

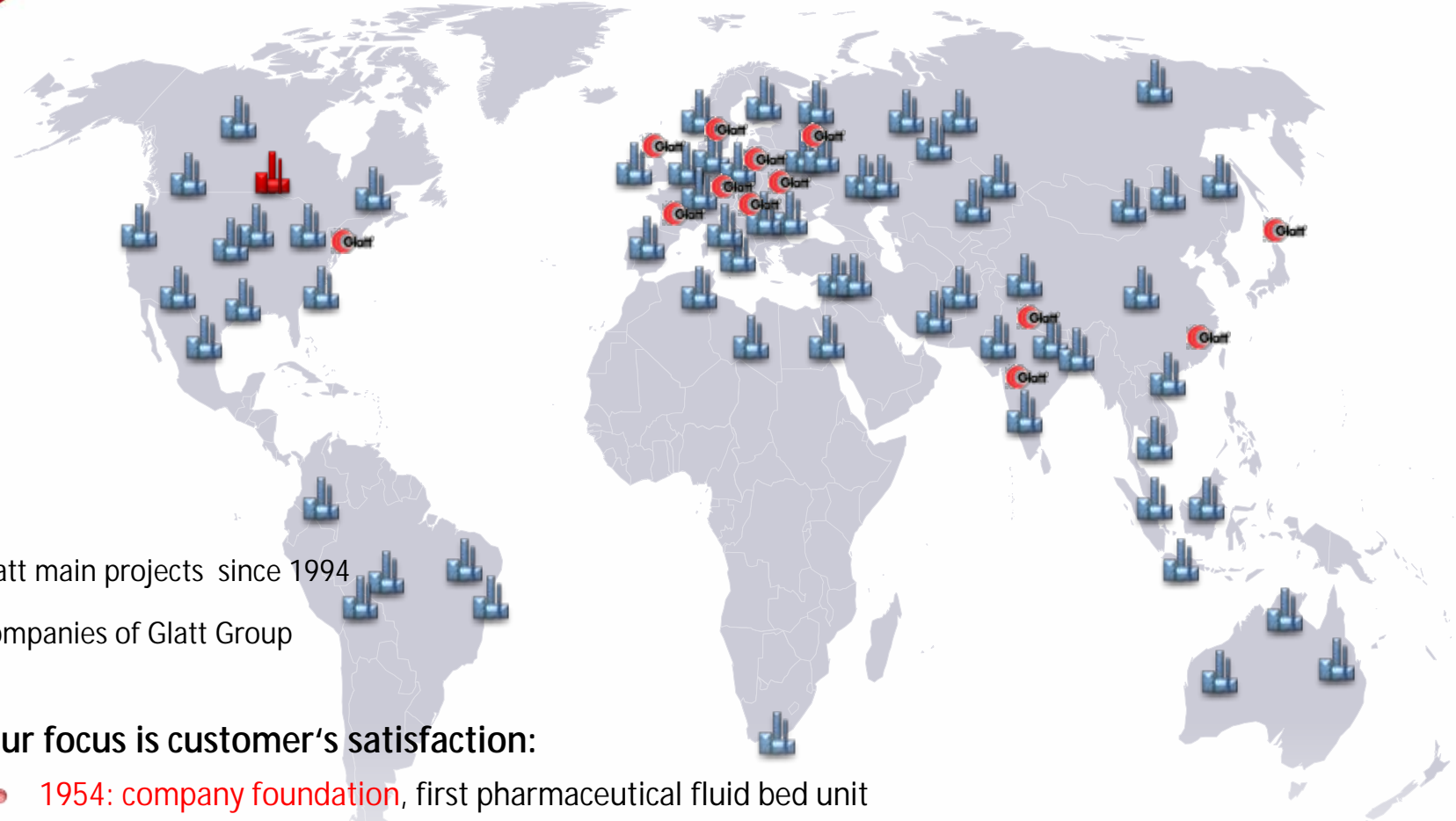


Plant Engineering & Design Consultancy

Concept Design | Basic & Detail Engineering | Qualification Protocols



The Company



Glatt main projects since 1994



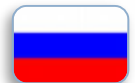
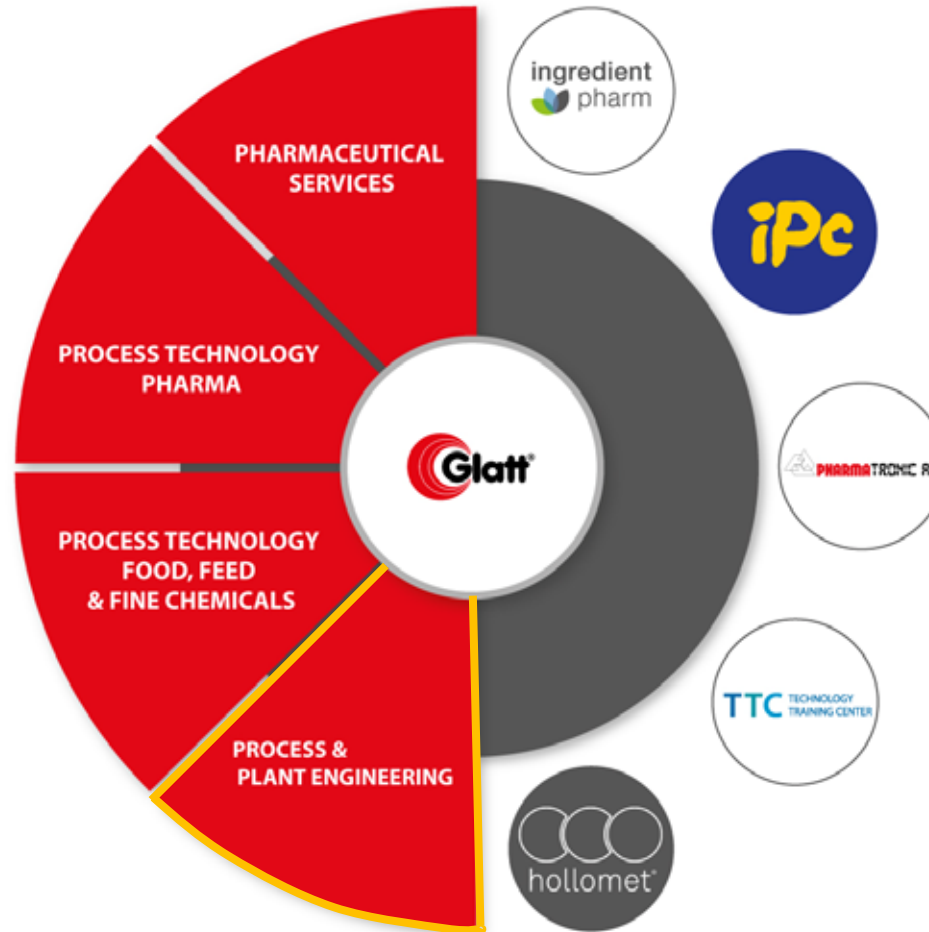
Companies of Glatt Group

Our focus is customer's satisfaction:

- 1954: company foundation, first pharmaceutical fluid bed unit
- today: global leader for integrated process technology
- international group of companies: **about 3000+** team members in an international network of about 14 companies



