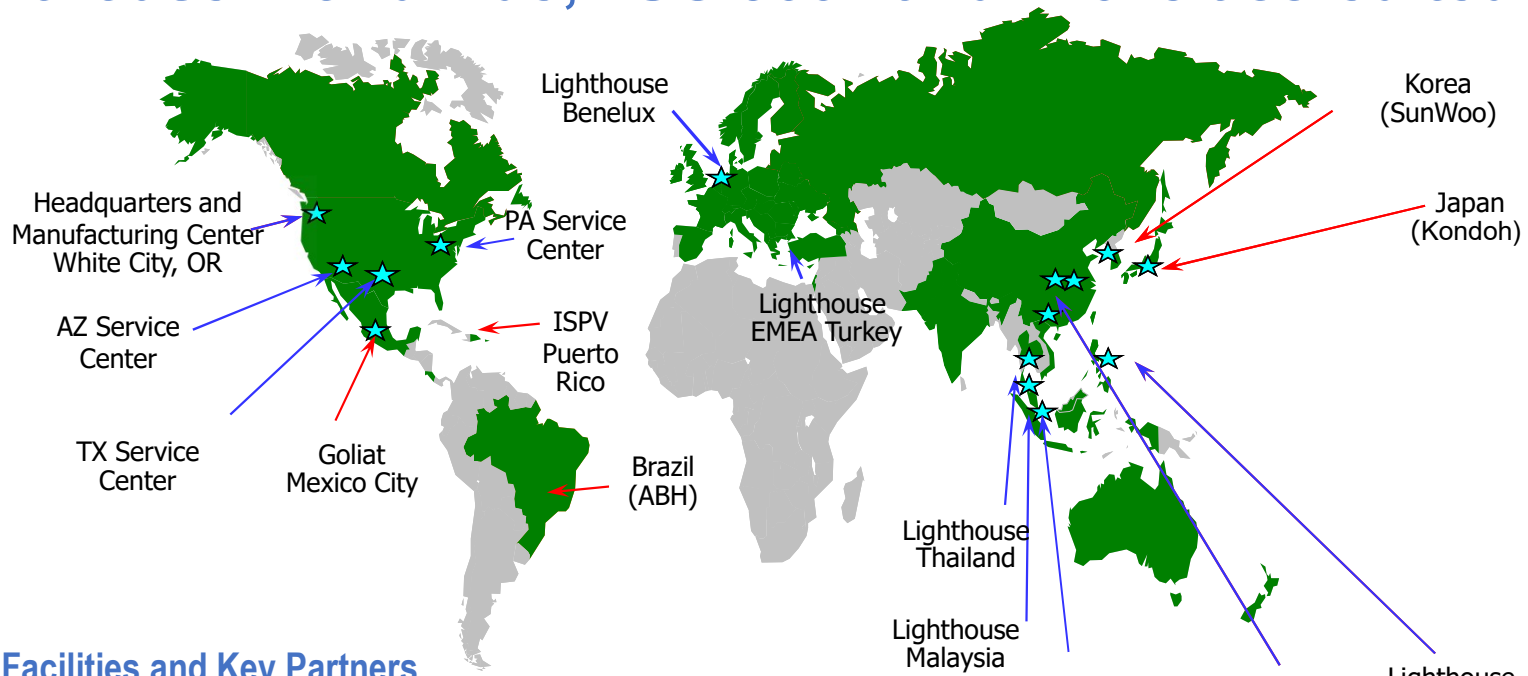
Microbial Contamination and Control Conference

Lighthouse Worldwide; ISO 9001 and 17025 accredited



- ✓ Lighthouse Facilities and Key Partners
- ✓ Design and Manufacturing in USA
- ✓ Direct Sales and Support in 13 Offices in 8 Countries
- ✓ Sales through our Valued Partners in 87 Countries

INDUSTRIES PERFORMING ENVIRONMENTAL MONITORING

Pharma/Biotech
Semiconductor
Med Device
Aerospace
Automotive
Electronics
Battery/EV
More…..

