EXPRESSION OF INTEREST

Request of Engineering Consultant for Proposed 7-aminocephalosporanic acid (*7-ACA*) project.

SCOPE OF WORK FOR ENGINEERING CONSULTANCY FOR 7-ACA PROJECT

BRIEF ABOUT THE COMPANY

- Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), a Government of India Enterprise, under Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals.
- The company was incorporated in 1981 on the recommendations of the Hathi Committee with an aim of supplying life-saving drugs to the general public at an affordable price.
- The plant started its commercial production in 1984.
- We are an PIC/S GMP Certified, ISO 9001:2015; ISO 14001:2015 & ISO 45001:2018 accredited.
- WHO-GMP approved company since 1985.
- The factory is located in Peenya Industrial Area, Bengaluru.
- The Corporate office is located at Nirman Bhavan, Dr. Rajkumar Road, Bangalore-560 010, which is located 8 km away from the factory site.

OBJECTIVE:

The objective of this document is to define the scope of works to be handled by the Engineering Consultancy regarding to the Concept Engineering, Basic Engineering & Detailed Engineering for the project of 7-ACA, started by KAPL-Bengaluru.

This document provides the expected deliverables, roles and responsibilities by the Engineering consultant at various stages of the project.

Minimum Criteria of Engineering Consultant:

1. Consultant to have minimum 15-20 years of experience in handling and execution of API projects and fermentation-based bulk drug manufacturing production projects.
2. Consultant having experience in the process execution of fermentation based bulk drug manufacturing plants shall be given preference.
3. To have a thorough process know how of biological and fermentation based KSM plant (Upstream & downstream Processes).

4. The consultant should have experience in establishing and commissioning of green field projects in the similar lines in India & abroad.
5. The consultant should have handled the projects with investments of not less than 75-100 Crores in API/ Biotechnology projects.
6. The consultant shall have technical and competent man power of not less than 80-100 personnel for handling the various areas of the project.
7. Engineering consultant in collaboration with Process Consultant shall design the plant to meet USFDA/EUGMP requirements.
8. Consultant can make a consortium with National / International Biotech / Engineering consultant of similar Biotech experience.
9. All Bidders should make an excel sheet for confirmation of Acceptance for each activity of the project.

Scope of Engineering Consultants during Concept Engineering

1. Background to the project.
2. Functional requirements of the client.
3. Study the site parameters.
4. Basis of design.
5. Assumptions and regulatory expectations.
6. Preparation of Preliminary Process Flow Diagrams
7. Review of Process Flow Diagram
8. Process Equipment sizing
9. Design safety review including preliminary HAZOP study
10. Preparation of analysis on stick build versus skid build versus super skids
11. List of process equipment's
12. Process equipment layouts
13. Automation requirements as critical parameter control strategy
14. Phases of development.
15. Site levels peripheral and approach roads with setbacks to be followed.
16. Building types and floor heights
17. Occupancy expectations.
18. Inventory and warehouse requirements
19. Update process description of functional unit and equipment group
20. Process blocks, pilot plant & R&D block and utility blocks requirement with proposed utilities
21. Tentative plant layout with men/material flow.

22. Requirements of various blocks with regard to environment temperature, humidity and cleanliness levels.
23. Requirement of any special blocks such as Hydrogenation area etc.,
24. Study of electrical power requirement of the plant, location of transformer yard, substations, and DG sets.
25. Water availability and water quality standards required for various application.
26. Types of water treatment possible.
27. Expansion philosophy planned.
28. Site master plan showing various building blocks
29. Preliminary Facilities Layout & 3D view of Master Plan Proposed
30. Discuss requirement of permitting documents with respect to the products being handled and manufactured and with respect to site specific issues
31. Define the air quality standards and pressure differential concepts intended to be followed
32. Utility concepts like steam generation equipment, chillers, cooling towers, water treatment, air compressor and Vacuum pumps etc.
33. Discuss automation & instrumentation levels required.
34. Solvents to be handled with approximate storage requirements.
35. Explain requirement of fire fighting systems as per statutory requirement.
36. Civil finish concepts to meet GMP standards
37. Tentative budgetary project cost.
38. Logistics systems should be planned which include roads, loading and unloading systems of raw materials/manufacturing equipment's/instruments/ finished goods etc. to be planned.
39. Weigh bridge facility to be designed during designing.