Process & Plant Engineering within International Glatt Group





Glatt Engineering Worldwide



Glatt Ingenieurtechnik, Weimar + Dresden + Wiesbaden (Germany)



Glatt Engineering Pvt. Ltd., New Delhi (India)



Glatt Ingenieurtechnik, Moskow (Russia)



Ramsey Design Group, Ramsey (USA)



300 +
Engineers
Globally
focused on
Consultancy*

** Focusing only on Healthcare, Chemical & Allied industries*



Process and Plant Engineering Range of Services

Consulting

- » Project development
- » Feasibility studies
- » Conceptual design
- » Licenses

Engineering & Design

- » Basic engineering
- » Detail engineering
- » General planning/engineering

Validation & Qualification

- » Qualification and validation master plans (QMP, VMP)
- » Risk analyses (RA)
- » Qualification plans for DQ, IQ, OQ
- » GMP-audits



Turnkey Projects*

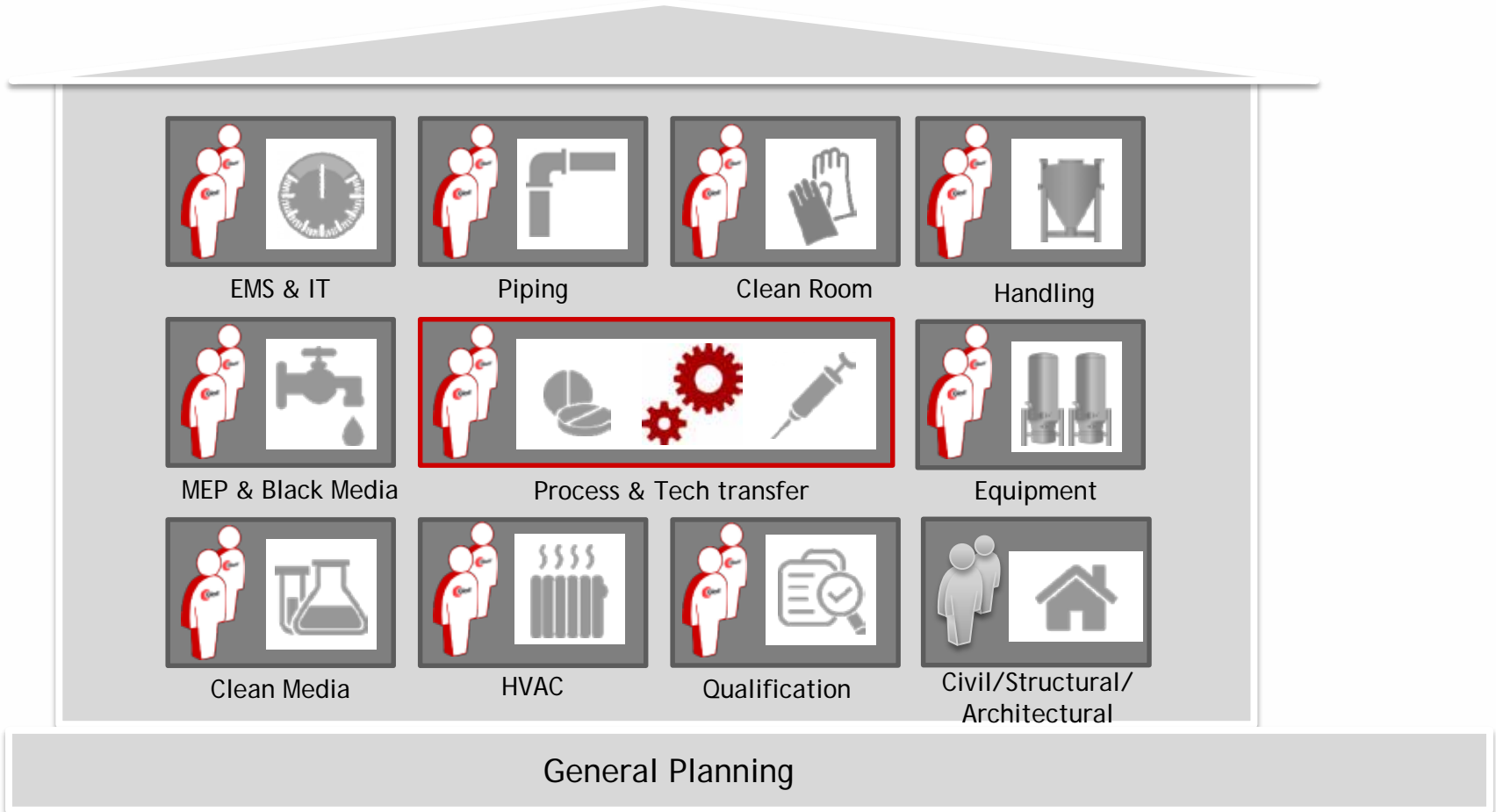
- » Procurement & expediting
- » Construction
- » commissioning
- » Operator training
- » Technical support/ After-sales-service



Project Management



Engineering Capabilities - in house

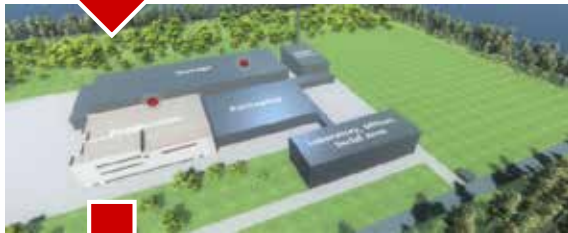




Kinds of Projects



Greenfield



Extension



Modernization, GMP upgrade/Reconstruction



Production transfer/
Removal from A to B





Glatt Engineering Global Teams



Germany



India

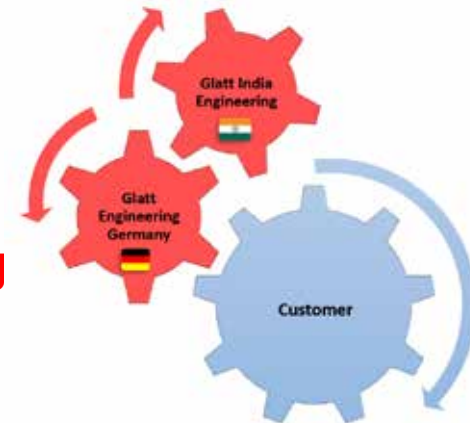
**Team 1
Glatt Germany**

- » Conceptual design
- » Basic & detail engineering
- » Process engineering
- » Project management
- » Clean media - HVAC | Water | Air
- » Qualification & Validation

**Team 2
Glatt India**

- » Conceptual design support
- » Basic & detail engineering support
- » Architectural design support
- » Media services support
- » MEP services
- » Q/V support

**German Subject Matter Experts (SME) during
entire life cycle of projects**





How do we work

- » *'Workshop Based Approach'* where we bring *'Engineering to your doorstep'*
- » *German Subject Matter Expert* in charge of the project team -> leads the design elements
- » This way we bring *'state-of-the-art'* parameters to our Layouts & Engineering

- » We Reduce Engineering timelines by up to 20%
 - » By working entirely on 3-D platforms we are able to achieve this by:
 - » *Have Greater Coordination and Collaboration between disciplines*
 - » *Waste Minimization*
 - » *Greater Error Detection*
 - » *Accuracy in bill of quantities*
 - » *Clash Detection*
 - » *Model Faster decision making due to better understanding of the design*



