

Lighthouse Worldwide Solutions
Master Presentation

R&D / Headquarters / Manufacturing







Medford, OR

- **★** Manufacturing
- **★Service & Repair Center**
- **★Central Calibration Lab**
- **★RMA Center**

Fremont, CA

- **★R&D**
- **★Engineering**
- **★Pilot Production**
- **★Executive Management**



New Headquarters: Silicon Valley



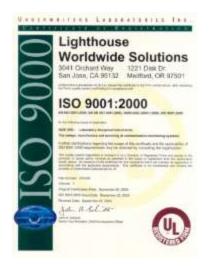






Lighthouse Focus on Quality

ISO 9001:2000 Facilities



United States: Medford, OR San Jose, CA



The Netherlands: Alphen



Singapore



Thailand

5 Lighthouse Locations are ISO 9000 Registered

Lighthouse Worldwide Solutions

★ Pharmaceutical Capabilities:

- **★** Particle counters and facility monitoring systems for meeting cGMP monitoring regulations
 - * 21 CFR Part 210 & 211
 - **★ 21 CFR Part 11**
 - **★ EU GMP Annex 1**
 - **★ PIC/S Annex 1**
 - *** WHO Guidelines**
 - **★ USP 788/797**
- **★** Systems designed for compliance
- **★** Project management services
- **★** Installation services
- **★** Validation services
- **★** Service, repair, retrofit of monitoring systems
- **★** Calibration per ISO 21501 standards
- **★** Contamination control consulting and training



Monitoring Solutions

General Monitoring

- **✓** Air Particle
- **✓ Liquid Particle**
- **✓** Temperature
- **✓** Humidity
- **✓** Differential Pressure
- **✓** Electrostatic Charge
- **✓** Air Velocity
- **✓ TOC**

Specific Applications

- **✓** Current on FFU's
- **✓** Chillers/Refrigerators
- **✓** Door Switches
- **✓** Oven Temp
- **✓ Dry Box Humidity**
- **✓** Gas Purity
- **✓** Incubators
- **✓** Large LCD Displays

Lighthouse Systems Experience

- **★** Lighthouse experience in FMS system installation, particle counter integration and software
- **★** Over 200 FMS system installations worldwide
- **★** Lighthouse is the number one shipper of remote particle counters (numbers exceeding 900 units / month)



Pharmaceutical Customers



























AMGEN

















Lighthouse Pharma Customers (System)

Large multi-building Pharma system which consists of particles counters and environmental sensors. These sensors are integrated to the FMS software with alarm beacons.

- **★** Baxter System
- * ROCHE
- * Sandoz
- **★** Bimagen
- **★** Beta Plus Pharma
- **★** Budelpack NV
- **★** Galapagos NV
- **★** Helvoet Pharma Belgium NV
- **★** Mediline NV
- * Salvamed
- **★** Novo Nordisk
- **★** Styker Howmedica –system

- **★** West Pharmaceuticals
- **★** Hospira / Abbott
- **★ GE Healthcare system**
- **★** Kabi Fresenius
- **★** Biogalenica
- **★** Favea
- **★** Vericore
- **★** Jugoremedia
- **★** Octapharma
- **★** Q- Med
- **★** Alcomed BV

N S

Lighthouse Pharma Customers (System) — Cont'd

- ***** Crucell
- **★** Dutch Veterian Institute
- **★** Fresenius Hemocare BV
- **★** Mallinckodt Medical/ Tyco
- **★** Microclean B.V
- **★** Nelipak / Seal Air
- **★** Sandoz
- **★** Schenker International
- **★** TNO –Dimes
- ***** ACE Pharmaceuticals
- **★** Allergy Therapeutics system
- **★** Aston University (Mayne-Parma)
- **★** Astra Zeneca system
- **★** Baxter system
- **★** Glan Clywdd Hospital
- ***** Medtronic

- **★** Glaxo Smith Kline system
- **★ NIBSC Stem Cell Bank**
- **★** Pfizer-system
- **★** University College London system
- **★** Vericore (Novartis) –system
- **★** Astra Zeneca system
- **★** Bassaire
- **★** IBA Molecular
- **★** Amgen
- * Chiron
- **★** Organogenisis
- ***** Pharmaforce
- **★** Cell Genesys
- **★** McGuff Pharma
- *** MDS Nordion**



Lighthouse Family of Products



World's Number One Particle Counters!