Scope of Engineering Consultants during Basic Engineering

1. Discuss in detail the concept engineering layout and based on additional inputs from client, develop one or two alternatives layouts in conformity with cGMP requirement
2. Finalise master plan with all building blocks. Plan, architectural elevation, 3D view of building and 3D view of master plan.
3. Finalising all drawings for statutory approvals.
4. Finalising civil buildings floor areas, roof heights, and structural loading requirements.
5. Schedule of civil finishes recommended
6. Preparation of Detailed Process Flow Diagrams
7. Finalise the process flow diagrams for the various processes.

8. Batch Cycle Time Preparation
9. Manufacturing Facility Capacity Calculations
10. Final sizing of process equipment's, with M.O.C
11. Preparation of process equipment URS for client review
12. Review of process equipment URS as updated from client
13. Preparation of Detailed Process P&ID
14. Process Equipment layouts
15. Men and Material flow plans
16. Automation requirements an critical parameter control strategy
17. Updated list of material specifications
18. Instrument process data sheets
19. Preparation of the automation basis of design and functional specifications
20. Preparation of a material balance including but not restricted to process, utilities and effluent.
21. Estimate the requirements of the various utilities & power
22. Develop the P&ID'S for utilities
23. Update Process and Utility interface P&IDs
24. Develops solvent storage yard location and area requirement. Distribution and automation, instrumentation workout.
25. Discussion on safety issues, HAZOP studies and level of implementation in final design
26. Work out requirement of number of hydrants & water storage requirements and statutory drawings for approvals
27. Preparation of equipment list with capacity/ratings in coordination with process consultant.
28. Tentative sizing of transformer, standby dg sets.
29. Recommendations of lighting levels to be designed for various areas.
30. Review the requirements of explosion proof fitting in hazardous areas.
31. Basic design of proposed system of HVAC with zoning concepts, air flow diagrams, and pressure differentials.
32. Basic master plan piping routing drawing and individual buildings
33. Basic of automation and instrumentations
34. Fire and access control, CCTV, PAB, basic.
35. Budgetary project costs based on basic engineering package.

36. In the master plan roads, lamp posts, CCTV surveillance systems, security posts, storm water drains to be planned.
37. Rain water harvesting system to be planned for all the installed units/ blocks.
38. Electrical un-conditional energy systems like solar/biogas generator to be planned by the engineering consultant.

Scope of Engineering Consultants during Detailed Engineering

1. **GENERAL**
   - i. Review of details of basic engineering package.
   - ii. Revalidation of assumptions during basic engineering design
   - iii. Value engineering inputs to design documents
   - iv. Confirmation on basis of criteria for design, use of applicable codes and standards
   - v. Safety review.
2. **ARCHITECTURAL & LAYOUT**
   - i. Site master plan
   - ii. Architectural composite building general arrangement (level wise)
   - iii. Architectural - detailed floor layouts (process & non-process)
   - iv. Men and material flow layouts
   - v. Architectural - detailed sections
   - vi. Architectural - elevations
   - vii. Detailed rooms construction drawings
   - viii. Typical detailed construction drawings
   - ix. Wall elevation drawings
   - x. Level wise architectural fire safety & fire compartment plan
   - xi. Ancillary structures drawings (plans, sections, elevations & details) including isometric views
   - xii. Interior design including finishing schedule
   - xiii. Architectural materials specifications
   - xiv. Preparation of reflected ceiling plans integrating the various services in the building.
   - xv. Effluent plant design in coordination with vendors.
   - xvi. Plumbing design and detailed drawings.
   - xvii. Design and detailed drawings with specifications for internal roads and pathways
   - xviii. Architectural documentation for statutory permissions

