

CTP SYSTEM

INTEGRATED COMPETENCES

VALIDATION

*FOR A COMPANY
CULTURE ORIENTED
TO THE QUALITY.*

*“Validation is an action of providing,
in accordance with the principles of
Good Manufacturing Practices,
that any procedure, process, equipment,
material, activity or system actually leads
to the expected results.”*

Good Manufacturing Practice issued by
European Community (EEC)

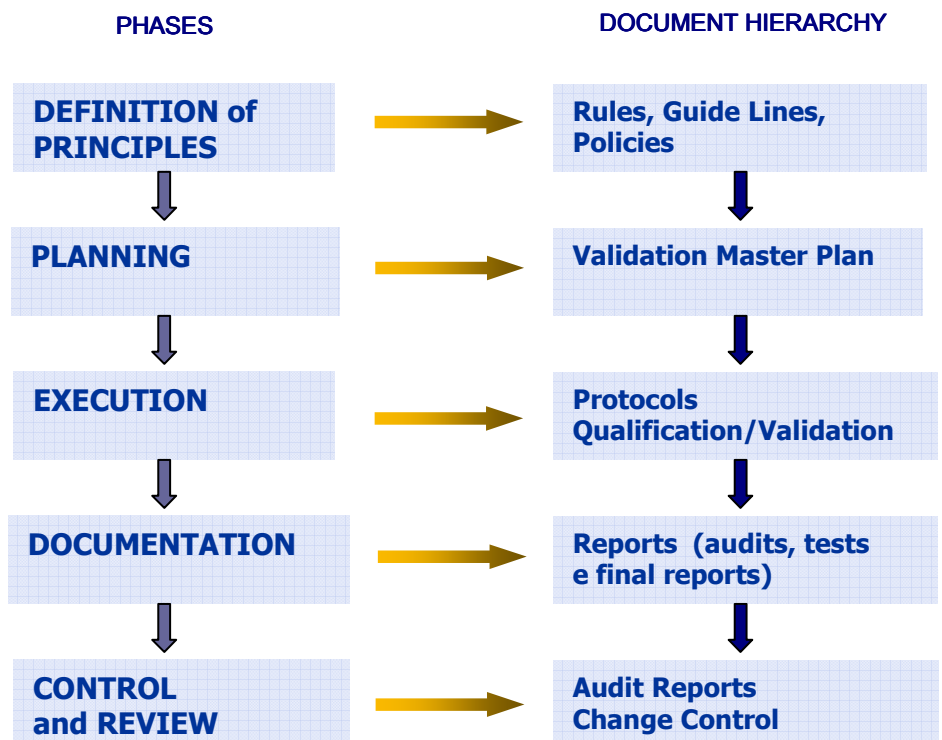
VALIDATION represents a necessary step for controlling **PRODUCTION** and **QUALITY CONTROL** in compliance with the **GMPs**.

The aim of **VALIDATION** is produce the documented evidence that the **PROCESSES** are “**UNDER CONTROL**”.

“Establishing documented evidence, which provides a high degree of assurance that specific process will consistently produce a product meeting its pre-determined specifications and quality attributes”.

FDA Guidelines on General Principles of Process Validation, May 87

The GMP approach in **VALIDATION** is:



SERVICES

- GAP Analysis
- Risk Analysis / Impact Assessment
- Design Qualification
- Validation Master Plan Preparation
- IQ / OQ / PQ of Manufacturing Equipment & Critical System
- Analytical Equipment Qualification
- Maintenance & Calibration
 - Metrology Plan
 - Preventive Maintenance Plan
 - Specialised services (vacuum, thermography,...)
 - Troubleshooting
 - SOPs

VALIDATION is not only oriented to satisfy regulatory needs because, otherwise, it would be just a cost.

CTP SYSTEM supports the Pharmaceutical Companies in the management and the direct execution of all the VALIDATION PHASES.

CTP SYSTEM is able to execute the validation of all kind of automation systems:

- DCS (Distributed Control System)
- SCADA (Supervisory Control and Data Acquisition)
- PLC (Programmable Logic Controller)
- BMS (Building Monitoring System)
- LIMS (Laboratory Information Management System)
- MES (Manufacturing Execution System)
- ERP (Enterprise Resource Planning)

The Team of **CTP SYSTEM** executes qualifications in any sort of equipment and systems for the Pharmaceutical Industry and other correlated Industries.

It has also a consolidated experience in **solving the problems** about documental lack and practical aspects.

VALIDATION, in compliance with the GMPs, is a **quality assurance instrument** involving all the proper business functions, according to their responsibilities. It is an opportunity of deep knowledge about process and production systems and also an effective training for the personnel.

It represents an inestimable added value, generously rewarding the investment.



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