GST Engineering

Projects for Industry

Oil & Gas

Life Sciences

Special Technologies

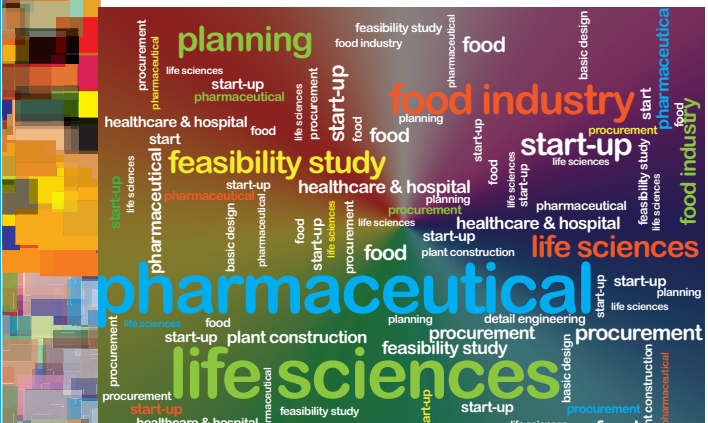
Life Sciences

Index

Who we are

GST is a Rome-based engineering firm that specialises in international industrial projects. We use our knowledge and experience of *Industrial Processes* – in the fields of *Oil Refining, Pharmaceuticals, Renewable Energy, Aerospace*, etc. – to develop the range of skills and capabilities that enable us to provide high-quality services, in relation to the various plant design phases and disciplines. Building up on our core **Chemical Process Design** expertise, we can now meet the all-round needs of our Customers delivering *Consulting, Engineering, Procurement* support and *Construction* and *Commissioning* supervision services, as well as complete *Turnkey* solutions for small-scale plants or plant units. Thanks to its specific expertise and qualifications, GST has been selected by **Technip Group** as its Official Representative, in Italy, for Industrial Projects in the Pharmaceutical Sector.

This brochure illustrates the activities we carry out and the services we provide in the **Life Sciences** Sector. For more information please visit our website at www.gstengineering.it and email us at info@gstengineering.it.



What we do

The **Life Sciences Sector** in which we operate (*references*) and in which we have built up our expertise (*competencies*), the **Disciplines** we master and the range of **Services** we provide.

The Life Sciences Sector

The term **"Life Sciences"** comprises all the scientific fields involving the study of *living organisms* (*plants, animals,* and *human beings*) and their care. At GST, we use this term to define the industry macro-sector and the related production facilities. The **"Life Sciences Industry"** (hereinafter abbreviated as **"Life Sciences"**, for simplicity's sake, omitting the word **"Industry"**, which refers to the scientific research activities and related industrial applications), therefore, covers a broad spectrum of activities, ranging from **Pharmaceuticals** to the **Food Industry, Healthcare & Hospitals**, etc. The Sector, therefore, involves a wide array of different facilities, also with regard to their size, but all of which require specific and sophisticated know-how, the implementation of which is still based on the conventional sequence of: *Feasibility Study – Basic Design – Detail Engineering – Procurement* of equipment and materials and, finally – *Plant Construction* and *Start-up*. However, any Project in this Sector is characterized by the need to ensure close coordination between ***Customer*** and ***Contractor***, in order to achieve the requisite quality and ensure compliance with the relevant timeframes and cost targets.

The table below summarizes GST's range of contractual capabilities in the Life Sciences Sector:

Typical Plant Value (1.000 euro = 1k euro)			GST Services
	Large-scale Plant	> **30,000 k€**	Consulting, Design, Procurement support and Construction supervision
15,000 k€ <	Small and Medium-scale Plant	< **30,000 k€**	EPC Management
	Small-scale Plant or Plant Unit	< **15,000 k€**	*TurnKey* - LSTK

Following are several peculiar aspects, and the relevant GST skills, with respect to each sector.

Pharmaceuticals

GST can boast a longstanding and specific experience in both synthesizing active ingredients and finalizing compounds with solvents, inerts and excipients, as well as in product packaging. In this sector, where the Customer's know-how is essential for laying out the **Process Development** blueprint, GST can be relied on to support any strategic decision, with respect to the Process development, Detailed Design, selection of critical equipment and assistance in the Construction and Start-up phases. Our experience in the handling and storage of both raw materials and final products should also be taken into account.
In this Sector, GST always operates as a *Customer Oriented Company*, i.e. in close partnership with the Customer, to maximize the synergy between the Customer's know-how and GST's engineering experience, knowledge of vendors and management experience.

Food Industry

At GST we can provide a wide range of services to the **Food Industry**, ranging from Basic Design to Construction and Start-up, for each production cycle phase, from the agricultural product to final packaging. Of great significance here is GST's specific experience in the production of *ethanol*, for both food and *sugar* refinery use.

