

# *CONSULTING & ENGINEERING SERVICES*

*FOR*



**BIOTECH & PHARMA PROJECTS**  
**( GREEN FIELD & BROWN FIELD)**

**Chemicon Biopharma Project consultants**

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# INTRODUCTION



**BIOSOL** “Chemicon Biopharma Consultants” is a Consulting & engineering Services ,providing complete solutions for any complex project to be realized within strictest cost and time parameters, in the field **Biotech , API ,Pharma & Nutraceuticals.**

**BIOSOL** provides Consulting & Engineering Services for :

- **Green field Projects** involving concept ,Basic & detailed Engineering, procurement assistance, Installation & Commissioning assistance and support for Validation& Documentation.

Scope of activities for **Green Field Projects** Comprises Project Planning & Scheduling, Basis of Design ,Budget Cost estimation , Process Engineering ,ie, Process Scale up , Design/Selection & Technical specification of Equipment, Preparation of PBD/PFD/P&ID, Utility (Plant & Clean) estimation & capacity determination, Design & development of Master site Plan, Civil basic Architect, Equipment Lay out with Foot Print, Clean room development, HVAC system, Utility & Piping Engineering, Instrumentation & Control System, Electrical system, Tender document preparation of all discipline , Procurement support ie Technical Evaluation of bids, FAT ,Installation & Commissioning support and Validation assistance.

- **Brown field Project** activities are Design review, Energy audit & conservation, Revamping & Trouble shooting of Process/Automation / Clean Utility, Process Validation support.

The design services offered by us are fully in compliance with latest GMP guidelines of **US FDA /WHO/Country specific GMP Guide lines.**

# Strength & Experties



- Rich experience in Design , selection and implementation of cost effective Process equipment specifically associated with Fermentation based API facility.  
**Highly focused in Fermentation Process Engg for Upstream/ Down stream & Solvent Recovery and Sterile API Fill & Finish , Pharma & Nutraceuticals**
- In-depth knowledge of Technical support Services in Facility renovation, Trouble shooting ,Sterile operation , technology upgrade, scale up, cost optimization, yield improvement, Techno – Commercial Feasibility studies , Energy conservation.
- Facility Design & Infrastructure for the above field Projects comprising development of Architectural & Master site plan in totality, Lay out , Clean room development & HVAC system configuration, Utility engineering ,Hazops/Risk assessment, SHE etc
- We have full fledged facility for all the activities being performed by us, backed by well qualified and experienced personnel with latest software / computer systems.

# KEY AREAS OF EXPERTISE



- **Biotech Facility** : Cell Culture & Microbial based Bioreactors system associated with MAB, Vaccine ,FMD, Enzymes etc. of various level Bioreactor capacity . (Successfully implemented three Bioharmaceutical green field projects in Kemwell & Cennagen, during Biophamax & Biozeen tenure)

- **Large volume Fermentation System** :

Successfully implemented Fermentors for Antibiotics up to 92 KL capacity(HAL/HMGB,Pune) , 60 KL capacity at Ranbaxy Paontasahib,20 KL capacity at VB Medicare, Hosur along with associated systems at Upstream, Down stream & Solvent recovery

- **API** : Non Sterile & Sterile API( Successfully implemented in HAL and designed for Biopharmax-Israel)

