

**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.*



**\*\*DCAT Sharp Sourcing Registration Closes Wednesday, July 6th!\*\***

**1. [Sanofi, BI Progress Multi-Billion Business Swap](#)**

Sanofi and Boehringer Ingelheim have signed contracts to secure the strategic transaction initiated in December 2015 that consists of an exchange of Sanofi's animal health business (Merial) and Boehringer Ingelheim's consumer healthcare business. This step marks a milestone before closing of the transaction, which is expected by year-end 2016 and remains subject to approval by all regulatory authorities in different territories. [Read More](#)

**2. [Pfizer To Invest \\$350 Million in New Biotechnology Center in China](#)**

Pfizer will invest approximately \$350 million in the development of a Global Biotechnology Center in the Hangzhou Economic Development Area in China. The facility will be Pfizer's third biotechnology center globally and the first in Asia. It will ensure the local production of biosimilar medicines for use in China and globally. [Read More](#)

**3. [Mayne Pharma To Acquire Generics From Teva for \\$652 Million](#)**

Mayne Pharma, an Australian pharmaceutical company, has agreed to acquire a portfolio of US generic products from Teva and Allergan for cash consideration of \$652 million. The portfolio consists of 37 approved products and five products filed with the FDA. The divestiture by Teva is required by the US Federal Trade Commission in connection with Teva's proposed acquisition of Allergan's generic drug business. [Read More](#)

**4. [Merck & Co, Moderna Partner for Personalized Cancer Vaccines & Manufacturing](#)**

Merck & Co. has formed a strategic collaboration and license agreement with Moderna Therapeutics, a clinical-stage biopharmaceutical company, to develop and commercialize messenger RNA (mRNA)-based personalized cancer vaccines. The collaboration will combine Merck's position in immuno-oncology with Moderna's mRNA vaccine technology and GMP manufacturing capabilities and includes funding to Moderna for the build-out of a GMP manufacturing facility in suburban Boston for personalized cancer vaccine manufacturing. [Read More](#)

**5. [Siegfried Gets Final Operating Approval for Nantong Production Site](#)**

The Chinese Environmental Protection Bureau has issued Siegfried Group the final operating approval for its production site for active pharmaceutical ingredients in Nantong, China. Consequently, all approvals and certificates required by the authorities for large-scale production have now been obtained. Trial operation for the commercial facilities had started a year ago. [Read More](#)

**6. [BIO, GPhA Square Off on Proposed Legislation for Data Exclusivity](#)**

The Biotechnology Innovation Organization and the Generic Pharmaceutical Association are squaring off over proposed US legislation, H.R. 5573 and companion legislation in the Senate, which

would shorten the exclusivity period for innovative biological products from 12 to 7 years. The data exclusivity provisions were enacted by the Biologics Price Competition and Innovation Act, which was part of healthcare reform signed into law by President Obama in March 2010. [Read More](#)

## **7. FDA Issues Quality Metrics Technical Conformance Guide**

The FDA has issued the *Quality Metrics Technical Conformance Guide*, a technical specification document, to serve as the technical reference for implementation of the draft FDA guidance for industry on *Request for Quality Metrics*. The FDA expects that quality metrics calculated from data that it collects will provide objective measures that, when used with additional internal data, will provide the agency with indicators of the effectiveness of pharmaceutical manufacturing quality systems. [Read More](#)

## **8. Kite Pharma Opens New Cell Therapy Manufacturing Plant**

Kite Pharma, a clinical-stage biopharmaceutical company, has opened a new commercial manufacturing facility in El Segundo, California for producing chimeric antigen receptor (CAR) and T-cell receptor (TCR) product candidates for clinical trials, as well as for the potential launch and commercialization of Kite's lead CAR T-cell product candidate. [Read More](#)

## **9. BI, Petrovax Pharm Sign Manufacturing Collaboration in Russia**

Boehringer Ingelheim (BI) has signed an agreement with Petrovax Pharm, a Russian pharmaceutical manufacturer, to localize full-cycle production of BI's thrombolytic drugs. By the end of 2019, BI intends to complete the transfer of technologies and quality controls and launch full-cycle production of its thrombolytic drugs at Petrovax Pharm's production facility in the Moscow region. [Read More](#)

## **10. FDA OKs New Hepatitis C Combo Drug from Gilead**

The FDA has approved Gilead Sciences' Eplclusa (sofosbuvir 400 mg/velpatasvir 100 mg), an all-oral, pan-genotypic, single tablet regimen for the treatment of adults with genotype 1-6 chronic hepatitis C virus (HCV) infection. HCV treatments are an important part of Gilead's product portfolio. Sovaldi (sofosbuvir) posted 2015 sales of \$5.3 billion, and Harvoni (ledipasvir and sofosbuvir) posted 2015 sales of \$13.9 billion. [Read More](#)

**\*\*Upcoming DCAT Event\*\***

### **DCAT Announces Its Newest Member Networking Event**

Enjoy all that Barcelona has to offer while making valuable industry connections at **DCAT After the Show**, DCAT's newest member networking event held immediately following CPhI Worldwide in Barcelona on Wednesday, October 5, from 6:00 PM to 8:30 PM. Located at the beautiful Casa Llotja de Mar, this venue is just steps away from the Gothic Quarter and Port of Barcelona, offering member company representatives the perfect opportunity to engage with colleagues they may have missed at the show before attending their customer events.

Registration for this event will open July 20, 2016. The reception is \$79.00 USD per person, and includes food and beverage, and transportation from the show to Casa Llotja de Mar, compliments of ACIC Fine Chemicals, Inc. Further event information and available branding opportunities may be found [here](#).

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

### **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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