Lab Monitoring

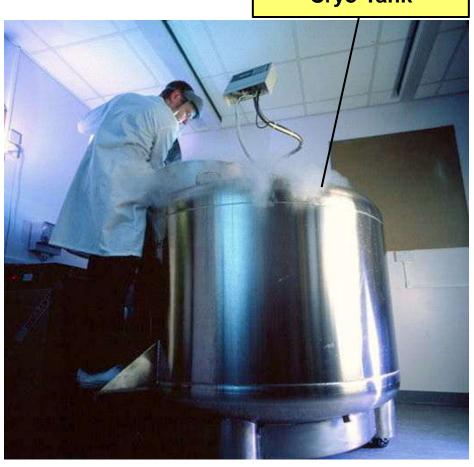


Lab Monitoring



Tank Levels and Status

Cryo Tank



- **★ LN2 Tank Level**
- **★ LN2 Tank Lid (Open/Closed)**
- **★ LN2 Bulk Tank Level**
- **★ Co2 Tank Level**
- **★ Oxygen Sensor**





Differential Pressure



- **★ Differential Pressure**
- **★ 4 20mA Output**
- **★** Gown Room Pressure
- **★** Cleanroom Pressure





HVAC System



- **★ HVAC Status**
- **★** Temperature
- **★** Power Consumption

Power Monitoring



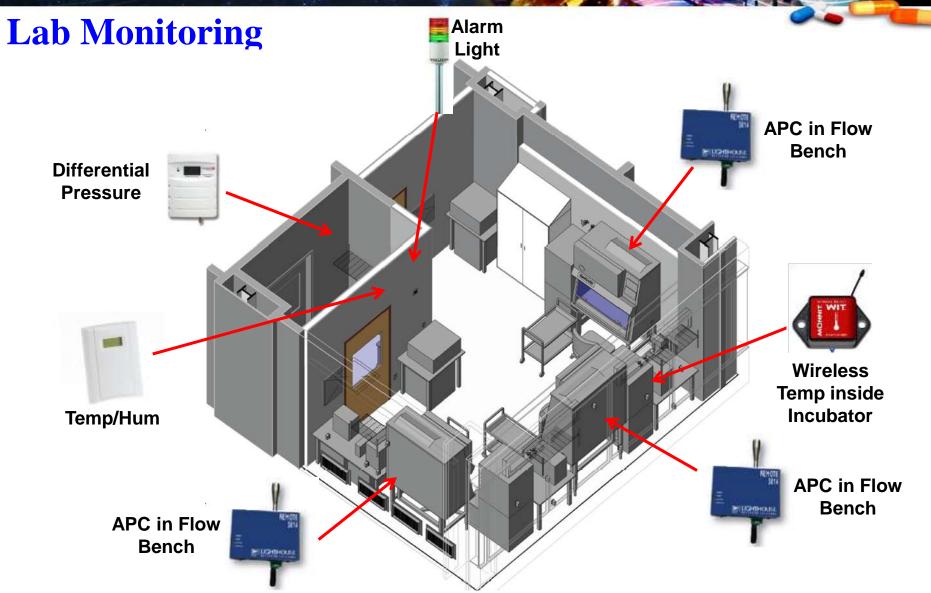
- **★** Voltage Monitoring
- **★** Current Monitoring
- **★** Split or Solid Core
- **★ 4 20mA Output**



