RISK MANAGEMENT
for Pharma Glass Primary Packaging

PTM Consulting supports Pharma companies in process optimization through mapping of operating and data flows, using an innovative proprietary system, **Cymapp**, a software tool that identifies risk factors and manages them in the frame of **Integrated Quality Risk Management**.

Over the years, PTM has gained specific experience in several areas including the Pharma Glass Primary Packaging Process, from production to use in Pharma companies, developing a strong expertise in plant and process analysis of glass packaging in the pharmaceutical field.

All PTM Consulting services are developed considering a **GMP** (Good Manufacturing Practices) approach, using QbD and industrial process optimization tools. The results is an effective, efficient and in *compliance* system.

Pharma Glass Primary Packaging Risk Management

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PHARMA GLASS PRIMARY PACKAGING MANUFACTURERS
from suppliers to pharmaceutical development partners

PTM's experience in risk management for the **Pharma Glass Primary Packaging** industry enables to provide **risk-based strategic services** suitable to the entire product life cycle: from initial specifications to finished packaging production. In the broad and complex context of the Pharma world, PTM presents risk management solutions that involve the major manufacturing processes, ensuring the development of a **risk management integrated to regulatory and GMP issues**.

GMP FOR PHARMA GLASS PRIMARY PACKAGING MANUFACTURERS

Ptm services supports the Glass Primary Packaging manufacturers to comply with an ever more urgent market and to make their processes meet the pharmaceutical customers' needs.

QUALITY ASSURANCE

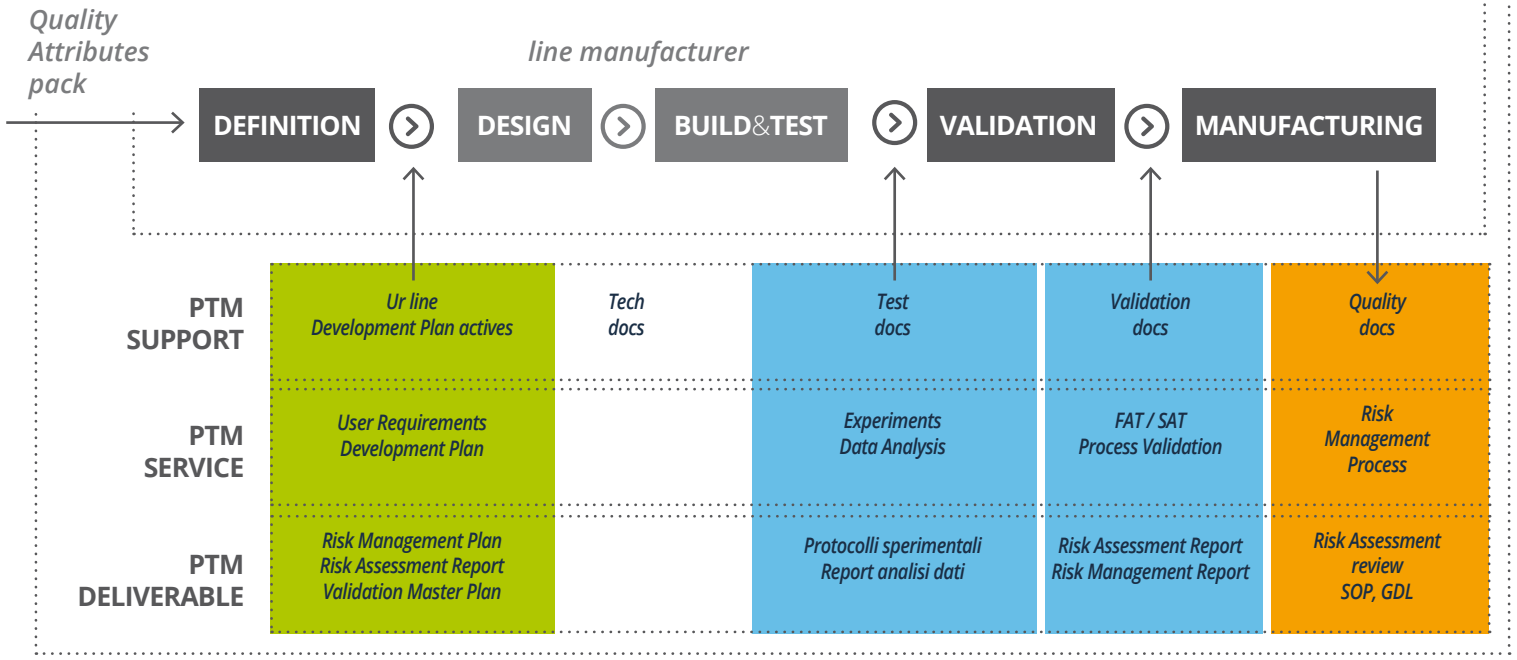
The activities realized to support the Pharma Glass Primary Packaging manufacturers guarantee that the suppliers' process is aligned to the pharma world requirements in terms of product quality and safety. This new perspective allows to work in a QbD scenario, optimizing the development and manufacturing processes, including the glass packaging producers in the pharmaceutical development process.

STRATEGIC RISK BASED CONSULTANCY

Ptm services for Pharma Glass Primary Packaging allows to integrate all the potential risks of the pharmaceutical partner. Within the development and manufacturing processes Pharmaceutical company and Glass Primary Packaging Manufacturer become partners for the pharmaceutical product development and thanks to PTM approach it is possible to gain benefits for both players. On one side, the Glass Manufacturer will comply to the pharma guidelines and requirements, on the other, the pharmaceutical company will be able to provide to the supplier clear and well defined requirements that will consider all risks aspects, be they of operative, regulatory or business nature.

PHARMA COMPANY

GLASS PRIMARY PACK COMPANY



During the line requirements project phase, PTM provides an integrated consultancy in QbD including:

Cymapp
Operative flow mapping

Risk Management
To support the Line and process User Requirements definition, to support the Development Plan and the Validation Master Plan.

Design of Experiments and Data Analysis between the Build&Test and Validation gate: thanks to the statistics expertise, PTM realizes technical protocols, data analysis reports, helpful in the validation documents issue.

Risk Management to support FAT/SAT and Process Validation

Quality Assurance: a correct risk management strategy within the process allows to reach the objectives reducing quality and regulatory risks both during the submission and the manufacturing.