European Experience with Similar Biological Products

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European Union has set up a legal framework allowing registration of “Similar biological medicinal products”. This legal framework may be applicable to any type of biologicals. The EMEA is responsible for setting up appropriate technical guidelines to provide ground for marketing authorization dossier submission. Several guidelines are already published and other are under way. Since then several products have been submitted at the European level and some of them have been authorized. An overview of these aspects will be presented.

EMEA Guidelines

http://www.emea.europa.eu/htms/human/humanguidelines/multidiscipline.htm