Qualification – Validation 1/2

Ekium is at your side to define and implement the Commissioning, Qualification and Validation strategies for all your facilities.

MADE-TO-MEASURE ACCOMPANIMENT

We offer an approach adapted to your projects and sectors of activity (medicines for human use, veterinary use, medical devices, hospital etc.) by accompanying you from your strategic choices to the finalisation of the tests.

- Master documents: VMP, Commissioning Plan, Risk Assesment
- URS and consultation stage
- Participation in the URS and specifications
- Regulatory design review
- Traceability matrix and test plans
- Management of the FAT/SAT commissioning stages
- Writing and carrying out DQ / IQ / OQ / PQ tests
- Process, Cleaning and Analytical Methods Validation
- Deviation management / Change control
- Maintenance of the qualified state
- Audit and Training

Qualification – Validation 2/2

ACCOMPANIMENT FROM THE CREATION TO THE STAGES OF PRODUCTION

- Process equipment
- Pharmaceutical fluids : PW, WFI, Process Air, Pure steam, pure gases
- Clean room / HVAC
- Barrier technology, Isolator
- Cleaning and heat treatment: CIP/SIP, washing machines/cabinets, autoclaves
- Packaging line
- Control systems and supervision

REGULATORY CONTROL AND GUIDELINES

- BPF
- cGMP
- GAMP and other ISPE guidelines
- ASPEC

contact@ekium.eu