

TURNKEY PHARMACEUTICAL PROJECTS

PLANTS FOR I.V. SOLUTIONS

PLANTS FOR DIALYSIS
PRODUCTS

PLANTS FOR BLOOD BAGS

PLASMA FRACTIONATION PLANTS

BIOTECHNOLOGY PLANTS

MULTIPURPOSE PLANTS

BRAM-COR[®]
PHARMACEUTICAL TECHNOLOGIES

BRAM-COR TURNKEY PHARMACEUTICAL PROJECT

We are proud to grant a complete design, engineering, construction, start-up new pharmaceutical facilities, even assisting the Clients through scouting activities of potential Know How Licensor, transferring the Know How, providing Validation Master Plans and Standard Operating Procedures, validating, aligning industrial processes to URS and regulatory requirements.

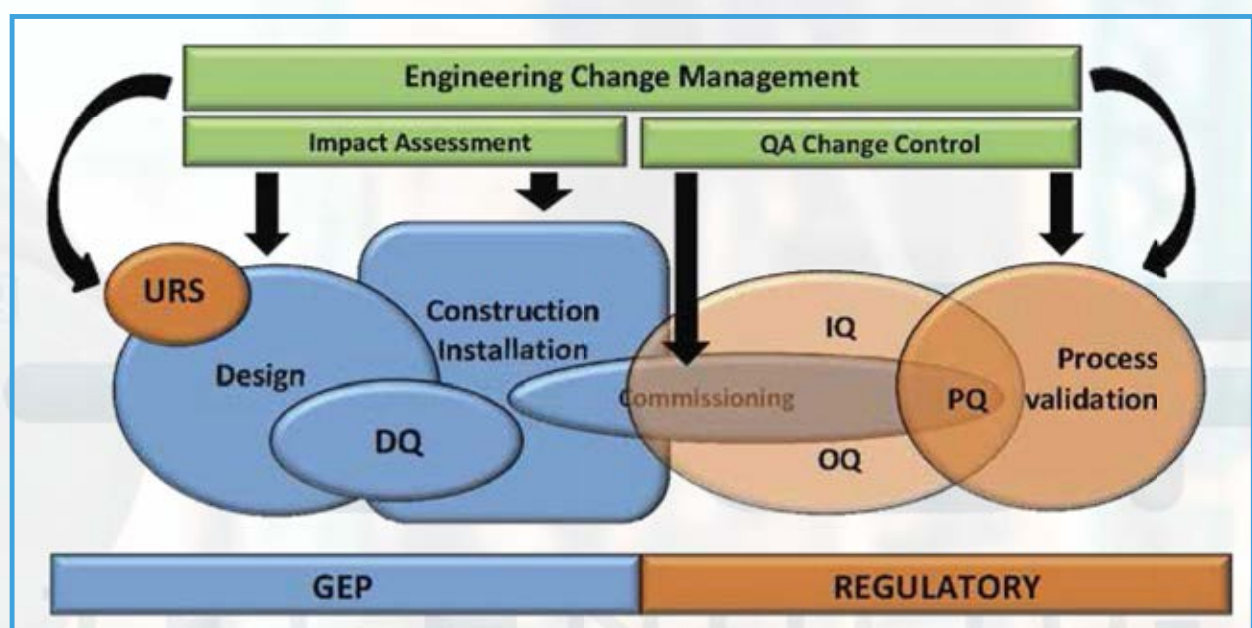
We propose reliable know-how & technologies about:

- **LVP** (Large Volume Parenterals) in PVC or PP bags
- **LVP** in Glass or Plastic Bottles
- **SVP** (Small Volume Parenterals) in Glass or Plastic vials and ampoules
- **Pre-filled Syringes**
- **Dialysis concentrate solutions and powders**
(Canisters, Bags, Cartridges)
- **Plasma Fractionation**
- **Biotechnological Plants**
- **Multipurpose Pharmaceutical Plants**

We perform a turnkey project through:

- ✓ **Procurement of Licensors and Know How Transfers**
- ✓ **Conceptual Design and Design Qualification (DQ)**
- ✓ **Detailed Engineering**
- ✓ **Validation Master Plan & S.O.P.**
- ✓ **Equipment Construction & Procurement**
- ✓ **Factory Acceptance Test**
- ✓ **Shipment and Installation**
- ✓ **Site Acceptance Test**
- ✓ **Standard & Validation Documentation (IQ/OQ/PQ Protocols)**
- ✓ **Training**
- ✓ **Commissioning, Calibration & Start up**
- ✓ **Regulatory Support**

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TURNKEY PLANTS FOR I.V. SOLUTIONS

Complete facilities to produce Intravenous (IV) Solutions both in Small (SVP) and in Large (LVP) volumes through standard or even modular configuration with capacities from 500 upto 24.000 pcs/h.