Few Software's Utilized

Program Name	Function	File Format
Microsoft Word	Documentation	*.docx
Microsoft Excel	Spread sheets	*.xlsx
Microsoft Access	Data bases	*.mdb
Microsoft PowerPoint	Presentations	*.pptx
Microsoft Project	Project Scheduling	*.mpp
Autodesk AutoCAD 2016	CAD	*.dwg
AutoCAD Building Design Suite 2016	BIM in 3D for MEP	*.dwg
Autodesk Electrical 2016	Electrical Design	*.dwg
AutoCAD Revit 2016	3 D Layout design	*.rvt
Visio Standard	Organisation, process flows	*.vsd



3D VIEW-SOUTH SIDE





Major challenges & achievements

- » Handling tons of materials per day - RM | FG | PM & Waste
- » Unique warehouse concept - *an ASRS (automated storage and retrieval system)*
- » Reduction in Technical floor space with *great utility design features*
 - » *CAPEX & OPEX optimization*
- » Utility concepts with *reductions in no. of AHU's + Piping etc.*
- » Unique design to address installations of equipment and utilities for Phase 2
 - » *How to get equipment in the plant with zero or min. disruptions?*
- » Addressing cross contamination issues between different batches
- » Vertical i.e. Tower Concepts
- » **Major Achievements for some projects:**
 - » Plants approved for US FDA | EU GMP | WHO etc.
 - » Facilities in ISPE FOYA (Facility of the Year award)
 - » Engineering completed in 6 months from Concept to DD
 - » Civil construction started 4 weeks in to design phase

We
design
&
build
Facilities for the
future...



Process & Plant Engineering Focused on Technology

Pharmaceutical industry

solid, semi-solid and liquid drugs

dosage forms:
e. g. tablets, coated tablets, capsules, infusions, injections



Biotechnology

blood plasma products
vaccines,
insulin



Food/ Feed industry

instant products and ingredients
like flavors, enzymes,
essential oils, proteins,
vitamins
others ...



Chemical / Fine chemical industry

technical salts,
fertilizers,
pesticides, detergents,
enzymes,
others ...



References

- » GMP solids, Germany
- » Infusions LVP Russia
- » API, Norway
- » Blood plasma, Russia
- » BCG vaccine, Ukraine
- » Insulin SVP Ukraine
- » Yeast, Syria
- » Baby Food, Russia
- » Flavors, France
- » Potash, Germany
- » Detergents, Germany
- » NaCN, Russia



Few Relevant References...

Sterile Liquids and OSD's (High Potent)





Solid Dosage Forms

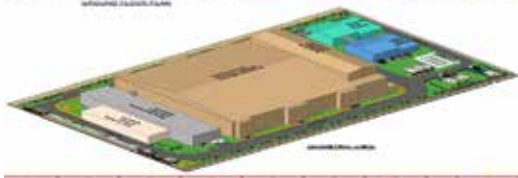
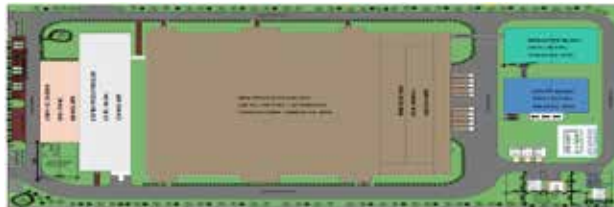
US FDA
Approved
Facility

Handling
more than 5
Tons of
Material a
day

One of the
Largest
Production
under one-
roof



Construction of new oral solid dosage facility for Zydus Cadila Healthcare Ltd.



location	Ahmedabad, India
products/ capacity	Oral Dosage Form and <u>Potent Block (HORMONE)</u> ≈14+ billion units/year
Scope of supply	Preliminary conceptual design, basic & detail engineering for the new production facility for tablets development and evaluation of layout alternatives including: <ul style="list-style-type: none">• Complete Engineering & Design• <i>Process and dimensioning assistance</i>• <i>Layout & SMP</i>• <i>Civil, Structural & Architectural design</i>• <i>cGMP concept</i>• <i>HVAC & MEP design</i>• <i>Machinery calculation</i>• <i>Personnel calculation</i>• <i>Cost estimation</i>• <i>Project Management for Scope</i>• <i>Periodic Site Visits</i>



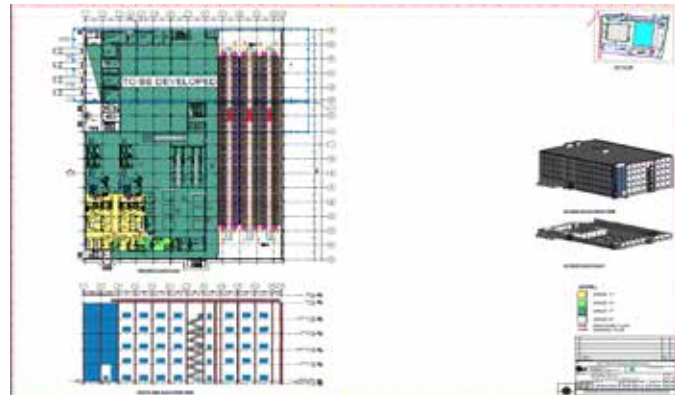
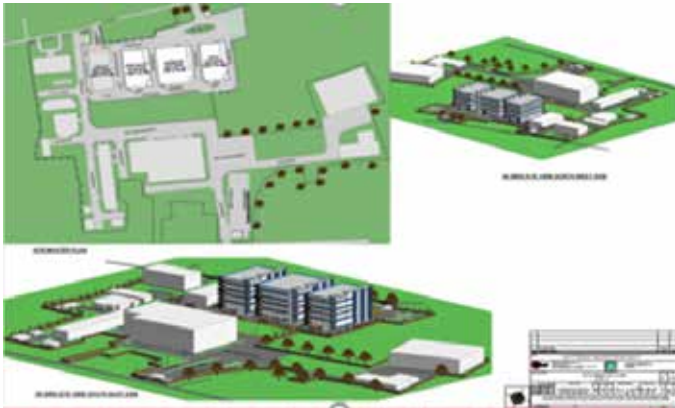
High Potent

Designed
as per US
FDA

One of the
Tallest
Manufac. Buildings
in
South East Asia



Multi product manufacturing facilities for ACI in Bangladesh



location

ACI | Bangladesh

products

'High - potent Blocks' (Solid / Sterile) + LVP | SVP | LCO Block

Scope of supply

- *Conceptual Design*
- *process optimization*
- *Basic design: layout for development, safety, cGMP concept*
- *Detail design*
- *Civil, Structural & Architectural Design*
- *drawing up of tendering documents, and preparation for awarding of contract*
- Validation / qualification documentation including:
 - VMP | MQP
 - RA (FMEA)
 - DQ | IQ | OQ protocols



