

Nanotechnology Meets Continuous Manufacturing: *Learning from the Future*

2023 Nano Day Symposium: Continuous Manufacturing of Nanomaterials

Xiaoming Xu, Ph.D.

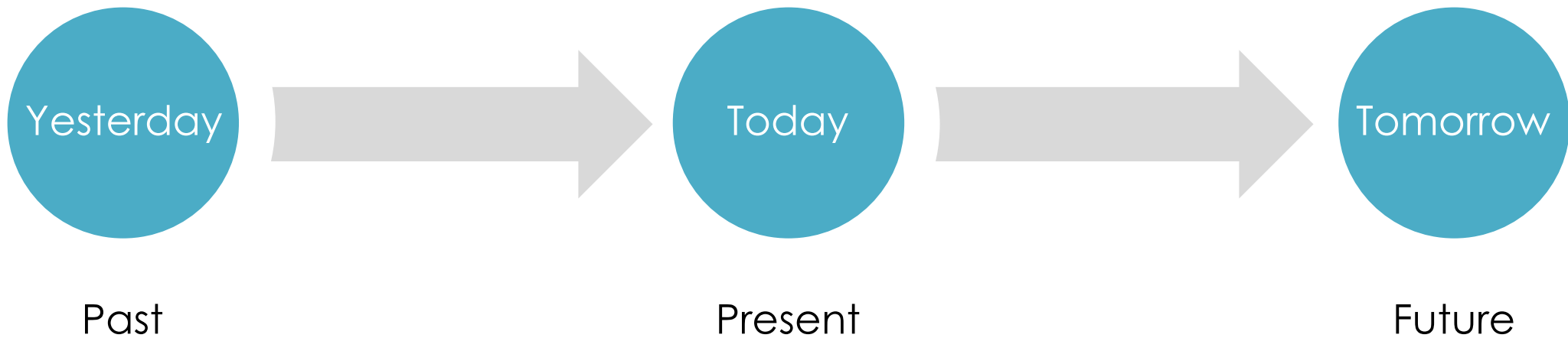
Director, Division of Product Quality Research
Office of Testing and Research, Office of Pharmaceutical Quality

