



- 6 Process R&D Labs (10 Walk-In Hoods; 16 Bench-Top Hoods)
- 8 GMP Kilo Lab Suites (16 Walk-In Hoods; 7 Bench-Top Hoods)
- Hydrogenation Suite (parr and 20-Liter Medium Pressure Vessels)
- 3 Isolated HEPA-Filtered Drying Suites
- Isolated HEPA-Filtered Packaging Suite
- Spectroscopy Suites 2 X (300 MHz NMR)
- Hazard Lab, Thermal Hazard Unit, DSC, TGA
- 3 Walk-in Cold Rooms
- 3 Chemical Storage Rooms

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

Also included is a hazard lab which contains multi-well DSC for performing calorimetry studies on intermediates and final products. TGA and DSC are also available. 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.



**SUITE 1 CONTAINS:**

- 1 x 50 Gallon GLR (DeDeitrich)
- 1 x 100 Gallon GLR (DeDeitrich)
- 1 x 100 Gallon Stainless Steel (Apache)
- 1 x 50 Gallon Stainless Steel Receiver
- Various Stainless Steel Nutsche Filtration Units
- Centrifuge Unit

**SUITE 2 CONTAINS:**

- 1 x 50 Gallon GLR (DeDeitrich)
- 1 x 100 Gallon GLR (DeDeitrich)
- 1 x 25 Gallon Stainless Steel (Apache)
- 1 x 50 Gallon Stainless Steel Receiver
- Various Stainless Steel Nutsche Filtration Units

**EDISON DRIVE PLANT CONTAINS:**

- 2 x 50 Gallon GLR (DeDeitrich)
- 2 x 100 Gallon GLR (DeDeitrich)
- Various Stainless Steel Nutsche Filtration Units

Our facilities house 3 mini plant suites with reactors up to 100 gallons. Each suite uses ASHRAE filtered air, and is fully isolated to ensure no cross contamination during API production runs.

**FILTRATION /DRYING:**

Supporting each suite are a variety of enclosed stainless steel Nutsche filters, centrifuges and tray dryers which are located in HEPA-filtered drying suites.

**CONTROL SYSTEMS:**

Heating and chilling is accomplished via a computer-controlled series of hot, ambient, and cold loops allowing for a temperature range of -20°C to 165°C. Vacuum is controlled via the computer system using water-ring or high-vacuum Bush oil pumps. A full scrubber system is also employed. Each suite has a control room with an Allen Bradley control system with graphical user interface.



**REACTOR BAY 1:**

- 1 x 50 Gallon GLR (DeDeitrich)
- 1 x 100 Gallon GLR (DeDeitrich)
- 1 x 300 Gallon GLR (DeDeitrich)
- 1 x 500 Gallon GLR (DeDeitrich)
- 1 x 200 Gallon GL Receiver
- 1 x 40" Centrifuge
- 1 x Helical Cone Dryer
- Various enclosed Stainless Steel Nutsche Filtration Units

**REACTOR BAY 2:**

- 1 x 75 Gallon, 250 psi Hydrogenator (Apache Stainless) in Separate Building
- 1 x 500 Gallon GLR (DeDeitrich)
- 2 x 300 Gallon GLR (DeDeitrich)
- 1 x 75 Gallon Cryogenic (-80°C) Reactor (Apache Stainless)
- 2 x 100 Gallon GLR (DeDeitrich)
- 1 x 50 Gallon GLR (DeDeitrich)
- 1 x 200 Gallon GL Receiver
- Various Stainless Steel Nutsche Filtration Units
- 1 x 26" Centrifuge
- 1 x 40" Centrifuge

The Washington Drive facility houses 2 main plant bays with reactors up to 500 gallons. Each bay contains several reactors and utilizes ASHRAE 95 filtered air.

**FILTRATION/DRYING:**

Also available to both plant bays are HEPA-filtered drying rooms accommodating tray dryers. In addition the Plant houses a helical cone dryer with agitation. Filtration is accomplished using portable, enclosed Nutsche filters or centrifuges.

**CONTROL SYSTEMS:**

Heating and chilling is accomplished via a computer-controlled series of hot, ambient and cold loops allowing for a temperature range of -20°C to 165°C. Vacuum is controlled via the computer system using water-ring or high-vacuum Bush oil pumps. A full scrubber system is also employed. A cryogenic reactor system is computer controlled using a liquid nitrogen loop system with control down to -80°C.

Each bay has a control room with an Allen Bradley control system with graphical user interface.



**MAJOR EQUIPMENT:**

- GC-FID (Agilent 5890 and 6890) with Headspace/Liquid Injection Capabilities
- GC-MS
- HPLC (UV, Diode, CAD, RI)
- LC-MS
- GC-MS
- FT-IR
- NMR (2 x 300 MHz)
- UV/Vis
- ICP-OES
- KF (volumetric and coulometric)
- Melting Point
- TGA/DSC

The facility houses a state-of-the-art analytical laboratory and controlled environmental chambers to support ICH stability studies. Cambridge Major provides analytical support for in-process controls, quality control release testing, reference standard qualification, and method development/validation in compliance with FDA cGMP requirements and ICH guidelines.

CML performs most compendial testing according to USP/NF, EP, BP, JP, and ACS monographs. This can be for raw materials, intermediates, or API release testing.

Our method development and validation services includes:

- Stability Indicating Methods
- Organic Volatiles Impurities
- Cleaning Validation/Verification method (specific and non-specific)
- In-Process Controls
- Forced Degradation and Impurity Identification

CML also offers comprehensive stability storage & testing by ICH guidelines. This includes ambient, intermediate, and accelerated conditions.