High Potent



High Potent manufacturing facility for Beacon Pharma | BANGLADESH



location

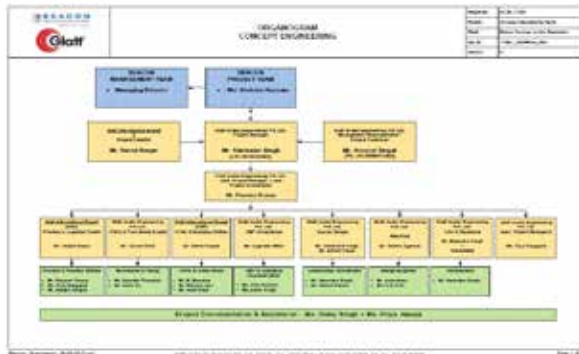
Beacon Pharma - Bangladesh

products

High Potent - OSD + Sterile Lyo Products

Scope of supply

- *Conceptual Design*
- *Equipment sizing/optimization*
- *Basic design: layout for development, safety, cGMP concept*
- *Detail design incl. URS's for Critical Equipment's*
- *Value Engineering*
- *Drawing up of tendering documents, and preparation for awarding of contract*
- *Technical Comparison & Recommendation*
- *Periodic GMP site visits*



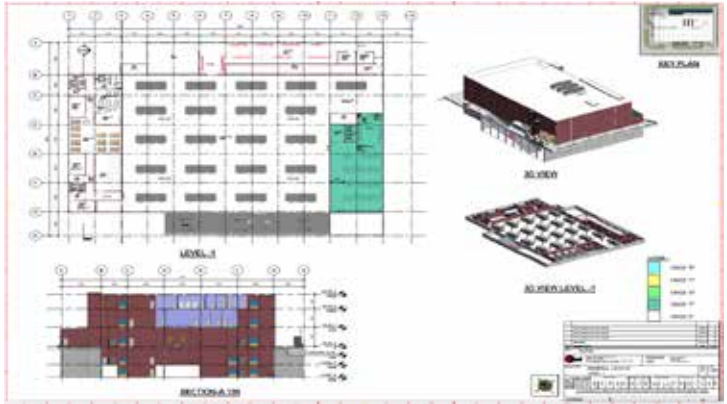
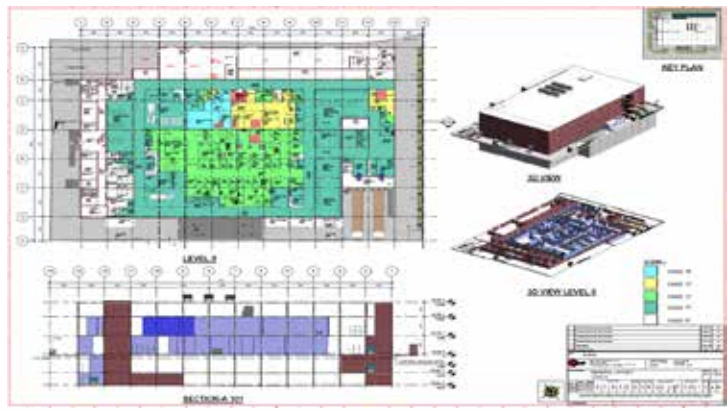


Multi Dosage Forms

Designed
as per US
FDA



New multi oral dosage and sterile facility for High Potent Products - ALGERIA



customer	Profam Spa
location	Algeria
schedule	2017-2018
products	General OSD, High Potent OSD and Injectable
Scope of supply	<ul style="list-style-type: none">- Concept Design Report- Basic Engineering- Detail Engineering up to Tender docs & BOQ- 'Workshop based approach'- Validation / qualification documentation including:<ul style="list-style-type: none">• VMP MQP• RA• DQ IQ OQ protocols



Multi Dosage Forms



New solid dosage and sterile injectable facility for AJA Pharma



location Hail, Kingdom of Saudi Arabia
products/
capacity **Solid / liquid / sterile (High-Potent)**
1.5 billion units/a

Scope of
supply

- *Conceptual Design*
- *process engineering*
- *technical project management for engineering of process technology and building services*
- *basic design: layout for development, safety, GMP concept*
- *detail design*
- *drawing up of tendering documents*
- *supervision of installation*
- Validation / qualification documentation including:
 - VMP | MQP
 - RA (FMEA)
 - DQ | IQ | OQ protocols





OSD and Sterile Injectable



OSD forms + suppositories and sterile injectable for SOTEX



location Russia
Product / capacity Solid / liquid / **sterile (High Potent)**
 3.5 billion units/a

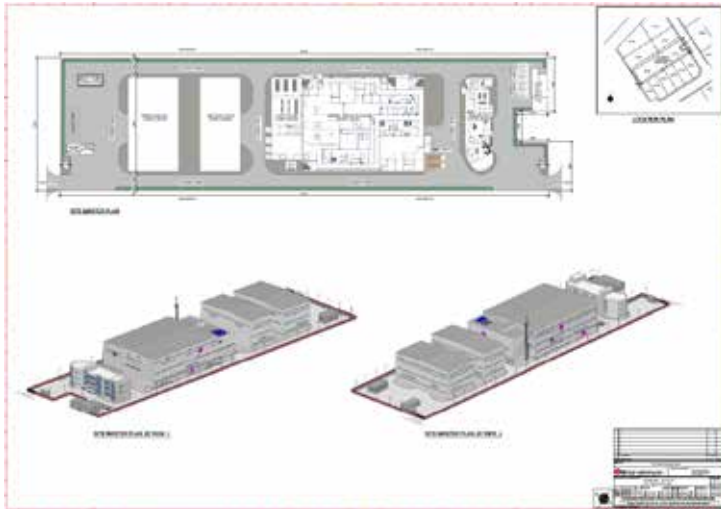
- Scope of supply
- *Conceptual Design*
 - *Technical project management for engineering of process technology and building services*
 - *basic design: layout for development, safety, cGMP concept*
 - *Detail design*
 - *drawing up of tendering documents, and preparation for awarding of contract*



Multi-product dosages



New Multi-product production block for Oral Solids | Liquid | Sterile products - QATAR



customer	MJFAK Group
location	Doha - Qatar
schedule	2018-2019
products	OSD C&O High Potent Solids & Sterile (Lyo)
Scope of supply	<ul style="list-style-type: none">- 'GAP' Report of existing design- Complete new Concept Design- Engineering up to Tender docs with BOQ's ± 5%- 'Workshop based approach'- Validation / Qualification documentation including:<ul style="list-style-type: none">• VMP MQP• RA• DQ IQ OQ protocols

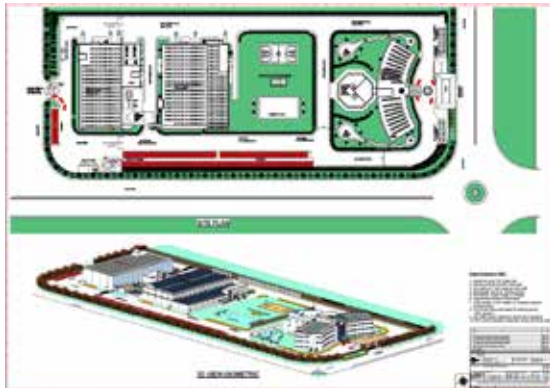




Liquid Form



Facility for liquid lab reagents for HORIBA, India



location Nagpur | India

schedule 2018 - 2019

products/
capacity Liquid - Reagents
5500 Tons p.a.

