Introduction

- Various systems out there

- Better than manual or different

- Experience of the Royal London PMU

- Pros and cons of electronic monitoring

- Considerations for operating an electronic system

Mobile Phone

- My mobile phone
  - It calls
  - It receives
  - It texts
  - It surfs very slowly
  - Plays music
  - It is an alarm clock and diary
  - It fits in my top pocket
  - The battery last 5 days

Smartphone
  - It calls
  - It receives
  - It texts
  - It surfs very fast
  - Plays music
  - Watch video
  - Play network games
  - It is an alarm clock and diary
  - The battery last 1 day

Environmental Monitoring

- Manual processes
  - Particles
  - Temperature (room, fridges, freezers)
  - Pressure
  - Humidity
  - Air flow

Manual operations

Advantages
• Minimal data interpretation?
• Not dependent on electronic technology
• Easy to train and execute?
• Robust?

Disadvantages
• Deviation awareness is passive
• Reliance on individual readings
• Interpretation (magnehelic readings)
• Time of reading
• Calibration of equipment
• Variety of monitoring equipment and accredited staff

EMS

Various manufacturers provide systems that:

- Displays
- Records
- Monitors

Such parameters are normally room/ equipment environmental factors which are compared against measured values against fixed alarm limits

Capability of EMS

- Continuous readings

- Visual alarms and audible notifications (texting possible)

- Temperature, pressure, particles, ….. anything that can produce an electrical signal.

- Unmanned….. but needs regular observation

URS

- Simple or complex depends on your needs and budget
- Number of rooms need monitoring
- What needs monitoring (temperature, pressure, humidity, particles, specialist requirements)
- Methods of recording, monitoring, reporting and Alarming
- Equipment integration (LFC, Isolators etc)
- Security and Contingency

Barts Health PMU and CPU

- Scale a bit different to most radiopharmacies but the principles are the same

- Operational since mid 2006

- Multiple Distinct areas

  – PMU

    - Non-sterile

    - Laminar Flow Cabinet Rooms

    - Negative Isolator room , Positive Isolator Room and Gassing Isolators Room

  – CPU

    - 5 rooms

    - 4 negative pressure isolators

- 30+ rooms being monitored across 2 sites

- Leading to over 200 data gathering points

Design Considerations

- Access (roof void, panels etc)
- Future proofing
- Lifecycles
- Future standards
- Additional Equipment
- Networked or localised
  - Wireless or wired can the signal get past shielding / walls
- Remote access (QA off site)

Costs

- Set up
  - Depends on size of unit and requirements
  - Which system
  - Could be in the region of £100K's

- Maintenance
  - Routine PPM (£10K's/year)
  - Repairs – depend on nature of problem and robustness/ quality of original equipment

Hardware and Software

- A PC running enVigil comprising client and server applications, configured to provide a user interface and perform data acquisition, alarm functions and logging. UPS 30min data backup. Main PC in QA, View Mode entrance to PMU, Remote PC in CPU at Barts

- Particle counter units have associated control units and vacuum pumps

- Pressure sensors monitor absolute room pressure or differential pressure between isolators + their associated room

- Temperature sensors monitor temperature in rooms, fridges, freezers and incubators

- Common LFC alarms indicating an alarm has occurred in one of the units in the room but not the exact nature
  - Missed at handover

Installation

- Hardware-
  - cabling, probe positions, sensors, transducers (datascanner)
  - Computers and associated printers
    - monitors/ remote screens
  - Equipment/location identifier tags (fridges, freezers, isolators, laminar flow cabinets, rooms)

- Software
  - Each company has own program
  - Antivirus
  - Networking
  - Operating system and upgrades
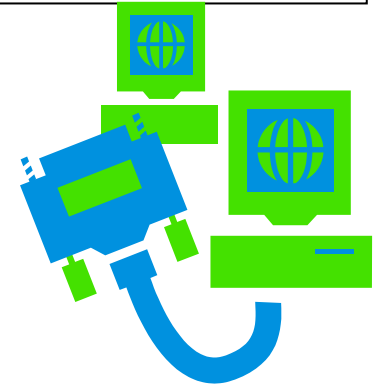
Validation and Setup

- Validation
  - FAT according to URS
  - SAT
  - IQ
  - OQ
  - PQ

- Setup
  - Parameter
  - Alerts Limits
  - Alert Delay
  - UPS (30 mins)
  - Backup
  - Schematic labelling
  - Reports

Security

- Wireless vs wired

- User access

- Administrator

- Network issues
  - Designated server, organisational server
  - viruses

- Data storage and recovery

System Maintenance

Routine

- Alarm acknowledgment
- Perform at least a daily check
- Routine interrogation when an alarm situation occurs + report significant excursions to QA/ Production management
- Comments entered where a cause can be attributed
- Historical report/ trending e.g. clinical trial fridge temperatures

Periodic

- PPM
- Annual calibration
- 6m system health check on main PC + View Mode PC
- 6m vacuum pump check
- 12m calibration of particle counters, temperature + pressure sensors
- 12m filter/vane change on vacuum pumps

