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The Synapse wireless data system provides secure, continuous environmental monitoring. Synapse is scalable and can be integrated into any existing infrastructure. Distributed Transceiver units monitor environmental conditions and wirelessly transmit the data to a central Receiver.

SYNAPSE
 WIRELESS DATA SYSTEM

Plug and Play features allow for Transceivers to search and select appropriate gateway for ease of implementation.

Benefits

- Ensure compliance to regulatory agencies requirements for temperature monitoring
- Receive alerts and alarms remotely based on user defined criteria
- Reduces cost & effort of monitoring once implemented
- Synapse is scalable as it can grow as your facility or requirement for control and monitoring grows
- Option for Networked, controls of multiply locations from one Head offices with decentralises alerts.

Data available for **inspection and analysis**, the Synapse Software can generate these reports:

- Sample Graphical report
- Detailed Graphical report
- Simple Tabular report
- Detailed Tabular report (includes MKT)
- Alarm Report
- Audit Log Report



An ideal system would constantly measure the required parameters and be capable of logging all the data collected and also be able to generate alerts and alarms to warn staff of an impending problem.

The Synapse system offers all of these features and being wireless can be easily implemented and installed. It is capable of monitoring any environmental parameter from temperature to soil solar flux.

In addition it can be used to control things such as fans, Shutters, blinds, boilers, air conditioners etc.

The Synapse system is fully CFR 21 Part 11 compatible allowing implementation of GMP and GLP solutions





Pharmaceutical manufacturing and Monitoring for GLP & GLP and CFR 21 part 11 compliance



There are a great number of Temperature sensitive products in Pharmaceutical manufacturing. How can we monitor extensive Pharmaceutical manufacturing and comply with regulatory health requirements?

Healthcare is never far from the media focus. This is largely due to the magnitude of the repercussions that can arise from even small mistakes, oversights or equipment failures. The Health authority is always under tremendous pressure to ensure that all aspects of its performance meet the expected levels.

Every year, hospitals and clinics potentially lose tens of millions of pounds worth of drugs, plasma and reagent products, simply due to the malfunction of refrigeration equipment and environmental storage conditions. Additionally the failure to adequately monitor and control the environment for biological specimens and samples can cause delay to, or failure of, patient condition diagnosis.

The potential for loss extends beyond just the products. The success of almost all clinical research and investigation projects is highly dependant on proper environment and storage monitoring and controls. Additionally any results obtained from such projects will require comprehensive audit documentation in order to be accepted. There are also the possible legal implications for patient care.



To a large degree the FDA has taken steps to ensure that such problems cannot occur as long as the health authority departments invest in suitable monitoring and alarm systems. Such a system would not only provide a complete and continuous data trail but would be capable of alerting the staff to potential problems before any serious losses were incurred.

The list is almost endless and if you have a monitoring requirement not listed above, call us because we will almost always have a solution.

More information related to FDA and cGMPs for the 21st Century visit [FDA](#) Website.

21 CFR Part 11 - Electronic Records Requirements

The final guidance for industry Part 11, Electronic Records, Electronic Signatures - Scope and Application clarifies the scope and application of the Part 11 regulation and provides for enforcement discretion in certain areas. The final guidance addresses the comments received during the comment period, including those concerning enforcement discretion, time stamps, and legacy systems. The guidance explains the goals of this initiative and removes barriers to scientific and technological advances and encourages the use of risk-based approaches. The Agency intends to begin rulemaking to revise Part 11, to provide further clarifications and adjustments consistent with the principles and enforcement policies described in this guidance document.

For more information on GLP and CFR 21 part 11 visit

<http://www.mhra.gov.uk>

<http://www.21cfrpart11.com>

http://www.fda.gov/ora/compliance_ref/part11

