



Breaking News on Global Pharmaceutical Technology & Manufacturing

## Janssen working on other continuous processes post US FDA OK for Prezista

By Gareth MacDonald+, 13-Apr-2016

Related topics: Processing equipment, Regulations, Processing

**Janssen is already working on continuous manufacturing methods for other drugs says Rutgers University which helped develop the new Prezista production process approved by the US FDA.**

On April 8 the US Food and Drug Administration (FDA) announced it cleared Janssen to *change* the production method for the 600mg version of the HIV drug Prezista (darunavir) from "batch" to continuous manufacturing.

In an accompanying blog post Lawrence Yu, deputy director of the FDA's office of pharmaceutical quality, said while the switch had not be easy, Janssen stands to gain "*significant rewards*" from doing so.

Craig Stoltz, Janssen manufacturing and technical operations spokesman, told us "*the benefits of Continuous Manufacturing include reduced testing-to-release time from 30 days to a target of 10 days by integrating technology-enabled real-time release testing throughout the control process for critical quality attributes.*

*"It also has the potential to increase yield by reducing waste by 33% and reduce manufacturing and testing cycle time by 80%"* he continued.

Stoltz added that the first Prezista produced in this way "*will likely make its way to the marketplace and patients by early Fall.*"

### Continuation

The Johnson and Johnson unit has been developing continuous manufacturing process for some of its solid dose drugs for the last five years in partnership with researchers as Rutgers University.

Project leader Doug Hausner told us "*Janssen is our strongest supporter and we work quite closely with them on both research as well as development projects.*

*"On the development side, we aided with their first CM solid dose product which has been filed for approval, we are working on a second, and there are placeholders for two more."*

Stoltz confirmed Janssen is working on other batch to continuous conversions.

*"Looking to the future, JSC is investigating continuous manufacturing in drug development on the R&D side and applications in different solids manufacturing processes, which could lead to reduced scale-up time and, eventually, shorter time-to-market."*

Copyright - Unless otherwise stated all contents of this web site are © 2016 - William Reed Business Media SAS - All Rights Reserved - For permission to reproduce any contents of this web site, please email our Syndication department [copyright@wrwm.com](mailto:copyright@wrwm.com) - Full details for the use of materials on this site can be found in the Terms & Conditions

© 2016 - William Reed Business Media SAS - All rights reserved.