IV FORMS

- **Bags** (both PVC and PP)
- **Glass Bottles**
- **Plastic Bottles** with Blow Fill Seal (BFS) Technology
- **Plastic Bottles** with Stretch Blow Molding (SBM) Technology

STANDARD SOLUTIONS IN VARIOUS CONCENTRATIONS

- Water For Injection
- Sodium Chloride
- Glucose / Dextrose
- Dextrose Solutions
- Mannitol
- Ringer Lactate
- Hartman

SPECIALISTIC SOLUTIONS

- Fat Emulsions
- Aminoacids
- Plasma expanders
- Pre-mixed heparine
- Ciprofloxacin
- Metrodinazole
- Paracetamol





FROM DESIGN TO VALIDATION

The scope of the project is the design, construction, equipment supply, installation, commissioning, training and validation of the **production lines** for manufacturing Intra Venous Solution Products. These lines include:

- **PHARMACEUTICAL WATER PROCESSING (WFI/PW/PS)**
- **SOLUTION PREPARATION**
- **FILLING, SEALING, STERILIZING, PRINTING, INSPECTING**
- **PACKAGING**

The main factors to be considered in preparing the layouts which determine "Flow Routes" are:

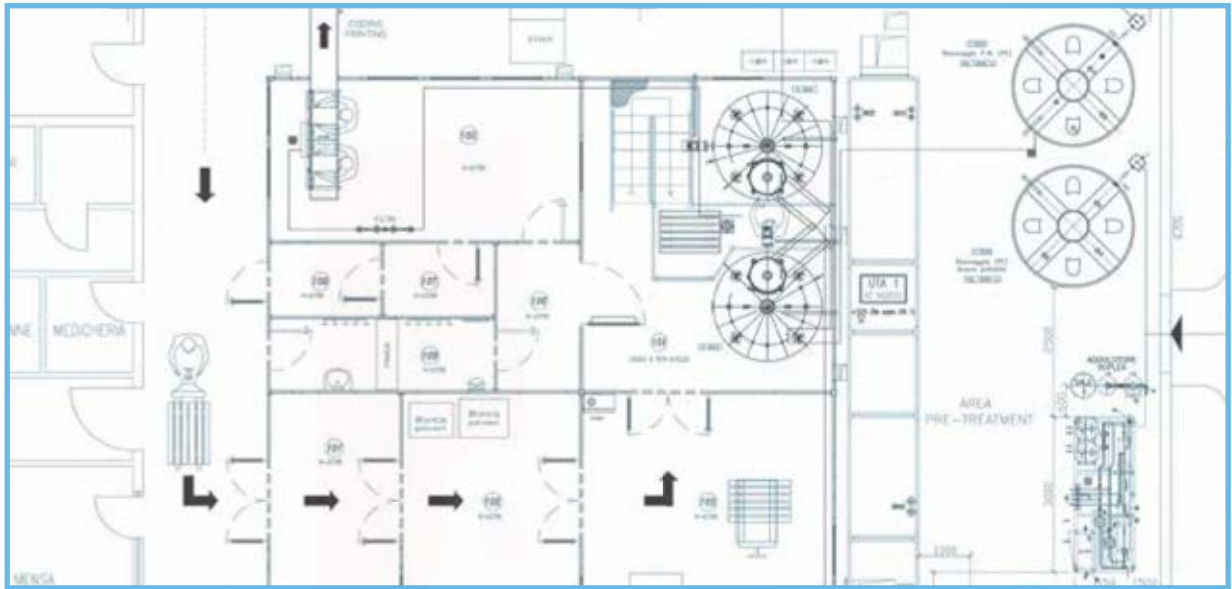
- **Required production capacity**
- **GMP compliance**
- **Flexible accomodation**
- **Quality of working environment**
- **Operational efficiency**
- **Ease of access for maintenance and validation**

Consideration of the segregation of the flow of

- **Materials**
- **People**
- **Wastes**
- **Finished product**

is essential to achieving GMP compliance.





TURNKEY DIALYSIS PRODUCTS PLANTS

Complete facilities to produce Products for Haemodialysis and Peritoneal Dialysis. In several cases these manufacturing lines are installed in devoted areas of Intravenous Solutions Projects.

