

Clean Room Application

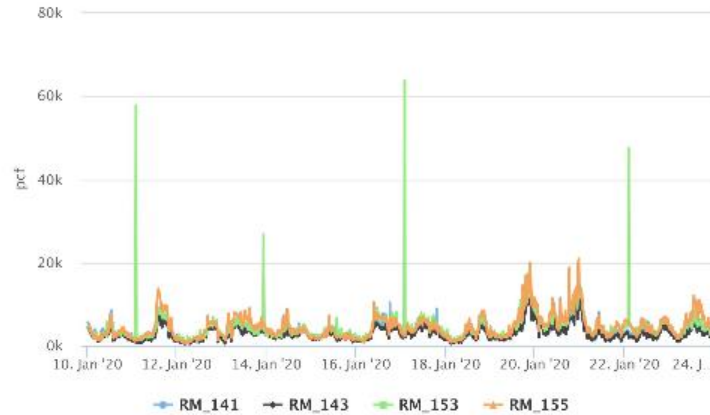


15 Years of Experience Controlling Particles with DBC

- Aircuity has been using Demand Based Control for control of TVOC, CO₂, & Particles for 15 yrs.
 - Laboratories varying ACH between 4/2 and 15 ACH
 - Vivariums varying ACH between 6/4 and 15 to 20 ACH
 - Sterile operating rooms between 4 and 20 ACH
- These applications very similar to cleanrooms
 - Vivariums are very relevant w/ 20 ACH requirements.
 - Control gain and dynamics similar
 - Typically also need low particle counts
- Billions of hours of DBC operation

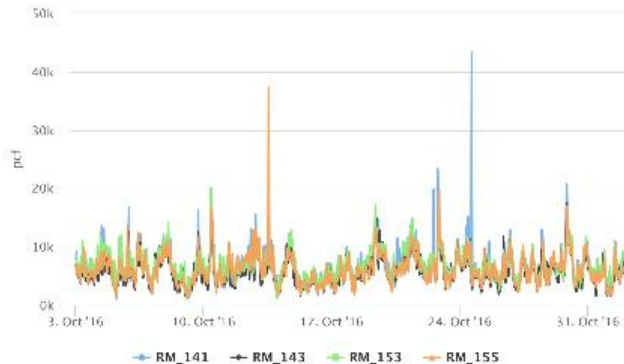
Years of Clean Vivarium Room Control (ISO 7 to 8)

0.5 – 2.5 μm Particles



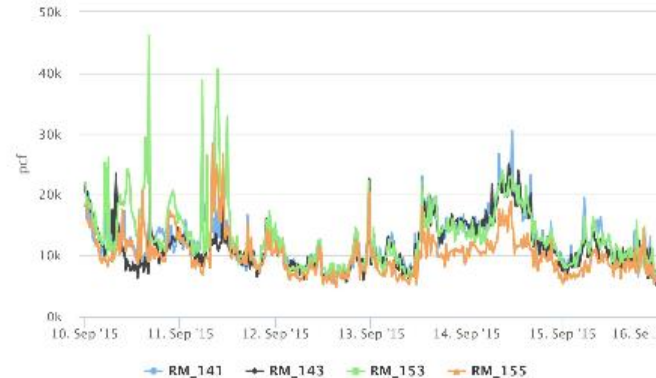
highcharts.com

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Direct Cleanroom Control Experience/Involvement

- Aircuity & Eli Lilly tested cleanroom DBC
 - Eli Lilly tested Aircuity in an operating cleanroom
 - ACH successfully reduced from 20-30 ACH to 6 ACH
- 2010-2020: Helped direct ASHRAE research
 - ASHRAE research project #1604:
 - PMS Member of “Demand Based Control of Cleanrooms”
 - Wei Sun, past president of IEST is principal researcher
 - Successfully demonstrated not only reduction of particle levels through demand control but also PID control of particle levels

Based Control Can Also be Used in Cleanrooms

- Demand Based Control for cleanrooms is currently subject of an ASHRAE research project:
 - ASHRAE RP-1604: Demand Based Flow Control for Cleanrooms
 - Founder Gordon Sharp is a member of the ASHRAE Project Monitoring Subcommittee advising the researcher.
 - Work far more stringent than needed for actual operation



Setpoints & Sampling Time Depend on Generation

Another ASHRAE Research project has done testing and documenting of typical Pharma room particle generation rates



Table 8: Range of particle generation rates for surveyed cleanroom processes.

Process	Particle generation rates (particles/cu.ft/hour)		
	$\geq 0.3\mu\text{m}$	$\geq 0.5\mu\text{m}$	$\geq 1\mu\text{m}$
Formulation (mixing and granulation)	525436.1 ± 372065.5	427075.7 ± 315031.8	398723.8 ± 297658.0
Compression (tableting and encapsulation)	784305.3 ± 836762.8	378179.3 ± 372736.7	142213.5 ± 132437.4
Milling/Blending	77336.8 ± 59291.5	4856.6 ± 3178.659	925.2 \pm 583.2
Cell culture and filling	7438.5 \pm 760.1	2060.2 ± 224.4133	667.1 \pm 59.6
Sterile packaging	10783.8 ± 2102.1	3836.1 ± 815.7724	1899.0 \pm 516.3
Purification	1879.6 \pm 1220.3	414.7 \pm 1115.3	192.5 \pm 568.8
Open powder dispensing*	28493.2 ± 40144.5	7356.8 \pm 10534.4	2107.7 \pm 3687.0
Packaging*	40996.6 ± 44900.4	27399.7 ± 34795.7	19692.1 ± 25815.6
Fermentation**		14050.1 ± 7311.0	4859.9 \pm 1060.5
Aseptic Filling	29684.0	11928.6 ± 1622.5	4903.8 \pm 944.0
Cell culture	9992.4 \pm 958.3	8230.7 \pm 639.2	3250.3 \pm 275.6