



Commissioning & Qualification:

Premises, Equipment and Utilities

Validation Master Planning (VMP)
API's, solid and liquid dosage forms
manufacturing plants
Sterile and aseptic manufacturing plants
Biotechnology plants
Containment Systems
Pharmaceutical water systems
Equipment and utilities in chemical,
biotech and pharmaceutical processing
Pilot plants

The validation of a manufacturing process requires a suitable operating environment.

This entails operating procedures, good methods and practices, trained personnel...and, in addition to this, the qualification of the facilities, equipment and utilities involved in the process.

Qualification, carried out under a risk management approach (ICH Q9) for ensuring the critical aspects of the qualified component are considered and, in addition, for optimizing time and resources, becomes a key factor to provide the necessary evidence of knowledge and control over the equipment and the process environment.

TDV approach to commissioning and qualification is based in the joint work with equipment suppliers, Engineering companies and the Engineering department of the end user.

This approach not only provides the necessary expertise to achieve the GMP compliance goals in the design, commissioning and qualification stages, but also provides the 'Quality Control' for those parts of the project, that although not being GMP relevant are important for the project and business success.

This ensures consistency and quality to the overall project.

TDV experience in commissioning and qualification of facilities is endorsed by years of successful audits and inspections.

For further information
about Commissioning &
Qualification, please contact:
Anna Cluet acluet@tdvct.com