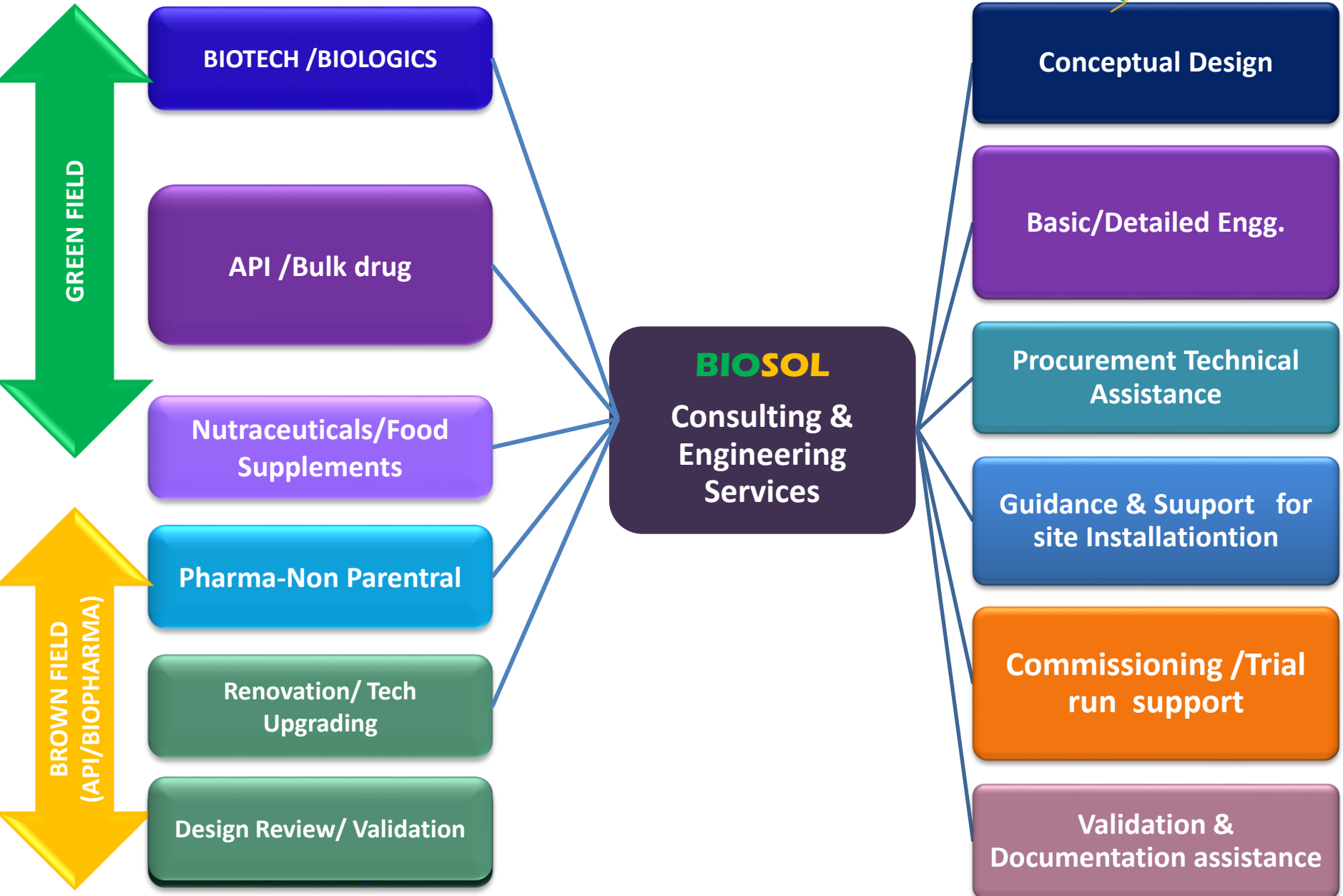
- **Nutraceuticals** : Food supplements/ Enzymes, Biofertilizer, Herbal Extraction( Implemented Enzymes Facility in Intron Life sciences/ Samilabs) and Herbal Extract in Supreme Pharma, Mysore)

- **Non-Parental Pharma/ Fill & Finish** ( Executed Green field Fill & Finish in Kemwell and Non Parental in HAL,pimpri)

- **Clinical Lab/ Bio Lab** ( BSL2/ BSL3) :Designed BSL3 Lab facility for H1N1 Disease surveillance in Gauhati and implemented IVF Facility for BORNHALL in Kochi & Gurgaon.

