

Center of Excellence Implementation of Emerging Technologies (Automation)

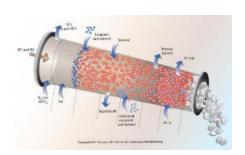
Jennifer Del Valle Ortiz Neda Hamandi

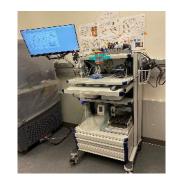
Office of Compounding Quality and Compliance CoE Annual Conference September 7, 2022

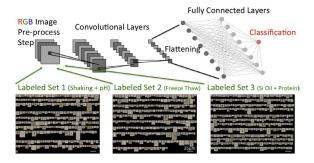


What are Emerging Technologies?

- Novel **manufacturing methods** to improve process robustness and efficiency
- Novel characterization methods for complex **dosage forms** or delivery systems to improve drug delivery and targeting
- Novel **analytical tools** to improve product quality testing, process monitoring and/or control







Calderon C et. al. J. Pharm Sci 2018 (107)



Current State of AP

- Level of Involvement of People
 - Laminar Flow Hoods
 - Manual Fill
 - Barriers
 - Isolators



Innovations

- Robotics inside Gloveless Isolators
 - Interior Decontaminated
 - HEPA Filtered Air
 - No Human Intervention
- Closed Vial Fillings



Speedbumps?

- Cost
- Proprietary
- Filling Speed
- Regulatory Requirements



Let's discuss...

