ProteOn™ XPR36 Protein Interaction Array System: Regulatory Tools for Drug Development

The regulatory guidelines set forth by the FDA are of the utmost importance to the safety of our food and drug manufacturing processes. Adherence to these regulations requires procedural (notification, training, standard operating procedures), administrative, and technical (software-related) controls. These controls support the good practices rulings observed within the pharmaceutical industry. Collectively known as GxP, these are: Good Laboratory Practice (GLP), Good Automated Manufacturing Practice (GAMP), Good Manufacturing Practice (GMP), and Good Clinical Practice (GCP).

Bio-Rad offers two regulatory compliance tools for use with the ProteOn XPR36 protein interaction array system to aid regulatory compliance in the drug discovery and development workflow. ProteOn Manager™ software, Security Edition assists with electronic record management per the U.S. FDA 21 CFR Part 11 ruling, and ProteOn XPR36 installation qualification/operation qualification (IQ/OQ) kit assists with adherence to the good practices rulings.

ProteOn Manager Software, Security Edition

Over the years, paper records delivered to the U.S. FDA by the truckload have given way to electronic data sources. This led to the introduction of the 21 CFR Part 11 regulations in 1997, which detail how to manage electronic records for internal and external audits and submissions to the FDA.

The FDA defines a “closed system” as a private network managed by individual organizations. The operation and maintenance of the system is controlled by personnel working within the user organization, and is usually governed by strict standard operating procedures. Therefore, all data, result, and protocol files generated by ProteOn Manager software, along with the audit trail and instrument log database, are considered electronic records generated in a closed system environment. The following controls are built into ProteOn Manager software to assist with 21 CFR Part 11 regulatory compliance:

- **Electronic signatures** — reviewers and approvers can digitally sign records. The name, date, time, reviewer/approver status, and reason (user comments) are associated with each signature and logged by the software. Once a file has been approved, it is reflected in the software, and changes can only be saved as a new file name or revision. The software will automatically update the file name to reflect a new revision. All electronic signatures require a username and password
- **Audit trail** — all auditable changes are recorded, including the date and time, originator of the record, and other related information. The audit trail cannot be changed or deleted by the user
- **Data validation** — accuracy of electronic copies is confirmed using a secure checksum to detect invalid or altered records
- **Identification codes and passwords** — the system administrator must set up unique user identification codes for each individual. User identification codes cannot be reused or reassigned to others. The Windows operating system ensures that all active user identification codes are unique and that all identification code and password combinations are unique
- **Device check** — the software records the identity (serial number) of the ProteOn instrument that it is controlling
- **System access and authority** — access rights are based on those assigned within the Windows domain/workstation user database. ProteOn Manager software, Security Edition uses the Windows operating system security feature to authenticate users and retrieve access levels via group membership. User permissions will determine access to the software functions
- **Generation of copies** — accurate and complete copies of the data can be generated within ProteOn Manager software and accessed later for inspection and review. The application also enables export of electronic records to ASCII (tab delimited) or XML (secure) file formats

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ProteOn XPR36 Installation Qualification/Operation Qualification (IQ/OQ) Kit

Under good practices rulings, all devices must meet installation and performance standards. After installation, all systems must be validated on a regular basis to ensure performance to manufacturer specifications. The ProteOn XPR36 IQ/OQ kit assists compliance with these rulings. The kit comes with the ProteOn XPR36 IQ/OQ software, OQ control reagents, sensor chip, and a user manual.

The IQ/OQ software provides an IQ protocol to verify the delivery of all system components, including electronic verification of system firmware and software. The OQ protocol verifies system operation within a series of defined tests and validation parameters. Electronic logs and printable PDF reports of the instrument's IQ and OQ are provided to meet internal documentation requirements. This kit performs unattended qualification protocols without requiring costly operator assistance.

These new regulatory tools complement one of the key advantages of using the ProteOn XPR36 protein interaction array system in the drug discovery and development workflow: increased data collection efficiency by reducing the time required for these procedures from days to hours.

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