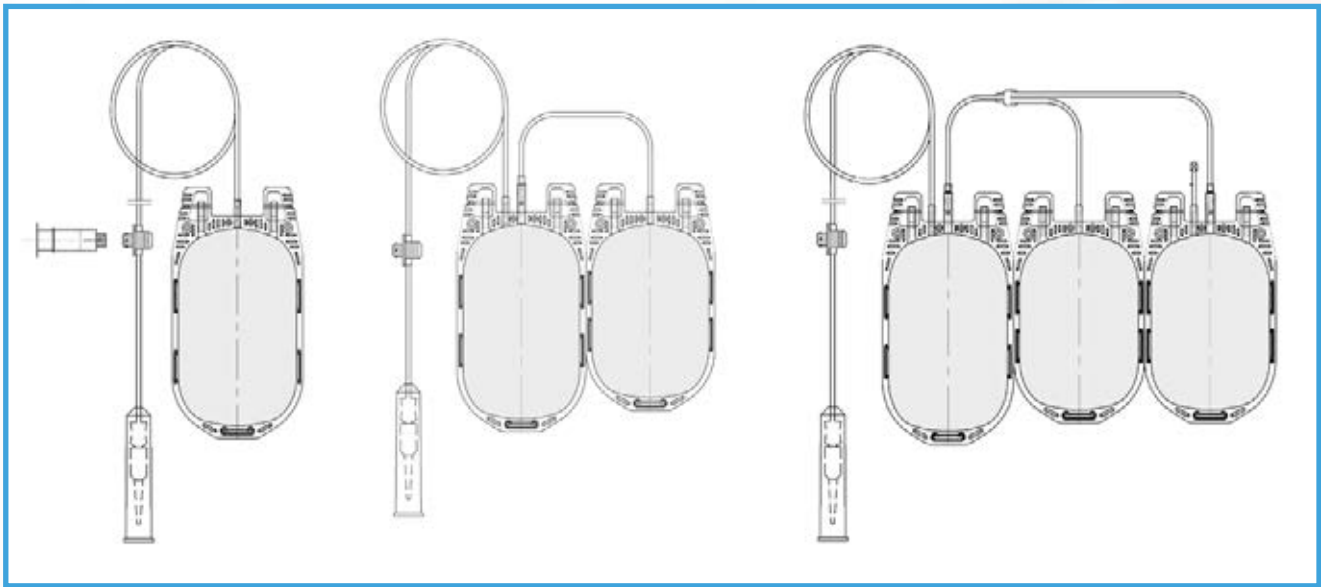
FORMS

- Canisters
- Bags
- Multichamber bags
- Cartridges

PRODUCTS

- 3.4 / 5 L Diacetate Bags
- 5 / 8 / 10 L Diacetate and Bicarbonate canisters
- CAPD bags
- Bicarbonate cartridges
- Priming solutions bags
- Multichamber bags



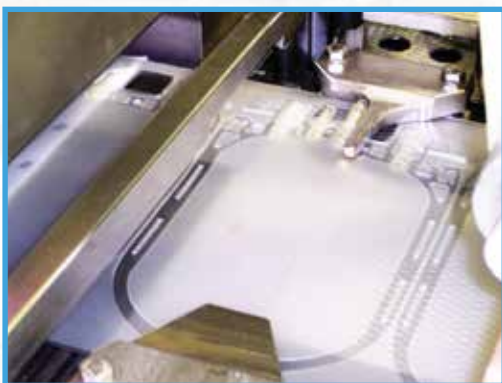


TURNKEY PLANTS FOR BLOOD BAGS

Complete facilities to produce Blood Bags with anticoagulant solutions. The plants can be designed for a full automatic production/assembly of the bags or through a semi-automatic process. It is possible to integrate the Blood Bags through Leucocyte filters.

