



S.T.P. Studi Tecnologie Progetti S.p.A.
Engineering & Contractor



THIRD CENTURY ENGINEERING FOR “PHARMACEUTICAL BULK”

**CERTIFIED
AND
VALIDATED
PRE-ENGINEERED
PRODUCTION-MODULES**



PRE-ENGINEERED PRODUCTION MODULES

STP, STUDI TECNOLOGIE PROGETTI S.p.A., already present in the chemical-pharmaceutical field for the implementation of Bulk active and intermediate principle projects propose the realization of the Plants by pre-engineered skid mounted production modules. The pre-engineered modules are preassembled on the basis of production requirements, certified by Quality Control and Quality Assurance, GMPs, GAMPs as well as FDA and ISO 9000, and allow significant saving on investment costs and fabrication schedule.

STP aims to improve the project engineering execution for the development of chemical-pharmaceutical plants by the new methodology based on the criteria described herebelow .

- The basic idea is to develop pre-engineered independent Productive-Modules, pre-defined according to technologies and machinery available on the market, by selecting qualified suppliers of technology, machinery and equipment.
- By this way, a wide range of Engineering Packages is already defined in the conceptual design phase. Basic and detailed engineering will be prepared for each Package according to GMP's, recent ISPE/FDA regulation and guidelines GAMP's, ISA.SP.88's etc., so that each Module will be easily convalidated and adapted as soon as the Client provides the basic requirements of his production Plant.
- The Productive Module is different from package realization concept, which is normally pre-assembled by one sole supplier.

- An example of Production Module is the crystallizer-filter-drier-mill system, shown in the side figures. Module has been built for the production of cephalosporine by Bristol-Myers Squibb at Sermoneta (Italy) and CIBA at Naples by two different conceptual and engineered design, thus wasting time, energy and not improving the investment cost. Each Productive Module is made of equipment and components supplied by different companies specialized in the particular technology.

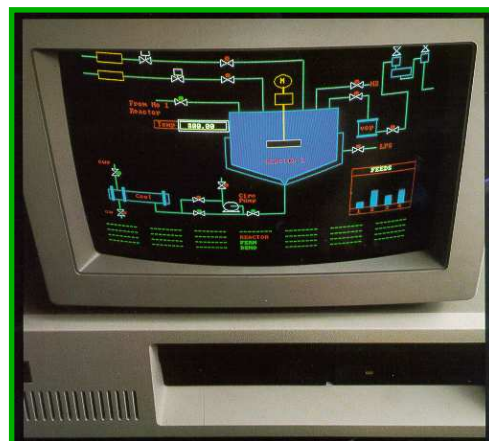


- The realization of the Production Module for cephalosporine by pre-engineered module could have been less expensive and more effective due to the duplication of the facility for both Plants.



- The Production Module can be designed in different sizes to meet the different production needs, and will have the flexibility required by Client's lot and batch size. The module can also be realized for pharmaceutical bulk and for plants producing pharmaceutical dosage forms.

- The Production Module is equipped with computerized system compatible with PLC System and suitable for Client's particular software, or in conformity with home standard and interfacing with a pre-existing or new DCS system.



- The Module can be conceived for installation inside building and suitable for production requirements according to the GMP's, and for cross-contamination and self containment regulation.
- As a result the building architecture can be conceived either to match the technological requirements of the Plant and promote the outside image by advanced civil realization.
- This avoids the construction of anonymous buildings, as whether multistorey or one-level, that are often built without even knowing what they are going to contain or produce.



EXPERIENCES & REFERENCES



<u>CLIENT</u>	<u>LOCATION</u>	<u>PROJECT</u>	<u>YEAR</u>
ENGELHARD	Roma, Italia	Gas Emission Recovery & Treatment	1999
TP/BIOSEARCH	Brindisi, Italia	Ramoplanine Production Plant	1999
Ind. Chimiche Caffaro	Colleferro, Italy	Multipurpose Benzoine Plant	1998
ECOBASIC	Sardegna, Italy	Bulk Pharmaceutical Plant	1998
Johnson & Johnson	Roma, Italy	Dilution Plant Revamping	1997
Bristol-Myers Squibb	Swords, Ireland	Irbesartan Pharmaceutical Plant	1997
Ind. Chimiche Caffaro	Colleferro, Italy	Acetaldeide Storage	1996
Ind. Chimiche Caffaro	Colleferro, Italy	Fenilglicina Production Plant Revamping	1996
Bristol-Myers Squibb	Swords, Ireland	Solvent Recovery Unit	1996
Bristol-Myers Squibb	Sermoneta, Italy	Oral Bulk Plant	1994
Bristol-Myers Squibb	Swords, Ireland	Bulk Pharmaceutical Plant	1994
Bristol-Myers Squibb	Sermoneta, Ireland	Silanes Distillation Revamping	1994
Bristol-Myers Squibb	Sermoneta, Italy	Distillation Plant Optimization	1994
Bristol-Myers Squibb	Sermoneta, Italy	Solvent Distillation and Wastes Oxidation	1993

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