


POTENT COMPOUND SUITE


Q4 2014



A recent increase in development of new active pharmaceutical ingredients (APIs), especially in oncology, is towards higher potency levels and pharmacological activity. In order to keep up with industry trends, Regis intends to add potent compounds handling to its services. Our plan for 2014 is to develop a wide range of advanced capabilities, from analytical and process development to GMP production at lab scale. This upgrade will enable Regis to supply potent APIs for pre-clinical and Phase I/II clinical trials.

Following the Board of Advisors decision to move forward with this new investment, the execution of an aggressive timeline has started:

- The concept design was created and equipment proposals were collected
- Chemical storage area was relocated to make space for the potent suite construction
- The containment isolator manufacturer has been selected
- Construction of new offices and conference room have been started on the second floor
- The mockup (full size model) of the containment isolator was constructed for evaluation of ergonomic aspects by future users
- Ventilated balance enclosures (3x) and hybrid isolator (1x) have been delivered to Regis site for installation in analytical labs and GMP production lab



Proper handling of potent compounds involves the use of specialized facilities that are carefully designed to minimize containment risks. This would involve equipment such as isolators, laminar flow hoods, and local exhaust ventilation appropriate for potent compound handling. The construction of dedicated laboratories will be the initial step by Regis to invest in potent API technology, with the potential for expansion and improvements to meet customer demand.

— Dragan Ristic, Process Engineer



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