xix. Room data sheets
xx. Constructability review
xxi. Estimated construction package cost.
xxii. Vendor due diligence and technical bid analysis
xxiii. Sample submittals and approvals
xxiv. Issuance of all good for construction drawing
xxv. Review and approval of shop floor drawings submitted by vendors
xxvi. Revision and reissuance of any good for construction drawings based on the review
xxvii. Addressing and providing data on technical RFI
xxviii. Preparation of the as built drawings related to architectural & layout related.
xxix. Each and every running bill or part invoices should be certified by the consultant under the letter head.
xxx. Contractor's bill certification is also part of consultant.
xxxi. Consultant is responsible for providing final work completion certificate.

3. CIVIL & STRUCTURAL

i. Typical steel standards
ii. Anchor bolt schedules
iii. Typical paving details
iv. Typical fence and entrance details
v. Typical waterproofing details
vi. Typical underground services details
vii. Paving and drainage layout plans and details
viii. Steel work calculations
ix. Storm water drainage design calculations
x. Fixing details and specifications for structures and supports
xi. Earthwork specifications
xii. Piping supports details and specifications
xiii. Column schedule
xiv. Lintel beams and stiffeners
xv. Staircase - plan, section and elevations details including specifications
xvi. Lift plans, wall elevation, sections and details
xvii. Floor general arrangement plans
xviii. Floor slab reinforcement layout, section and details
xix. Floor beam schedule, sections and details

xx. Concrete cast in item plans and details
xxi. Floor penetration GA / schedules
xxii. Roof framing plan, section and details
xxiii. Platform layout, elevation, section and details
xxiv. Equipment and machine foundation layouts, elevation, section and details
xxv. Constructability review
xxvi. Preparation of civil and structural construction package
xxvii. Estimated construction package cost
xxviii. Vendor due diligence and technical bid analysis
xxix. Sample submittals and approvals
xxx. Tender, BOQ
xxxi. Vendor finalization
xxxii. Issue of Good for Construction Drawing
xxxiii. Commissioning support
xxxiv. Each and every running bill or part invoices should be certified by the consultant under the letter head.
xxxv. Contractor's bill certification is also part of consultant.
xxxvi. Consultant is responsible for providing final work completion certificate.

4. PROCESS IN COORDINATION WITH PROCESS CONSULTANT

i. Process equipment layout
ii. Instrument process data sheets
iii. Preparation of the automation basis of design and functional specifications
iv. Preparation of a material balance including but not restricted to process, utilities and effluent.
v. Preparation of detailed equipment list with power and utilities.
vi. Finalisation of utility P&ID'S with review of interfaces in coordination with client.
vii. Design of utility piping for process equipment.
viii. Layout finalisation
ix. Men and material flows.
x. Inputs for approval of the GA drawings for the process equipment including but not limited to nozzle orientation plan; battery limits, electrical connections, and valve sequence matrix
xi. HAZOP / Safety review including vent analysis and sizing
xii. Tagged Equipment Requisitions for Inquiry/Bid Technical Analysis

5. UTILITIES

i. Detailed specifications for Hot Water Systems / Steam Boilers
ii. Detailed specification for Air Compressors
iii. Detailed specifications for Chilling Plants for Air Conditioning and Process Cooling.
iv. Detailed specifications for Chilled Brine Plant for Process Cooling.
v. Detailed specifications for Vacuum systems
vi. Detailed specifications for Cooling Towers.
vii. Detailed specifications for pumps both for Process & Utilities
viii. Detailed specifications for Gas Generation and Distribution Systems
ix. Each and every running bill or part invoices should be certified by the consultant under the letter head.
x. Contractor's bill certification is also part of consultant.
xi. Consultant is responsible for providing final work completion certificate.

