• 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

• Nuremburg Code (Directives for Human Experimentation)

• Japanese government regulated sale of medicinal products

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

• Declaration of Helsinki

• Medicines Act (UK)

• 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

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

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

• Human Fertilisation and Embryology Act

• ICH Guideline on Good Clinical Practice

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

• Oversight of Human Embryonic Stem Cells

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

• Human Tissue Act 2004 (UK)

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

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