Around the World with AMRI, Part 1

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With markets and opportunities constantly changing, growing and shifting around the globe, pharmaceutical companies are now, more than ever, eager to tout their global capabilities. In the world of pharmaceutical contract manufacturing, this desire is no different. While many pharmaceutical outsourcing providers may claim to have global reach, it is the rare company that can back up this statement with physical operations and personnel in many of the world's hottest marketplaces. AMRI, which maintains its corporate headquarters in Albany, NY, is one of those companies that has the facilities and technical expertise to operate anywhere in the world.

The company boasts operations in Albany, Rensselaer and Syracuse, N.Y.; Burlington, Mass.; Hyderabad and Aurangabad, India; and Holywell (Wales), United Kingdom. According to Steven Hagen, Ph.D., the company's Vice-President of Pharmaceutical Development and Manufacturing at AMRI, the company's goal is to "carry out services in an integrated fashion. We try to utilize our assets around the world to provide timeliness, service and quality to provide value to our customers."

The company accomplishes this by leveraging its global facilities and the specific expertise each site has to offer. As Hagen explains, "In general if you have a commodity type of product you might look toward India; if in Europe you could use our UK site; if you need high capacities or tonnage of API the Rensselaer facility is ideal for that. We have aligned our operations to provide our customers with a complete supply chain no matter where they are in the world, and the quality and capability of our staff is comparable regardless of location."

The World Tour

The capabilities of AMRI's worldwide facilities are loosely categorized as either providing pharmaceutical services or chemical development services. The pharmaceutical services sites mainly provide drug product development and manufacturing, as well as the associated regulatory capabilities, while the chemical

development sites provide chemical process development and small and large scale API manufacturing capabilities. But within this network there is much crossover and complementary overlap.

For example, the company's Albany site provides formulation development and preformulation studies in support of non-sterile GMP drug product manufacturing in Rensselaer, NY, and aseptic fill and finish GMP manufacturing in Burlington, MA. The Holywell, UK operation offers kilo lab, pilot plant (GMP) and large scale manufacturing capabilities. And, as Hagen points out, it also offers a number of benefits to the company and its customers, "The UK site can perform chemical process development and small scale manufacturing. We often see Holywell as an entry point into the rest of AMRI for our European customers. What we have found is that for development scale work most of our customers want someone relatively close by to get the work started and then once the project gets some legs and starts to expand you can bring it into a larger network. But at the beginning it's very complicated; there are a lot of people involved and you need to move quickly – it's good to have a local point of contact."

AMRI's Hyderabad Research Centre offers custom synthesis services from lab scale-up to kilo lab amounts. The Centre's cGMP analytical chemistry services include: chromatographic (HPLC, GC) method development and validations; stress degradation studies to develop and validate stability indicating methods; impurity identification by LCMS, GCMS and NMR; reference standard certifications; and wet chemistry tests as per USP.

The Hyderabad research facility works in conjunction with and complementary to AMRI's Aurangabad facility which offers facilities for generic API production and has a capacity of approximately 70,000 liters. The facility also manufactures GMP intermediates and boasts two 500 liter, two 1,000 liter glass-lined reactors, and a 750 liter cryogenic reactor.

Closer to home and falling more under the chemical development umbrella are the facilities in Albany, NY which provide services such as process development, design of experiments (DOE), critical processing parameter (CPP) studies and tech transfer along with biocatalysis and fermentation capabilities. The Syracuse, NY site offers small scale pre-clinical batch production of APIs and intermediates, rapid response services and route selection and early scale-up activities.

"All of our sites can handle API development," notes David Lathbury, Ph.D., AMRI's Vice President of Chemical Development, "but each have their strengths. Underneath everything is the need for process understanding and analytical capabilities. You have to put all of this together. For example you need to know – this is how it works, why it works, this is why we get these impurities, this is how we identify and control impurities and it all comes together. Process understanding ultimately leads to process validation which then enables you to file for approval. However, even in early phase API development, process understanding is vital in terms of future optimization and basic risk management."

"The integration of manufacturing with analytical and chemical development is our

strength. Some companies do bits of it well – but our approach to eventual commercial manufacturing sets us apart from many other CMOs," he concludes.

Commenting on the company's wide breadth of pharmaceutical services and chemical development capabilities, Hagen sums it up succinctly, "What we've tried to create is a pharmaceutical services organization that can handle just about any lead compound, get it to where it can be applied to animal or human studies, work that through development and commercialization so that our customers can efficiently get it out on the market."

Please tune into tomorrow's Chemical Equipment Daily *for part two of this five-part series.*

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