EM Concerns in Pharmaceutical

- Regulatory Driven, Internal Quality
- Real-time monitoring, room classification, and periodic monitoring
- ISO5 – 8
- .5 and 5 micron particle
- Viable and Non-viable
- Significant investment (key driver in Manufacturing)
- *Contamination Control Strategies* and *Risk Assessments* are heavily employed

EM Concerns in Semiconductor

- Internal Quality and Performance Driven (10, 7, 5, .5 nm….)
- Real-time monitoring, room classification, and periodic monitoring
- ISO1 – 8 (class 1- class 100,000)
- .01 micron and lower
- No viable sampling needs
- Liquid particle counting (UPW)
- *Contamination Control Strategies* are heavily employed and Facilities are highly automated

EM Concerns in MedDevice

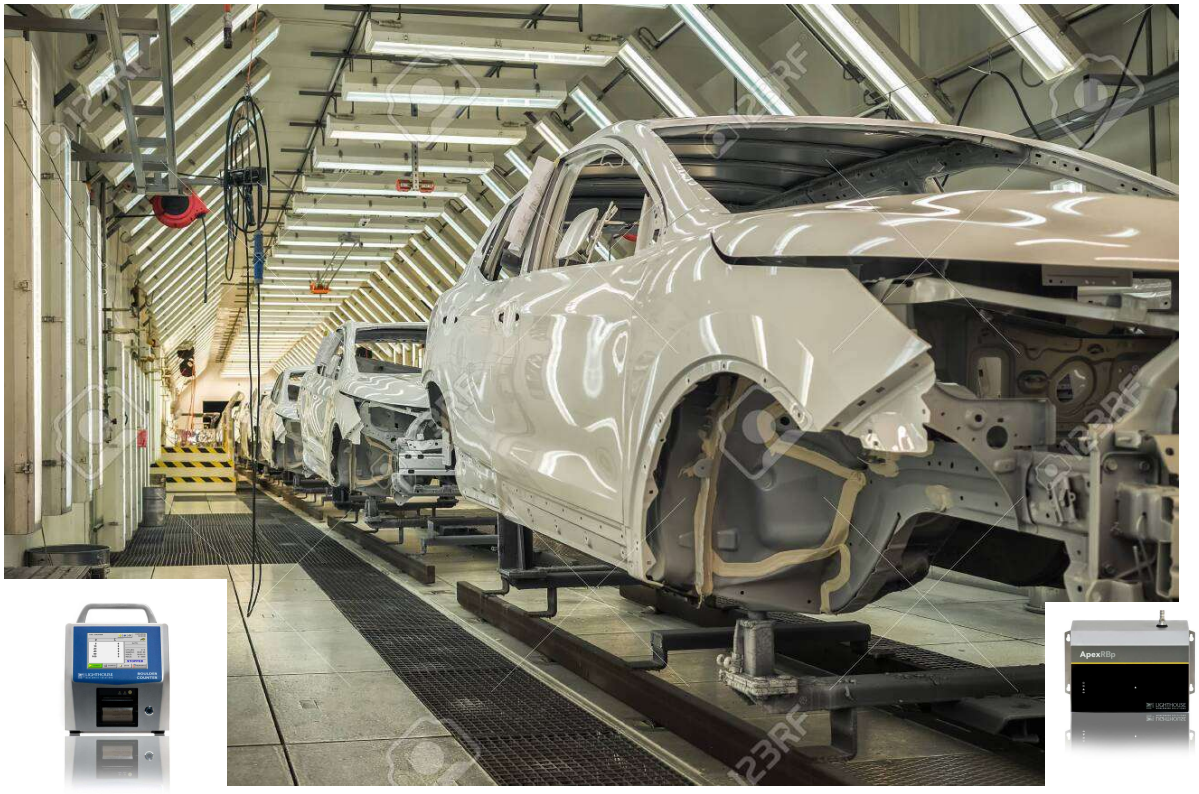
- Both Internal Quality and Regulatory Driven (product dependent – gray area)
- Real-time monitoring, room classification, and periodic monitoring
- ISO5 – 8 (Grade A-C)
- .5 and 5 micron driven
- Viable and Non-viable sampling requirements
- Class 1, 2, or 3 products by risk to patient (only 2 & 3 use EM)
- Terminal Sterilization or Aseptic Manufacturing
- *Contamination Control Strategies* and *Risk Assessments* can be employed

