



QUALITY BY DESIGN

Quality in processes DNA

Pharmaceutical evolution, considering quality and competitiveness, brought to process development and product management rethinking.

In this context PTM specialized to provide consultancy to pharmaceutical companies for process design and development, in order to optimize resources and time, thanks to

QbD-based methodologies.

PTM Consulting approach to projects, built on quality paradigms introduced by the ICH Q8, constantly applies QbD systemic philosophy to achieve quality objectives and defined cost thanks to thorough understanding of product, production process and mainly development process.



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



QUALITY BY DESIGN

A winning methodology

The QbD approach, a **fundamental set of guidelines for the pharmaceutical industry of the new millennium**, requires a change in the way of working, designing and conceiving the quality of drug products from the early stages of development: **“Quality can not be tested in products; ie, quality should be built in by design”**.

This approach requires the implementation of analytical tools to develop not only product quality, but also process quality starting from the early stages of product development.



METHODOLOGY



PROJECT DEFINITION

Identification of quality, time and costs objectives considering the whole product life cycle

PROJECT SCENARIOS DEVELOPMENT

Optimizing time and resources according to project criticalities

DEVELOPMENT PROCESS OPTIMIZATION

- ✓ Risk Management
- ✓ Statistics Tool

VERIFICATION PLAN

Quality Goals and Company Goals alignment



QUALITY BY DESIGN

QbD methodology benefits

The working principles of QbD framework PTM used in different projects allow to achieve **three fundamental goals**:

- ✓ increase the understanding of the product and its production process;
- ✓ increase product and process robustness;
- ✓ use scientific methods to support business.

QbD

MAIN CORE SERVICES

- Productive Process Optimization
- DoE for product and process, shelf life estimate
- Development Support in QbD
- Formulation Support
- Product Life Cycle Management
- Pharma Glass Primary Packaging Risk Management
- Software selection in QbD