CDER | U.S. FDA

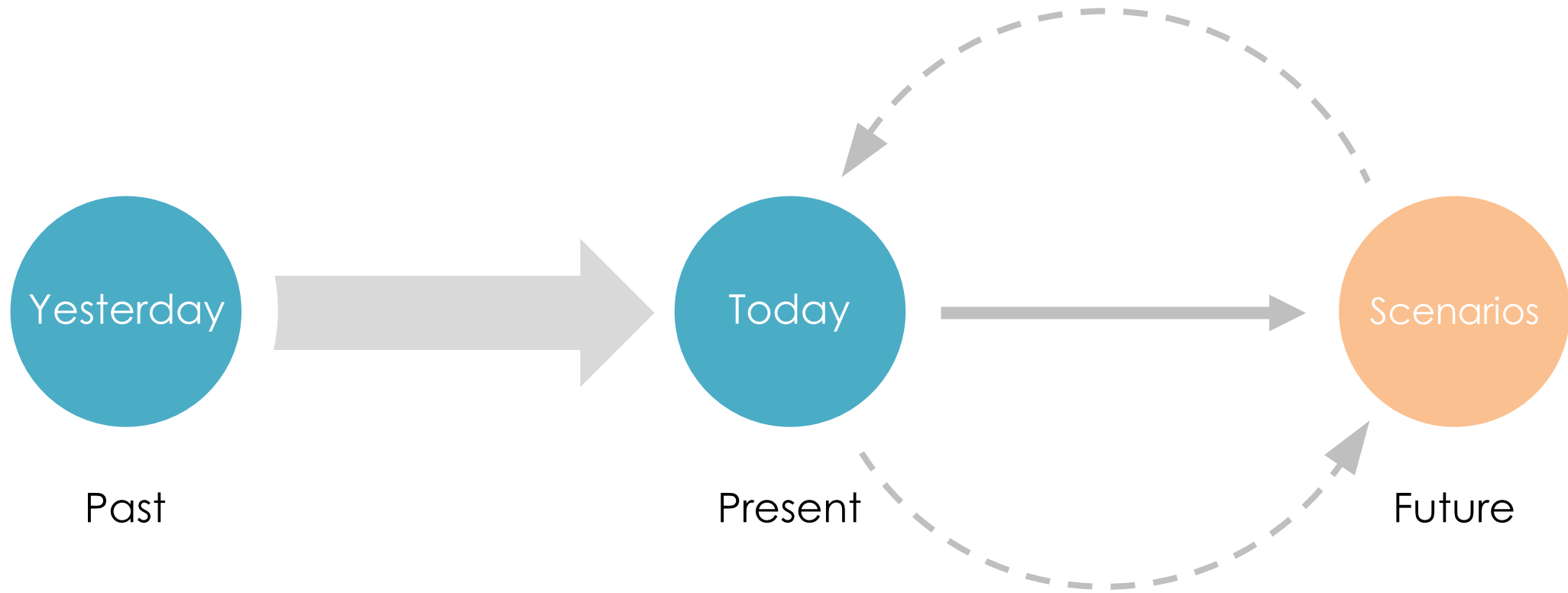
October 11, 2023



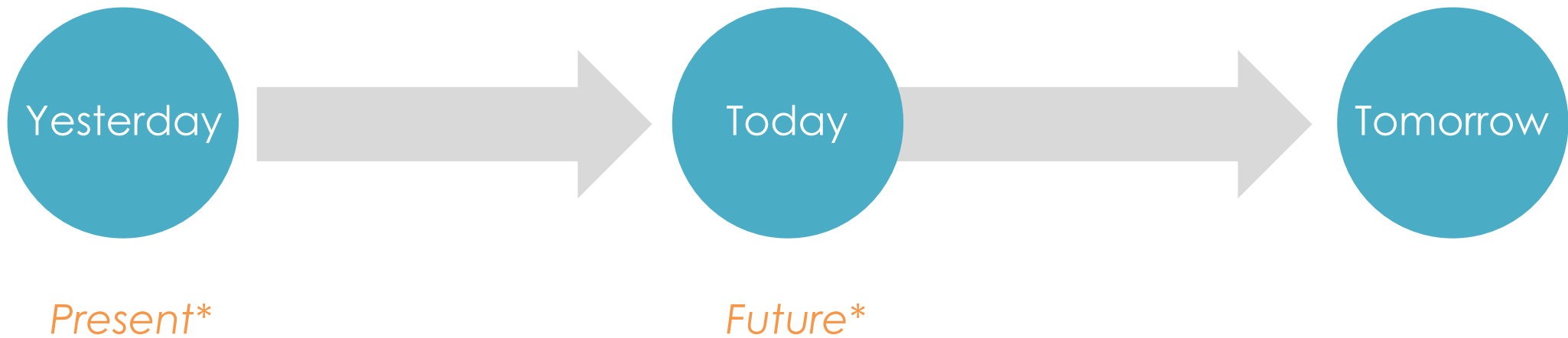
Yesterday, Today, Tomorrow



Yesterday, Today, Tomorrow

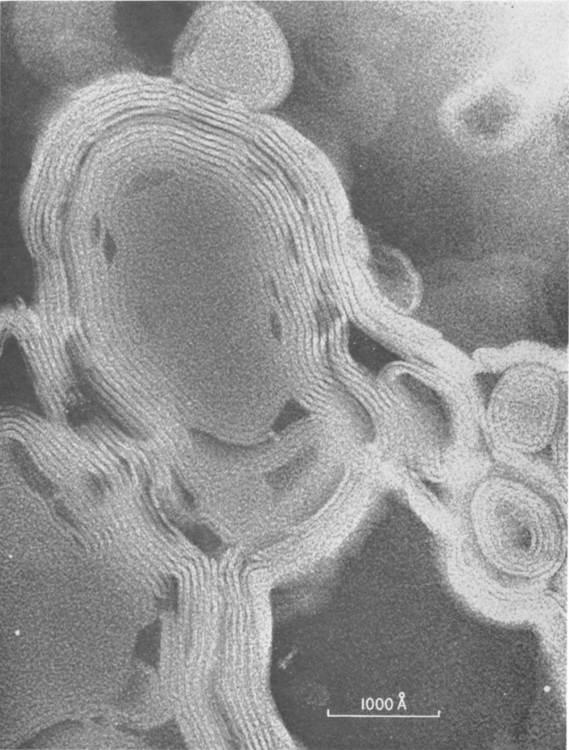


Today is yesterday's future

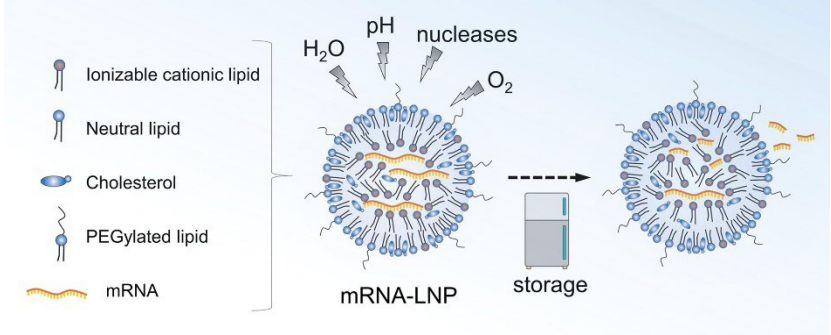
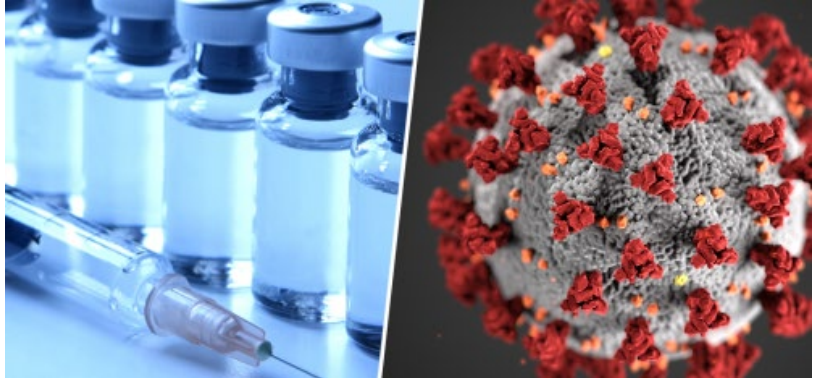


Nanotechnology

- Conception of nanotechnology and its use dates back
- Lipid nanoparticles were the Future in the Past



A.D. Bangham, R.W. Horne. Negative staining of phospholipids and their structural modification by surface-active agents as observed in the electron microscope. *J. Mol. Biol.*, 8 (1964), pp. 660-668



Linde Schoenmaker et al. mRNA-lipid nanoparticle COVID-19 vaccines: Structure and stability, *International Journal of Pharmaceutics* (2021) 120586

Considering Whether an FDA Regulated Product Involves the Application of Nanotechnology

Points to Consider:

- 1. Whether a material or end product is engineered to have at least one external dimension, or an internal or surface structure, in the **nanoscale** range (approximately 1 nm to 100 nm);*