Scope of
supply

- *Conceptual Design*
- *basic design: layout for development, safety, GMP concept*
- *detail design incl. drawing up of tendering documents and preparation for awarding of contract*
- *Qualification / validation documentation*
- *Periodic site GMP visits*





Multi-product dosages



Multi-product site for Oral Solids | Condoms | Sterile products - Bangladesh



customer	SMC Group
location	Bangladesh
schedule	2018
products	OSD Condoms High Potent Solids & Sterile (Lyo)
Scope of supply	<ul style="list-style-type: none">- Concept Design incl.<ul style="list-style-type: none">- Site master plan options- Layouts for all blocks- Complete Equipment lists- Costing with international vendors- 'Workshop based approach'- RA 1- Executability statement for the design





Few Relevant References...team India

Oral Solid Dosage Forms



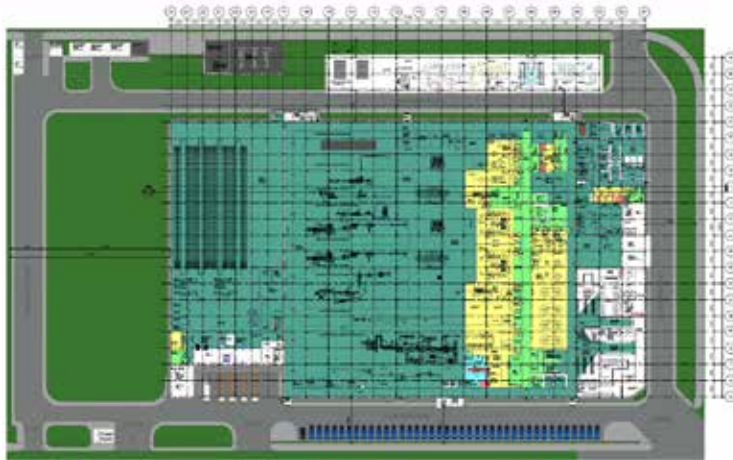


Multi Dosage Forms

Designed
as per US
FDA



New multi oral dosage and sterile facility for Advance Pharmaceuticals



location Jeddah, Kingdom of Saudi Arabia
products/
capacity **Solid / liquid / Sterile - LVP + SVP**
1.5 billion units/a

Scope of
supply

- *Conceptual Design*
- *Process equipment*
- *Technical project management for engineering of process technology and building services*
- *Basic design: layout for development, safety, cGMP concept*
- *Detail design*
- *drawing up of tendering documents and preparation for awarding of contract*
- *Qualification & validation documentation*
- *Periodic Workshops at site*





Solid & Liquid Dosage forms



Expansion of an existing pharmaceutical production site for NESHER Pharmaceuticals



location USA

products/
capacity **Solid & liquid dosage forms (controlled substances)**
≈ 3 billion units/year

Scope of supply Preliminary *conceptual design study* for the new production facility and evaluation of layout alternatives including:

- *process optimization and dimensioning*
- *Layout*
- *cGMP concept*
- *HVAC philosophy*
- *Machinery calculation*
- *Personnel calculation*
- *Cost estimation*

Zone	Temperature		Humidity	
	[°C]	Tolerance ± [K]	R.H. [%]	Tolerance ± [%]
D (production areas)	21	3	50	20
D (low production rooms)	21	3	35	10
CNC	20	5	50	30
HC	20	10	N/A	-

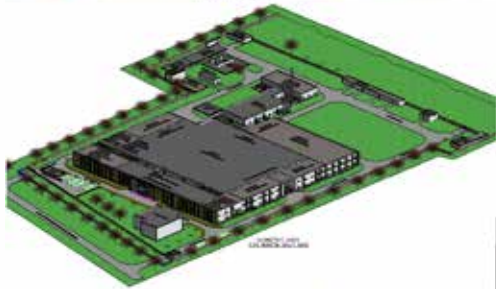




Solid Dosage Forms



Construction of oral solid dosage facility for Jubilant Generics



location

Roorkee, India

products/

Oral Solid Dosage (green & brown Field)

Scope of supply

- *Conceptual Design*
- *Technical project management for engineering building services*
- *Basic design: layout for development, safety, cGMP concept*
- *Detail design*
- *Drawing up of preparation for awarding of contract incl. TC / TR*
- *Civil design*
- *Periodic GMP visits*



Solid Dosage form



Office and Lab for COLORCON

location Greater Noida, U.P.

schedule 2016 - 2017

product Office & Lab

Scope of supply » Engineering & Design Consultancy





Solid Dosage Forms



Facility for new oral solid dosage for Dr. Willmar Schwabe, India



GROUND FLOOR VIEW



location	U.P. India
schedule	2015 - 2016
products/ capacity	Solid 1.4 billion tablets p.a.

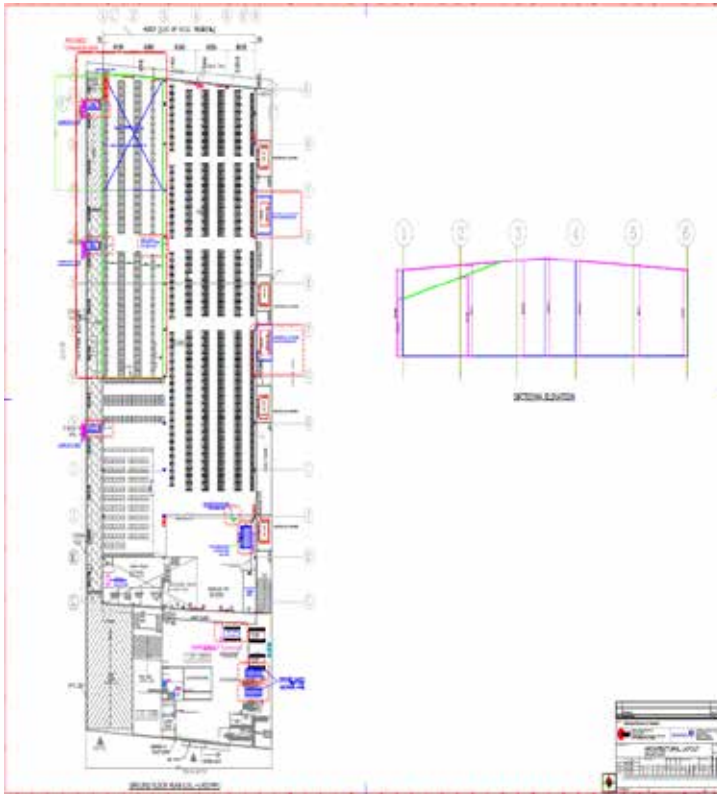
Scope of supply	<ul style="list-style-type: none">• <i>Conceptual Design</i>• <i>process engineering</i>• <i>technical project management for engineering of process technology and building services</i>• <i>basic design: layout for development, safety, GMP concept</i>• <i>drawing up of tendering documents and preparation for awarding of contract</i>• <i>Qualification / validation documentation</i>
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Capacity Expansion



Warehouse Expansion Facility for Dr. Reddys Laboratories Ltd.



location

U.P., India

product

Capacity Expansion

Scope of supply

- *Engineering Design*
- *technical project management for engineering building services*
- *basic design: layout for development, safety, cGMP concept*
- *detail design*
- *drawing up of tendering documents and preparation for awarding of contract*
- *As-built finalization*
- *Periodic site visits*



Few Relevant References...

