SOLUTION SPOTLIGHT

George T. Hall Company

The FDA regulates companies in the health care, pharmaceutical, medical device, and life science fields to confirm they are in compliance with strict guidelines for consumer safety. The FDA 21 CFR Part 11 was designed to ensure the authenticity, integrity, and confidentiality of electronic records in these industries. This code includes a number of requirements including:

- Limitation of system access
- Authority checks
- Time-stamped audit trails
- Accurate and retrievable record-keeping

GTH offers a number of instruments and software solutions that comply with the strict requirements of CFR Part 11.

Honeywell

Honeywell Paperless Recorders

The benefits of paperless recorders have been widely recognized for their features including real time data acquisition, informational graphics, and on demand data access. Honeywell's Trendview Recorders offer all of the standard benefits of paperless as well as fully compliant records for more efficient FDA reviews and approvals of regulated products. Powerful features facilitate an easy set-up and effective recording of continuous data or batch data. An intuitive interface, simple maintenance, flexible connectivity, and secure data ensure the benefits of paperless records in the most stringent regulatory environments.

PARSEC™

Parsec Electronic Batch Records

TrakSYS real-time decision support for manufacturing execution is designed to help manage operational complexities and improve quality and productivity. In FDA-regulated industries, batch records represent a significant opportunity for improvement. These electronic records can also be easily connected via Manufacturing Operations Management (MOM) software to improve efficiencies as well as compliance and real-time data analysis.

Paperless Recording with TrendView

CFR Part 11 White Paper

Parsec Electronic Batch Records