



Pharmaceutical Solutions

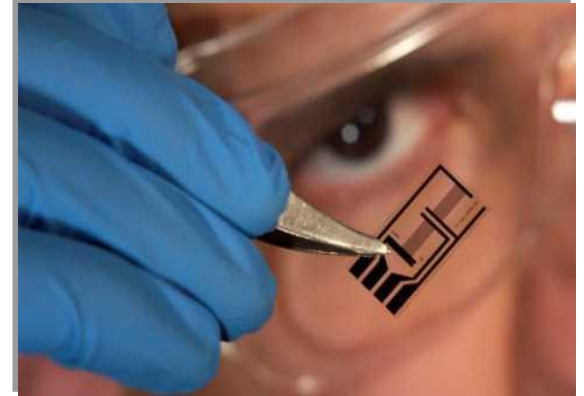




Presentation Overview

Topics of Discussion:

- Safety of stock and storage environment
- Implementing a safe transportation environment
- Scientific and Bio lab monitoring
- Monitoring FDA and EU regulation standards
- Choosing a solution that best optimizes your environment





Safety of stock and storage environment challenges

- Multiple locations
- Sensitivity of the goods
- Validation of the storage location
- Different parameters to monitor according to goods
- Alarm notification in case of system failure
- Report management





Safe transportation environmental challenges

- Reducing environmental barriers
- Water proof
- Information about door position
- Online alarms in the driver cabin
- Reduce communication failure between shipper, transporter and receiver
- Receiver receipt





Scientific and Bio lab monitoring challenges

- Following the entire scientific process
- Validation and calibration
- Monitor various parameters
- Avoid spoilage
- History and audit trail
- Accurate monitoring
- Eagle eye view





Monitoring FDA and EU regulation standards

- **FDA** sanitary guidelines state that the primary cause of spoilage stems from **improper temperature control during transportation and storage.**
- EU and UK legislation stipulate that **appropriate temperature must be maintained**, monitored and recorded **during transport and storage.**
- **The FDA recommends** that persons engaged in transport **concentrate their efforts on monitoring appropriate temperature control.**
- **Good communication between shipper, transporter and receiver** also significantly improves product quality during transportation and storage.



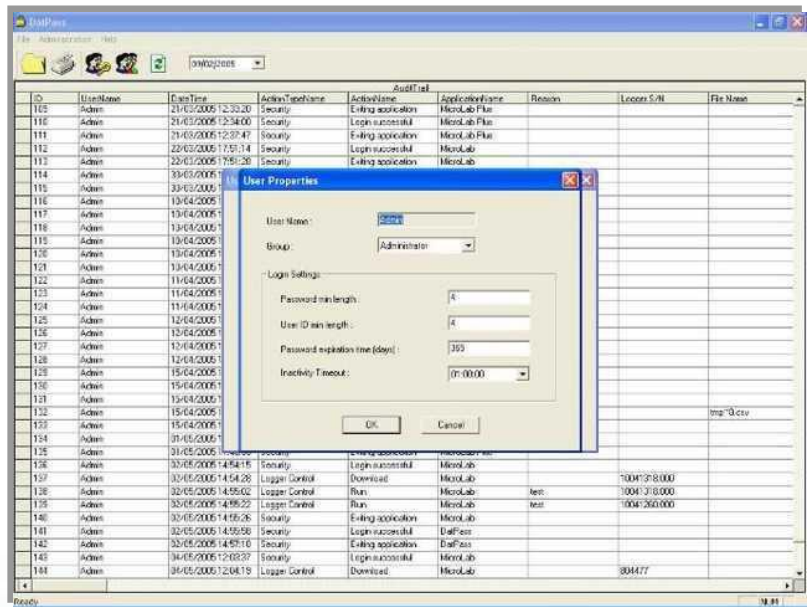


Compliance with CFR21 Part 11

DatPass - a user administration software which defines menu permissions for user groups.

DatPass software pack includes:

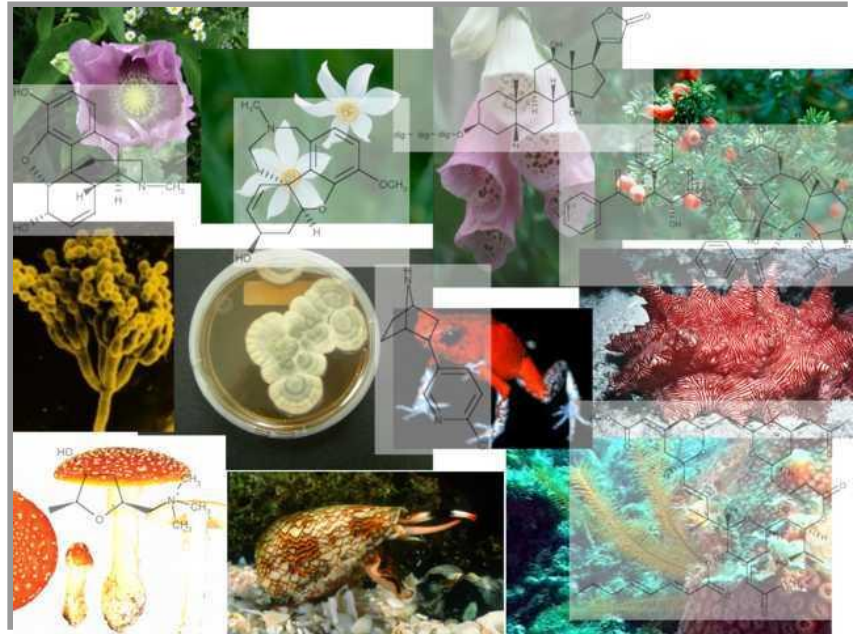
- DatPass software
- MicroLab 21 CFR Part 11 software
- GAMP4 (IQ,OQ)
- Security dongle