6. CLEAN UTILITY GENERATION AND DISTRIBUTION

i. Preparation of clean utility flow diagrams
ii. Preparation of clean utility P&IDS
iii. Equipment selection
iv. Detailed specifications for clean utility generation equipment viz.. Purified Water Generation and Pure Steam.
v. Clean Utility Balancing.
vi. Operational time cycle analysis and sizing of equipment
vii. Tender, BOQ
viii. Vendor finalization
ix. Issue of Good for Construction Drawing
x. Commissioning support.
xi. Each and every running bill or part invoices should be certified by the consultant under the letter head.
xii. Contractor's bill certification is also part of consultant.
xiii. Consultant is responsible for providing final work completion certificate.
xiv.

7. PIPING

i. Design criteria, codes and regulations
ii. Preparation through approval of detailed P & I diagrams

iii. Preparation through approval of battery limits between equipment, skids and piping
iv. Preparation of piping layouts
v. Instrument process data sheets
vi. Specifications of equipment's associated with process piping including but not limited to pumps, heat exchangers, point of use heat exchangers, and filtration systems
vii. Pipe sizing based on flow rates and pressure drop calculations.
viii. Selection of M.O.C and relevant pipe standards
ix. Pipe routing drawing.
x. Specifications for pipes including insulation
xi. Pipe support details
xii. Piping GA drawings
xiii. Typical piping details
xiv. Tender, BOQ for piping
xv. Vendor finalization
xvi. Issue of Good for Construction Drawing
xvii. Commissioning support.
xviii. Each and every running bill or part invoices should be certified by the consultant under the letter head.
xix. Contractor's bill certification is also part of consultant.
xx. Consultant is responsible for providing final work completion certificate.

8. HVAC

i. Preparation of room data sheet
ii. Preparation of detailed room books
iii. Heat load calculation and balancing
iv. HVAC zoning, Air Flow Patterns, Pressure Balancing and AHU zoning diagrams
v. Air flow block diagrams and P&ID
vi. HVAC equipment sizing and detailed specification
vii. HVAC equipment layout
viii. Standard equipment support specification
ix. HVAC ducting routing with calculations
x. HVAC single ducting drawing including plans, sections and elevations
xi. Piping diagrams for connections of Black Utilities to the HVAC equipment

xii. Chilled water and steam / hot water pumping and distribution system
xiii. HVAC controls package including but not limited to pressure, temperature, relative humidity, fire safety, filter health, etc. - monitoring and controls
xiv. Vendor finalization
xv. Issue of Good for construction drawing
xvi. Commissioning support.
xvii. Each and every running bill or part invoices should be certified by the consultant under the letter head.
xviii. Contractor's bill certification is also part of consultant.
xix. Consultant is responsible for providing final work completion certificate.

9. CLEAN ROOM

i. Preparation of the floor wise layout for the clean room panels
ii. Preparation of the reflected ceiling plans for the clean room ceiling
iii. Specification of the clean room components including the support frameworks and joinery details
iv. Preparation of drawings - plan, section and elevation for the clean rooms in coordination with vendors
v. Preparation of the interface drawings with services including but not limited to electrical, HVAC, process and utility piping, equipment, plumbing and drainage
vi. Clean room equipment specifications like clean room furniture, pass through systems, and utility pendants
vii. Detailed specifications for all material for the construction package
viii. BOQ for clean room panels, false ceiling, doors, raisers, view panels etc.
ix. Specification for clean room flooring
x. BOQ for clean room flooring
xi. Vendor finalization
xii. Issue of Good for Construction Drawing
xiii. Commissioning support.
xiv. Each and every running bill or part invoices should be certified by the consultant under the letter head.
xv. Contractor's bill certification is also part of consultant.
xvi. Consultant is responsible for providing final work completion certificate.

