ICH-Update

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ICH is a collaborative project that brings together the regulatory authorities of Europe, Japan and the United States and the experts from the pharmaceutical industry in the three regions in order to seek ways to eliminate redundant or duplicative technical requirements for registering new medicinal substances and products. It seeks to identify areas where modifications in technical requirements or greater mutual acceptance of research and development procedures could lead to a more economical use of human, animal and material resources, without compromising safety. The first ICH conference was held in Brussels in November 1991, the second in Orlando in October 1993 and the most recent just ended yesterday in Yokohama. Significant progress has been made and recommendations are being adopted by the three regulatory bodies and offering guidance to the pharmaceutical industry that was not previously available on such a scale. This presentation will review and discuss the most recent progress made prior to and at the Yokohama meeting and future trends of ICH. The focus will be on the development of guidelines affecting clinical development from both an efficacy and safety point of view. The current status of incorporation of these guidelines in the requirements applicable for registration in the European Union will be presented.