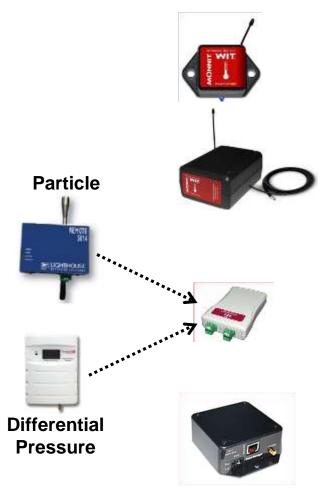
Summary

Description	Temperature	Humidity	Amp	Pressure	Dry Contact
HVAC run status Ah-1	•	•	Х		
HVAC run status Ah-2			X		
HVAC run status AC 1 TI			X		
HVAC run status AC 2 TI			X		
HVAC Temp AC 1 TI	X				
HVAC Temp AC 2 TI	Х				
Clean Room Temp Cord Blood 1	X				
Clean Room Temp Cord Blood 2	X				
Clean Room Temp Process Room	X				
Clean Room RH Cord Blood 1		X			
Clean Room RH Cord Blood 2		X			
Clean Room RH Process Room		X			
Room Pressure Corridor				X	
Room Pressure Exit				X	
Room Pressure Gown 1				X	
Room Pressure Gown 2				X	
LN2 Storage Tank Low level alarm					X
LN2 Storage Tank Low level alarm					X
LN2 Storage Tank High level alarm					X
LN2 Storage Tank High level alarm					X
LN2 Storage Tank Lid Open					X
LN2 Storage Tank Lid Open					Х
LN2 Bulk Tank Low Level Alarm					X
Oxygen Sensor Cord Blood					X
Oxygen Sensor Process room					X
Co2 Bulk Tank Low Level Alarm					X
Genset Start alarm					X
Incubator #23					X
Incubator #24					X
Incubator #25					Х
Freezer #30	X				
Freezer #50	X				
Refrigerator #47	X				
Refrigerator #19	X				

This is a list of all parameters being monitored by LMS Pharma at this customer site.



Wireless



Wireless Temp Sensor with Internal Probe

Wireless Temp/Humidity Sensor with External Probe

Wireless Converter (4 – 20mA to Wireless)

Receiver

Considerations:

- ★ Building Construction
- ★ Installation (inside or outside)
- ★ Distances
- **★** Sampling Frequency
- ★ Response Time
- ★ Battery Life vs. Powered



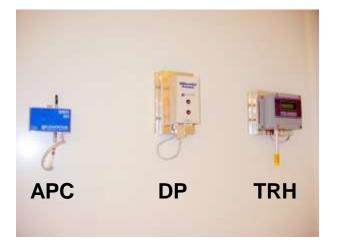
Environmental Monitoring





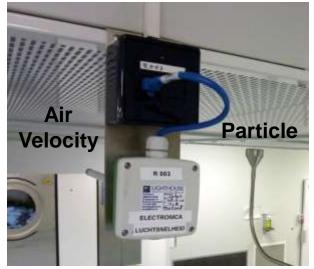


- **★** Temperature/Humidity Sensors
 - **★** Room
 - **★** Ovens
 - **★** Freezers
- **★ Differential Pressure**
 - **★** Room to Room
 - **★** Mini Environment
- **★** Air Velocity
 - ★ Cleanroom
 - **★** Ducts













Air Velocity in Duct



Monitor Air Velocity in Ducts



Air Velocity in a Duct







Fluid or Tank
Levels

Incubator Temperature



Dry Box Humidity and Particle



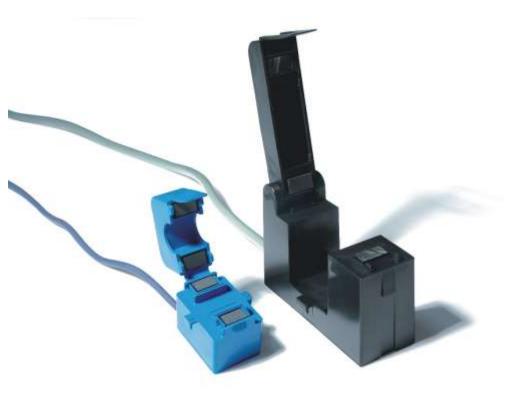
Leak Detection



- **★** Real Time Leak Detection
- **★** Analog Signal



Power Monitoring



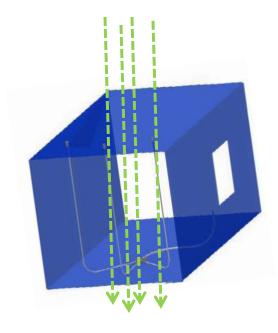
- **★ Voltage Monitoring**
- **★ Current Monitoring**
- **★** Split or Solid Core
- **★ 4 20mA Output**