Healthcare & Hospital

In the **Healthcare & Hospital** sector, which is characterized by stringent and severe design and implementation requirements, GST's experience can be of great help to the Customer, in respect of the study of environmental conditions control and the layout of the wards, treatment facilities, operating theatres and test laboratories, through the ergonomic optimization of the diagnostic and treatment equipment. Moreover, GST operates on the basis of a number of different contract arrangements, according to the stage of the Project and the Customer's needs.

Disciplines

The core activity of GST is **Process Design**, which is closely tied to **Detailed Design** and all the **Engineering** disciplines needed to build a plant.
Following is a brief description of these disciplines and what GST can do for each of them.

Process Design

In the Life Sciences sector, characterized by a broad range of facilities, also with regard to their size, GST can develop – as part of its core business – complete Process *Packages* for any type of Unit, including the relevant utilities, also integrating the Customer's specific know-how.
A Process Package should be considered as an integrated set of documents, ready to be utilized as a basis for developing the Detailed Design.

Engineering Disciplines

GST can also rely on a number of highly-qualified specialists in the various **Engineering Disciplines** (*Civil Works, Pressure Vessels, Piping, Machinery, Heaters and Boilers, Electrical, Instrumentation* and *Automation, Telecommunications*). The *multidisciplinary* nature of all the sectors in which GST operates – as well as the ongoing market trend that requires *Contractors* to deliver all-round services, regardless of their size – necessitates the capacity to engage in increasingly broader fields and state-of-the-art specialist sectors.

Services

At GST we offer a broad range of **Services**, which can be grouped into two main families: **Consulting Services** and **EPC Services**. In particular, GST operates as a **Consultant** in **Process Management** and **Project Management**, to identify and meet its Customers' business needs, by means of competitively priced professional services. With regard to EPC Services, at GST we have the know how to cover every phase in the implementation of an industrial Plant, targeting both the **Construction of New Plants** (*Grassroot or Expansion*) and the **Upgrading of Existing Plants** (*Revamping*). GST engages in the most widespread **Contract** arrangements (e.g.: *Reimbursable, Lump Sum of Services*, etc.), according to Customer needs and Project characteristics. In the case of small/medium-scale plants – (except for pharmaceutical plants, which are traditionally developed on a reimbursable basis) – on a *Target Price, LSTK* or *Converted LSTK* basis. A detailed description of GST's *Consulting Services* and *EPC Services* for the Life Sciences Sector is given below. Furthermore, several examples of *Consulting Service Packages*, in respect of which GST's experience may be found to be very useful and valuable, are also shown, as an example of GST's know-how in the Life Sciences Sector.

Consulting Services

GST **Consulting Services** may be generally divided into **Technical Consulting** and **Project Management** Services and several **Consulting Service Packages** tailored to the Live Sciences sector.

Technical Consulting and Project Management

Technical Consulting and **Project Management** are the services typically provided by an Engineering Firm, to support Customers across the spectrum of Project development Phases and Disciplines. Generally speaking, Consulting services involve locating and eliminating sources of trouble (*troubleshooting*), or identifying and removing Plant bottlenecks (*debottlenecking*), selecting the most suitable state-of-the-art technology or the most appropriate materials for the relevant operating conditions, Feasibility Study, etc. In order to be effective, Consulting services must be accurate and based on specific expertise and skills, as well as timely and tailored to the Customer's needs. GST's streamlined and flexible structure is particularly suited to delivering these services. *Technical Risk Analysis* is a further example of the consulting services we provide: at GST we can conduct these analyses based on the most appropriate assessment procedure for the specific process and the relevant implementation phase [e.g.: *PHA* during the *Feasibility Study, HAZOP* and *SIL* (*Safety Integrity Level*) during the design phase, etc.].

Conceptual Design

Thanks to our background, at GST we have the suitable resources and expertise to assist our Customers in developing **Conceptual Design** activities, conducting detailed analyses, identifying the options, listing the advantages and disadvantages for each option, evaluating the *Licensors'* proposals, and participating in the preparation of the final recommendation report.

Feasibility Study

The **Feasibility Study** is the decision-making tool for establishing whether and how to proceed with an investment, on the basis of the Conceptual Design output. The key technical and commercial aspects of the Project need already to have been defined, while alternative options should be minimized. The Feasibility Study includes a number of steps, such as *Technical Analysis, Market Analysis*, project *Cost Estimate*, an analysis of the financial resources and a *ROI* (*Return on Investment*) report. In the Life Sciences Sector, GST can assist its Customers in defining the investment scenario and thoroughly investigating the relevant technical and commercial aspects, as well as performing a detailed analysis for each step.