- Lifecycles issues

Could be a full time job just looking after the system
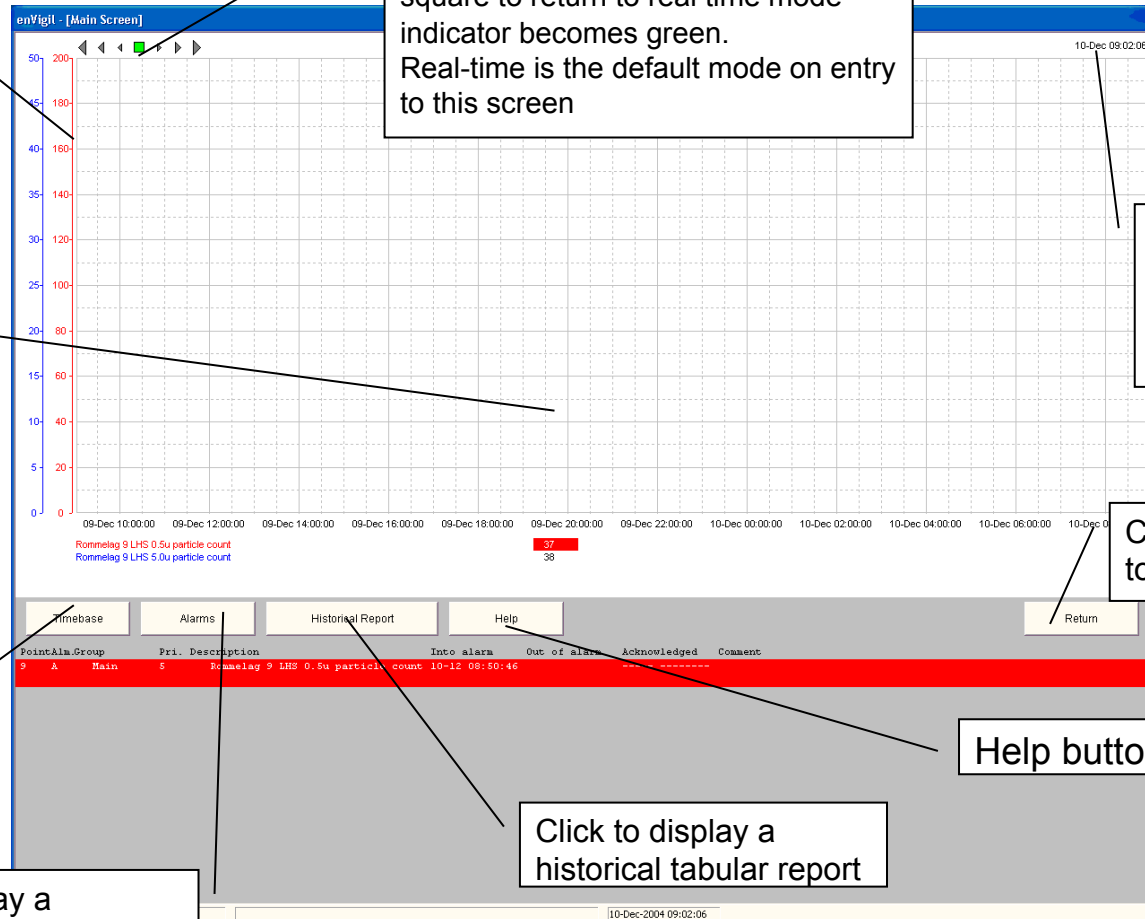
Data generation and interpretation

Time scroll controls. Indicator is red if trend is in historic mode. Click the red square to return to real time mode – indicator becomes green.
Real-time is the default mode on entry to this screen

Y axis scale(s). One is present for each parameter being trended. Each is colour coded to match the parameter's colour.

Clock shows current time in real-time mode, or time of cursor in historic mode.

Point descriptors, values and units. Values shown are current values in real-time mode, or the value under the cursor in historic mode. Values in alarm are shown on a red background.

Click to return to main screen

Click to choose a start date and duration for trends and reports

Click display a reconciled alarm report

Click to display a historical tabular report

Help button

enVigil - [Main Screen]

Rommelag 9 LHS 0.5u particle count   37
Rommelag 9 LHS 5.0u particle count   38

Timebase   Alarms   Historical Report   Help   Return

Point Alm.Group   Pri. Description   Into alarm   Out of alarm   Acknowledged   Comment
9   A   Main   5   Rommelag 9 LHS 0.5u particle count 10-12 08:50:46

10-Dec-2004 09:02:06

Data trending

Data overload

"The greater our knowledge increases the more our ignorance unfolds."

President John F Kennedy

System Failure and Contingency

- We have information from a BMS but still need information for localised equipment

- What will you do
  - Back equipment
    - Temperature data loggers
      - Min/max thermometer
    - Manometers
    - Amemometer
    - Portable Particle Counter

- Failures

There's your problem!

  - Power supply
    - Interruption
    - Surge from restart
  - Lifecycle (component failure) - ? years
  - Calibration failure/ delays
  - Damage to equipment with abnormal practise
  - Viruses
  - Computer hardware failure

Quality Assurance and the QMS

Snap Shot details

- Green indicates no alarms

- Red indicates at least one alarm present

- Flashing indicates unacknowledged alarms

- Cyan indicates particle counters are off

- Magenta indicates physical error e.g. Datascan Solo failure

- Click to review a rooms or equipment parameters

- Recent alarm list is displayed

- System Health indicates state of the system, provides info on disk space, particle counter failures, vacuum pump failures and communication from Datascan solo devices

Common Issues

- Particle Counting
  - Pump failures
  - Cap left on
  - Can not be in operation due to alcohol damaging the sensors

- Power Interruptions

- Explaining excursions (clinical trials, calibration breaks etc)

Tweaking the system

- When to run particle counters
  - Timed control or operator start
- Pressure decay tests not possible when running particle counters
- Alcohol and hydrogen peroxide damages particle sensor
- Defrost cycles on fridges within limits and delays for alarms need risk assessment against product integrity

Conclusions

- Greater Degree of Quality Assurance
- Far more details of the integrity of your environment
- Remote access to data
- Alarming as an active and not passive process
- Requires more time resource and attention
- Increases costs