10.ELECTRICAL

a. HT works

i. Preparation of Building Wise Electrical Load List

ii. Preparation of the overall site summary on electrical load requirements
iii. Design of the HT power requirements
iv. Design of the backup captive power generation requirements
v. Sub-station layout
vi. Sizing of the power transformers, HT breakers, HT cable and other components
vii. Substation equipment specification preparation (indoor and outdoor units)
viii. Detailed design of the HT distribution network
ix. Cost estimation of the set up
x. Documentation related to the statutory approval of the HT system.
xi. Each and every running bill or part invoices should be certified by the consultant under the letter head.
xii. Contractor's bill certification is also part of consultant.
xiii. Consultant is responsible for providing final work completion certificate.
xiv. Preparation of tender documents.
xv. Technical evaluation and vendor finalization.
xvi. Designing has to be dong as per local electrical supply company norms for all systems, including equipment's, machines and instruments etc. to be designed meeting IS norms an also complying for electrical

b. LT works

i. Preparation of electrical room book building wise for LT power
ii. Balancing of electrical load across various blocks
iii. Preparation through approval of single line diagrams
iv. Prepare specifications for procurement of DG set & BOQ for erection of DG set, synchronization of captive power & integration to main supply.
v. Preparation of electrical distribution diagram for lighting, power circuits, motor connections, and equipment connection
vi. Preparation through approval of functional specifications of electrical systems
vii. Detailed specifications of electrical equipment like power control panels, motor control panels, UPS units, and distribution panels.
viii. Detailed specifications for components of electrical components like cables, switches, plugs and sockets, light fixtures, conduits, and electrical cable support systems.

ix. Electrical calculations for components like cables, Light fittings, and earthing systems.
x. Preparation of compartmentalization strategy for hazardous and safe areas
xi. Calculations of lighting requirements based on lux levels.
xii. Electrical distribution GA drawings
xiii. Tender, BOQ for electrical
xiv. Technical evaluation and recommendation to client.
xv. Vendor finalization
xvi. Good for Construction Drawing Approval
xvii. Commissioning support.
xviii. Each and every running bill or part invoices should be certified by the consultant under the letter head.
xix. Contractor's bill certification is also part of consultant.
xx. Consultant is responsible for providing final work completion certificate.

11.INSTRUMENTATION, AUTOMATION AND INTEGRATED BMS

i. Detailed Automation Philosophy for Project.
ii. Design Criteria, Codes, Standards and Regulations
iii. Coordination with Process Equipment vendor for Process Automation
iv. Preparation of Building Wise, System Wise, and Function Wise Functional Specifications
v. Support Routing for Cable Trays and Conduits for Instrumentation
vi. Scheme Finalization
vii. Tender, BOQ, Vendor Finalization
viii. Cable Routing GA Approval
ix. Commissioning Support.
x. Each and every running bill or part invoices should be certified by the consultant under the letter head.
xi. Contractor's bill certification is also part of consultant.
xii. Consultant is responsible for providing final work completion certificate.

12.WAREHOUSING

i. Design criteria codes, regulations, and standards
ii. Preparation through approval of detailed layouts for the warehouse
iii. Area segregation of warehouse based on GMP requirements, regulations, hazard, and material compatibility
iv. Preparation through approval of warehouse material flow

v. Preparation of detailed specifications for material handling equipment including but not limited to Dock Levelers, Truck Bay Guides, Lift Tables, Forklift Truck, and Pallet Trucks - manual and motorized
vi. Preparation of detailed specifications for warehouse equipment including but not restricted to De- Dusting Equipment, Pallet Exchange Systems, Material Identification Equipment, Weigh Bridges, Weighing Systems, Pallet Washing Systems, Racking System, Sampling and Dispensing Systems, Material Handling Systems, Freight Elevators.
vii. Preparation of layout for vendor review and quotation
viii. Technical evaluation and recommendation to client.
ix. Each and every running bill or part invoices should be certified by the consultant under the letter head.
x. Contractor's bill certification is also part of consultant.
xi. Consultant is responsible for providing final work completion certificate.

