

Timeline

1930s

•A mistake in the formulation of a children's syrup (sulphanilamide in ethylene glycol) caused a number of deaths and led the FDA (US) to set up a product authorisation system

1947

•Nuremburg Code (Directives for Human Experimentation)

1950s

•Japanese government regulated sale of medicinal products

1960s

•Effects of thalidomide a synthetic drug, triggered a review of practices in Europe

1964

•Declaration of Helsinki

1968

•Medicines Act (UK)

1970

•Tuskegee Syphilis Experiment - the exposure of the 40 year US public health study of the progression of syphilis infection led to change in the law governing the protection of research participants

1989

•WHO Conference of Drug Regulatory Authorities produced action plans for regulation of medical research

1990

•First ICH meeting held between EU, Japan and US regulatory authorities to harmonise practices

1990

•Human Fertilisation and Embryology Act

1996

•ICH Guideline on Good Clinical Practice

2001

•EU Directive on Clinical Trials (2001/20/EC)

2003

•Oversight of Human Embryonic Stem Cells

2004

•Medicines for Human Use (Clinical Trials) Regulations 2004 (UK)

2004

•Human Tissue Act 2004 (UK)

2005

•EU Directive on Good Clinical Practice (2005/28/EC)

2005

•Research Governance Framework for Health and Social Care (UK)