

Opportunities and Challenges of Expanding US-based Manufacturing

FDA pre-check:

- Voluntary approach to accelerate new U.S. facility construction/expansion
- Earlier more frequent interactions
- Pre-application CMC engagement
- Needs to connect to permitting certainty, inspection predictability, and lifecycle change flexibility to be effective

Key Considerations:

- Construction permits
- Approval inspections
- FDA pre-check
- Moving a process to the U.S. does not mean removal from other global sites

No requirement for US manufacturing to supply the US market:

- Tariffs provide a driving force
- FDA pre-check provides an incentive

How might U.S. manufacturing on-shoring harmonize with the following?

- Post approval changes
- Site transfers
- Other regulatory pathways
- Other ways than only building out new manufacturing sites
- Increased export from US manufacturing
- CPPs following US approval may help global expansion

Can the following guidance facilitate U.S. manufacturing on-shoring?

- Advanced manufacturing technology
- Emerging Technology Program
- ICH Q12

Optimize U.S. Manufacturing While Enhancing Global Supply