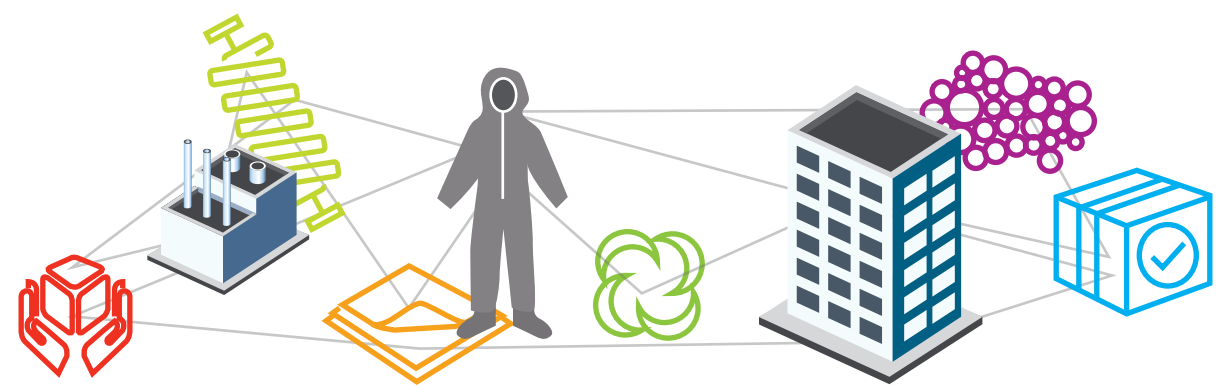


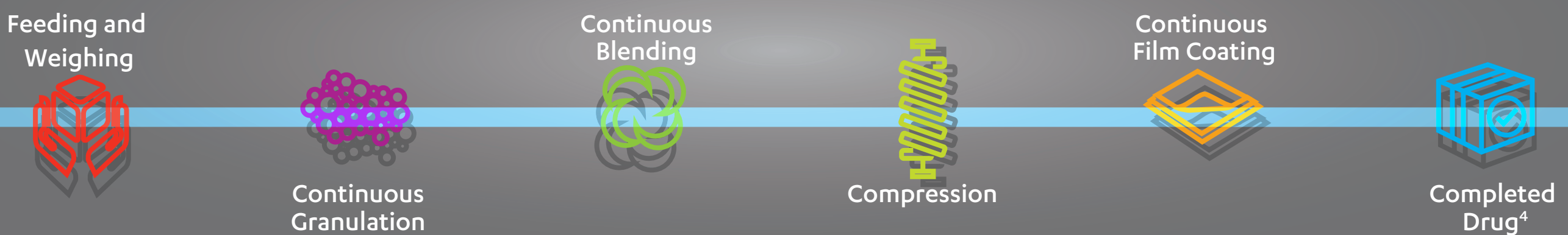
# Advances in Pharmaceutical Supply Chain:

## Continuous Manufacturing (CM)

**Traditional pharmaceutical manufacturing:** multiple, separate time-consuming steps



**CM:** all steps occurring simultaneously on a single line<sup>4</sup>



Benefits of **CM** over traditional pharma manufacturing:



Incorporation of **real time release testing (RTRT)** and **process analytical technology (PAT)**



