API Lab of the Future Drives Scientific Excellence

The API (Active Pharmaceutical Ingredient) Lab of The Future (LOTF) has arrived and is positively impacting the Pfizer portfolio by rapidly providing process understanding and subsequently impacting commercial chemistry, driving API costs down and scaling-up with greater robustness.

The prototype labs were strategically designed to run development activities in parallel, implement novel predictive scale up tools, streamline documentation and use highly coordinated activity plans, including efficient project management, real-time engineering and analytical engagement, and releases. Enhanced process understanding enables savings in time and resources and increases the speed of workflow execution.

“PharmaTherapeutics Pharmaceutical Sciences’ $1.2 million investment in two prototype labs has already delivered impressive results in the first few months of their operation,” said Chemical Development Vice President Lynne Handanyan. “In addition to the tangible benefits to several projects, we have also seen a change in culture that has resulted from closer working and integration between the scientists from a range of disciplines; chemists, engineers and analysts, who collaborate to produce API manufacturing technology.”

Traditional vs. New LOTF Labs

LOTF promotes efficient use of chemistry labs, with dedicated spaces set up to conduct experiments using the most appropriate equipment. In the old laboratory system, colleagues worked within a fixed space. More efficient use of equipment in dedicated spaces means floor space can be released for other uses.

TRADITIONAL LAB
Like a closet, traditional lab space can quickly fill up with clutter due to the constant set up and breakdown of equipment during experiments.

API LAB OF THE FUTURE
The new prototypical labs encourage the “intensification" effect; more is packed into a smaller footprint.

The API Lab of the Future also offers comprehensive set of innovative laboratory technologies which bring diverse disciplines together, allowing scientists and engineers to use a greater range and sophistication of tools to when solving a scientific problem. For example, jacketed reaction vessels allow reactions to be more carefully controlled and measured with analytical technology allowing scientists a greater ability to understand the chemical process under optimization. This greater clarity allows underlying problems to be identified more quickly and solved.

Another LOTF advantage is the co-location of team members from different disciplines. Chemists, engineers and analysts are able to communicate more frequently and effectively in this environment.

Savings in Time and Material Resources

LOTF's more integrated workflow drives scientific excellence across disciplines and is delivering impressive results in its first several months of operation.

Groton scientists working on PF-04802540, a schizophrenia candidate, needed to find chemistry that was robust enough to transfer to a Contract Manufacturing Organization (CMO) in China to meet the bulk demands of the program. Timelines were tight, and the chemistry was very challenging, with non-reproducible yields and highly exothermic chemical reactions. These problems, intractable to many conventional scientific approaches, were solved by a team using the API LOTF in a matter of weeks and delivered an estimated $500,000 in material savings.

In another example, the PF-02341066 API team in Sandwich was challenged to rapidly deliver commercial API technology. This was needed to support a 150 kilogram API campaign planned for early 2010 to support clinical trials of this fast moving oncology program.

Traditional development approaches would have produced results over many months. However, applying the capabilities and collaborative workflows in LOTF enabled the project team to deliver a process at one-third the cost of the original route and facilitate decisions within 10 weeks. The more efficient process only required half the number of steps as the original process. These improvements translated into big savings; nearly $500,000 in raw material costs were saved in the 150 kg campaign, potentially saving millions of dollars per year at the commercial scale of production.

"This process understanding allows us to more effectively nominate the most economical bond-forming chemistry and design the most efficient process in time for downstream campaigns," said Gemma Cansell, a member of the PF-02341066 project team. "The knock on effect of this is fewer raw materials at lower cost."

LOTF Impact: Transformational Change

In just one year of operation, API projects executed in LOTF labs have reduced the raw material costs for ongoing and planned campaigns by over $1.6 million, while significantly increasing knowledge and understanding of the API technology.

In 2010, the Lab of the Future will expand from a pilot program in two prototype labs, rolling out to several additional API labs in both Groton and Sandwich.

"Everyone involved in the API LOTF network is really excited by the progress we have made so far. The value is clear to all of the projects and teams that have experienced working in this environment," said LOTF Program Team Leader Laurence Harris.