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Good Distribution Practice For Clinical Trial Materials

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For each clinical protocol, the latest stability data are used to define the acceptable temperature range and allowed excursions.

IMPs (Investigational Medicinal Products) are not mentioned in current GDP guidance e.g. the EU GDP guidance or USP 1079 in the USA, but GMP and GCP regulations and principles request the same or even higher level of traceability and quality for IMP distribution and storage than for commercial medicinal products. At each moment in the clinical trial, sponsor, monitor and investigator must know the location, status, distribution history and usage of each individual IMP package. The whole supply chain must be documented, and related documentation is part of clinical trial files, including the investigator...