



- 4 Process R&D Labs (8 Walk-In Hoods; 8 Bench-Top Hoods)
- 5 GMP Kilo Lab Suites (10 Walk-In Hoods; 5 Bench-Top Hoods)
- 1 Hydrogenation Suite (parr and 20-Liter Medium Pressure Vessels)
- 3 Isolated HEPA-Filtered Drying Suites
- 1 Isolated HEPA-Filtered Packaging Suite
- 1 Spectroscopy Suite (300 MHz NMR; In-Process GC's, HPLC's)
- 2 Walk-in Cold Rooms
- 3 Chemical Storage Rooms
- Hazard Lab (RC-1, DSC, TGA)

Kilo Labs have independent air handling systems with once-through air. Each has temperature, humidity, and room pressure control. GMP suites are isolated under positive pressure with ASHRAE 95 filtration. Labs have central vacuum as well as Glycol loops for reaction cooling or chilling of condensers. Each lab can accommodate a wide variety of glassware up to 50-liter scale.

BUCHI-ROTOVAP BENCHES

Each lab is equipped with Buchi-Rotovap benches and can accommodate multiple rotovap systems. Therminol loops (-20°C) are available at each Buchi bench for more efficient use of condensers.

KEYCARD SECURITY SYSTEM

The kilo lab areas are accessed via a keycard security system.

HYDROGENATION SUITE

The hydrogenation suite contains once-through air with an appropriate level of safety to house several parr

shakers and a 20-liter medium-pressure hydrogenator (300psi).

HAZARD LAB

CML's Hazard Lab contains RC-1, DSC, and TGA for performing calorimetry studies on intermediates and final products. CML will perform hazards analysis on projects going from laboratory to plant, as well as any materials where a potential hazard exists.

DRYING AND PACKAGING SUITES

The drying suites are each HEPA-filtered once-through air, with an air lock corridor. Each accommodates a vacuum tray drying oven. The packaging suite is also once-through HEPA-filtered air, and accommodates a walk-in hood where the packaging occurs. All rooms are accessed via keycard security system.

DESIGN OF EXPERIMENTS

CML can perform process research with automated parallel experimentation, analogous to combinatorial chemistry in drug discovery. CML has the resources to incorporate design of experiments (DOE) to set up modeling. Through DOE experiments, multiple variables are changed simultaneously to find the optimum process, as opposed to the more classical approach of changing one variable at a time (OVAT) and finding the best value of one parameter before moving on to the next.



4 PROCESS R&D LABS:

- 4 walk-in hoods; 20 bench top hoods
- 250 ml to 25 Liters
(50 total reactors totaling > 500 L)

4 SCALE-UP GMP KILO LABS (CLASS 100.000):

- 30 L glass lined reactor
- 50 L glass lined reactor
- 50 L Hastelloy-C reactor
- 60 L vacuum filter (stirred)
- 20 L, 30 L, 2 x 50 L separating funnels
- 2 Hastelloy closed filters

DRYING AND STORAGE CAPABILITIES

- Drying capabilities up to kg level
in vacuum tray dryer
- GMP storage

NEW LABS COMPLETE

- 10 bench top hoods for Process
R&D in 2 separate labs
- 2 fully isolated GMP suites
 - Class 100.000 equipped with
1 bench top hood and 2 walk-in
hoods
 - 250 ml to 35 Liter scale
- Solid State Lab (see separate list)

The facility houses a complete capability for process research, development, and scale-up with a variety of benchtop and walk-in hoods to accommodate projects from gram scale up to multi-kilo production in a GMP environment. Labs are outfitted with glassware up to 80 liters, rotary evaporators, and drying capabilities up to kilogram scale.

The laboratories contain equipment capable of -100C up to 250C, as well as high pressure equipment and capabilities for high vacuum distillations. The design and layout of the laboratories ensures that projects will flow smoothly in a controlled environment from lab scale up to pilot plant. Several jacketed reactor systems mimic the plant environment, thus making process scale-up into the plant as predictable as possible.