13.FIREFIGHTING, FIRE DETECTION, ACCESS CONTROL AND CCTV

i. Preparation of Fire Detection and Fire Fighting Strategy
ii. Single line diagram for Fire Hydrant System, Sprinkler, and Inert Gas Systems, etc.
iii. Detailed specification of fire detection and alarm systems
iv. Detailed specification of expansion of Fire Fighting System including Fire Hydrants, Fire Extinguishers and related support systems.
v. Tender, BOQ
vi. Vendor finalization
vii. Good for Construction Drawing Approval
viii. Commissioning Support.
ix. Each and every running bill or part invoices should be certified by the consultant under the letter head.
x. Contractor's bill certification is also part of consultant.
xi. Consultant is responsible for providing final work completion certificate.
xii. Impact analysis has to be performed by the Engineering Consultant.
xiii. Public address system has to be included in the design of the Fire Fighting, Fire Detection and Safety measures.
xiv. In the master plans, evacuation and provision for safe assembly to be designed for personnel during emergency which meets the OSHAS Norms.

14.SOLVENT STORAGE SYSTEM (AS PER LOCAL REGULATIONS)

i. Specifications for underground tank / overhead tanks
ii. Basic drawing of underground solvent tank yard, drum storage shed. For review by third party for getting approval from statutory authorities.
iii. Design for inert gas blanketing wherever necessary
iv. Piping design and detailing with P&IDs
v. Distribution and automation scheme finalisation
vi. Vendor finalisation
vii. Good for Construction drawing approval
viii. Commissioning support
ix. Each and every running bill or part invoices should be certified by the consultant under the letter head.
x. Contractor's bill certification is also part of consultant.
xi. Consultant is responsible for providing final work completion certificate.

15.BOILER DESIGN

i. Boilers should be designed as per the process requirement on consultation with the process consultant.
ii. The HSD (High-Speed Diesel Oil)/ Pressurized Natural Gas as a fuel boilers have to be designed .
iii. The design of the boilers should be interchangeable for both HSD and PNG.
iv. Design has to be prepared as per
    a. Steam requirement for plant to be quantified and designed and help to get approval as per the regulatory requirements by providing the documents from the suppliers .
    b. Boiler to meet the IBR(Indian Boiler Regulations)./
    c. Steam line has to be designed as per the boiler capacity, consultant has to assist KAPL in preparation of URS and the TBA & CBA.
    d. Boiler has to be designed as per efficient condensate recovery system and as per energy conservation norms.
    e. Suitable chimney for boiler, boiler house design and fuel pipe line design should be done by consultant and should assist KAPL in TBA & CBA process of procurement.

16.EFFLUENT TREATMENT PLANT (ETP):

i. Engineering consultant should design the ETP as per the process requirement,

ii. Keeping in view for future expansion requirements an additional 25% expansion capacity provision has to be taken into consideration during designing of ETP.
iii. ETP should be designed as per Central Pollution Control Board norms and State Pollution Control Board.
iv. The ETP has to be prepared as per PCB norms for RED/ORANGE Category Industries whichever is applicable and all the necessary document/designs details has to be prepared and should comply the norms.
v. If the treated ETP effluent has to be sent to Central Effluent Treatment Plant the necessary Infrastructure should be designed and set up.
vi. Provision for complete in-house ETP treatment should be designed in case of failure or absence of Centralized ETP.
vii. Disposal plan of the solid waste generated has to be designed as per the local solid waste disposal norms.
viii. The Biological Oxygen Demand and Chemical Oxygen Demand have to be calculated as per the process and ETP has to be designed accordingly.

