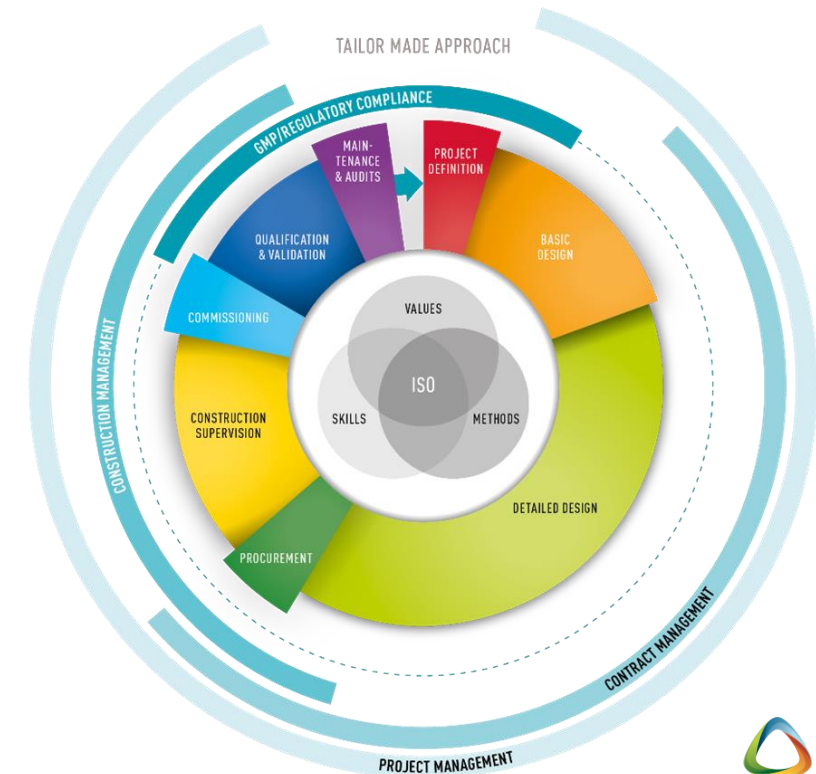


Process 1/2

PROCESSES

- ⌚ Storage, Weighing (isolators), Preparation of media
- ⌚ Chemical reactions
- ⌚ Fermentation / Cell culture
- ⌚ Separation (liquid/liquid, filtration, centrifugation, dewatering...)
- ⌚ Purification (chromatographic, UF/DF, dialysis)
- ⌚ Formulation, distribution/filling
- ⌚ Freeze-drying, Granulation, Spraying, Drying
- ⌚ Conditioning (line, futs, big bag)
- ⌚ Treatment of Volatile Organic Compounds
- ⌚ Cleaning (CIP), sterilisation (SIP) In Place
- ⌚ Laundry, Sterilisation (Autoclave)
- ⌚ Effluent treatment skid
- ⌚ Laboratory equipment



Process 2/2

UTILITIES

- ⌄ Pharmaceutical waters
- ⌄ Treatment of Volatile Organic Compounds
- ⌄ Pure steam
- ⌄ Grey Utilities
- ⌄ Gas utilities
- ⌄ Liquid effluents
- ⌄ Rainwater/Wastewater
- ⌄ Liquid nitrogen
- ⌄ Thermal fluids
- ⌄ Own utilities

REGULATION

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

LES LIVRABLES

- › Block diagram, PFD, PID/UID
- › Production chronograms, flow chart, locations
- › Balances (materials, thermal, etc.), calculation notes, dimensioning (piping, pumps, exchangers, valves, etc.), lists, etc.
- › Dimensioning, Definition & Technical and functional specifications of equipment (CCTP, Datasheet, sketch...)
- › Utility balance sheet (pharmaceutical, grey)

- › Conception and Design of Complete unit as a skid
- › Risk analysis (APR, HAZOP, ...), impact study, ATEX zoning
- › Functional description
- › Technical memo, study report, budget estimate, planning
- › Validation strategy by time-reducing capitalisation
- › Assistance and Interfaces with the General Installatuib, HVAC, GC/Structure, EIA packages

