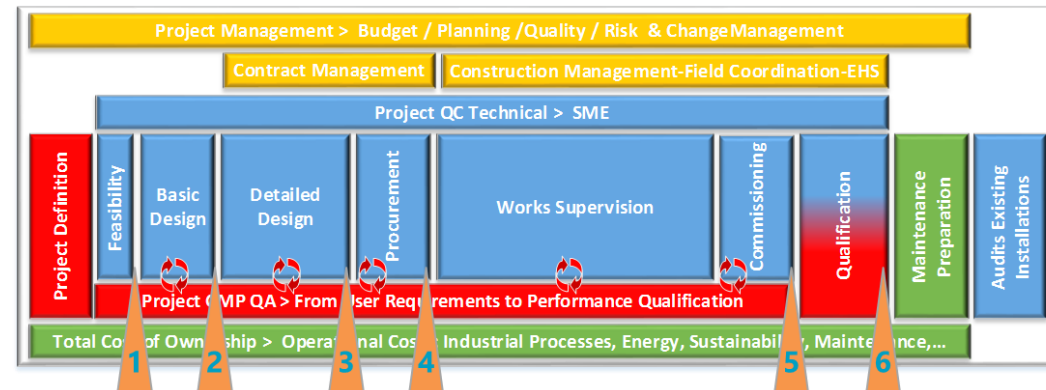


# Clean rooms - Controlled environments 1/2

## APPLICATIONS

- ⌚ Aseptic and/or confined areas in (radio-) pharmaceutical production according to GMP
- ⌚ R&D Laboratories and Biological Risk Production Areas, Radioisotopes, Fine Chemistry,...
- ⌚ Cellular Therapy, Immuno Therapy, Medical Diagnostics, Pet shops
- ⌚ Food & beverages, Flavours & Fragrances, Aerospace
- ⌚ Hospital Critical Areas: Production of cytotoxics and sterile products...
- ⌚ Climatic chambers (Ecotrons,...) and Biotechnology Incubation Chambers
- ⌚ Decontamination/Disinfection Processes
- ⌚ Environmental Monitoring
- ⌚ Production equipment (Insulators, Weighing, Washing, Sterilisation, Lyos,...)



# Clean rooms - Controlled environments 2/2

## UTILITIES

- ⌚ HVAC Clean Rooms (asepsis and containment)
- ⌚ Pharmaceutical Utilities: Purified Water, Water for Injection, Pure Steam, Gas, Liquid Nitrogen
- ⌚ Partitioning and Finishing
- ⌚ Effluent Treatment
- ⌚ Cleaning (CIP), sterilisation (SEP)
- ⌚ Specialised Handling Equipment

## DELIVRABLES

- › Project Definition, Programming, Block diagrams, PFD, P&ID
- › Analysis of Regulatory Gaps
- › Flow diagram, locations
- › Simulation of Production & Logistics Capacities, Utility Balances
- › Master Plans, Feasibility Studies
- › APD, APS, Detailed Studies of all techniques and Equipment
- › Sizing, Definition & Technical and Functional Specifications, Tender Documents

## REGULATION

- ⌚ BPF/GMP
- ⌚ FDA
- ⌚ ICH
- ⌚ ISO 14 644
- ⌚ NF EN ISO 13 485
- ⌚ NFS 90 351



- › Project management and EPCMV
- › Design/Realization
- › Risk Analyses (GMP, HAZOP,...), ATEX zoning, Irradiation, nuclear contamination, ...
- › Budget estimates and planning
- › Validation and Verification Plans (ASTM 2500)
- › Assistance with Specifications and Management of Interfaces with Production Equipment
- › Construction & EHS (Environment, Health, and Safety) Management