



Swiss Association  
for Quality and Management  
Systems (SQS)

ISO 15378:2011

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# Primary packaging material for medicinal products – Particular requirements for the application of ISO 9001, with reference to Good Manufacturing Practice (GMP) rules

## *Incentive*

Controlled processes must be put in place for the manufacturing of primary packaging for pharmaceutical products and great care must be taken during production due to the many different risks of contamination. The regulatory and statutory conformity of the products and processes is also of major importance. Verification that a company has the required systems in place to ensure Good Manufacturing Practice (GMP) is mandatory for buyers of pharmaceuticals. The requirements have been standardised in ISO 15378:2011 in order to eliminate any room for interpretation and to preclude the uncertainties which can arise through different understandings. The standard sets out what is required in respect of a quality management system and how the requirements apply to the design, manufacture and supply of primary packaging for medicinal products.

## *Outcome*

ISO 15378 guarantees that the measures are in place to ensure product safety, product quality, legal conformity, process optimisation and risk minimisation.

## *Target groups*

Companies and organisations of all sizes which make packaging and packaging material for the pharmaceutical industry.





### *Validity*

3 years – there is an annual audit to ensure that standards are being maintained and a recertification audit after three years.

### *Recognition*

The SQS certificate of conformity with ISO 15378 has international recognition.

### *Combinations*

ISO 15378 contains the requirements set out in ISO 9001 (quality management) and is compatible with all other management system standards like ISO 14001 (environmental management) and OHSAS 18001 (occupational health and safety), etc.

### *Contact*

Further general information can be obtained from our office in Zollikofen.

Our auditors are also available to answer queries on specific subjects.

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