- **Design & implementation of Energy efficient Continuous Bio Kill system**( 65 % energy saving) (Desined & Commissioned three units for Biozeen & Biotree Bangalore)

# Scope of Services



# CONSULTANCY STRUCTURE

**Process Engg. (Biopharmaceuticals/  
API/Nutraceuticals)**

**Facility Design (Layout/Clean  
Room/HVAC)**

**Utility & Piping Engg. ( Black & Clean)**

**Electrical & Automation Engg.**

**Support/ Co-ordination  
(Procurement, Installation & Commissioning)**

## About Us

- **Founder & Director : Mr. I C Sahu, BE(Chem) & h  
Business background**

A seasoned professional with 25 years of rich experience in Production, Process Engineering and Project Execution of Bulk drugs & Fermentation based API manufacturing Plant .

Around 15 years experience in providing Consulting & Engineering services in setting up Green field manufacturing facilities “Concept to Commissioning” and revamping/ upgrading/trouble shooting of Brown field Facility in Biotech / API/ Nutraceuticals & Pharma .

He is ex VP from Biozeen and has previlledged to work at responsible position in Hindustan Antibiotics, Hindustan Maxgb ,Ranbaxy, Biopharm and is credited with successful implementation of various Projects of Large Volume( Antibiotics/Statin) and Low Volume (high molecule)Fermentation facility set up.

- **BioSol Team** : BioSol comprises small group of experienced & skilled personnel of relevant discipline. Few of section heds are given as under:
  - Mr. C N Shukla: Inst. & Automation head, +30Years Experience in Pharma
  - Mr. K P Rajan: Head Facility & Project Engg, +25 Years Pharma Project



**❖ Parenteral Formulation**

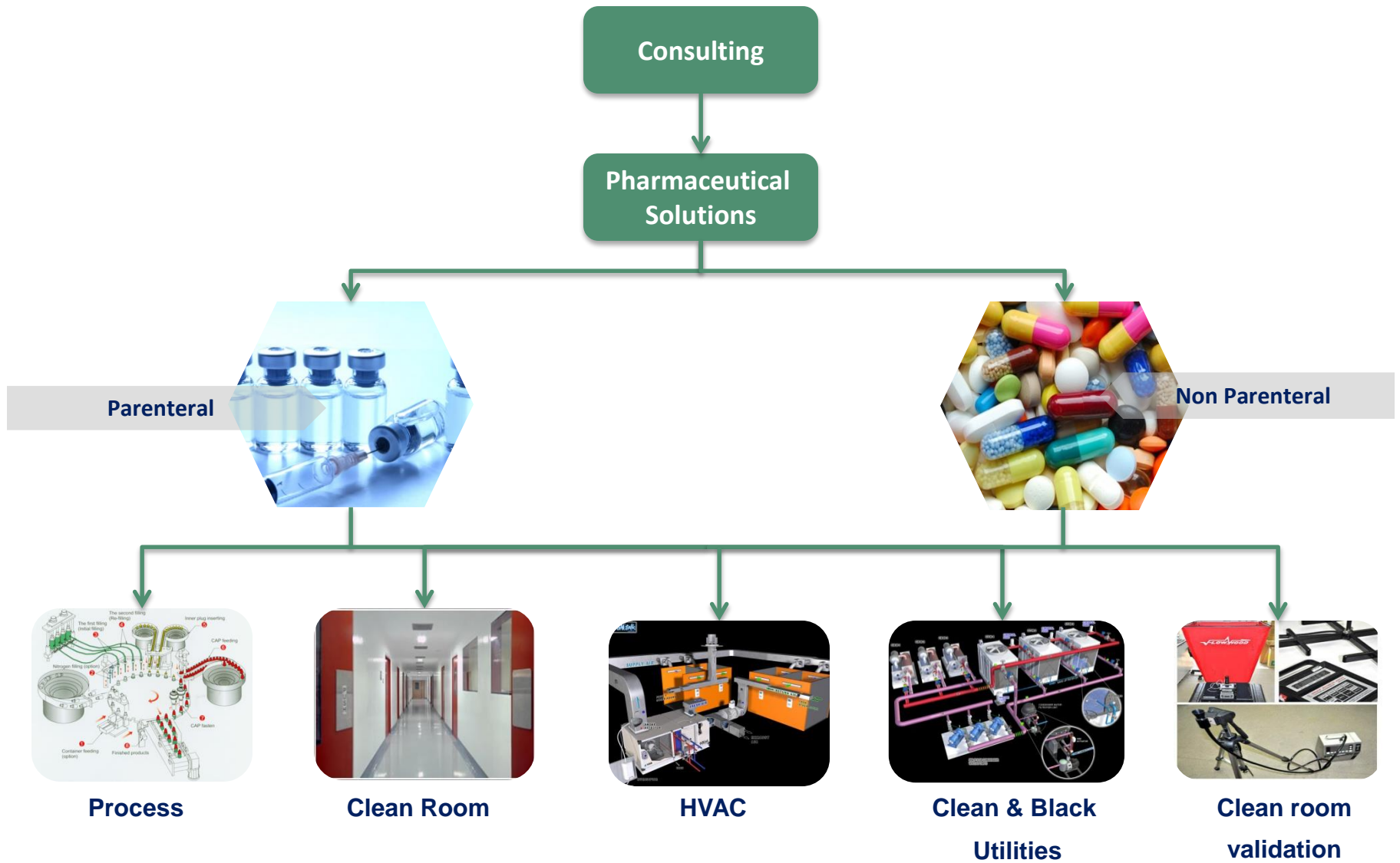
- Solution preparation
- Liquid blending
- Liquid vial filling
- PFS system
- Lyophilized solid dose filling system