- 2. Whether a material or end product is engineered to exhibit properties or phenomena, including physical or chemical properties or biological effects, that are attributable to its dimension(s), even if these dimensions fall outside the nanoscale range, up to one micrometer (1,000 nm).*

Imagine a future

- Accessible
- Agile
- Individualized
- Affordable
- Trustworthy

Everyone deserves confidence
in their *next* dose of medicine.

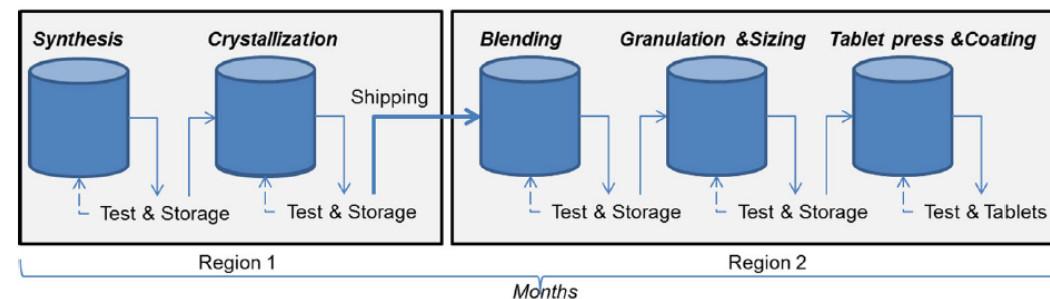
Pharmaceutical quality
assures the
availability,
safety,
and efficacy
of *every* dose.

Continuous Manufacturing

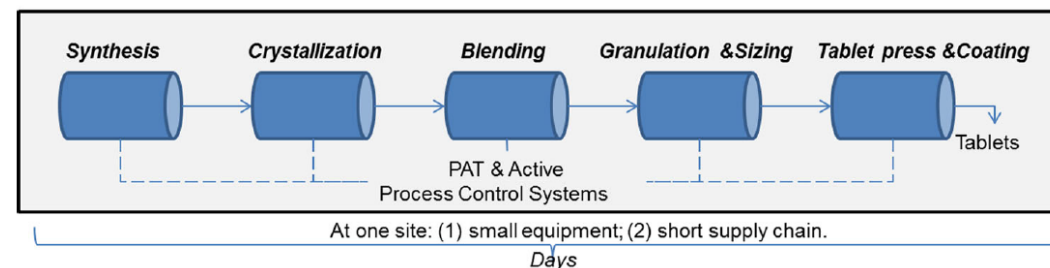
- A new way to manufacture drug products

- CM is an integrated process
- Consists of two or more steps
- Continuous flow of material
- Intensified process

A typical batch manufacturing process



A conceptual integrated continuous manufacturing process



To date, CDER has approved 15 drug products utilizing CM technology (all small molecules drugs). No approved application utilizing CM of nanomaterials yet.

Today



- Experience in continuous manufacturing (current trend).
- *Investment* in future of manufacturing nanomaterials
- Anticipating future challenges and opportunities
- Get involved and take action.
- Start today. Change tomorrow.