

Outsourcing's Boomerang Effect

More projects are being sourced closer to home, but, attention to detail is critical, wherever partners are based, says Ash Stevens CEO Stephen Munk.

BY PAUL THOMAS, SENIOR EDITOR

MICHIGAN API manufacturer Ash Stevens has grown to the point where it now has an international supplier and client base. Stephen Munk, President and CEO, discusses pharma outsourcing trends and shares some of his company's strategies and best practices. Clear communication and attention to detail are key, he says. (Note: For the full audio version of this interview, visit Pharma-Manufacturing.com.)

PhM: It seems that drug manufacturers are staying closer to home in choosing suppliers and contracting partners. Would you agree, and what explains it?

S.M.: Absolutely. Certainly, the darling of the industry was outsourcing to low-cost regions like India and China. But I think communications, difficulties in project management, and some quality issues—we're all aware of the heparin problems and issues that Ranbaxy has had—have driven people back to the United States. Partners still do, however, expect pricing that's more comparable to what they see in Asia.

PhM: Pricing pressures are something you deal with every day, but you've chosen to invest in your Michigan facilities and expand there, rather than to look overseas or outsource. Can you elaborate on this decision from a business perspective?

S.M.: We're a relatively small company but have chosen to invest on the order of \$20 million here, and we'll continue to invest here. We've sourced a lot from Asia, and there are a large number of reputable firms there, but for the foreseeable future our investments will continue to be in the United States.

I don't want to have to manage sites across multiple time zones. North Carolina or Nevada might be fine, but I don't want to have to manage something 12 time zones away. We've certainly had success in North America, and we have a good pool of talented scientists and engineers from which to choose, and having good control over our

product is important—that's what our customers expect.

PhM: You do source from all parts of the world. What criteria do you use to assess potential suppliers and vendors?

S.M.: Reputation. Typically if they have a good reputation we'll give them some small projects that are less on



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the critical path for us. If they continue to do a good job and we develop a relationship, we'll give them bigger and bigger projects. The things that drive our decisions of who to source with are timeliness of delivery, quality, and communication skills.

And certainly once we get the product we'll do rigorous testing if it's not made in our facilities, no matter where in the world it comes from. Rigorous testing is mandatory.

PhM: You mentioned communication skills. I gather it's not just a language thing but a broader communication issue?

S.M.: It's more a question really of project management. Chemistry is still very much an experimental science, and as such you frequently encounter rocks in the road. It's very important to communicate quickly and clearly what issues are when they come up. There certainly are occasions in an experimental field when timelines aren't able to be met, and we expect quick, clear, and concise communication when those hiccups arise.

Some people believe they can manage through a crisis and avoid having to deliver bad news. From our

perspective, we want to know bad news much quicker than we do good news.


PhM: *What kind of raw material testing and assessment do you do, and what kind of guarantees do you expect from suppliers?*

S.M.: It certainly depends on the material. HPLC and GC for purity are critical, and we try whenever possible to have weight-based assays. We had an experience a couple years ago in which someone sent us a raw material that they wanted us to qualify. By HPLC the material was clean. Our analyst noticed, however, that the area counts were low compared to what she anticipated, so she did a little further investigation and found there was high ash. So you have to be certain that the tests you use are technically and scientifically relevant. Often it's a combination, rather than just one metric. Especially with HPLC, if you're not looking for something you're not always going to find it.

PhM: *You yourselves are scrutinized as a supplier for global manufacturers. What have you learned about satisfying their expectations and navigating different regulatory environments?*

S.M.: In general the difference between a successful project and less successful project is an attention to detail. Certainly, various [global] regulatory agencies have different expectations. The FDA tends to spend the bulk of its time reviewing analytical chemistry data and analytical labs. When we were visited by the Japanese Ministry of Health, they actually got up on our roof and looked into our HVAC units to see how clean they were. So it's important to pay attention to all the details and understand that there are cultural and country differences in how inspections may proceed.

PhM: *You've been able to weather the tough economy better than some other manufacturers. What's been your secret?*

S.M.: FDA has really only approved 100 new chemical entities in the world in the past six or eight years, and we make three of those, so that helped get us through what for many was a difficult period. The reason that we had that success was due to a relentless pursuit of details and a focus on regulatory compliance. 

OUTSOURCING NEWS AND NOTES

California's AutekBio, Inc. will build Asia's largest biologic CMO facility in southern Beijing. The company received more than \$100 million in venture capital from various sources.

Indian API supplier **Aurobindo Pharma** has launched a contract manufacturing services division, **AuroSource**, to cater to global pharma and biotech companies. **AuroSource** will function as a division within the company providing custom R&D and manufacturing (CRAMS) services.

Specialist pharma **Auralis** has contracted with UK-based **SCM Pharma** to manufacture its new epilepsy product, **Buccolam**, which is administered buccally.

Cambridge **Major Laboratories, Inc.**, **Avantium Pharma**, **Xcelience**, and **Beckloff Associates** have formed a consortium to launch **Chemistry Playbook**, an CMC solutions program designed to accelerate drug development. "We fit the process to the situation, not the other way around," says **Xcelience** CEO & President **Derek Hennecke**.

Michael Curry has been named Director of Sterile Operations at **DPT Laboratories'** Center of Excellence for Sterile & Specialty Products in Lakewood, New Jersey. **Curry** held previous positions with **BioVigilant Systems**, **The Medicines Company**, **Dendreon Corp.**, **Wyeth**, **Baxter Bioscience**, and **Schering-Plough**.

W. R. Grace & Co. has earned Good Manufacturing Practices (GMP) certification of its facility in Baltimore. The certification encompasses **Grace's** Quality Management System that includes the standards, procedures and manufacturing operations used in the production of pharmaceutical grade silica.

The International Quality and Productivity Centre has recognized contract packager **Anderson Packaging** with a Process Excellence Award for a Lean Six Sigma project on its Rockford, Illinois pharma bottling lines.

Compass Pharma Services has upgraded its Clifton, N.J. packaging to include ISO Class 8 facilities, and added blister packaging capacity.

Cardinal Health was awarded a \$206,434,187 prime vendor contract by the U.S. Department of Defense for distribution of pharmaceutical items.

Patheon reported greater first-quarter losses than expected, due to "soft market demand" and lower revenue in its pharmaceutical development services unit, said CEO **Wes Wheeler**, who also stated, "we have seen an encouraging increase in new sales activity as improved funding has become available."

CRO's Pharmaceutical Product Development, Inc. and **Southern Research Institute** will collaborate on pandemic and seasonal flu vaccine research and development.