Compliance of The Discovery Series™ Software From Bio-Rad Laboratories With Food and Drug Administration 21 CFR Part 11

In 1997, the United States' Food and Drug Administration (FDA) published Title 21 Code of Federal Regulations (CFR) Part 11 — Electronic Records; Electronic Signatures. The scope of the regulation is to ensure that electronic records and electronic signatures are "trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper". This regulation is now becoming mandatory for our customers, scientists in the pharmaceutical and biotechnology industries.

At Bio-Rad Laboratories, we are committed to adapt to our customer needs in a changing environment. Therefore, we are currently working diligently on implementing changes in The Discovery Series™ Quantity One® 1-D analysis software and The Discovery Series PDQuest™ 2-D analysis software to make them compliant with 21 CFR part 11. **We plan to release compliant versions of Quantity One and PDQuest during the year 2003**.

Today, there are already features in The Discovery Series software managing a number of the requirements for a software audit trail. Quantity One software version 4.4 includes:

- User login with name and password
- Ability to define time limit for automatic logout
- Ability to automatically save scan backup files in separate directory
- Complete read-only file history, logging modifications by user with a date and time stamp

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