Information Guide

PQSmitra
Simple & Practical

ISO 15378

Quality Management System for Medicinal Packaging Material

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What is ISO 15378?

ISO 15378:2017 (GMP) is an application standard for the design, manufacture and supply of primary packaging materials for medicinal products. ISO 15378 requirements include compliance to ISO 9001 and Good Manufacturing Practice - GMP requirements applicable to primary packaging materials for a quality management system. Where an organization needs to demonstrate its ability to provide primary packaging materials for medicinal products, which consistently meet customer requirements, including regulatory requirements and International Standards.

Good Manufacturing Practice - GMP is a term that is renowned worldwide for the control and management of manufacturing, testing and final quality control of food / beverage and pharmaceutical goods and their primary packaging. GMP is a setof rules that gives you the affirmation that your item is safe. GMP is responsible for the safety, efficiency, and quality of pharmaceutical products, cosmetic products and edible products and their primary packaging.

The quality approach of GMP guarantees to enable organizations to limit or eliminate instances of contamination, mistakes, and errors. This thus shields the customer from purchasing an item, which isn't effective or even dangerous. It is accepted that GMP is one of the best business tools, which will refine both the compliance and performance of the organization.

Which Organizations are eligible for ISO 15378 Certification?

- The certification is availed primarily by the companies which are into design, manufacture and supply of primary packaging materials for medicinal products. This ISO 15378 standard can also be used in other industry sectors when a quality management system with additional requirements over an ISO 9001:2015 system is needed.
- NOTE : The eligible organizations shall be able to furnish data related to primary packaging materials for medicinal products while certification audit.

What are the focus points of ISO 15378 Certification?

- Integration of customer requirements specific to primary packaging materials for medicinal products
- Streamlining and Standardizing the manufacturing processes and other business processes
- Manufacturing Process Control and Monitoring
- Risk management and Contingency planning
- Formulating Quality Policy and Objectives
- Setting up system for documentation and records.
- Management information system
- Business performance and sustainability.

What are the document requirements for ISO 15378 Certification?

The organization shall demonstrate continual improvement in the field of quality management system by maintaining, establishing, implementing and providing documented information.

The documented information required for ISO 15378:

- The organizations scope
- The organizations Quality policy and Quality Objectives
- A Quality Manual
- Standard operating Procedures
- Records at individual process / department. E.g. Sales, Purchase, Production, Quality Assurance, Maintenance, Customer Service.

How did ISO 15378 evolve throughout the year?

- **Year 2006** – ISO 15378 standard was published
- **Year 2011** – 1st Revision of the standard
- **Year 2015** – 2nd Revision of the standard
- **Year 2017** – 3rd Revision of the standard

ISO 15378:2017 Reference Standards

- ISO 9000:2015 - Quality management - customer satisfaction - Guidelines for complaint handling in organizations
- ISO 10012, Measurement management systems — Requirements for measurement processes and measuring equipment.

What happens to my existing Certificate when any standard is revised?

- Generally, whenever there is a revision, the previous standard is kept valid for 2 to 3 years. It is also called as transition period. Earlier the organization certified as per previous standards is expected to upgrade and get certified in accordance with revised new standard.

Is QMS ISO 15378 Certification (ISO Registration) difficult?

- An ISO certification will need time, effort, and improvement from a variety of departments inside a company. The steps that must be done, however, are well worth it for any organization. Owners, staff, and customers will all gain from it.

How to check the validity of the QMS ISO Certification?

- To identify the authenticity of your accreditation body, one must
- Visit the IAF - International Accreditation Forum website home page
- Go to the IAF - International Accreditation Forum MLA–Multilateral Recognition Arrangement signatory's category
- Select the recognized AB – Accreditation Body sub category or recognized region sub category
- From there you will select your country or the country your accreditation body belongs to
- After which you can visit the website and look for your certification body.

How PQSmitra help you with a Hassle – free Implementation for ISO 15378 Certification?

ISO 15378 being a specific standard for primary packaging materials for medicinal products, the required controls and monitoring of the quality management system and actual on floor practices are very specific and stringent. In such scenario, the practical, easy and effective implementation of the system is very essential. PQSmitra team with an expertise more than 20 years has supported many clients implement GMP – Good manufacturing Practices and get ISO 15378 certification.

The ISO 15378 implementation process is described below:

- Review of the existing Quality Management System. This review is carried out through discussions and verifications of records during visits to the client organization. The pharma customer specific requirements are taken into consideration to make this activity effective.
- Good manufacturing practices - GMP based system designing and documentation (Records and Procedures). 100% documentation support is offered by PQSmitra. This includes shop floor controls as well as control on documentation and records.
- Training on GMP and QMS related requirements
- Routine assistance and system verification to ensure compliance to the requirements.
- Internal audit and Management review
- Certification audit – Stage 1 and Stage 2
- Submission of action plan on audit observations
- Review of report by the certification authority and awarding the certificate to the organization.

PQSmitraService Features appreciated by clients

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