Choosing a solution that best optimizes your environment

- **Environmental analysis**
 - existing infrastructure
 - monitoring needs
 - no. of monitoring locations
- **Solution requirements**
 - **Readings**
 - Display
 - Battery backup
 - **Number of Monitoring Points**
 - **Online - Offline**
 - **Alarm style**
 - Email
 - GSM
 - external reports





Wireless Monitoring Solutions I

- Multiple location monitoring from a single network
- For hospitals, laboratories, storage and production environments
- Multiple Wireless monitoring unit
 - Temperature, pressure, humidity, pH, CO₂ , differential pressure and more
- Meeting regulation standards with environmental monitoring





Wireless Monitoring Solutions II

- Historical data reports sent electronically as programmed
- User-friendly integration to existing facilities
- Information management via wireless data loggers
- Environmental management with real-time wireless data monitoring to ensure safety during medical and pharmaceutical procedures





Wireless Monitoring Solutions III

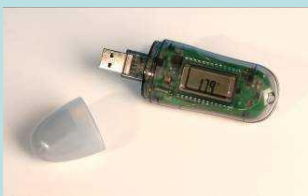
- Data loggers keep systems working despite power failure or systems maintenance
- Data Loggers require lower power and have more rugged batteries



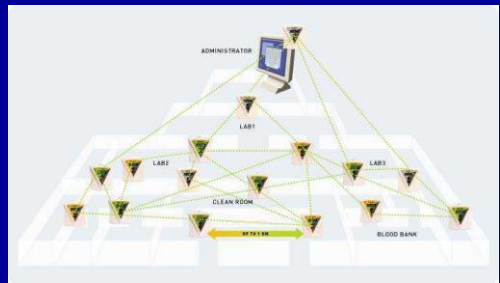


Fourier data logging solutions

1. Record data
2. USB connection to PC
3. MicroLab Lite graphical data display



MicroLite:
Portability and transport
 High functionality,
 multi-trip plug-in logger



DataNet: High Functionality large networks - Intelligent wireless ZigBee data logging

DaqPRO: 8-channel multi-data acquisition

DaqLink – 4 Channel Multi-probe Data Logger

MicroLog/PRO: Long-term General Data Logging

External sensor input

Thermal portable printer - simply scan MicroLog's infrared beam

MicroLab software automatically saves and produces daily status reports



Data Logging Solutions Overview

- **DataNet Solution**

- Wireless intelligent logging network featuring 16-bit resolution
- Supports direct measurement of PT-100, voltage, current and more



- **MicroLog Solution**

- General data logger of temperature and RH



- **MicroLite Solution**

- The plug & record mini data logger - temperature



- **DaqPro Solution**

- All-in-one system for universal data acquisition and analysis



- **DaqLink Solution**

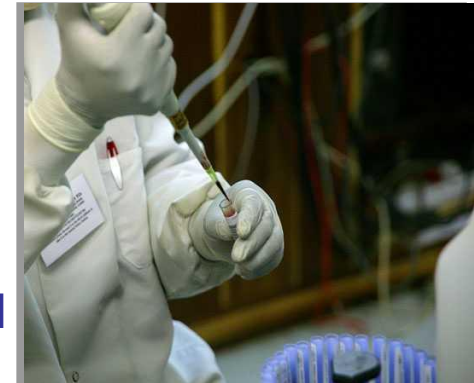
- 4 Channel Multi-probe Data Logger
- 4 external inputs + internal humidity and temperature sensors





Case Study Overview

- Taiwanese government [monitored umbilical cord blood lab](#)
- Malaysian Ministry Of Health – [Malaysian hospital](#)
- [Pharmaceutical Industries](#) developing and marketing branded pharmaceuticals & active ingredients.
- Genetic Unit in the Institute of [Medical Genetics in Portugal](#): Meeting ISO working standards via a wireless solution
- [Spanish Laboratories](#) fighting bacteria in public water systems





Key Take-Aways



Success factors in monitoring environments:

- Best practices for data acquisition
- Various Solutions
- Maintaining safe and secure logistics and processes





Thank you

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