**❖ Non Parenteral formulation**

- Tablet
- Capsule
- Ointment
- Bottle Filling

**❖ Clean room development for sterile formulation & filling****❖ Clean room development for non-sterile formulation****❖ HVAC design****❖ Clean Utilities****❖ Ware house**

# Pharmaceuticals-Parenteral & Nonparenteral



**Process**

- cGMP, US FDA, ISPE, GLP, GAMP 5, MHRA, EDQM, PMDA

**Utilities**

- **Clean Utilities** :ASME-BPE 2012, ASME B 36.19M, ISO 1127
- **Black Utilities** :ASME B 36.10M & 36.19M, IS 1239/3589 part-1.
- **Clean Piping &Fittings**: Piping, fitting Valves & Flanges : ASME B 16.9 & 16.11, ASME B 16.10 & 16.5

**HVAC &  
Clean Room**

- EU GMP, ISO 14644-1, ASHRAE, ARI 550/590 – 2003, IS 8148, IS 1391- part I & part II, DW 142, SMACNA.

**Electrical &  
Automation**

- International Electro-technical Commission (IEC), IP55 class as per IEC 60529, NEMA (National Electrical Manufacturers Association), EHS.
- 21 CFR Compliant, GAMP 5

## DOCUMENTS

- Study of URS & preparation of preliminary report
- General Project description
- Facility Concept Design for
  - Process
  - Utilities
  - HVAC & Clean room
  - Electrical
  - Automation
- Mass & energy balance
- Stage wise volumetric balancing
- Utility Matrix & Distribution Schematics
- Capacity estimation & sizing of equipments & list preparation for
  - Process
  - Utilities
  - HVAC & Clean room
  - Electrical



## DRAWINGS

- Master Site Plan
- Traffic / Flow Diagrams
- Process Flow Diagram
- Process operational Block Diagram
- Clean Room development
- Man Material Movement Lay out
- Equipment Layouts for
  - Warehouse
  - Manufacturing
  - Fill & Finish
  - Utility Block
- Classification, Pressurization & AHU zoning layout
- Raw Water storage & Pretreatment system Layout

**DOCUMENTS**

- Process Equipment URS / Design / Tech. Specifications
- Utilities Equipment selection
- Utilities Distribution Network
- Black & Clean Utilities' equipments URS/ Tech. Spec.
- Clean Room Design & Room data sheet
- HVAC Design/URS/Tech. Spec.
- Electrical Load distribution & Design (External & Internal)
- ELV ( FAS,PAS,ACS)
- URS/Design/Tech. Spec. for
  - Electrical Equipments
  - Support Equipments
  - Instruments & Automation

