Barbara Römer

2001/20/EC - A European Directive?

Major Regulatory Objectives for a Real Harmonisation in Europe

Tectum

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List of Abbreviations

Abbreviation	Explanation
AEMPS	Spanish Agency of Medicinal Products and Health Products
AGES	Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH (AT)
AIFA	Agenzia Italiana del Farmaco
ASCII	American standard code for information interchange
ASR	Annual safety report
AT	Austria
BASG	Bundesamt für Sicherheit im Gesundheitswesen (AT)
BE	Belgium
BEC	Bioethics committee (PL)
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte (DE)
CA	Competent authority
CCMO	Centrale Commissie Mensgebonden Onderzoek
CGR	Stichting Code Geneesmiddelenreclame
CI	Chief investigator
CIOMS	Council for International Organizations of Medical Sciences
CPMP	Committee for Proprietary Medicinal Products of the European Community
CRF	Case Report Form
CTA	Clinical trial application
CTFG	Clinical Trials Facilitation Group
CV	Curriculum vitae
CZ	Czech Republic

DE	Germany
DK	Denmark
EC	Ethics committee
ECPLO	Ethics committee providing local opinion (BE)
ECPSO	Ethics committee providing single opinion (BE)
EE	Estonia
EFPIA	European Federation of Pharmaceutical Industries Associations
e.g.	Exempli gratia (for instance)
ES	Spain
EU	European Union
FAMHP	Federal Agency for Medicines and Health Products
FDA	Food and Drug Administration (US)
FI	Finland
FR	France
GCP	Good Clinical Practice
GCP-V	GCP-Verordnung (GCP-Decree)
GMP	Good Manufacturing Practice
GR	Greece
HMA	Heads of Medicines Agencies
HU	Hungary
IB	Investigator's Brochure
ICH	International Conference on Harmonisation
i.e.	id est (that is)
IT	Italy
IMP	Investigational medicinal product
IMPD	Investigational medicinal product dossier
incl.	including

ISS	Istituto Superiore di Sanità (IT)
LKP	Leiter der klinischen Prüfung (Coordinating Investigator in Germany)
LREC	Local research ethics committee
LU	Luxembourg
LV	Latvia
MA	Marketing authorisation
Max.	Maximum
MEC	Multi-centre ethics committee (CZ)
METC	Medisch Ethische Toetsingcommissie (NL)
MHRA	Medicines and Healthcare products Regulatory Agency (UK)
MREC	Medical Research Ethics Committee (NL)
MREC	Main Research Ethics Committee (UK)
MS	Member State
NCA	National competent authority
NHS	National Health Service (UK)
No.	Number
NL	The Netherlands
NMEC	National medical ethics committee (SI)
NRES	National research ethics service (UK)
PASS	Post authorisation safety study
PEI	Product under clinical research
PEI	Paul-Ehrlich-Institut - Bundesamt für Sera und Impfstoffe (DE)
PI	Principal investigator
PIP	Paediatric investigational plan
PL	Poland
R&D	Research and development

REC	Research ethics committee (UK)
SAMM	Safety Assessment Marketed Medicines
SCO	Ministerio de Sanidad y Consumo (ES)
SI	Slovenia
SK	Slovakia
SmPC	Summary of product characteristics
SOP	Standard Operating Procedure
SSA	Site specific assessment
SSIF	Site specific information form
SUKL	State Institute for Drug Control (CZ)
SUSAR	Suspected unexpected serious adverse reaction
TSE	Transmissible spongiform encephalopathy
US	United States of America
UK	United Kingdom
VWS	Ministry of Health, Welfare and Sport (NL)
WHO	World Health Organization
WMO	Medical Research Involving Human Subjects Act (NL)