Continuous manufacturing in the pharmaceutical industry

- Trends and opportunities

Meeting in the Biopharmaceutical Section, The Danish society of Pharmaceutics

Wednesday the 26th of April 2017

in the Benzon Auditorium, FARMA, Universitetsparken 2, 2100 Kbh Ø

While continuous manufacturing has been widely used in several industries such as food, fertilizers and oil refining, the implementation of continuous manufacturing as an alternative approach to the conventional “batch” technology approach is in its infancy in the pharmaceutical industry. The first examples of regulatory approval of manufacturing processes based on continuous manufacturing are starting to emerge and the expected numerous benefits and advantages can be presented. The whole issue on scale up may be seen in another perspective as well as fewer breaks in the continuous manufacturing process enables a faster production and more reliable products through an uninterrupted process. As such added benefits of a more efficient development and production of quality products can reduce manufacturing costs and possibly lower drug prices for consumers. Continuous manufacturing also allows manufacturers to respond quicker to changes in demand, potentially contributing to prevention of drug shortages.

Some examples on implementation of continuous manufacturing in the pharmaceutical industry are seen. For instance Vertex Pharmaceuticals’ product Orkambi (lumacaftor/ivacaftor) for cystic fibrosis in 2015 where the approved manufacturing process is a continuous process and Janssen Products, LP product, Prezista (darunavir) for the treatment of HIV-1 infection where a change from batch manufacturing process to a continuous process has been approved*.

Implementing continuous manufacturing requires a change of mind-set from “batch” manufacturing to continuous manufacturing for the manufacturer. And even though the change is encumbered with benefit and advantages, still resistance is seen in some part of the pharmaceutical industry and there is a need for sharing in-sights and experiences.

At the meeting an up-date on the pharmaceutical industry positions with regard to continuous manufacturing will be presented together with a presentation of different
process analytical tools, such as rheological tools and spectroscopy as drivers for continuous manufacturing of both solid and semi-solid products.

**Program:**

14.00-14.05 Introduction and welcome  
Niels Christian Felumb, Gitte Pømmergaard Pedersen  
Biopharmaceutical Section in the Danish Pharmaceutical Society

14:05-14:30 Continuous manufacturing. A qualitative analysis of challenges and opportunities for introducing continuous manufacturing in pharmaceutical companies, Vibeke Jessen, LEO Pharma

14:30-15:15 ConsiGma™, Oscar Goldstein, Regional Support Manager, APC Pharma Solids, GEA

15:15-15.25 Short Break

15:25-16:10 ConsiGma™, Oscar Goldstein, Regional Support Manager, APC Pharma Solids, GEA, cont.

16:10-16:40 Break, with refreshments

16:40-17:00 Effects of material properties in continuous process development, Troels Pedersen, Novo Nordisk

17:00-17.20 Process analytical technologies for advanced in-line rheology measurements of topical formulations, Pernille Qwist Reckey, LEO Pharma

17:20-17:40 Chemical imaging within continuous manufacturing environment, Magnus Edinger, University of Copenhagen

17:40-17:50 Wrap up

*Lawrence, Yu. Continuous Manufacturing has a strong impact on drug quality, FDA Voice, 12th of April 2016, U.S. Food & Drug Administration*