EM Concerns in Aerospace

- Internal Quality Driven
- Real-time monitoring, room classification, and periodic monitoring
- ISO5 – 8 (class 100 – 100,000)
- .3 and above
- Non-viable sampling needs (rarely viable)
- Parts Cleaning applications can be critical (liquid monitoring)
- Facility tools and cleanrooms can be quite large
- *Contamination Control Strategies* can be employed

EM Concerns in Automotive

- Internal Quality and Client Driven
- Real-time monitoring and periodic monitoring
- ISO7 – 8
- .5 and 5 (ISO), but larger particles impact quality most
- Non-viable sampling requirements
- Ease of installation is important (large facilities)
- Real-Time Contamination Control in this area is new to the industry (historically surface samples)

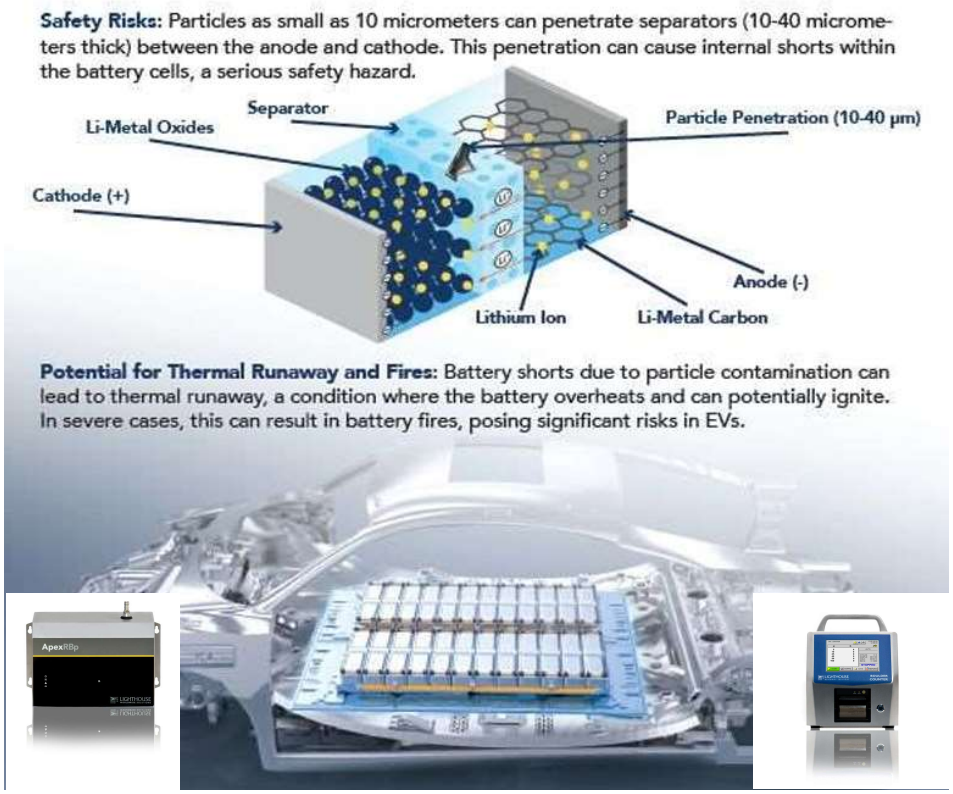


EM Concerns in Electronics

- Internal Quality and Client/Marketing Driven
- Periodic monitoring
- ISO7 – 8
- .5 and 5 driven (ISO check-the-box exercise)
- Non-viable sampling needs
- Considered a competitive advantage
- Customer Facing Parts focus
- ISO Classifications are rarely certified, often only a goal for HVAC
- *Contamination Control Strategies* and *Risk Assessments* are not employed