Bulk API

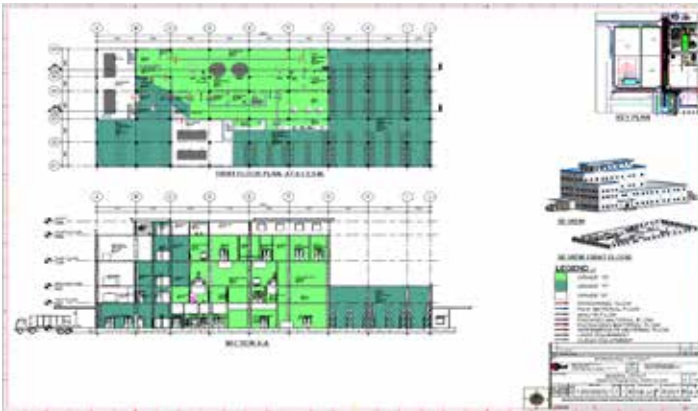




API



Construction of an API facility for Jubilant LifeSciences



location

Gujrat, India

products/

API - 7000 MTPA

Scope of supply

- *Conceptual Design*
- *Technical project management for engineering building services*
- *Basic design: layout for development, safety, cGMP concept, HAZOP*
- *Detail design*
- *Drawing up of preparation for awarding of contract incl. TC / TR*
- *Civil + Structural design*
- *Periodic GMP visits*
- *VMP + Qualification docs up to OQ*





Semi-solid and API's



Intermediate, API & Ointment Manufacturing Facility for Anuja Healthcare Ltd.



location Derabassi, Punjab
products/ capacity **Ointments and API's**

Scope of supply

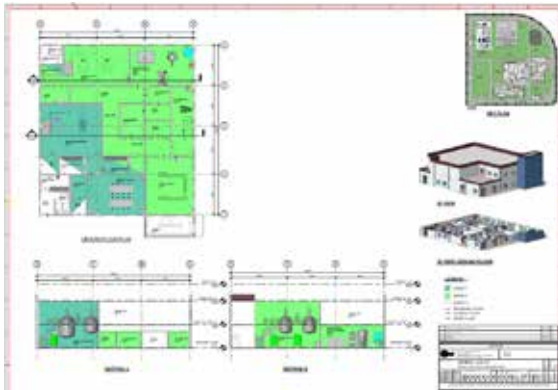
- *Conceptual Design*
- *Process optimization*
- *basic design: layout for development, safety, GMP concept*
- *engineering design*
- *drawing up of tendering documents, and preparation for awarding of contract*
- *qualification documentation*





GLATT Reference in Iran

Imagen Biotech Company



location	Iran
product	Bulk API
building	complex for production, laboratory, warehouse, administration, media

scope of our supply	conceptual design of entire compact building complex including options for extension: layout, master plans, time schedule and cost estimation
---------------------	---



Team's Project References in Iran



Project Reference in Iran

ATRA PHARMA
(TPICO)

Peptide Sterile Bulk & Formulation Facility

TAMIN PHARMA
(TPICO)

Sterile Formulation Facility





Few Relevant References...

Biotech



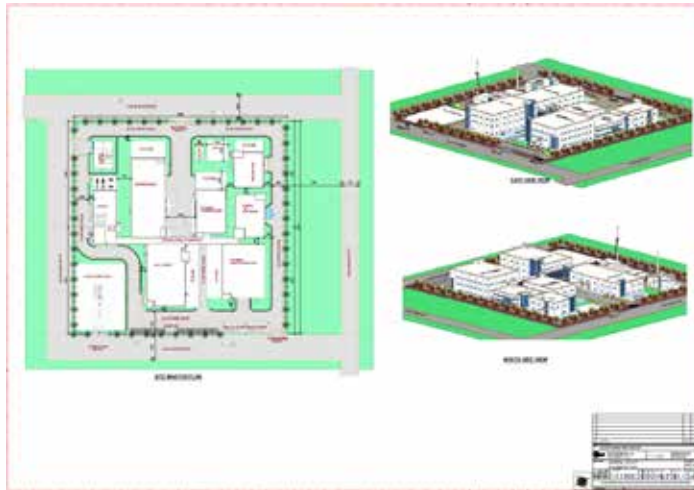


Biotech Facility

Designed
as per EU
GMP



New Biotech facility for Blood Plasma Fractionation



location	Bangalore, India
schedule	On-going
products/ capacity	500,000 Lt /year
scope of our supply	Design of biotech module including storage, fractionation and final goods manufacturing / packaging Scope: <ul style="list-style-type: none">- Concept Design- Basic & Detail Engineering- Civil, Structural & Architectural- Periodic site & cGMP visits- Validation & qualification documentation



Biotech Facility



New Biotech facility for Blood Plasma Fractionation



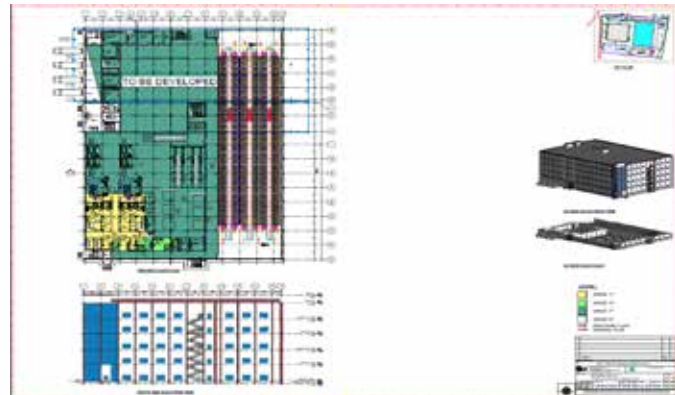
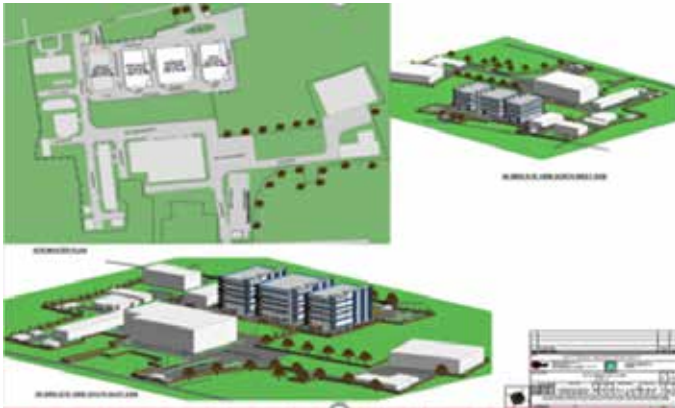
location	INTAS Ahmedabad, India
schedule	On-going
products/ capacity	1 Million Lt /year
scope of our supply	Design of biotech module including storage, fractionation and final goods manufacturing / packaging Scope: <ul style="list-style-type: none">- Concept Design- Basic & Detail Engineering- Civil, Structural & Architectural- Periodic site & GMP visits



Multi Product



Multi product manufacturing facilities for customer in Bangladesh



location

ACI | Bangladesh

products

Bio-speciality Block for MAB's & Insulin

Scope of supply

- *Conceptual Design*
- *process optimization*
- *basic design: layout for development, safety, cGMP concept*
- *Detail design*
- *Civil, Structural & Architectural Design*
- *drawing up of tendering documents, and preparation for awarding of contract*
- *qualification documentation up to OQ incl. VMP + RA*