PROJECT MANAGEMENT AND ENGINEERING

17. Provide support to KAPL to develop & deliver the capacity desired at industrial level which will be part of Basic Engineering and Detail Engineering.
18. The consultant shall support KAPL during TBA (Technical bid analysis) and CBA (Commercial Bid Analysis) for process equipment's.
19. The engineering consultancy shall support the KAPL in coordinating with the process consultancy and tech provider in reviewing and finalizing the feasibility, concept and safety reports not limiting to the below mentioned process engineering aspects.
    a. Computer aided flows- sheeting for mass and energy balance.
    b. Process and Instrumentation diagram.
    c. Utility sizing, requirements and specifications.
    d. Equipment design, equipment specifications and URS.
    e. Piping and Instrument specifications.
    f. Material Specifications.
    g. Facility layout man and material movement.
20. The engineering consultancy shall support the KAPL in coordinating with the process consultancy and tech provider in reviewing and finalizing the feasibility, concept and safety reports not limiting to the below mentioned basic engineering aspects.

a. Feasibility analysis
b. Conceptual design
c. Preliminary design
d. Economic analysis and cost evaluation and analysis
e. Facilities planning
f. Site master planning and site selection and entire project outlay.
g. Technology evaluations
h. Process engineering

21. The engineering consultancy shall support the KAPL in coordinating with the process consultancy and tech provider in reviewing and finalizing the feasibility, concept and safety reports not limiting to the below mentioned detailed engineering aspects.
    a. Civil engineering and architectural engineering
    b. Structural engineering
    c. Chemical engineering services
    d. Specifications for the buildings.
    e. Piping design and piping engineering
    f. Electrical and instrumentation engineering
    g. Equipment selection and specifications
    h. Process safety and loss prevention
22. The consultant shall support KAPL to select the contractors and vendors as part of procurement assistance.
23. The consultant should help KAPL to establish Building Information Management (BIM) during the initial stages of the project in consultation with the technology provider and engineering consultant.
24. Consultant shall help KAPL to identify the long lead items during basic engineering and help to develop the specifications and coordinate for design development and design review with the design builders, and coordinate with the design builders for timely delivery of the long lead items to avoid project delays.
25. Engineering consultant shall coordinate with design consultant and help KAPL to prepare tender documents for different contractors like
    a. Civil contractors
    b. MEP (Mechanical, electrical and plumbing) contractors.
    c. Equipment fabricators and vendors.
    d. Fire safety coordinators.

26. Engineering Consultant should coordinate with technical consultant to prepare the tender documents for Construction management scope, identify the construction management firm and different contractors support in TBA and CBA for the construction management firms and contractors and construction management strategy.
27. Consultant should eliminate any major risk in the project from detail design to contraction.
28. Consultant shall support to develop the plot plan and entire project layout in accordance with the building regulations and code meeting USFDA/ EUGMP requirements.
29. The consultant should provide support KAPL to create suitable ware house, solvent storage, explosive yard, scrap yard, acid and alkali management system, and also provide support to create a safe and GMP compliant industrial plant for KAPL.
30. The consultant should support KAPL to create infrastructure of plant with mechanization and instrumentation which would reduce the excess manpower engagement and help in optimum man power utilization.
31. The consultant shall support KAPL to establish Effluent treatment Plant (ETP) and Zero Liquid Discharge Plants in coordination with the design team as per the process, detailed designing of the complete ETP complying with all the statutory requirements and review the vendor detailed engineering drawings and specifications of the plant.
32. The consultant shall support KAPL during review meeting with the technology provider during water trials and commissioning and shall assist KAPL in manufacturing of 3 exhibit batches and certifying the yield as per the pre designed process specifications.
33. The consultant shall support KAPL for the expansion of installed capacity and future integration plant requirements if required.
34. The consultant should visit vendor sites during fabrication of the equipment's if required, and coordinate with the procurement teams for on time delivery of the materials to avoid delay of the long lead items.
35. The consultant should help KAPL to develop strategy for procurement of the material to avoid unnecessary over expenditure of capital and help to reduce overhead expenses.
36. The consultant should support KAPL team in FAT (Factory acceptance testing), SAT (Site acceptance test), CQV (Commissioning, qualification and validation) of the equipment's.

