March 17, 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. **President Trump to Nominate New FDA Commissioner**

   President Donald Trump plans to nominate Scott Gottlieb, MD, former FDA Deputy Commissioner for Medical and Scientific Affairs at the US Food and Drug Administration (FDA), as the new FDA Commissioner. Read More

2. **Roche, Mylan Settle in Licensing Deal for Biosimilar of Roche's Herceptin**

   Mylan has settled with Roche relating to patents for Herceptin (trastuzumab), one of Roche's top-selling cancer drugs with 2016 sales of CHF 6.78 billion ($6.73 billion). The settlement provides Mylan with global licenses for its biosimilar trastuzumab product. Read More

3. **Pharmaceutical Inspection Co-Operation Scheme Sets 2017-2019 Goals**

   The Pharmaceutical Inspection Co-operation Scheme (PIC/S), an informal co-operative arrangement between regulatory authorities overseeing GMP of human and veterinary medicines, has issued an action plan for the next two years that includes increased training, regulatory authority compliance, and harmonization of GMP/GDP guidance. Read More

4. **FDA Considers New Office of Patient Affairs**

   The FDA is considering establishing a new Office of Patient Affairs that would create a single, central entry point to the FDA for the patient community and which will be tasked with supporting and coordinating patient engagement activities across medical product centers. Read More

5. **Dr. Reddy's Addresses FDA GMP Violations Report**

   Dr. Reddy's Laboratories is addressing a violations report issued by the FDA for its formulation manufacturing facility in Duvvada, Visakhapatnam, India following an FDA inspection there for cGMP issues. Read More

6. **Wockhardt Subsidiary Receives FDA Warning Letter**

   The FDA has issued a Warning Letter to Morton Grove Pharmaceuticals, a subsidiary of Wockhardt, an Indian biopharmaceutical company, for cGMP violations related to finished pharmaceuticals at Morton Grove's drug manufacturing facility in Morton Grove, Illinois. Read More

7. **FDA Lifts Import Alert on Sun Pharma's Indian Manufacturing Plant**

The FDA has informed Sun Pharmaceutical Industries that it will lift an import alert imposed on the company's Mohali, India manufacturing facility, which will clear Sun Pharma to supply approved products from the Mohali facility to the US market. **Read More**

8. **FDA Issues Warning Letters to India and China API Manufacturers**

The FDA has issued Warning Letters to three active pharmaceutical ingredient (API) manufacturers for cGMP violations at their respective manufacturing facilities. These include facilities in India run by Megafine Pharma and Badrivishal Chemicals & Pharmaceuticals and a facility in China run by Lumis Global Pharmaceuticals. **Read More**

9. **Takeda Partners on New Biotech Venture**

Takeda has partnered with Innovation Network Corporation of Japan, a public-private partnership promoting Japanese businesses, and Medipal Holdings, a networking group of manufacturers, medical institutions, and retailers, to jointly invest Japanese yen 10 billion ($87 million) to establish Scohia Pharma, a new biotechnology company. **Read More**

10. **Pfizer Recalls More than 582,000 Units of GI Drug**

Pfizer has initiated a voluntary Class III recall of 582,165 vials of the gastrointestinal drug, Protonix (pantoprazole sodium) for injection, due to subpotency concerns following out-of-specification results on drug potency at the six-month stability time point. **Read More**

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