



Connectware™

Digi assists pharmaceutical companies to comply with 21CFR11

The Pharmaceutical market which is highly sensitive to secure and documented procedures, is being required to provide secure electronic signatures as part of 21 CFR Part11 regulations. The new requirements ensure that Electronic Records and Electronic Signatures are trustworthy, reliable and generally equivalent substitute for paper records and handwritten signatures. As interaction between equipment, operators and computers become commonplace it is important to establish a secure means to communicate and store information. Ethernet communications is becoming the network of choice in these applications replacing many of the proprietary networks.

The applications are deploying the use of a database with an automated audit trail for tracking modifications. Ethernet TCP/IP provides a common transport media for all equipment such as PLCs, Process Controllers, and laboratory & Analytical instrumentation. Pharmaceutical companies are uncovering advantages of a network environment to include:

- **A validated server with audit trail & security can be used to save GMP data from multiple systems.**
- **Ability to monitor & alarm multiple systems from one location.**
- **Easier and less costly to maintain the system.**

The use of Digi One IAP as a means to interface to the PLC, Process, and Laboratory instrumentation provides a necessary means to link these devices to Ethernet. OPC interfaces provide a means to communicate to a large variety of equipment from the Validated Server. Data is automatically extracted and stored without human interaction. Changes or access to this data can be traced and logged to insure security and proper access.