37. The consultant should help KAPL to prepare VMP (Validation Master Plan) and to identify the commissioning boundaries and to coordinate between the construction team and turnover team for smooth transition from construction to commissioning.
38. Consultant has to support the KAPL team in commissioning and qualification protocols (IQ, OQ, PQ) and support to design SOP and Preventive Maintenance procedures and schedules for all the procedures and equipment's for safe operation of the commissioned plant.
39. The consultant should review the fire safety basic data and fire safety requirements and to provide the inputs to the vendors for design, supply and installation of the same as per the process requirements.
40. The consultant should review/check and design details/drawings provided by the equipment vendor for finalizing the basic engineering of the facility.
41. The consultant shall support KAPL to establish the safety measures required to be installed and also support in designing the safety plan and to identify the contractor providing the installation and commissioning of the safety equipment.
42. Consultant should review the electrical, mechanical, piping, building plans, mechanical structures, fire detection designs provided by the contractors and release for execution duly authorized with sign and seal.
43. Consultant should provide vendors list for all the works carried out and the list shall be scrutinized by KAPL if required.

SUPPORT IN ESTABLISHING SUPPORTING AND ANCILIARY DEPARTMENTS.

44. The consultant should provide support for establishing the Quality control and Microbiology departments and support in designing the utility layout designs and support in establishing clean rooms.
45. The consultant shall support KAPL to establish a state of the art laboratory which would meet all the regulatory and laboratory compliance with all the safety requirements in coordination with the process consultant.
46. The consultant shall support KAPL to establish the SOP (Standard Operation Procedures), Preventive Maintenance Procedures and preventive maintenance schedules with coordination with the equipment manufacturer for the equipment's installed in production, engineering, safety and quality departments etc.
47. Consultant should support the quality team for preparation of critical equipment related documents.

48. The consultant shall support KAPL in training of the hired staff in the engineering and maintenance departments.
49. The consultant shall provide post commissioning support for a period of 1 year.
50. The consultant should support KAPL team for preparing layouts, engineering drawings, P&Id for the utilities.
51. The consultant shall help KAPL to establish the specifications for materials used in the construction and utilities.
52. Support in preparing training manual, calendar and implementation of QMS systems like risk analysis & management, CAPA procedures as per cGMP requirements.
53. The consultant should support in qualification of equipment's, area, validation of procedures.
54. Consultant should support and guide KAPL in obtaining all the necessary regulatory permissions and approval required during various stages of the project.

SUBMISSION OF BIDS:

1. Interested parties shall submit their bids in two separate sealed envelopes
2. Technical bid shall be sent in a separate sealed envelope super scribed as "TECHNICAL BID" along with the Tender Number and date on the top of the envelope.
3. Commercial bid shall be sent in a separate sealed envelope super scribed as "COMMERCIAL BID" along with the Tender Number and date on top of the envelope.
4. If technical and commercial bids are submitted in a single sealed envelope such bids will be rejected.
5. Selected vendors shall be informed to pay Earnest Money Deposit (EMD) of Rs 10.0 Lakhs within 10 days after selection of Technical Bid. Any vendor, who is not submitting EMD, will be disqualified.
6. EMD shall be sent in the form of Demand Draft in favour of "KARNATAKA ANTIBIOTICS AND PHARMACEUTICALS LIMITED" payable at Bengaluru.
7. Technical Bid and Commercial Bid should reach on or before 05.06.2021.

8. All bids shall be addressed to

"The Company Secretary & Asst. General Manager(Admn)"
Karnataka Antibiotics and Pharmaceuticals Limited
Nirman Bhavan, Dr. Rajkumar Road
1st Block, Rajajinagar
Bangalore-560010, India.

Any Tender which does not comply with the requirements of the Request for Tender including these Conditions of Tender may be rejected at the KAPL's sole discretion.