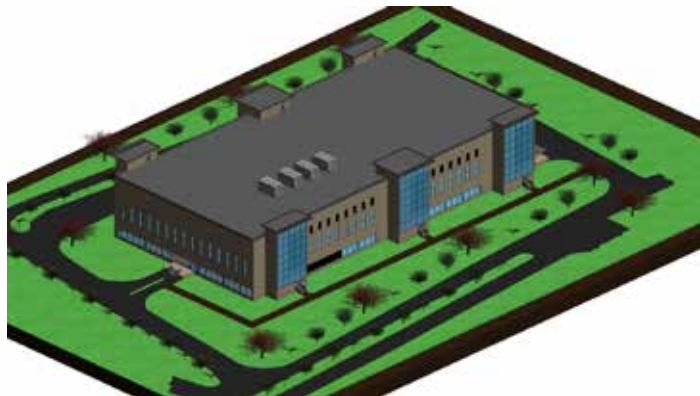


Oral Vaccination

Designed
as per US
FDA



Construction of Vaccine Plant for (confidential) at China



location	Wuhan, China
schedule	2014 - 2018
products/ capacity	Oral Vaccination 80 million p.a.
process	Manufacturing of hexavalent, oral, live attenuated vaccine based on a cell factory process
Scope of supply	<ul style="list-style-type: none">• <i>layout and concept design</i>• <i>cost evaluation</i>• <i>cGMP philosophy</i>• <i>man / material flow philosophy clean media</i>• <i>utility calculation</i>





Few Relevant References...

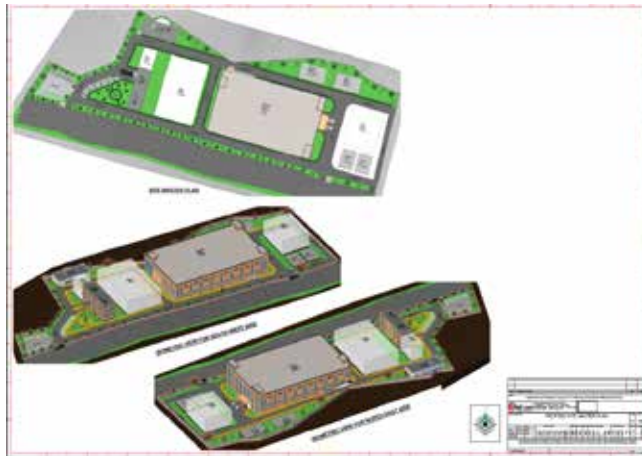
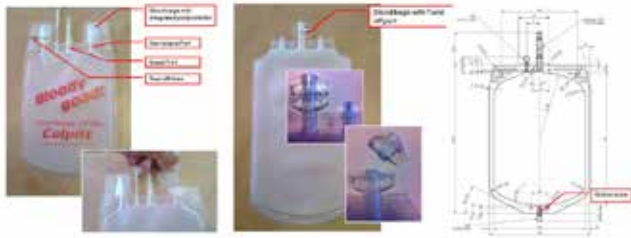
Medical Devices





Blood bag facility for HLL Lifecare Limited, Thiruvananthapuram

Blood Bag Components



location Thiruvananthapuram, India

schedule 2015 - 2016

product Blood Bags

Scope of supply

- *Conceptual Design*
- *process engineering*
- *technical project management for engineering of process technology and building services*
- *basic design: layout for development, safety, cGMP concept*
- *drawing up of tendering documents and preparation for awarding of contract*
- *qualification documentation*



Medical Devices



Construction of new facility for Medical Devices for BL Lifesciences

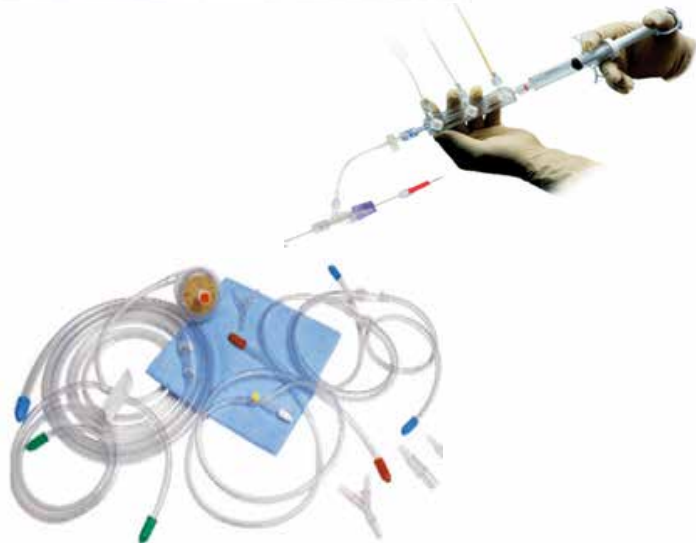


location Greater Noida, U.P.

products/ **Medical Devices**

Scope of supply

- *Conceptual Design*
- *process engineering*
- *technical project management for engineering of process technology and building services*
- *basic design: layout for development, safety, GMP concept*
- *detail design*
- *drawing up of tendering documents, and preparation for awarding of contract*





Few Glatt Germany References



Recombinant human insulin



New large scale biopharmaceutical plant for Julphar - Gulf Pharmaceutical Industries



location	Ras Al Khaimah, United Arab Emirates
schedule	2009 - 2012
product	recombinant human insulin
building	new large scale biopharmaceutical plant for API production

- scope of our supply
- » management consulting,
 - » integrated engineering (from conceptual design to detail engineering for complete process),
 - » on-site project coordination,
 - » supervision,
 - » qualification,
 - » commissioning support



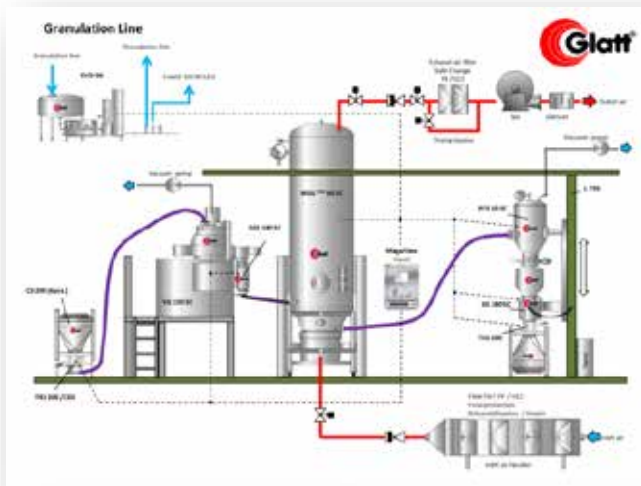
* Client reference of Dresden Bio Team members with former company Linde-KCA-Dresden GmbH (LKCA)



High Potent- Solid Dosage Forms



Construction of a new production facility for HIGH POTENT OSD forms for R-Pharm



location	Moscow, Russian Federation
product	tablets, capsules
capacity	116 kg/batch
scope of our supply	equipping the new production with a granulation line for total containment: adaptation of URS and detailed design of the customer, specification, delivery, installation and commissioning of the complete granulation line for very high potent and sensitizing API



