

BAXTER BLOOMS

MICHAEL BORLET, Sr. Director of Sales, and **RAUL SOIKES**, Sr. Director of Program Management at Baxter Healthcare Corporation, talk to *Future Pharmaceuticals* about the BioPharma Solutions facility in Bloomington, Indiana and what sets it apart from other CMOs

Future Pharmaceuticals Let's start with a view on the market landscape. **What is happening in the contract manufacturing organization (CMO) market as it relates to outsourcing of parenteral pharmaceuticals and the role of the BioPharma Solutions facility in Bloomington, Indiana?**

MICHAEL BORLET There are a number of accelerators and decelerators in the injectable CMO market right now. Examples of these include the fact that outsourcing of new approved molecules doubled from 2007 to 2008, a trend towards non-blockbuster molecules, and various economic conditions including mergers and acquisitions. New approvals have been robust with an increased portion of units being outsourced. However, total units per approval have been lower and the future approvals pipeline continues to be robust with about a 50/50 split between small molecules and biologics. These economic pressures and

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the pharma industry's evolution are driving a turbulent set of dynamics that offers opportunities and threats to future growth.

This also means that competition for molecules has grown stronger with the trend towards more injectable molecules with fewer units. That is, when a company does outsource a molecule, they are looking for a CMO that is as committed to the molecule's success as they are. It has been important for us at our Bloomington, Indiana facility, where we provide fill and finish services for syringes, vials and cartridges, to implement processes that will set us apart within the market landscape.

FP What is the Bloomington advantage? And you mentioned setting yourself apart from other CMOs — how are you accomplishing this?

RAUL SOIKES Our Bloomington facility has a proven track record of being a reliable primary and secondary supplier with strong parenteral knowledge, a world-class research and development team, redundant filling lines, quality processes, an excellent regulatory track record, and most importantly, best-in-class employee teams. In our history of manufacturing, we have helped many partners improve their production yield and minimize the loss of costly API during production processes.

We also understand that many existing CMO customers describe their current service providers overall as “minimally acceptable.” We have listened to our clients and have designed and set up our processes around them to make working with us easier. We have done a number of things this year, including adding cross-functional client teams, so that every client has the resources dedicated for their project's success. These resources enable the client to seamlessly initiate, develop and track their molecule's journey to market. This model works well for our Halle, Germany facility and is a best practice for us.

In addition, we have made significant investment in our capabilities surrounding both vial and syringe filling. The Bloomington facility houses some of the most advanced sterile manufacturing equipment, and we take pride in our leadership and expertise in aseptic filling.

Baxter is enthusiastic about these changes and so are our clients. In fact, in 2006, we were awarded the ISPE Facility of the Year award for our \$100 million expansion, and then most recently, we were honored with the 2008 North American Contract Manufacturing Customer Service Leadership of the Year award from Frost & Sullivan.

FP What has been the employee impact of winning these awards?

RS It really confirms and supports our passion for customer service and

continuous improvement. Our employees have earned the trust of our customers by meeting specific customer needs and understanding the marketplace in which they participate. We recognize that our ultimate customer is the patient, and that our efforts play a vital role in saving and sustaining lives.

FP What are some other areas that set Bloomington apart?

MB We have also introduced Process 360° to our clients, which is an effective project management system that offers an efficient and reliable path from the planning stages to the production of their product, whether it is a pre-filled syringe or a freeze-dried vial that we are manufacturing. The Process 360° experience allows our clients to effectively plan, monitor and measure their projects transparently from start to finish in six easy steps. This process allows us to engage in constant communication with our clients, keep them updated with metrics and ensure that we are delivering quality service at all times. We also recognize the importance of operational excellence and have embraced this within our culture.

In addition, our regulatory group is also a key differentiator. Our clients are looking for a CMO that can provide proven expertise to minimize regulatory risks and launch delays and a partner that has experience across the world. We have a strong record of compliance and have manufactured products for more than 40 countries across the globe. This support is directly related to the confidence a pharma partner can have in the services we provide.

FP In relation to customer focus, please describe some of the programs that are in place to engage employees and reinforce client-centric attitudes.

RS Our vision is to be the global manufacturing partner of choice by caring for our customer's product as if our own health depends on it. Our employees understand our purpose and we also have a program called “What I Do Today” that is a campaign to remind employees of the important responsibility we have to the ultimate client of the products we produce — the patients and their families. There are reminders of this higher purpose throughout our facility.

FP What will your group do to remain competitive in the future?

MB As I mentioned, there are a number of factors that are affecting the marketplace. We will continue our relentless focus on flawless execution and outstanding customer service and look for new opportunities to add value to our partners' products. We believe that there is an opportunity to innovate drug delivery surrounding patient convenience. We look forward to partnering with our clients to better serve healthcare. **FP**



MICHAEL BORLET is Sr. Director, Sales, with Baxter BioPharma Solutions at Baxter Healthcare Corporation. He has been with Baxter since April 2007. Previously, he served as BioPharma Solutions' Director of Marketing, where he was responsible for all business-to-business global marketing activities related to product launch, market intelligence, services, brand management and strategy. He is an 18-year veteran of the life science and biotech industries.



RAUL SOIKES is Sr. Director of Program Management with Baxter BioPharma Solutions at Baxter Healthcare Corporation. He is responsible for global contract manufacturing, project management of small volume parenteral products, and small/large volume enhanced parenteral packaging using Baxter's proprietary technology. His expertise includes process/product development, validation, in-house/contract drug substance, drug product and immuno-diagnostics manufacturing, project management, risk management and more.