

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. GSK Plans UK Mfg Cuts; Nixes Plan for New Biopharma Facility

GlaxoSmithKline (GSK) has announced plans to adjust its UK manufacturing network, which includes a potential sale of its cephalosporins antibiotics business and associated manufacturing, the closure of a consumer healthcare manufacturing site, the nixing of a planned biopharmaceutical manufacturing facility, and an investment in a manufacturing site for respiratory and HIV medicines. [Read More](#)

2. Mylan Advances Biosimilar of Roche Blockbuster Drug

A FDA advisory committee has recommended for approval a proposed biosimilar to Roche's cancer drug Herceptin (trastuzumab) from Mylan and Biocon, a Bangalore, India-based biopharmaceutical company. Herceptin is a top-selling drug for Roche with 2016 sales of CHF 6.78 billion (\$7.04 billion). The news is part of *DCAT Value Chain Insights Pipeline News*. [Read More](#)

3. FDA Advisory Committee Recommends Amgen's and Allergan's Biosimilar

A FDA advisory committee has recommended for approval a proposed biosimilar from Amgen and Allergan to Roche's cancer drug, Avastin (bevacizumab). Avastin is one of Roche's top-selling drugs with 2016 global sales of CHF 6.78 billion (\$7.04 billion). The news is part of *DCAT Value Chain Insights Pipeline News*. [Read More](#)

4. White House Stresses Position on User Fees to Fund FDA

Following the passage in the US House of Representatives of a bill that would reauthorize user fees for prescription drugs, generic drugs, biosimilars, and medical devices, the White House issued a statement to reiterate its position to fund premarket reviews by the FDA 100% by user fees, which would result in more than a \$1-billion increase in user fees over current levels. [Read More](#)

5. FDA Plans Pilot and Meetings on Drug Supply-Chain Security

The FDA plans to establish a pilot-project program under the Drug Supply Chain Security Act to assist in the development of an electronic, interoperable system that will identify and trace prescription drugs as they are distributed within the US. The DSCSA was signed into law in November 2013 and outlined steps to build this system by 2023. [Read More](#)

6. Lilly Reaches Settlement in US Cialis Patent Litigation

Eli Lilly and Company has entered into a settlement agreement with generic companies to resolve pending patent litigation regarding the unit-dose patent for Cialis (tadalafil), one of Lilly's top-selling drugs with 2016 global sales of \$2.47 billion. [Read More](#)

7. AstraZeneca To Invest \$79 Million in Australian Plant

AstraZeneca plans to invest AU \$100 million (US \$79.2 million) in its manufacturing sites in Sydney, Australia to fund three specialized production lines for respiratory medicines. [Read More](#)

8. Ocular Therapeutix Receives CRL from FDA for Manufacturing Issues

Ocular Therapeutix, a biopharmaceutical company, has received a Complete Response Letter (CRL)

from the FDA for manufacturing issues regarding its resubmission of a new drug application for Dextenza (dexamethasone), a drug to treat ocular pain following ophthalmic surgery. [Read More](#)

9. [FDA Issues CRL for Amgen's and UCB's Osteoporosis Drug](#)

The FDA has issued a Complete Response Letter (CRL) to include additional clinical data for the biologics license application for Amgen's and UCB's Evenity (romosozumab) as a treatment for postmenopausal women with osteoporosis. [Read More](#)

10. [FDA Commissioner Highlights Staffing Priorities](#)

FDA Commissioner Scott Gottlieb highlighted the staffing priorities at the agency and how the agency plans to fill more scientifically advanced and technical positions. [Read More](#)

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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