**DRAWINGS**

- PID(System/Interconnection)
- Utility Distribution Matrix
- Black & Clean Utility P&ID
- Process & Utility Pipe Routing & Lay out
- Pipe Rack support design
- HVAC Duct Routing, Air flow drawings
- Electrical Single Line Diagram ( Ext & Inter)
- Cable Tray routing
- Co-ordination drawings for Pipe Racks , Ducting & Electrical cable Tray.
- Draining System (external &Internal) Lay out
- Isometric views & 3D

**BOQ**

- BOQ for :
  - Process Equipments
  - Black Utility
  - Clean Utility
  - Clean Room facility
  - HVAC
  - Electricals
  - Instrumentation & Controls
  - Support Equipments
  - Fire & Safety system
  - Misc items

**TENDER DOCUMENTS & EVALUATION**

- **Process Equipment**
- **Clean Utility Generation Equipment**
- **Black Utility Generation Equipment**
- **Process Piping**
- **Clean Utilities Distribution & Piping**
- **Process Drain Piping**
- **Black Utilities Distribution & Piping**
- **Clean Room Partition & False Ceiling Works**
- **HVAC Systems**
- **Internal & External Electrification Works**
- **Instrumentation & Automation Systems**
- **Fire & Safety alarms, Access Security system**
- **Other Support / Misc. Systems**
- **ETP**

**ACTIVITIES**

- **List of approved vendors**
- **Floating of Tender Enquiry**
- **Receipt of bids**
- **Preparation of technical statement & evaluation**
- **Technical recommendation**
- **Assisting client for order finalization**