High Potent- Solid Dosage Forms



Construction of a new production facility for Astra Zeneca



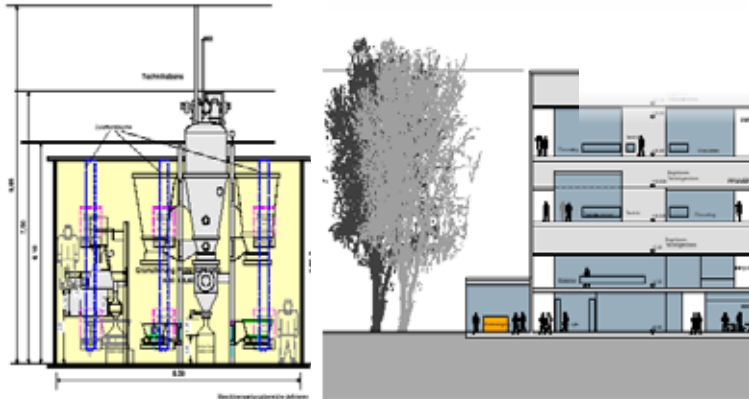
location	Vorsino, Russian Federation
product	High Potent OSD
capacity	up to 600 million tablets/year
building	building complex, consisting of production buildings, storage facilities, utility building
scope of our supply	Design, process, building services, architectural for entire building complex, procurement, expediting, qualification, execution engineering



Solid Dosage Forms



Construction of a new containment facility for Boehringer Ingelheim

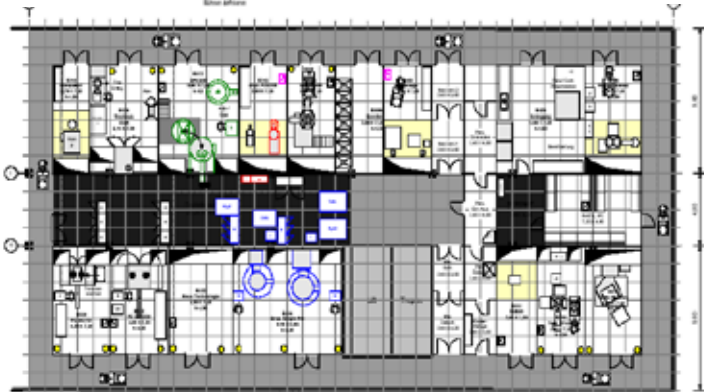


customer: **Boehringer Ingelheim**

location: Biberach, Germany

product: solid dosage forms **with highly potent ingredients (containment)**

scope of supply: consulting/audit for new solid production/generics
project support,
quality assurance,
conceptual design, basic- and implementation planning for building services





Solid Dosage Forms



Construction of a new pharmaceutical production facility for Novartis Pharma AG.



location	Russia
product	solid dosage forms
capacity	0,5 billion/a bulk production 1 billion/a packaging
building	complex for production, laboratory, warehouse, administration, media
scope of our supply	conceptual design of entire compact building complex including options for extension: layout, master plan, URS preparation, time schedule, cost estimation, site inspections, review report on costs for infrastructure and evaluation of landscape protection



Biopharmaceuticals



New MAB Plant at F. Hoffmann-La Roche AG



location	Basle, Switzerland
schedule	03/2003 - 02/2007
product	anticancer drug Avastin = new cell culture of monoclonal antibodies (MAB)
scope of our supply	<ul style="list-style-type: none"> » project coordination » conceptual design » basic engineering » detail engineering » support in procurement » engineering support during installation and commissioning

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FDA
Approved
Facility

* Client reference of Dresden Bio Team members with former company Linde-KCA-Dresden GmbH (LKCA)



Vaccines for Humans



Revamp and upgrade of a production area for GSK Biologicals



location	Dresden, Germany
schedule	02/2016 - 12/2016 Basic engineering, since 01/2017 continuation with Detail Design and implementation
product	Flu vaccines (seasonal flu)
scope of our supply	Re-design of a production support area for aseptic production (including installation of new washing machines and autoclaves)



Largest Biotech Production Plant in Europe



WYETH BioPharma Campus Dublin



- Location Grange Castle Campus, Dublin/Ireland
- Product ENBREL® and Pneumococcal Conjugate Vaccine
- Type of Plant: Biopharmaceutical multi product campus with three separate facilities:
- R&D center
 - Cell culture plant (drug substances)
 - Fill and Finish plant including QA/QC and infrastructure

Scope of supply Consulting during integrated construction and validation (ICV), Acceleration program, de-bottlenecking

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BIO
TEAM*

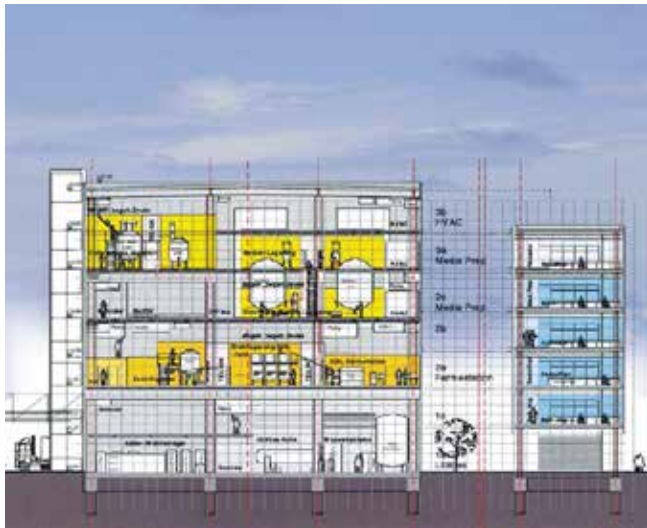
* Client reference of Dresden Bio Team members with former company Linde-KCA-Dresden GmbH (LKCA)



Recombinant Blood Coagulation Factor VIII



New plant for the production of KOGENATE for Bayer AG in Germany



location	Wuppertal-Elberfeld, Germany
product	KOGENATE (recombinant blood coagulation factor VIII, pharmaceutical ingredient in high-cell-density perfusion cultures of BHK cells and purification of the glycoprotein)
building	new buildings for the production
scope of our supply	<ul style="list-style-type: none">» know-how and technology transfer from production and R&D in USA to Germany and into design basis» conceptual design for all disciplines



* Client reference of Dresden Bio Team members with former company Linde-KCA-Dresden GmbH (LKCA)



Glatt Worldwide Projects



Glatt Projects



Satisfied Customers - Globally





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CERTIFICATE



for the management system
according to ISO 9001:2008

The proof of the conforming application with the regulation was furnished and in accordance with certification procedure it is certified for the company



Nordstraße 12, 99427 Weimar / Germany

Scope

Development, planning, implementation and installation of equipment, systems and turn-key projects for the pharmaceutical, medical-technology, chemical and related industry, supply of machinery and equipment for medical-technology, as well as contract manufacturing of free-flowing solids (granules) using fluidised bed technology.

Certificate Registration No. TIC 15 100 64311

Valid until 2012-12-19

Audit Report No. 3330 267C D0

Initial certification 2006

This certification was conducted in accordance with the TIC auditing and certification procedures and is subject to regular surveillance audits.

A. Drechsel

TÜV Thüringen e.V.
Certification body for
systems and personnel



Jena, 2010-01-12



TGA-ZM-03-06-00



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