PRODUCTS

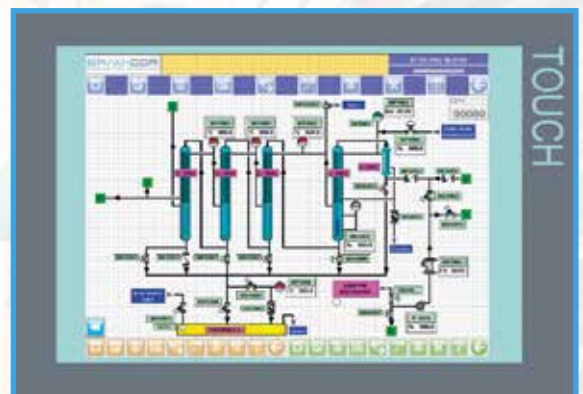
- Single Bags
- Double Bags
- Triple Bags
- Tetra Bags Top-Top
- Tetra Bags Top-Bottom

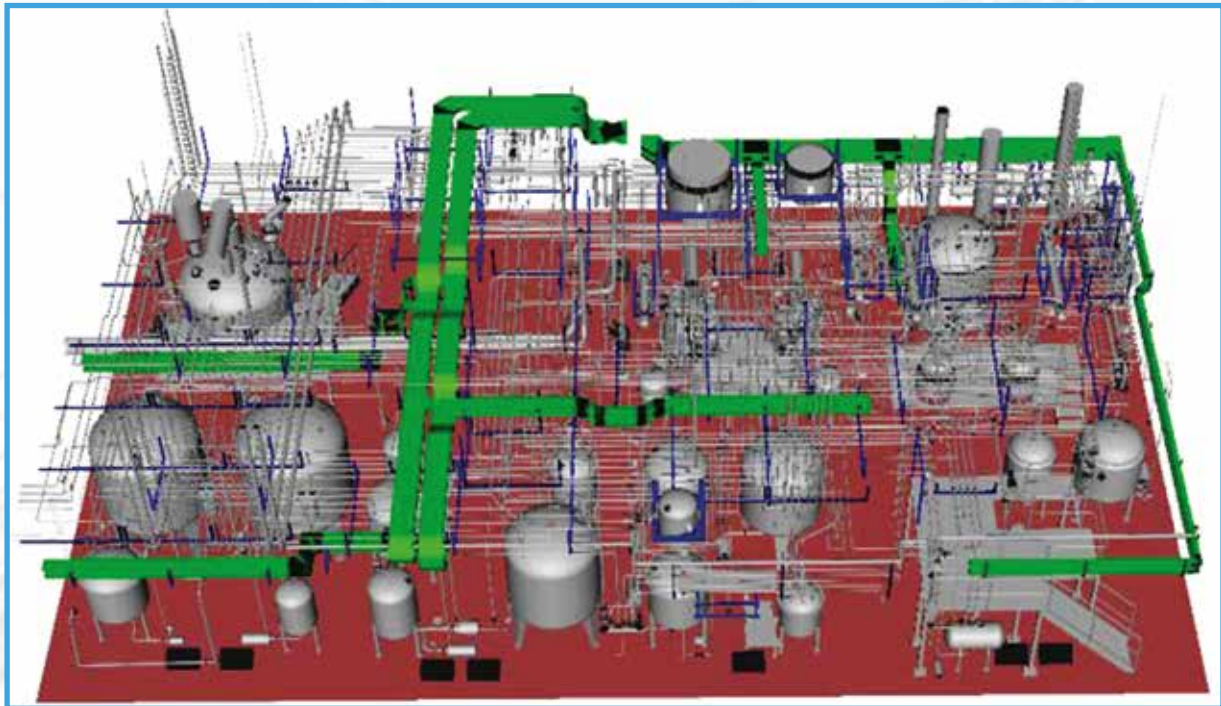




Complete facilities to produce Haemoderivatives from Plasma. High efficiency extraction deriving from proper Know How Licensing by primary pharmaceutical industries that fractionate the plasma in top quality plants that also ensure the best virus inactivation processes.

- **Antihemophilic** (Factor VIII and Factor IX)
- **Immune Globulin (IG) Hyperimmune** (Tetanus, Rh, etc.)
- **Immune Globulin Intravenous (IGIV)**
- **Albumin**
- **Plasma Protein Fraction (PPF)**
- **Anti-Inhibitor Coagulant Complex (AICC)**
- **Antithrombin III**
- **Fibrin Sealant**
- **C1 Inhibitor**



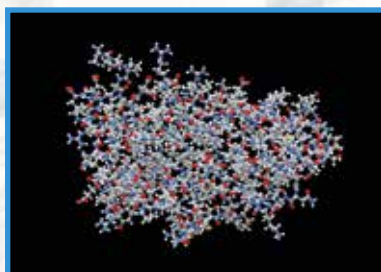
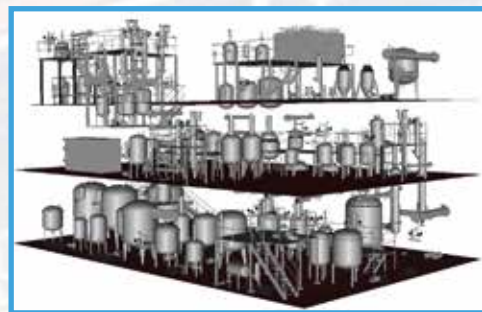


