

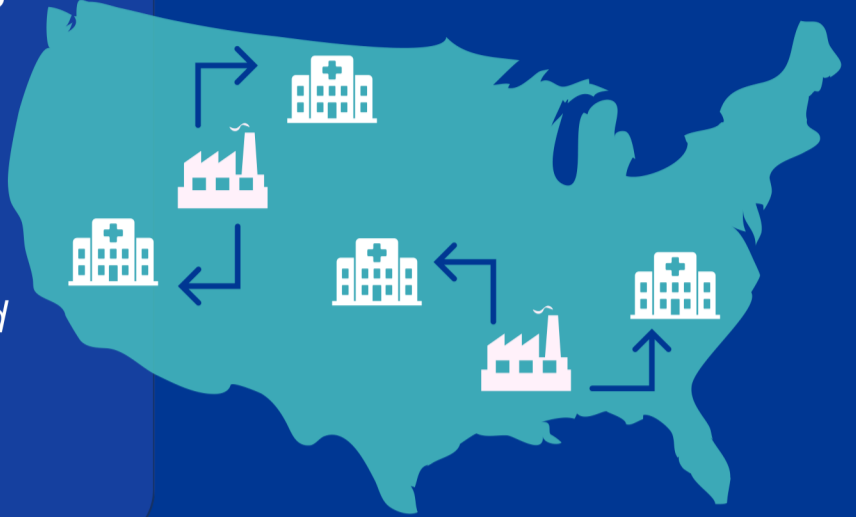
FDA DEFINITIONS:

CGT Manufacturing Models

01 Decentralized Manufacturing

Manufacturing occurs at multiple locations (regional facilities)

Manufacturing is replicated and geographically dispersed to shorten supply chains and increase supply reliability.



02 Point of Care Manufacturing

Manufacturing occurs at host sites in close proximity to patient care

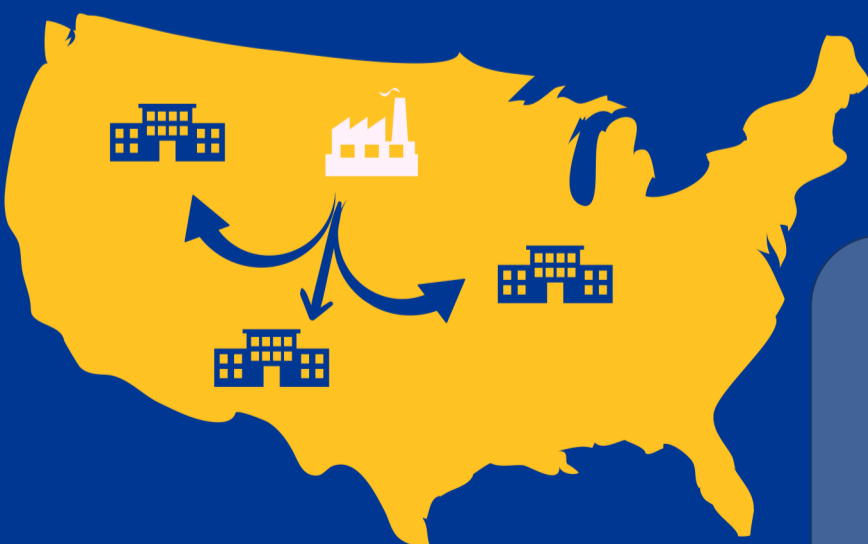
Non-traditional GMP environments and end users may not share similar experience to traditional manufacturing operators at centralized manufacturing facilities.



03 Distributed Manufacturing

Manufacturing occurs at multiple locations (decentralized facilities) via deployed manufacturing units

May initially take place at a centralized facility and contain GMP environment similar to that in a traditional manufacturing facility



04 Centralized Manufacturing

Typically consists of a manufacturing facility producing the product and distributing to end users