



ISO 15378

Primary Packaging Materials for Medical Products

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DQS Inc. is an accredited (DAkKS) ISO 15378 and Approved (F4SS) AuditOne Certification Body and your international provider of quality management systems and regulatory compliance audit and certification services for organizations providing primary packaging of medicinal products.

The ISO 15378 requirements integrate quality management system requirements (utilizing the framework and particular requirements associated with ISO 9001) with the good manufacturing practices (GMP) specific to medicinal products .

ISO 15378 is intended for primary packaging of medicinal products made from glass, rubber, plastics, aluminum containers / components, films, foils and laminate containers. As these materials come in direct contact with medicinal products, they need to comply with quality, safety, efficacy and reliability requirements.

Benefits of ISO 15378 Certification:

- A framework for effective quality management, risk management control and validation of materials, products and processes
- Ensures the company's ability to consistently meet and exceed customer requirements, including global market regulatory-compliance requirements
- Discover ways to minimize/eliminate potential sources of contamination, product mix-ups, or other manufacturing / process errors
- Improves management system process efficiencies and cost effectiveness within the organization;
- Provides framework for monitoring and increasing customer satisfaction through the implementation and maintenance of a management system.

Achieving ISO 15378 certification under a globally recognized accredited program represents your organization's commitment to continuously improving your quality system to your customers, external stakeholders and other interested parties.

Other Audit, Inspection and Certification Services Offered by DQS:

- European Directive -- Medical Devices Directive
- MDSAP--MedicalDevicesSingleAudit Programs
- AuditOne -- Audit and Certification Services
- ISO27001fortheHealthcareIndustry --InformationSecurityManagement Systems
- ISO 14971 -- Risk Management for Medical Devices
- ISO 13485 -- Quality Management Systems for Medical Devices
- As well as other management systems, audits, and certification services including AS 9100, IATF 16949, ISO 9001, ISO 14001. To see the entire list please visit www.dqsus.com