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## Q&A with

**Shaun Newlon, vice-president of manufacturing  
at Baxter International**

**PharmTech:**

Do you see a new industry trend emerging?

**Newlon:**

For solutions, I see a trend toward the production of more biologic agents, rather than conventional, chemically synthesized drugs, which translates to a major shift in manufacturing processes. With the higher value of biologic active ingredients, our manufacturing risk of loss increases. We have seen a strategic shift away from traditional economies of scale and high-speed lines toward small batch sizes with the goal of eliminating scrap and minimizing losses. Our manufacturing systems must be designed for more agility instead of our traditional focus on high run rates.

I also see a trend toward greater use of contract manufacturing services. Small biotech firms and large pharmaceutical companies are identifying manufacturing capability gaps or focusing internal assets on research activities, which spurs them to seek outside manufacturing as extensions of their own operations. Contract manufacturing plants must be customer-oriented entities that provide services and deliver products.

**PharmTech:**

What is the most common demand your clients are currently making of you?



**Newlon:**

One of our most regular client demands is the concept of available capacity on demand, especially in contract manufacturing. The desire for instant access and instant response has permeated our collective consciousness, and that extends to pharmaceutical manufacturing. We have to recognize immediacy as a customer expectation and design our contracting and planning systems accordingly. Although not always easy to manage, it's a necessary part of our successful business model.

Another request we get is to have greater flexibility in the quality agreements that define and govern our daily operating parameters. It is extremely challenging for two companies, each with different risk profiles, to be comfortable with the particulars of each other's quality systems and make them work in complementary fashions in a strict global regulatory environment. The good news is that people in our industry are passionate about acting responsibly to do what is right for patients.