## Installation & Commissioning support

- Co-ordination with Vendor for supply & Installation assistance

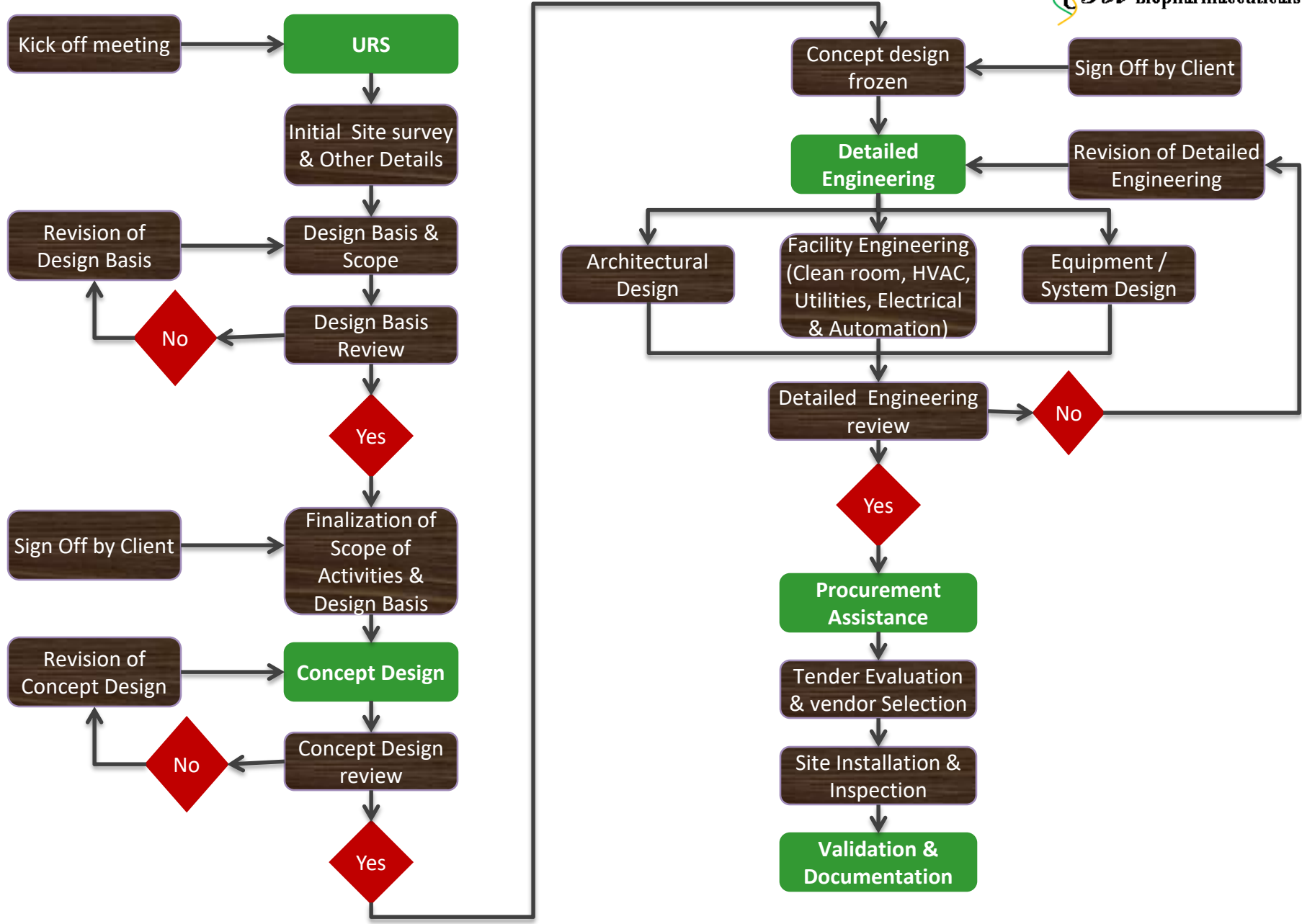
## Documentation support

- In association with Vendor
- Clean Utilities Validation
- HVAC & Clean room validation
- Verification of Calibration Documents
- Process Equipment Validation

## Assistance for Facility & Validation Equipments

- In association with Vendor
- Project Quality Plan
- Project Schedule / GANN Chart
- Risk Analysis / Impact Assessment Report
- Qualification – Design, Installation & Operation (DQ,IQ,OQ)



