Around the World with AMRI, Part 5

MIKE AUERBACK, Editor-in-Chief, Pharmaceutical Processing

This is part five of a five-part piece. Part one can be found here. *[1]* Part two can be found here. *[2]* Part three can be found here. *[3]* Part four can be found here. *[4]* [4]

Commercial Production

Moving on to the larger production capabilities at the site, AMRI Rensselaer offers:

1. Four large production buildings.
2. 42 discrete chemical reactors, comprising a mixture of glass-lined steel, Hastelloy and stainless steel reactors.
3. Four dedicated pressure-rated vessels for hydrogenation capable of operating up to 90 PSIG.
4. Eight jacketed pressure filter-dryers (1.5 to 6.0 m2).
5. Additional drying capabilities that include cone dryers, tumble dryers and vacuum tray dryers.
6. Experienced technical services, chemistry and engineering services for process evaluation, implementation, use testing, reaction monitoring and trouble-shooting.
7. Full-service GMP warehousing with ambient, USP, refrigerated and freezer storage conditions.

Backing up and providing an essential service to all of this pilot plant, scale-up, high potency and production capacity is the site's quality control lab. According to Brian

Haney, Ph.D., Section Head Commercial Manufacturing, one of the benefits to having all of that analytical capability on-site is for rapid troubleshooting. “If we are conducting early scale-up work and something goes wrong, we can immediately assign resources to the problem. Our scientists can usually figure out what the problem is very quickly, which gives us ideas how to adjust the scale-up process.”

“That’s where the power of these labs comes in handy -- the immediate response to situations as they arise,” Haney concludes.

From analytical and quality control services, to compound and process development, pilot plant and scale-up through commercial manufacturing, AMRI offers a wide range of capabilities to the pharmaceutical customer looking for an outsourcing partner.

“We have everything a large pharma company has, but without that large pharma culture,” says Saffee. “We deliver on the costs, the quality and consistency of service, and we are focused on our customers’ deadlines and success.”

“When we demonstrate how thorough we are in our operations -- we gain our customers trust and they keep coming back.”

“For a customer the value/benefit is that they can stay with AMRI the whole way. In addition, customers get a very capable project management team. Most members of our project management teams are scientists, they have come through the development function, so they can speak the language, and they understand the chemistry and serve as the go-between and the voice of the customer when they are not around. Our customers are global -- and we are available 24 hours a day.”

Looking Forward

With a worldwide operation backed by the technical expertise needed to provide exemplary service to a global customer base, one might think that the company would be content to rest on its laurels, but that’s not the case. AMRI recently launched a new program called SMARTSOURCING™, which is a series of strategic sourcing options for its current and future customers to reach more successful outcomes.

SMARTSOURCING™ is a pioneering approach for the industry that is fit for purpose in today’s world and puts the power of decision making, without compromise, in the hands of the customer.

According to Thomas E. D’Ambra, Ph.D., President and CEO of AMRI, “Pharma companies are looking for more supplier accountability, greater trust and consultation. They want a better balance of risk, but also greater flexibility and tailored business models that address their unique needs. We wouldn’t be in business without our customers and we take this seriously. Our goal is to continue to improve our operations and performance because helping our customers to succeed is our mission.”

To read part one of this five-part series, please click here. *[1]To read part two of this five-part series,* please click here. *[2]To read part three of this five-part series,* please click here. *[3]To read part four of this five-part series,* please click here. *[4]*

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