

**DCAT**

# TOP Industry NEWS

*BUSY WEEK? Here are the  
TOP INDUSTRY NEWS stories  
you might have missed, as  
selected by DCAT Editorial  
Director Patricia Van Arnum.*

## 1. [Shire Plans \\$400 Million Biomanufacturing Facility in Ireland](#)

Shire plans to expand its global biotechnology manufacturing capacity over the next four years by investing \$400 million for a biologics manufacturing campus on a 120-acre site at Piercetown, County Meath, Ireland. Construction of the new site will begin in mid-2016 and is expected to be operational by mid-2019. [Read More](#)

## 2. [Allergan Voluntarily Recalls Nearly 600,000 Bottles of Generic Drug](#)

Allergan is voluntarily recalling 593,019 bottles impacting 48 lots in four dosage forms of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, and amphetamine sulfate tablets, a generic version of Adderall, a drug to treat attention deficit hyperactivity disorder, due to failed impurities/degradation specifications. [Read More](#)

## 3. [FDA Issues Draft Guidance on Data Integrity](#)

The FDA has issued draft guidance to clarify the role of data integrity in current good manufacturing practice (CGMP) for drugs. FDA issued the draft guidance due to an increase in observed CGMP violations involving data integrity during FDA GMP inspections, which have led to numerous regulatory actions, including warning letters, import alerts, and consent decrees. [Read More](#)

## 4. [FDA Grants Accelerated Approval for Cancer Drug by AbbVie and Roche](#)

The FDA has granted AbbVie's and Roche's Venclexta (venetoclax) accelerated approval for patients with a hard-to-treat type of chronic lymphocytic leukemia. Venclexta is jointly commercialized by AbbVie and Genentech, a member of the Roche Group, in the United States and commercialized by AbbVie outside of the United States. [Read More](#)

## 5. [J&J Outlines Public Health Strategy in Africa](#)

Johnson & Johnson has announced its global public health strategy at the opening of its on-the-ground global public health operations in Cape Town, South Africa. The initial implementation of the strategy starts with this new site in Africa and will focus on three core areas: HIV, tuberculosis (TB), and maternal, newborn and child health. [Read More](#)

## 6. [AstraZeneca, Eli Lilly Advance Alzheimer's Disease Drug Candidate](#)

AstraZeneca and Eli Lilly and Company will continue a Phase III study of AZD3293, an oral beta secretase cleaving enzyme (BACE) inhibitor currently in development as a potential treatment for early Alzheimer's disease. [Read More](#)

## 7. [FDA Accepts Roche's BLA for Its Cancer Immunotherapy Atezolizumab](#)

Roche moved closer to a commercial entry in the immunotherapy market as the FDA has accepted Roche's biologics license application (BLA) and granted priority review for its immunotherapy, atezolizumab, for the treatment of people with locally advanced or metastatic non-small cell lung cancer. This is the second BLA acceptance and priority review for atezolizumab. In March 2016, the FDA accepted the company's BLA and granted priority review for atezolizumab for treating locally advanced or metastatic urothelial carcinoma. [Read More](#)

## 8. [Recipharm Completes Buy of Indian Sterile Injectables CMO](#)

Recipharm, a CDMO based in Jordbro, Sweden, has completed its previously announced acquisition of a majority stake in Nitin Lifesciences Limited, an Indian sterile injectables CMO. Headquartered at Karnal in Northern India, Nitin has three facilities for manufacturing small-volume parenterals. [Read More](#)

## 9. [PharmaChem Technologies Breaks Ground on New Manufacturing Plant](#)

PharmaChem Technologies (Grand Bahama) Ltd. has broken ground for its new \$120 million pharmaceutical manufacturing facility in Freeport, Grand Bahama. Plant completion is expected in early 2019. This new facility is supported by Gilead Sciences. The companies first formed a manufacturing pact in 2005. [Read More](#)

## 10. [GE Healthcare's Life Sciences Expands Biomanufacturing Capabilities](#)

GE Healthcare's Life Sciences reports that its European manufacturing and distribution site for sterile liquids has expanded its capabilities to include production of large volumes of buffers, process liquids, and cell culture media, and that it has launched a rapid production service for prototype cell culture media and buffers. [Read More](#)

### **\*\*Save the Date: DCAT Sharp Sourcing\*\***

Mark your calendar for **Tuesday, July 12** for DCAT Sharp Sourcing, the must-attend event for pharmaceutical companies, contract service providers and suppliers engaged in the pharmaceutical manufacturing value chain. This year's event will be held at the Hyatt Regency Hotel in New Brunswick, New Jersey and will feature solution-based practical insights from leading industry experts, specialized educational forums for buyers and suppliers, networking opportunities, and a special keynote speaker. Gain peer and customer insight on best practices and ways for optimizing your internal and external manufacturing and supply networks. Watch for announcements from DCAT for further details.

*The DCAT organization is happy to provide this service to its members each Friday.  
Have a great weekend!*

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### **About Top Industry News**

The DCAT organization recognizes its members have minimal time to keep up with the continuous flow of news covering this dynamic industry. To help ensure our members never miss the most important stories impacting the global pharmaceutical manufacturing industry, we will deliver each Friday, the week's Top Industry News, as selected by DCAT Editorial Director Patricia Van Arnum.



The Drug, Chemical & Associated Technologies Association (DCAT) is a not-for-profit, global business development association whose unique membership model integrates both innovator and generic drug manufacturers and suppliers of ingredients, development and manufacturing services, and related technologies. We are committed to provide programs, events and services that help our members meet their business objectives, expand their network of customers and suppliers, and gain insight into industry trends, markets, and those issues impacting pharmaceutical development and manufacturing.



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