- Premarketing Risk Assessment （http://www.fda.gov/cder/guidance/6357fnl.htm）
- Development and Use of Risk Minimization Action Plans （http://www.fda.gov/cder/guidance/6358fnl.htm）
- Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment (http://www.fda.gov/cder/guidance/6359OCC.htm)

EU では、European Medicines Agency (EMEA), Committee for Medicinal Products for Human Use(CHMP) から、2005 年 11 月 14 日にガイドラインが 3 つの Annex A, B, C とともに公表された。

- Guideline on Risk Management Systems for Medical Products for Human Use (EMEA/CHMP/96268/2005)
- Annex A: Epidemiological Methods for Post-Authorisation Safety Studies
- Annex B: Methods for Risk Minimization[108]
- Annex C: Template for EU Risk Management Plan (EU-RMP)[109]

[108] http://www.emea.europa.eu/pdfs/human/euleg/9626805en.pdf （guideline 本文と Annex A, B を含む）

[109] http://www.emea.europa.eu/pdfs/human/euleg/19263206en.pdf