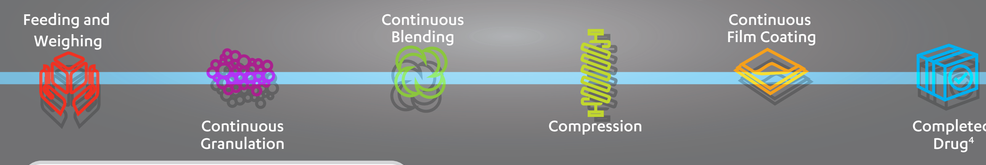
Advances in Pharmaceutical Supply Chain:

Continuous Manufacturing (CM)

Traditional pharmaceutical manufacturing: multiple, separate time-consuming steps

CM: all steps **occurring simultaneously** on a single line[4]



Benefits of CM over traditional pharma manufacturing:

- Incorporation of **real time release testing** (RTRT) and **process analytical technology** (PAT)
- Operating costs can be **reduced** by as much as **50%**[1]
- **Fewer steps =** reduced processing times from days/weeks to **minutes/hours**[3]
- **Reduced waste**[2]
- **Increased production volume**[3]
- **Reduced environmental impact**[2]
- **Smaller footprint**[3]
- **Consistent quality**[2]
- **No manual handling =** increased safety[2]
- **Reduced** active pharmaceutical ingredient (API) consumption[4]
- **Leaner and faster** tech transfers[4]

Eliminating transportation

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Cutting "**DEAD TIME**" between steps

Greatly reduced processing time

FDA ON CM:

The FDA approves of CM and sees the opportunity in drug development and manufacturing for increased:

- **RELIABILITY**
- **QUALITY**
- **FLEXIBILITY**
- **UNIFORMITY**

CM ALLOWS FOR QUALITY MONITORING DURING PRODUCTION, WHICH:

1. Eliminates the need to discard an entire batch when a correction is needed
2. Ensures more thorough quality assessment throughout the process

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

JSC is partnering with the Rutgers University Engineering Research Center for Structured Organic Particulate Systems (C-SOPS) and the University of Puerto Rico at Mayagüez to implement CM production of **PREZISTA®**[4] at Janssen's plant in Gurabo, Puerto Rico.

CURRENT APPROACH	7 rooms utilized	2 week production timeline	Make-then-test approach to quality assessment
WITH CM	2 rooms utilized	1 day production timelines	Continuous monitoring of **QUALITY**

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.[4]

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. Accessed March 27, 2015. 4 Internal sources