

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. [Mylan, US Finalize Settlement for EpiPen for \\$465 Million](#)

Mylan has reached a \$465-million settlement with the US government to resolve claims relating to the classification of the company's EpiPen Auto-Injector and EpiPen Jr Auto-Injector for purposes of the Medicaid Drug Rebate Program. [Read More](#)

2. [Sanofi Files Suit Against Merck & Co. Over Top-Selling Drug](#)

Sanofi has filed a patent-infringement lawsuit against Merck & Co. in a federal district court regarding Sanofi's Lantus (insulin glargine), which had 2016 sales of EUR 5.7 billion (\$6.7 billion). [Read More](#)

3. [Amgen Loses Ruling Against Pfizer in Biosimilar Litigation](#)

Amgen lost a round in litigation in seeking to defend its product, Epogen (epoetin alfa), a drug to treat anemia associated with chronic renal failure and cancer chemotherapy, from biosimilar competition. Epogen is a top-selling product for Amgen with 2016 sales of \$1.28 billion. [Read More](#)

4. [Biocon To Resubmit Biosimilar Filings Over Manufacturing](#)

Biocon, a Bangalore, India-based pharmaceutical manufacturer, plans to resubmit its marketing authorization application to the European Medicines Agency for biosimilar candidates to Roche's Herceptin (trastuzumab) and Amgen's Neulasta (pegfilgrastim) following inspections of manufacturing facilities making these products. Roche's Herceptin had 2016 sales of CHF 6.78 billion (\$7.04 billion), and Amgen's Neulasta had 2016 sales of \$4.65 billion. [Read More](#)

5. [GSK Opens New \\$57-Million Facility for Vaccine Production](#)

GlaxoSmithKline (GSK) has opened a new £44-million (\$57 million) manufacturing plant to support vaccine production in Montrose, Scotland. The facility will manufacture sterile aluminum salts for vaccines for tetanus, pneumonia, diphtheria, and whooping cough. [Read More](#)

6. [Bayer Recalls 1-Million Plus Cartons of Alka-Seltzer](#)

Bayer has issued a voluntary Class II recall of more than one million (1,067,520) 12-count cartons of its over-the-counter product, Alka-Seltzer Original, due to defective blister packaging. [Read More](#)

7. [German Regulators Cite Dr. Reddy's for GMP Non-Compliance](#)

German pharmaceutical regulators have issued a statement of noncompliance of good manufacturing practice (GMP) to Dr. Reddy's Laboratories for its dosage-form manufacturing plant in Bachupally, Hyderabad, India. The notice means that the company will not be able to supply product from the facility to the European Union until successful re-inspection of the plant. [Read More](#)

8. [Pfizer To Invest \\$100 Million in Gene Therapies Plant](#)

Pfizer plans to invest \$100 million to expand a gene-therapy manufacturing plant in Sanford, North Carolina. Pfizer had acquired the facility as part of its acquisition of Bamboo Therapeutics, a Chapel Hill, North Carolina-headquartered biotechnology company, in 2016. [Read More](#)

9. [SK Capital To Buy Perrigo's API Business in Israel for \\$110 Million](#)

SK Capital, a New York-based private investment firm, has agreed to acquire Perrigo API, Perrigo's active pharmaceutical ingredients (API) business in Israel, for \$110 million. [Read More](#)

10. [FDA Issues Draft Guidance for Biologics Manufacturing Changes](#)

The FDA has issued draft guidance to recommend the types of manufacturing changes for approved biologics license applications that need to be documented in an annual report. The guidance describes CMC post-approval manufacturing changes that the FDA generally considers to have a minimal potential to have an adverse effect on product quality. [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.



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