Particle Monitoring in Ducts

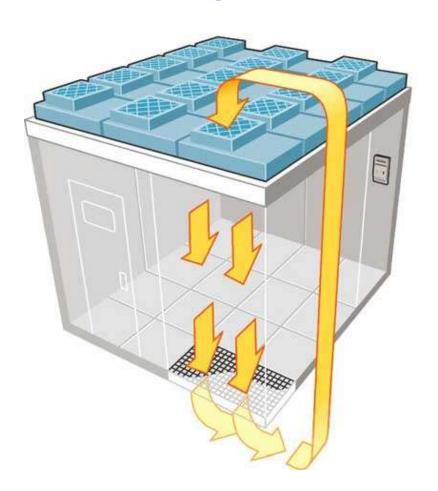


- ★ 0.2 to 100 Micron
- **★ Early Warning System**
- **★ Immediately Notification of Catastrophic Failure**



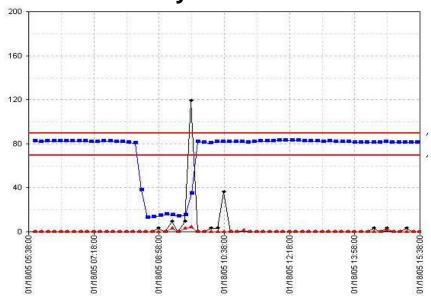


- 4 Success Stories in the US this year
 - 1. Kopin Semiconductor
 - 2. UCSB
 - 3. Moffit Cancer Research Center
 - 4. University of Oklahoma
- **★\$400,000** in sales and growing
- **★**Some power companies are offering incentives

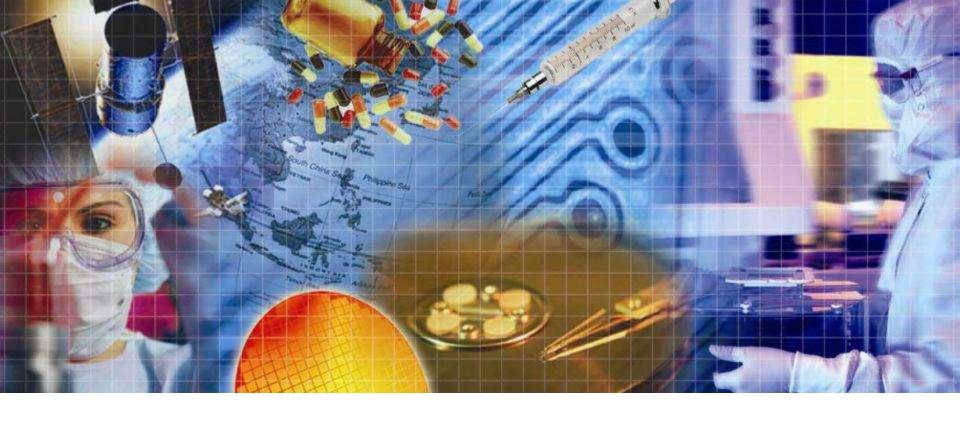


- **★** Typical Flow Rates 70 120 FPM
- **★Reduced Air Changes = Power Savings**
- **★Particle Counters Used to Verify Performance**
- **★Particle Count Data is fed back to HVAC** system
- **★VFD** is required for FFU or HVAC system

Air Velocity and Particle Data



- ★ Step 1: Verify room performance through certification
- **★Step 2: Select optimum sample locations (Critical and Busy Sampling)**
- **★Step 3: Lower FFU speed and monitor for an increase in particle counts.**
- **★Step 4: Set new acceptable air flow rate based on testing**
- **★Step 5: Set alarming parameters**
- **★Step 6: Install the system**
- **★Reduced Air Changes = Power Savings**
- **★Particle Counters Used to Verify Performance**



Thank You