April 21, 2017

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. **BMS in Licensing Deals with Roche, Biogen for $1 Billion-Plus**

   Bristol-Myers Squibb has formed two licensing deals for drug candidates, respectively with Roche and Biogen, potentially worth up to more than $1 billion, collectively. **Read More**

2. **Lilly's Potential Blockbuster Arthritis Drug Has Setback With FDA's Complete Response Letter**

   Eli Lilly and Company and Incyte have received a FDA Complete Response Letter for their new drug application for baricitinib, an investigational rheumatoid arthritis drug. The FDA is seeking additional clinical data. **Read More**

3. **Merck & Co. Receives Complete Response Letter for Diabetes Drugs**

   Merck & Co. has received a FDA Complete Response Letter for its supplemental new drug applications for Januvia, Janumet, and Janumet XR, regarding a proposed labeling change to include clinical data on cardiovascular outcomes. Januvia and Janument are top-selling products in Merck's diabetes franchise with 2016 sales of $3.9 billion and $2.2 billion, respectively. **Read More**

4. **Teva Receives FDA Warning Letter for Chinese API Plant**

   Teva has received a Warning Letter from the FDA for its active pharmaceutical ingredient facility in China, which cites concerns with manufacturing control and sampling processes during an inspection conducted in September 2016. **Read More**

5. **Mylan Receives FDA Warning Letter for Indian API Plant**

   Mylan has received a Warning Letter from the FDA related to data-integrity issues for finished pharmaceuticals at its drug manufacturing facility in Maharashtra, India, which the FDA inspected in September 2016. **Read More**

6. **Fujifilm to Invest $130 Million to Expand Bio CDMO Business**

   Fujifilm plans to invest approximately Japanese Yen 14 billion ($130 million) in the US and UK for two new facilities to increase production capacity and process development capabilities for its contract development and manufacturing business. **Read More**

7. **US House, Senate Seek Common Ground in User Fees Reauthorization**

Leaders of the US House of Representatives and Senate health committees have released a discussion draft of bipartisan legislation for reauthorizing the FDA's user-fee programs for pharmaceuticals, generic drugs, and biosimilars. The user-fees are set to expire in September 2017 and need reauthorization by Congress to continue. **Read More**

8. **FDA, EMA Report on Completed Quality by Design Pilot Program**

   The FDA and the European Medicines Agency have released a report on their recently completed joint pilot program for assessing applications containing Quality by Design (QbD) elements. The aim of this program was to facilitate implementation of QbD concepts introduced through ICH and to harmonize regulatory decisions across the two regions. **Read More**

9. **PhRMA Seeks Improved Communication for FDA Inspection Process**

   The Pharmaceutical Research and Manufacturers of America provided comments to a recent report released by the FDA in November 2016 in which the agency assessed its communication and transparency of information, including on drug-manufacturing inspections, for new molecular entity new drug applications and original biologics license applications. **Read More**

10. **UK Regulatory Agency Issues Trend Analysis on GMP Deficiencies**

    UK's Medicines & Healthcare products Regulatory Agency released a new report on the trends from its inspection activity of dosage form manufacturing plants and related GMP deficiencies in 2016. Quality systems and sterility assurance were leading areas for GMP deficiencies. **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.

One Union Street, Suite 208, Robbinsville, NJ 08691
Local: +1.609.208.1888 · Toll Free: +1.800.640.DCAT(3228) · Fax: +1.609.208.0599
www.dcat.org