Project Management Consulting

In the Life Sciences sector, GST operates as a **Project Management Consultant** to identify and meet its Customers' business needs, by cooperating in the selection of the most suitable state-of-the-art technology and providing competitively priced professional services.

Technical Consulting

During the implementation of a Project, a Customer may require specialized skills and *know how*, to tackle any Process Design problems (e.g.: *technology selection, technical risk analysis, materials selection*, etc.). At GST, we have the suitable resources and expertise that enable us to promptly provide tailored solutions, in respect of all Life Sciences related activities.

Consulting Service Packages

In addition to the above mentioned Consulting Services, GST also provides several **Consulting Service Packages** – based on GST's invaluable experience in the Life Sciences sector – which represent an all-round answer to certain specific project problems.

Conceptual Design for Fund Appropriation

Sometimes, Customers need to prepare a **Conceptual Design** for the possible implementation of new production facilities, or the expansion of the existing ones, containing a concise description of the scope and benefits of the Project, to be presented to the Top Management, in connection with the annual budget. GST is available to support the Customer in preparing both the technical report and illustrating the reasons for the investment, also developing, if required, a profitability analysis complete with an overall Project schedule and a ± 30 % cost estimate. As a next step, GST may support the Customer in preparing a Preliminary Project (*Basic Design*), together with a ± 10% cost estimate for Project approval and the go ahead for construction.

Contract Management

A Customer, after having awarded a contract for implementing a Project, may require assistance in order to better review a Contractor's activities. Assessment and support activities, in fact, are necessary not only in case of reimbursable type Contracts (e.g.: the Contractor may request a refund for any items not actually due, etc.), but for LSTK Contracts as well (e.g.: the Contractor may issue a number of Variation Order Requests, which then need to be evaluated and discussed). GST can step in, with its experienced staff, to support the Customer and protect its interests.

Permits

Permit applications can often cause quite a headache, involving, as they do, in succession, the preparation and updating of an *Environmental Impact Analysis*, the preparation of the building permit application, with the relevant support documents, the application for commissioning the plant, with the relevant permits from the fire fighting authorities, etc. GST can conveniently prepare any type of document requested by the competent Authorities and support Customers in all aspect of permit application management.

Appraisal of Local Vendors and Subcontractors

In some cases, a Customer may need to carry out an assessment and preselection of local Vendors or Subcontractors, at short notice, before issuing a Request for Proposals for the supply of materials or construction activities. GST can perform fast and accurate assessments thanks to its qualified and experienced staff.

Process Control

From the Basic Design phase, and throughout the implementation of a Project, it is important to outline a *Preliminary Control System Architecture* and select the most suitable state-of-the-art technology, as well as to evaluate the possibility of utilizing special technical options, such as the *Fieldbus* or *Wireless* technology. It is therefore necessary to manage the various process control steps, from the preparation of the requests for proposals for the supply of *PCS*, to the preparation and implementation of the *FAT* and *SAT* procedures, also based on the S/W management and the access control policy. GST has the qualified resources to assist Customers throughout the Process Control cycle.

Staff Training

GST can also provide qualified services for Training Staff members, Supervisors and plant Engineers, by means of classroom sessions and training simulation programmes, ensuring improved self-confidence when interfacing with Plant facilities, in connection with both normal operations and emergencies situations. State-of-the-art dynamic simulators provide an effective and reliable reproduction of process plant performance, taking into account all the equipment and relevant control systems, and simulating the operations and response of the process variables when the input data are changed: however, staff should be accurately trained in order to take full advantage of the capabilities of these systems.

Quality Assurance

At GST we make it a point of assisting our Customers, with specialized staff, in respect of all types of Project, irrespective of size, to prepare the *Project Quality Plan*, conduct the audits and manage any non-conformities. Also, GST is prepared to provide the services for directly performing – or managing the performance by others of – the necessary Plant Qualification activities. The Project Quality Plan is always tailored to the specific Validation requirements of each project. The basic Validation documents, such as *Master Plan* (with *annexes*) and typical *IQ/OQ Protocols* need to be drafted at a very early stage of the activities, so that the necessary provisions and requirements are introduced from the very beginning. As a rule, GST provides for the formal issuing of all the required documents, such as the *Validation Master Plan (VMP), User Requirements (UR), Installation Qualification Protocols (IQP), Operation Qualification Protocols*

(OQP), *Performance Qualification Protocols* (*PQP*), etc. All the Protocols are divided in sections, with reference to the different control operations, giving a detailed description of the following:

- the system in question;
- the purpose of the control;
- the method and the tools used to perform the control;
- the requisite support documents;
- the acceptance criteria;

always taking into account that the activities have to be carried out assuring the repeatability of the tests. Each *Validation Protocol* includes the list of reference documents, standards and specifications supporting the tests results.

