

# ISO 15378 – GMP for Drug Packaging Manufacturers

The ISO 15378 Standard provides the standards for the development of a Quality Control System (QCS) for the suppliers of materials designed to be used in the primary packaging of pharmaceutical products. It was developed by investors in the pharmaceutical sectors that used as a basis the application requirements of the 9001:2015 Standard and the reference to the Good Manufacturing Practices (GMP) applicable to materials for primary packaging.



Materials for primary packaging are an important risk factor in pharmaceutical production processes since they are in direct contact with the product and must be considered a key raw material, so their origin and suppliers must be strictly controlled. The ISO 15378 standard is designed to be an international standard of the quality system for allowing Organisations to show their capacity of supplying primary packaging materials for pharmaceutical products, which comply strictly with regulatory requirements and the requirements of Clients, as well as with international practices.

## WHAT ARE THE BENEFITS OF ISO 15378?

- Risk management: the ISO 15378 standard certification is designed to help organisations to identify, control and manage risks.
- Demonstrates good quality, manufacturing and safety controls.
- Aligns with the ISO 9001:2015 standard that allows certified companies to optimise implementing the requirements of the ISO 9001 standard.



- Protects the brand and its image, both publicly as well as with the key interested parties.
- Regulatory compliance: the 15378 standard supports the efforts of the Organisation to meet regulatory and legal requirements.
- Client satisfaction: it is designed to improve client satisfaction, including the processes for continuous improvement and the guarantee of compliance with the client's requirements.

The standard has the same requirements of the ISO 9001 standard and incorporates other requirements of the Good Manufacturing Practices (GMP) pertaining to the pharmaceutical industry such as:

- Terms and definitions that allow the manufacturers of primary materials and the laboratories to speak the same language
- Good documentation practices
- Traceability
- GMP Creation
- Environmental Control (clean areas)
- Agreements between client and suppliers
- Control of changes
- Supplier approval
- Process validation
- OOS
- Inspection and tests of starting material
- Process control
- Final inspection
- Retained samples
- Batch release

Additionally, it has 3 annexes:

Annex A: Regulation relating to GMP requirements for printed primary packaging materials

Annex B: Document relating to the recommendations for the requirements for verifying and validating primary packaging materials

Annex C: Document relating to the recommendations for risk management of primary packaging materials

**CAN YOUR COMPANY RECEIVE THE ISO 15378  
CERTIFICATION?**

The ISO 15378 Standard is applicable to the Design, Manufacture and Supply of primary packaging materials for medicinal products; the standard is generic and aims to be applicable to any organisation irrespective of its type, size or the products and services it provides.

## WHY CHOOSE CERTIFYING WITH APPLUS+ CERTIFICATION?

Applus+ Certification is part of the Applus+ Group and it specialises in the certification of management systems. We can independently and reliably provide the certification for the ISO 15378 standard for your manufacturing operations of packaging materials for pharmaceutical products. During the audit prior to the certification, we analyse your operations to highlight your main strengths as well as the areas of improvement. Our teams are multidisciplinary, and we have experts in auditing management systems.