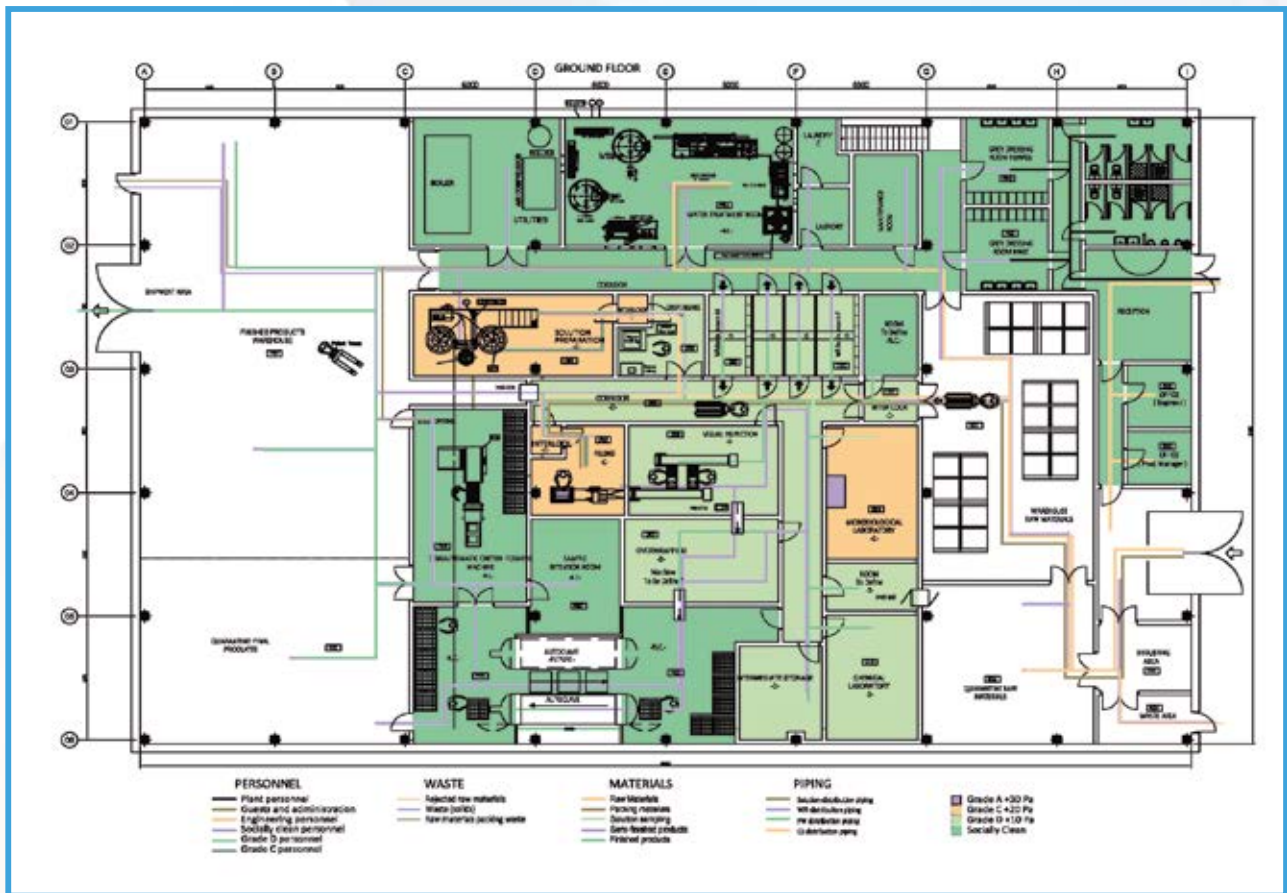
TURNKEY BIOTECHNOLOGY PLANTS

Complete facilities to produce biotechnological products with standard, disposable or mixed technology. Most advanced fermentation technologies deriving from proper Know How Licensing by primary pharmaceutical industries that also ensure the top QA controls.

