

# How to Choose a Monitoring System?

Mapping & Monitoring for Controlled Environments

## Webinar Speakers



David Love



Steve Chenal

# Agenda & Takeaways

## Interview topics

1. Terms & Definitions
2. Do you need a monitoring system?
3. Which regulations drive my decisions?
4. Important features
5. Integration
6. Alarming & notifications
7. Data integrity and security
8. Is a change needed?
9. Lifetime cost and maintenance
10. Choosing a vendor

## Takeaways

- Know what questions you should be asking monitoring system vendors.
- Know the most important aspects of choosing a system.

# What is a Monitoring System?

- Sensors are used to monitor the environmental conditions for such things as temperature and humidity.
- The monitoring system includes time and date information and may include additional data such as door openings.



# Do I need a Monitoring System?

- A monitoring system will be necessary for products that are overseen by a governing regulatory body such as the FDA.
- A monitoring system can help to ensure that a product's quality is not put at risk



World Health Organization (WHO)



An tÚdarás Rialála Táirgí Sláinte  
Health Products Regulatory Authority

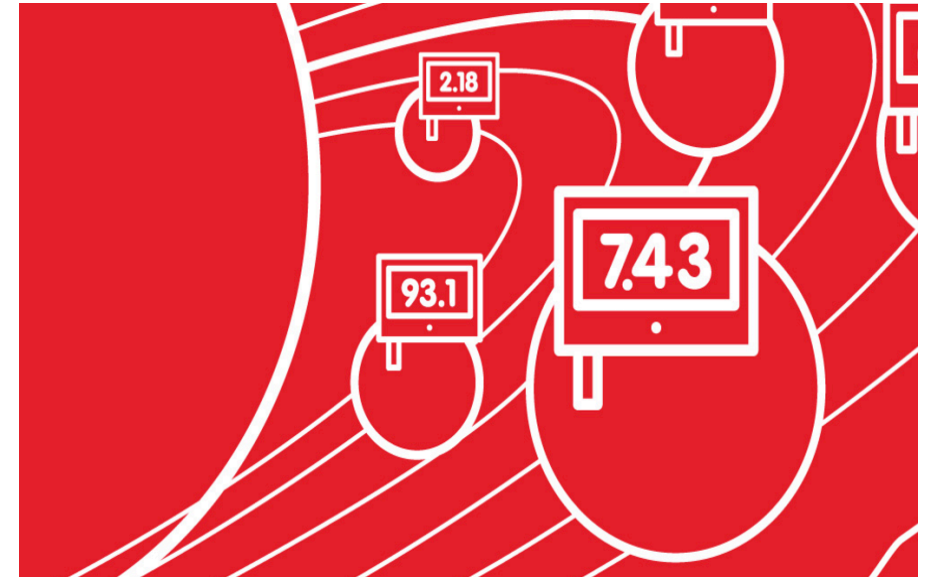
# What should I be concerned with when choosing an environmental monitoring system?

- What parameters do you want to measure and to what specification do you need to measure them?
- Network Configuration, LAN, Wireless, Power/Backup, 3<sup>rd</sup> party sensor integration
- Locally Hosted vs Cloud
- Installation, Configuration, Validation/21 CFR Part 11 Compliance



# What about integration with existing systems?

- Integration can be difficult if an existing system is not validated or not 21 CFR Part 11 compliant
- BMS
- LAN / Wireless





# Comments & Questions

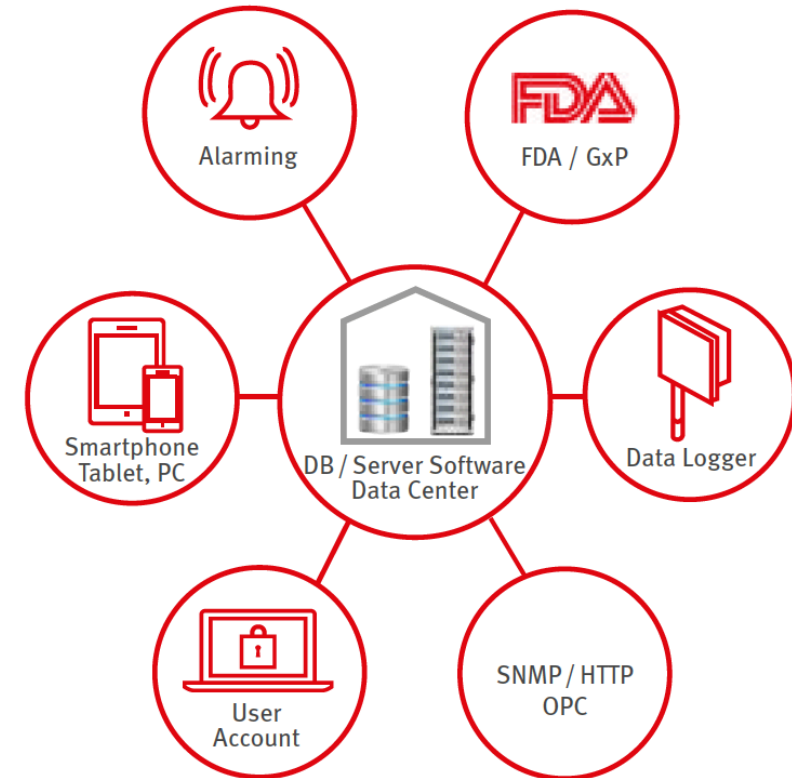


Please type your questions into the chat box at the lower left portion of your screen.



# Alarming and Notifications Options

- Alarms
  - Complexity
  - User recorded
- Event Log
  - 21 CFR Part 11
- Alarm Notification & Response
  - Email
  - SMS
  - Automated Phone Call



# The importance of data integrity & security

- User Access
- 21 CFR Part 11 compliance
- Archiving



# How do I know if a change is necessary?



**“What if we don’t change at all ...  
and something magical just happens.”**

# Indications that change is needed

- Warning letter
- New Products
- Product Quality
  - Not just the shipped product, but also the ingredients that go into a product



# Lifetime Cost & Maintenance Requirements

- IT support
- Calibration
- Seasonal mapping





# Choosing a Vendor

- What does the environmental system include?
  - Software type?
  - How many sensors does it support?
  - What types of sensors are available or supported?
  - What parts of the system does the vendor manufacture?
  - Are the reading digital or analog?
  - After sales support?



# Summary

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2. Do you need a monitoring system?
3. Which regulations drive my decisions?
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5. Integration
6. Alarming & notifications
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# Takeaways

- Big, actionable takeaways
  - One from Steve
  - One from David

# Comments & Questions



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# Rotronic Academy

- Resources for cGMP mapping
- Resources for environmental monitoring

[www.rotronic-usa.com/academy](http://www.rotronic-usa.com/academy)



# Next Webinar

## **How to Choose the Correct Number and Placement of Sensors**

Wednesday, February 15<sup>th</sup> 1:00PM EST

[www.rotronic-usa.com/webinars](http://www.rotronic-usa.com/webinars)

# Thank you!

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