembly
- 
12. Mechanical catalogue
  13. Operating manuals
  14. Purchasing

## ELECTRICAL PLANNING

B<sub>3</sub>

1. Calculation of short circuit currents
2. Selecting relays
3. Sequence of priorities and restarts
4. Single-line electrical panels, power units and engine-starting panels
5. Medium and low voltage single-line electrical cables
6. Cable size
7. List cables
8. Single-line lighting
9. Ground network map
10. Telecommunications map
11. Interconnections diagram
12. Construction drawings of electrical equipment
13. Substations map
14. List of materials
15. Purchasing

## TOOL PLANNING

B<sub>4</sub>

1. Tool specifications
2. Tool-connecting drawings
3. Electronic instruments control room maps
4. Electronic instrument control circuits
5. Pneumatic tool-connecting drawings
6. Drawings for the identification of junction boxes and tool line routes
7. Electrical and electronic equipment connecting diagrams
8. Interlocks diagrams
9. Final survey of material
10. Control of outlet points of instruments on axonometric drawings
11. Purchasing



# Synergy**SWISSENGINEERING**

**Synergy Swiss Pharma Sagl**  
Street/Via Luigi Lavizzari 4,  
6850 Mendrisio, Switzerland

**Phone:** +41 (0) 79 295 19 29

**E-Mail:** [engineering@synergypharma.ch](mailto:engineering@synergypharma.ch)

**Web:** [www.synergypharma.ch](http://www.synergypharma.ch)

