



vqms

# VALIDATION, QUALITY, MANUFACTURING SUPPORT

## Continuous Validation

PTM Consulting always promotes product and process innovation and continuous improvement.

This approach to face projects is reflected in VALIDATION, QUALITY, MANUFACTURING SUPPORT service which supports product and process life-cycle management and optimization from continuous improvement perspective.

This service should be applied to:

- ✔ Implement Risk-Based Validation and Continuous Process Verification approaches to Validation activities;
- ✔ Enhance quality assurance and product reliability through quality support activities;
- ✔ Support manufacturing through process monitoring, control and optimization activities.



**PTM Consulting S.r.l. a socio unico**  
 Piazza IV Novembre, 6  
 42049 S. Ilario d'Enza (RE) Italy  
 C.F./PIVA: 02039750340 - REA 265267  
 Tel: +39 0522-472812 | info@ptm-consulting.com  
[www.ptm-consulting.com](http://www.ptm-consulting.com)



# VALIDATION, QUALITY, MANUFACTURING SUPPORT

## Validation Support

Process validation is a fundamental activity, that must be managed through a risk-based method, accordingly to **EMA and FDA guideline**.

PTM Consulting supports its customers in the implementation of the Risk-Based Validation and Continuous Process Verification approach to reduce time and effort required by validation activities, while increasing productivity and profitability.

### THIS METHODOLOGY ALLOWS TO:

- ✓ Increase knowledge about the product and the process in order to build a robust and consistent control strategy;
- ✓ Make decisions and set validation activities on the basis of objective and consistent rationale, also through the use of technical analysis tools (eg statistical tools).

## VQMS

### MAIN CORE SERVICES

- Process Validation
- Computer System Validation (CSV)



## VALIDATION, QUALITY, MANUFACTURING SUPPORT

### Quality Support

Over the years PTM developed a range of services to support activities in the Quality area, to optimize these activities and to integrate risk concepts into the quality aspects.

#### THE MAIN BENEFITS OF THIS SERVICE ARE:

- ✓ Clear, shared and objective management of product and process information;

- ✓ Quality activities optimization in terms of time and costs;
- ✓ Decision-making support through a risk-based approach.

Quality support service involves change and CAPA management, proactive planning for supply chain optimization, supplier and CMO/CRO audit for Pharma, API and Laboratories.

## VQMS

### MAIN CORE SERVICES

- ▶ QA/QC Support
- ▶ Audit GMP/ISO
- ▶ Lean Lab
- ▶ Laboratories equipment validation
- ▶ Elemental Impurities
- ▶ Reagents and Solvents Risk Analysis



# VALIDATION, QUALITY, MANUFACTURING SUPPORT

## Manufacturing Support

PTM Consulting also provides technical and methodological support to Manufacturing Area. Quality by Design and a risk-based approach is a key approach to achieve three fundamental goals:

- ✔ Increasing understanding of the product and its production process, focusing on collaboration between research functions and production functions;
- ✔ Increasing product and process robustness, leading to a reduction in product variability, and consequently a reduction in associated costs due to lack or to “too much” quality;

- ✔ Use “scientific” methods to increase the robustness of the business.

Manufacturing area services are conceived to optimize process flow through time and cost reduction, out-specification, scheduling and improvement of test and sampling activities, definition of process monitoring and control activities.

## VQMS

### MAIN CORE SERVICES

- Process monitoring and control with statistical tools
- Manufacturing new product assessment