EPC Services

Design and Engineering

In the Life Sciences sector, GST can develop an all-round **Process Design** Package, based on the specific and different know-how that are distinctive of this type of Plant. GST can also develop complete and detailed **Engineering Design** *packages* enabling the Site staff to efficiently carry out all the requisite activities, avoiding delays and potentially costly rectification on site. In particular, GST is capable of developing Detailed Engineering activities, based on the Customer's – or its own – General Design Specifications, tailored to the Project characteristics and providing a complete set of deliverables (also including, where required, *mechanical catalogues* and *operating manuals*), in view of ensuring the efficient and safe Construction and Start-up of the Plant. We need to highlight, in this respect, that our engineering activities are always developed based on the *"Intrinsic Safe Design"* approach, which involves strict compliance with the European (e.g.: *ATEX, PED, EN 61511*) and international standards, or with the best engineering practices, in the latter case, whenever the available standards are not up-to-date and in step with the most state-of-the-art technologies, as in the fastest-growing sectors.

Procurement

In the Life Sciences sector, GST can provide all-round **Procurement** services on the basis of the *Integrated Materials Management* principle, i.e.: from the preparation and issuing of the request for proposal to the arrival of the materials at the Site. In particular, the *Expediting* and *Inspection* activities are carried out by qualified specialists, as part of the supervision and monitoring of the entire production phase, with a view to ensuring compliance with the delivery schedules and design specifications.
In the case of *small/medium-scale* Projects, Procurement activities may be carried out – in conjunction with the Engineering activities – on a *Turnkey* basis, with the integrated management of all the Plant equipment and materials.

Construction, Commissioning and Start–Up

In the Life Sciences sector, **Construction, Commissioning** and **Start-up** activities, in the case of *small/medium-scale* plants, can be delivered on the basis of a turnkey type Contract. GST can also provide support services for preparing test run procedures, the validation of the test run reports, for troubleshooting and instrument data reconciliation.

EPC Services for Revamping Projects

Thanks to our background, at GST we can provide special expertise in this special type of Project, by managing the relevant technical aspects and preparing suitable construction documents. Revamping Projects require an accurate planning of the Plant shutdown, both in terms of date and duration, as well as a special design approach, in order to maximize the works that can be carried out before the shut-down. GST's experience can be useful to optimize the overall schedule and minimize loss of production. We ensure a special focus on safety, in particular as regards equipment layout definition, analysis of peaks of manpower, the necessity of work round the clock and in confined spaces, etc.

How we do it

The basis of the GST organization, how we organize our resources and the techniques we apply to tackle problems in the Life Sciences sector.

Project Organization

GST is a *Customer-Oriented Company* built on an in-depth knowledge of the industry in which it operates. Life Science Projects – which require a different, albeit equally sophisticated, know-how – are also best tackled according to a **Task Force** approach, due to its flexibility and to the fact that it ensures a fast exchange of information. However, the **Project Organization** is constantly monitored and tailored to the Project characteristics: for example, GST often applies the *"Integrated Management"* method, according to which the expert responsible for preparing the equipment specifications and the request for proposal also supervises the later stages of the procurement process, from issuing the relevant order to shipment to the site.

Quality Management System

Quality Assurance is an inherent component of GST's operating procedures. The development of an effective Project Quality Plan from the onset of the Project enables the Quality Assurance of all the Project phases, avoiding any misunderstandings about Project's targets and the Client's expectations. The development of this implementation plan also facilitates the involvement, from the start, of the *Customer's Production Department*, in respect of the definition of the *User Requirements* and general *Project Specifications*. In the case of Life Sciences projects, which feature very stringent and specific regulations, GST has gained experience in applying the *Federal Drug Administration, EMEA* and *Italian Health Ministry* regulations, as well as many other domestic and international standards, as a result of which we can guarantee an output that is fully consistent with the industry-specific quality requirements, including (if required by the customer) the Installation Qualification Protocols (*IQP*) and Operational Qualification (*OQP*) needed to use the plant.

Planning

In the Life Sciences sector, GST develops both general and detailed **Project Schedules**, on the basis of *Project Milestones*, and the succession and length of activities, and monitors Project progress and development by means of a dedicated software, based on network charts and the *Critical Path* method.

Estimating and Cost Control

GST can prepare preliminary or detailed **Cost Estimates**, according to the status of the Project; we also prepare Project budgets and perform **Cost Control** activities, throughout the Project's life cycle, evaluating the forecasted cost of the Plant and identifying any corrective actions.

Project
NetSociety - Rome

Design
Aton - Rome

All the images and photographs contained in this brochure are for illustrative purposes only.
They neither refer to people who work in GST nor to projects GST has been involved in.

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