**Fewer steps** = reduced processing times from days/weeks to **minutes/hours**<sup>3</sup>



**Reduced waste**<sup>2</sup>



**Increased production volume**<sup>3</sup>



**Reduced environmental impact**<sup>2</sup>



**Smaller footprint**<sup>3</sup>



**Consistent quality**<sup>2</sup>



**No manual handling** = increased safety<sup>2</sup>



**Reduced active pharmaceutical ingredient (API) consumption**<sup>4</sup>



**Leaner and faster tech transfers**<sup>4</sup>

Eliminating transportation



Cutting **“DEAD TIME”** between steps

**Greatly reduced processing time**

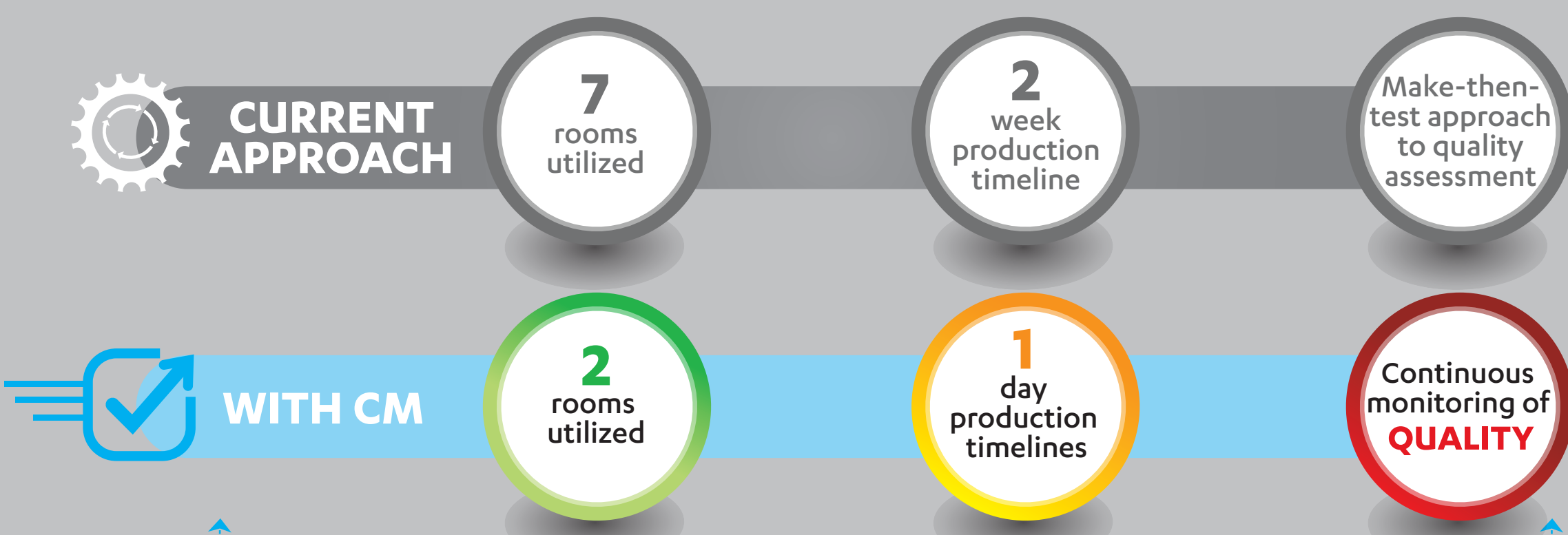
### GLOBAL OPPORTUNITY:

Working with various health authorities around the world to capitalize on opportunity in drug development and manufacturing for increased:



Janssen Supply Chain (JSC) is at the forefront of CM advancement, focusing on a more reliable process that will yield waste reduction and time to market savings—especially important in the pharmaceutical industry in light of breakthrough therapies.

The European Medicines Agency (EMA) has approved the implementation of a CM production line for **PREZISTA®** (darunavir) 600 mg tablets at the company’s manufacturing facility in Gurabo, Puerto Rico. With this approval, Janssen will be able to use its state-of-the-art, continuous production and control technology to deliver the treatment to 28 EU Member States.



This effort is not only transforming the manufacturing process at the plant, but has also led to a partnership with the FDA to create regulatory pathways for the use of CM in pharmaceutical production. Looking to the future,

JSC is investigating CM in drug development on the R&D side and applications in biologics manufacturing, which could lead to reduced scale-up time and eventually shorter time-to-market.<sup>4</sup>

Overall, with the integration of CM, Janssen and J&J aim to:



Manufacture **70%** of “highest-volume products” using CM within eight years



Increase yield by reducing waste by **33%**



Reduce manufacturing and testing cycle time by **80%**

References:  
 1 Wall Street Journal. Drug Making Breaks Away from Its Old Ways. <http://www.wsj.com/articles/drug-making-breaks-away-from-its-old-ways-1423444049>. Accessed March 27, 2015.  
 2 U.S. Food and Drug Administration. FDA Perspective on Continuous Manufacturing. <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM341197.pdf>. Accessed March 27, 2015.  
 3 U.S. Food and Drug Administration. Modernizing Pharmaceutical Manufacturing – Continuous Manufacturing as a Key Enabler. [https://iscmp.mit.edu/sites/default/files/documents/ISC-MP2014\\_Keynote\\_Slides.pdf](https://iscmp.mit.edu/sites/default/files/documents/ISC-MP2014_Keynote_Slides.pdf). Accessed March 27, 2015. 4 Internal sources