

## **8.0 Test Method Data Quality**

### **8.1 Adherence to National and International GLP Guidelines**

Ideally, all data supporting the validity of a test method should be obtained and reported in accordance with GLP guidelines (i.e., OECD 1998; EPA 2003a, 2003b; FDA 2003). These guidelines provide an internationally standardized approach for the reporting requirements of studies designed for regulatory submissions, internal audits of laboratory records and data summaries, the archive of study data and records, and information about the test protocol and laboratory personnel, to provide assurances regarding the integrity, reliability, and accountability of the study.

The initial ECVAM validation studies for the five *in vitro* pyrogen test methods were conducted "in the spirit of" GLP requirements (i.e., written protocols and approved SOPs were followed during the entire course of the study). In the catch-up validation studies, two GLP laboratories and two National Control Laboratories participated.

### **8.2 Data Quality Audits**

Formal assessments of data quality, such as a QA audit, generally involve a systematic and critical comparison of the data provided in a study report with the laboratory records generated for the study. No attempt was made to formally audit the quality of the data presented in the five ECVAM BRDs. However, as indicated in **Section 5.2**, the raw data from the validation studies are available from the participating laboratories for a quality analysis.

### **8.3 Impact of Deviations from GLP Guidelines**

The impact of the deviations from the GLP guidelines, as reported in the ECVAM BRDs, was not evaluated.

### **8.4 Availability of Laboratory Notebooks or Other Records**

All records are stored and archived by the participating laboratories and are available for inspection.

### **8.5 Need for Data Quality**

Data quality is a critical component of the validation process. To ensure data quality, ICCVAM recommends that all data generated during the validation of a test method be available, along with the detailed protocol(s) under which the data were produced. Original data should be available for examination, as should supporting documentation such as laboratory notebooks. Ideally, the data should adhere to GLP guidelines (ICCVAM 1997). Data protocols for the validation studies summarized here are available from ECVAM (see **Appendix A**), and the data from the individual laboratories are available for inspection, as indicated in **Section 8.4**.