INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

## ICH HARMONISED TRIPARTITE GUIDELINE

# POST-APPROVAL SAFETY DATA MANAGEMENT: DEFINITIONS AND STANDARDS FOR EXPEDITED REPORTING E2D

Recommended for Adoption

at Step 4 of the ICH Process

on 12 November 2003

by the ICH Steering Committee

*This Guideline has been developed by the appropriate ICH Expert Working Group and has been subject to consultation by the regulatory parties, in accordance with the ICH Process. At Step 4 of the Process the final draft is recommended for adoption to the regulatory bodies of the European Union, Japan and USA*

# POST-APPROVAL SAFETY DATA MANAGEMENT: DEFINITIONS AND STANDARDS FOR EXPEDITED REPORTING

**ICH Harmonised Tripartite Guideline**

Having reached *Step 4* of the ICH Process at the ICH Steering Committee meeting on 12 November 2003, this guideline is recommended for adoption to the three regulatory parties to ICH

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