

**ICH Guidelines
Good Clinical Practice
Clinical Safety Data Management**

Book M1

**ICH Guidelines for
Good Clinical Practice and
Clinical Safety Data
Management**

- **ICH Guideline E6(R2):
Integrated Addendum to Good
Clinical Practice (R1)**
US-adopted version + ICH Step 4
addenda
- **ICH Guideline E2A: Clinical
Safety Data Management:
Definitions and Standards for
Expedited Reporting**
US-adopted version

**Mini Size
3" x 5"**

