PCI Synthesis Identifies Trends Affecting the Generic Drugs Sector in 2018

Innovation is driving the sector from medical polymers to pharma foods

Newburyport, Mass., Dec. 18, 2017 - PCI Synthesis, Inc. (www.pcisynthesis.com), a pharmaceutical manufacturer of new chemical entities (NCEs), generic active pharmaceutical ingredients (APIs), and other specialty chemical products, issued its annual list of trends that will affect the emerging biotech and generic drug sectors, as well as Contract Development and Manufacturing Organizations (CDMOs), Contract Research Organizations (CROs) and Contract Manufacturing Organizations (CMOs) in 2018.

"We're expecting a wave of innovation to drive the sector," said Ed Price, president of PCI Synthesis. "When we looked at it, the one thing most of our trends this year have in common, it's innovation, whether it's the demand for medical-grade polymers that allow for new delivery systems to make medicine more effective or pharma foods that need GMP manufacturing while offering patients new ways to treat chronic diseases. Next year should be a good one in terms of driving change in how we develop new drugs and therapies."

Here are some of the trends that PCI Synthesis expects will impact the industry next year:

1. **Keeping talented employees will be an important advantage, given an upcoming labor shortage.** In Massachusetts alone, the industry is projected to need to fill 11,600 new jobs by 2022, with manufacturing jobs seeing a 32% increase over 2016's level, according to MassBioEd. While Massachusetts and some industry associations are promoting STEM majors, that's not enough to ensure there are enough skilled people necessary to fill those new jobs. Recruiting and training quality employees will be important but maintaining talented employees will be a key competitive advantage.
2. **Demand for medical-grade polymers heats up.** From novel drug delivery systems to new materials in ophthalmic applications, medical-grade polymers are being used in a range of different applications. We expect demand to continue to grow with more experience and new science continuing to push out the frontiers of what's possible.
3. **Digital drugs may be the latest thing in branded pharma but won't take off in generic form.** The FDA approved an antipsychotic pill that lets doctors track whether patients are taking their meds, as a way to ensure patient compliance, which sounds great. But don't count on seeing generic versions anytime soon. The reason: slim margins on generics preclude the extra costs of adding a tiny chip inside a pill.
4. **GMP manufacturing isn't just for drug discovery.** The value of incorporating Good Manufacturing Practices (GMP) manufacturing is increasingly sought by pharma foods. In contrast to unregulated nutraceuticals, pharma foods include a pharmacological additive to improve health, and undergo clinical testing and must meet FDA guidelines – which is why companies need GMP. Some expect this to be the next frontier.
5. **M&A will continue to be strong in 2018.** Based on a strong market and the perception of a deal-friendly DOJ, we expect to see more deals in 2018, many focused at combining complementary resources. These new companies will need to be more efficient, and the people and expertise are part of the deal.
6. **The FDA won't roll back regulations.** We don't see much change within the FDA in 2018 because we haven't seen much in 2017. Unlike some other federal agencies, the FDA is still behaving as it always has, and we don't expect a significant rollback of regulations.

About PCI Synthesis

PCI Synthesis is a Pharmaceutical Development CMO (Contract Manufacturing Organization) based in Newburyport, MA and is the largest small molecule drug substance manufacturer in the New England area. PCI is also a commercial manufacturer of new chemical entities (NCEs), generic active

pharmaceutical ingredients (APIs), and other specialty chemical products for the medical device industry. As a contract manufacturing organization (CMO), PCI provides emerging and mid-sized pharmaceutical companies access to the expertise needed to develop and manufacture complex small molecules. To learn more about PCI Synthesis, its proprietary NCE development activities and process R&D capabilities please visit www.pcisynthesis.com.

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