EM Concerns in Battery/EV

- Internal Quality driven
- Real-time and Periodic monitoring
- ISO 6-8
- .5 and 5 micron (ISO), but 20-40 identified as MPPS (Most Problematic Particle Size), especially metals
- MPPS can imbed in Anode/Cathode separator creating short-circuit
- *Risk Assessments* and *Contamination Control Strategies* can be used
- Hydrogen Cells and lines need verified clean-air during production
- Particle-free production considered critical to reducing dendrite formation and thermal runaway (fires)



Emerging Markets

Data Centers
- ISO 7 & 8 design
- Wide range of drivers (risk, energy, eff.)
- Air and liquids

Healthy Building Design
- More stringent IAQ standards
- High awareness since Covid
- HVAC Bank monitoring
- IAQ; PM2.5

Healthcare/OR
- ISO 7
- Strong in Europe
- Dynamic environment
- Blood centers, tissue banks, pharmacy, etc

Food & Beverage Manufacturing
- New standards being examined (GMP), currently *very* low
- Several high profile problems
- Viable monitoring based (currently reactive)

Various Classification Standards

GMP Annex-1:2009

Current 2009	Maximum permitted number of particles per m³ equal to or greater than the tabulated size			
	At Rest		In operation	
Grade	≥ 0.5µm	≥ 5.0µm	≥ 0.5µm	≥ 5.0 µm
A	3.520	20	3.520	20
B	3.520	29	352.000	2.900
C	352.000	2.900	3.520.000	29.000
D	3.520.000	29.000	not defned	not defned

FDA vs GMP Air Classifications (in operation)

FDA	FDA	FDA	GMP	FDA	GMP	FDA	GMP	GMP	GMP
Clean Area Classifications 0.5µm particles/ ft³	ISO Designation	≥ 0.5µm particles/ m³	GMP Grade	Microbiological Active Air Action Levels (cfu/m³)	Microbiological Active Air Action Levels (cfu/m³)	Microbiological Settling Plates Action Levels (diam. 90 mm; cfu/ 4hours)	Microbiological Settling Plates Action Levels (diam. 90 mm; cfu/4hours)	Contact Plates (diam. 55 mm; cfu/plate)	Glove Print 5 fingers (cfu/ glove)
100	ISO 5	3.520	A	1	<1	1	<1	<1	<1
1.000	ISO 6	35.200	not defned	7	not defned	3	not defned	not defned	not defned
10.000	ISO 7	352.000	B	10	10	5	5	5	5
100.000	ISO 8	3.520.000	C	100	100	50	50	25	not defned
not defned	not defned	not defned	D	not defned	200	not defned	100	50	not defned

ISO 14644-1:1999 Classification of air cleanliness by particle concentration

ISO Class (N)	≥ 0.1µm (m³)	≥ 0.2µm (m³)	≥ 0.3µm (m³)	≥ 0.5µm (m³)	≥ 1.0µm (m³)	≥ 5.0µm (m³)	FED-STD-209 * ≥ 0.5µm (ft³)	≥ 5.0µm (ft³)	Class
ISO 1	10	(2)							
ISO 2	100	24	10	(4)					
ISO 3	1.000	237	102	35	(8)		1		1
ISO 4	10.000	2.370	1.020	352	83		10		10
ISO 5	100.000	23.700	10.200	3.520	832	(29)	100		100
ISO 6	1.000.000	237.000	102.000	35.200	8.320	293	1.000	7	1.000
ISO 7				352.000	83.200	2.930	10.000	70	10.000
ISO 8				3.520.000	832.000	29.300	100.000	700	100.000
ISO 9				35.200.000	8.320.000	293.000			

◯ = Becomes due in ISO 14644-1:2015

Thank you for your time today, any questions?