

August 12, 2016



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
AFTER THE SHOW *A Member Company Networking Event* **BARCELONA 2016**
DON'T MISS THIS INAUGURAL EVENT...
WEDNESDAY OCTOBER 5TH • 6:00 PM – 8:30 PM • CASA LLOTJA DE MAR

1. [Biogen Names Planned Hemophilia Spin-off Bioverativ](#)

Bioverativ will be the name of Biogen's stand-alone, publicly traded global biotechnology company focused on treatments for hemophilia and other blood disorders. Biogen had announced in May 2016 that it was planning to spin off its hemophilia product business. Biogen expects Bioverativ to launch as a stand-alone company in early 2017. [Read More](#)

2. [Teva Launches Generic Version Of Novartis' Gleevec](#)

Teva Pharmaceutical Industries has launched the generic equivalent to Novartis' Gleevec (imatinib mesylate) tablets, 100 mg and 400 mg, in the US for multiple indications including certain forms of leukemia. Gleevec, marketed as Glivec in Europe, had 2015 global sales of nearly \$4.7 billion. The drug had annual sales of approximately \$2.42 billion in the US, according to IMS data as of May 2016 and as reported by Teva. [Read More](#)

3. [EMA, PIC/S Issue Guidance on Data Integrity](#)

The European Medicines Agency (EMA) has released new good manufacturing practice (GMP) guidance for data integrity for data used in testing, manufacturing, packaging, distribution, and monitoring. The Pharmaceutical Inspection Co-operation Scheme (PIC/S), a non-binding body of regulatory authorities for harmonizing GMP inspection practices, has issued draft data-integrity guidance as well. The FDA had issued draft guidance in April. [Read More](#)

4. [Mallinckrodt To Acquire Regenerative Medicine Company](#)

Mallinckrodt, a specialty pharmaceutical company, has agreed to acquire Stratatech Corporation, a privately held regenerative medicine company focused on skin-substitute products. Stratatech's lead product is a biological "off-the-shelf" skin-substitute product for treatment of severe burns. Financial terms were not disclosed. [Read More](#)

5. [Merck & Co.'s Follow-On Insulin Application Accepted by FDA](#)

The FDA has accepted Merck & Co.'s new drug application for an investigational follow-on biologic of insulin glargine, a long-acting insulin, for people with Type 1 and Type 2 diabetes being developed by

Merck with partial funding from Samsung Bioepis, a joint venture between Samsung BioLogics and Biogen. If approved, the drug will compete with Sanofi's long-lasting insulin, Lantus, the company's top-selling drug facing generic competition, and Toujeo, its next-generation long-acting insulin, as well as with a recent entry from Eli Lilly and Company for basal insulin. [Read More](#)

6. Kyowa Hakko Kirin Completes \$70 Million mAb Plant In Japan

Kyowa Hakko Kirin has completed construction of a JPY 7.1 billion (\$70 million) monoclonal antibody manufacturing plant in Takasaki City, Gunma, Japan. The facility is slated to begin operations later in 2016 and to come on line with commercial production after 2019. [Read More](#)

7. Agilent to Expand Oligonucleotide Manufacturing Capacity

Agilent Technologies has acquired 20 acres in Weld County, Colorado, on which it plans to build a pharmaceutical manufacturing facility to more than double its commercial manufacturing capacity for nucleic acid active pharmaceutical ingredients. [Read More](#)

8. Alynlam Moves Forward With New RNA Manufacturing Facility

Alynlam Pharmaceuticals, based in Cambridge, Massachusetts, has awarded Jacobs Engineering Group a contract to provide engineering services and procurement for Alynlam's new manufacturing facility in Norton, Massachusetts to supply RNA interference (RNAi)-based therapeutics for clinical and commercial needs. [Read More](#)

9. Perrigo Divests Vitamins Business To IVC

Perrigo has completed its previously announced divestiture of its US vitamins, minerals & supplements business to International Vitamin Corporation (IVC), a Freehold, New Jersey-based custom manufacturer and vitamins and nutritional supplements supplier. The acquisition, announced in June 2016, adds additional manufacturing, packaging and distribution operations to IVC. [Read More](#)

10. Helsinn, Mei-Pharma Sign \$469 Million Drug Development Pact

Helsinn, a Lugano, Switzerland-based pharmaceutical company focused on cancer-care products, and MEI Pharma, a San Diego, California-based oncology company, have formed a drug-development pact worth up to \$469 million for pracinostat, a drug candidate for treating acute myeloid leukemia and other potential indications. [Read More](#)

****Upcoming DCAT Event****

DCAT After the Show

Don't miss DCAT's inaugural networking event following CPhI Worldwide in Barcelona on Wednesday, October 5th from 6:00 PM to 8:30 PM at the beautiful Casa Llotja de Mar. Located just steps away from the Gothic Quarter and Port of Barcelona, this event offers the perfect opportunity to utilize that time between the tradeshow and your late-night dinner plans to catch up with colleagues and establish valuable industry connections.

Registration for this event is now open. 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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