# Project Road Map



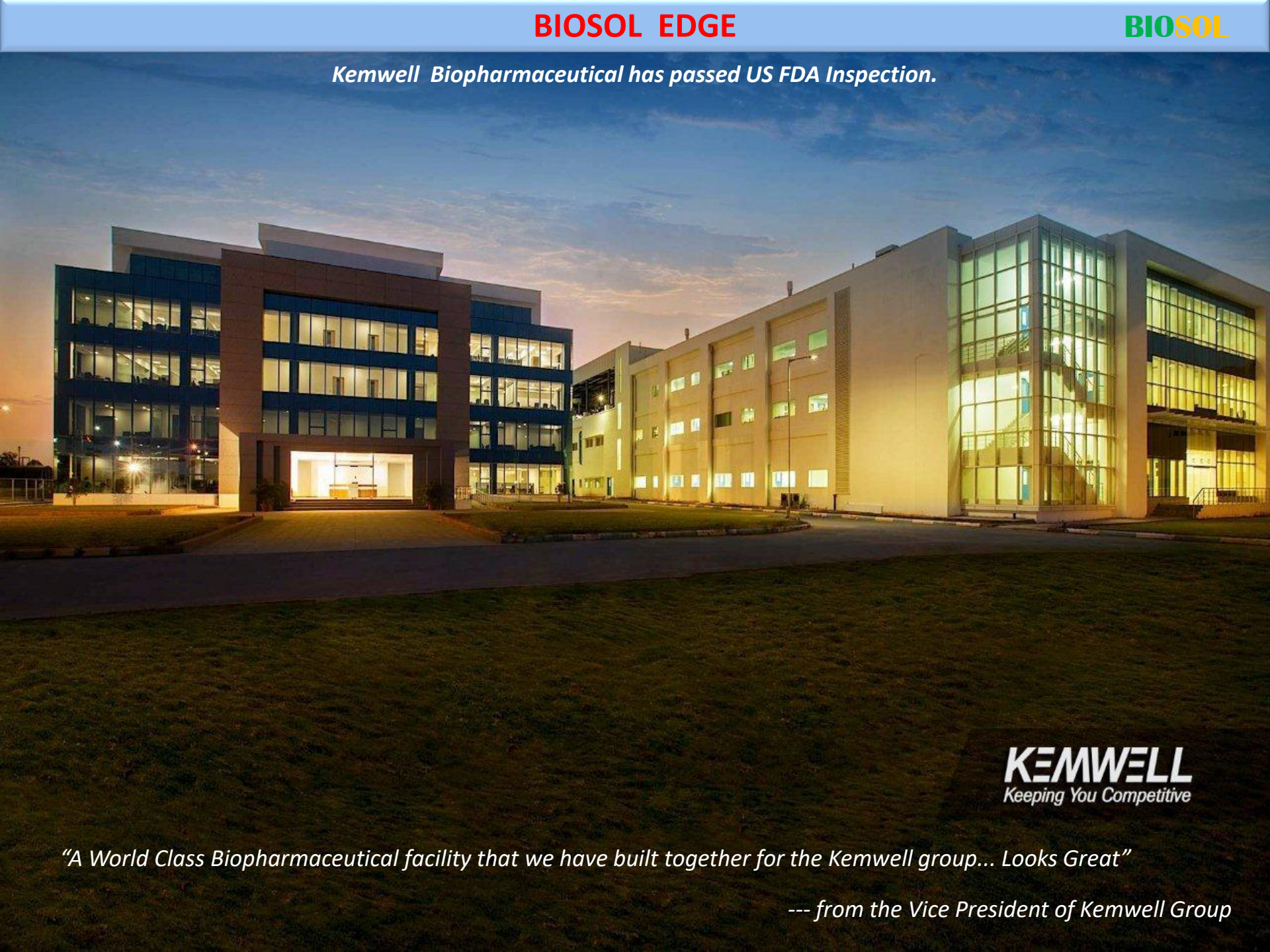
# CONTINUOUS BIO KILL SYSTEM



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Client	I C SAHU EXPERIENCE BEFORE & DURING BIOZEEN PERIOD 2010-2013)	Remarks
<p>Project Implemented during 1985 to 2006 – Large Volume Fermentation system</p> <p>( I C SAHU WORK ACCOMPLISHMENT –AS PROJECT MANAGER – WORKING IN MANUFACTURING INSTITUTIONS)</p>	<p><b>A. HINDUSTAN ANTIBIOTICS &amp; Max gb ,Pimpri ,Pune</b></p> <ul style="list-style-type: none"> <li>- New 4X 91 KL Fermentation for Penicillin &amp; Upgrading Streptomycin facility</li> <li>- Revamping of 14X91 KL Fermentors system in association with gist-brocades, Holland</li> </ul> <p><b>B. RANBAXY PAONTASAHIB UNIT</b></p> <ul style="list-style-type: none"> <li>- 1X10KL &amp; 3X60 KL Fermentation system for Pravastatin &amp; Lovastatin .</li> </ul>	<p>Successfully implemented,</p>
 <p>Bangalore, Neelmangale</p>	<p>MAB (Cell Culture): A Green Field Project Services for setting up a GMP Compliant Biopharmaceutical facility Multi level (Cell culture &amp; Microbial culture) product,</p> <p><b>Manufacturing block :8220 m2,</b> <b>Fill &amp; Finish block :1320 m2 &amp; (Liquid Fill,Lypholised Solid Fill,PFS,including QC/QA</b></p>	<p>Completed (Biozeen)</p>
	<p>Muti Biopharmaceuticals Facility-Cell &amp; Microbial Culture)Consultancy Services (Concept, Detailed Engineering, Procurement Assistance, Validation) for</p>	

*Kemwell Biopharmaceutical has passed US FDA Inspection.*



**KEMWELL**  
*Keeping You Competitive*

*“A World Class Biopharmaceutical facility that we have built together for the Kemwell group... Looks Great”*

*--- from the Vice President of Kemwell Group*

# Thanking You!!

Contact us:

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