EXAMPLE OF PRODUCTS

- Interferon
- EPO (Erythropoietin)
- EFG (Epidermal Growth Factor)
- Insulin
- hGh (Human Growth Hormone)
- Monoclonal Antibodies





TURNKEY MULTIPURPOSE PHARMACEUTICAL PLANTS



On specific request we can provide complete pharmaceutical facilities covering most of the available technologies, such as:

- Antibiotics Projects
- Veterinary Projects
- Multipurpose Generics plants (oncology, cardiology, etc.)
- Etc.



TURNKEY PROJECT DRIVERS

All Pharmaceutical Facilities need to be up-dated, competitive and efficient in operation, to diversify production programs, to reduce life-cycle costs and, above all, to comply to the appropriate pharmaceutical GMP regulation. BRAM-COR project drivers are aimed at satisfying all pharmaceutical regulatory and QA requirements, aligning the final product to the international Pharmacopoeias and capitalizing upon a careful, customer-oriented project management. Equipment and processes are designed to allow a logical flow in order to avoid mix-ups of components, drug product, closures, labeling, in-process materials or cross contamination achieved through the development of

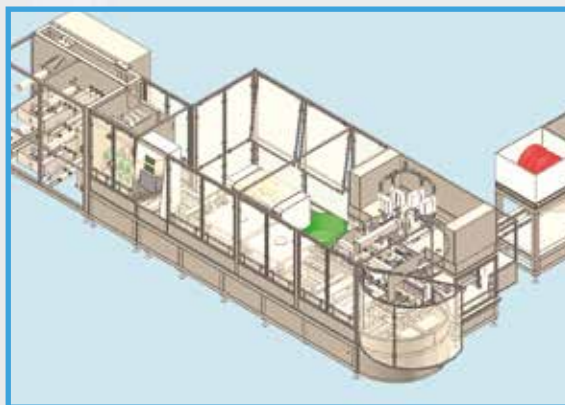
CONCEPTUAL DESIGN

describing the general project organization

DETAILED ENGINEERING

considering all process flows (raw materials, finished products, personnel, waste, etc.) and detailed project specifications.

During the initial phases of the process we assist our Clients with a feasibility study and an engineering support due to optimize the entire project from the overall investment point of view, considering operational costs reduction. Through our software we can perform all necessary simulations and recommend the best solutions. Either counting or not on our initial engineering support, we provide a complete set of specifications in our DESIGN QUALIFICATION protocols, which are submitted to our Customer for approval before starting the equipment construction.



INSTALLATION, START-UP AND TRAINING

Professionalism in installation is a basic requirement in all pharmaceutical technologies. We provide installation teams composed of qualified supervisors, patented welders and skilled piping assemblers working in accordance to BRAM-COR sanitary piping procedures all over the world. All product critical parameters are carefully monitored, such as: fluid flows, pump duties, alarms, valves, emergency power and software modules. Our FAT and SAT protocols provide a complete documentation of testing activities.

The necessary training for operation and maintenance of BRAM-COR pharmaceutical systems is provided by our expert technicians at the system start-up, ensuring a full understanding of how the equipment works and how to operate for effective sanitization/sterilization and troubleshooting.



BRAM-COR KEY DESIGN CONCEPTS

A full understanding of the drug production process is the key concept for correct design. BRAM-COR engineering focuses specially on production processes for sterile injectables, such as parenteral solutions, oral solutions, ophtalmic solutions. The definition, assessment and monitoring of critical parameters directly affecting product quality are the baseline for the application of suitable Process Analytical Technologies for in-line and at-line quality control. BRAM-COR work breakdown structure consists in following main activities:

- Design
- Construction (mechanical, electro-pneumatic, SW configuration)
- Testing
- Documentation
- Installation
- Validation
- Service

Every process follows rigorous cGMP-compliant Standard Operative Procedures. Specification, construction and verification steps within the lifecycle are carried out according to GAMP "V-model", considering risk assessment, architecture of system components, functional specification, sanitization and validation issues with special overview to a sustainable maintenance of the system.



WORLDWIDE SERVICES

We are currently delivering our machines and building complete processing lines all over the world. Top quality GMP equipment must necessarily be integrated through a proper high level of professional services including: **Technical Documentation, Factory Acceptance Test, Installation, Commissioning, Site Acceptance Test & Start-up, Training, Validation, After Sales Service**. Our worldwide network of skilled agents and our affiliated companies ensure assistance to our Clients in over 50 countries, from the very beginning of a pharmaceutical project throughout decades after start-up. Our **After Sales Dept.** grants punctual and quick deliveries of spares and ongoing technical support.

