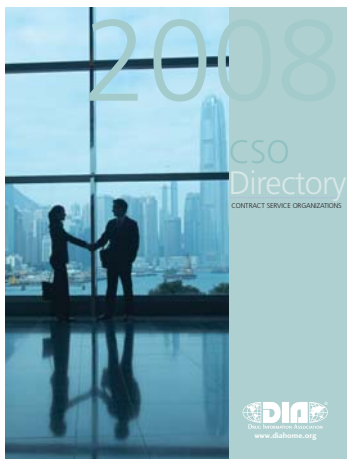


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- **Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001** on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

- **Commission Directive 2005/28/EC of 8 April 2005** laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products

- **Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004** laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

- **Volume 9A of the Rules Governing Medicinal Products in the European Union – Guidelines on Pharmacovigilance for Medicinal Products for Human Use (March 2007)**



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