ASPR Administration for Strategic Preparedness & Response

Enabling Innovations and Technologies Office

Center for Industrial Base Management and Supply Chain

WHAT IS THE OFFICE OF ENABLING INNOVATIONS AND TECHNOLOGIES?

The Office of Enabling Innovations and Technologies (EIT) is part of the Center for Industrial Base Management and Supply Chain (IBMSC). Its role is to strengthen U.S. manufacturing and make supply chains more resilient, so the country is better prepared for public health emergencies.

EIT focuses on bringing production back to the U.S., helping new technologies move into the marketplace, and expanding flexible manufacturing for critical medicines. This work helps ensure that important drug ingredients and products are available, especially during times of high demand in emergencies.

POPULATION SCALE FILL-FINISH

EIT is leveraging Blow-Fill-Seal (BFS) aseptic drug packaging via connectable components to create pre-filled delivery systems at development and commercial scale. EIT is developing novel thermal processes that enable production of temperature-sensitive therapeutics and small molecule drugs within BFS.

Agile and Distributed Drug Substance and Drug Product Manufacturing

Distributed manufacturing

EIT is developing a rapidly adaptable, scalable, and distributed network of medicine-producing systems comprised of nodes, including drug substance and drug product manufacturing nodes that complement point-of-care sterile/non-sterile medicine compounding nodes.

EIT is addressing the need to improve the U.S. pharmaceutical base through scalable and distributed manufacturing and production of IV fluids, starting with 0.9N saline, with potential to expand into other fluids or medications for infusion therapies or dialysis, at the point of need.

On-Shoring of drug substance and drug product production

EIT is onshoring the production of essential medicines to the United States. This will generate domestic self-sufficiency for manufacturing critical generic active pharmaceutical ingredients (API) and finished drug products to prevent future shortages with semi-continuous processing and manufacturing.

Agile manufacturing

EIT is creating the technology and process model for real-time qualification of finished drug products produced in agile manufacturing platforms. This will establish AI-driven or algorithmic approaches for producing multiple MVP drugs on the same hardware. This also will support point-of-need manufacturing, addressing the needs of the American public during public health emergencies, and enabling a resilient pharmaceutical supply chain.

Biologically-derived drug substance manufacturing

EIT is creating a new manufacturing paradigm that can produce at population scale, and onshore drug production in novel ways to be globally competitive. This effort is one of the first efforts to commercialize engineered living systems that make small molecule drug substances for analgesics, clotting agents, anticholinergics, and reversal agents using simple inputs. EIT's performers are accelerating innovation, integrating synthetic biology, AI, and process engineering to re-shore production of critical key starting materials and APIs.

BioMap Consortium

In partnership with the Biomedical Advanced Resource and Development Authority, EIT is executing multiple efforts through the BioMap Consortium. This consortium supports and facilitates development of the technological infrastructure within the domestic bioengineering industry to provide new materials, products, capabilities, and manufacturing paradigms for the nation.

EQUIP-A-PHARMA

In collaboration with the Defense Advanced Research Projects Agency, EQUIP-A-Pharma aims to develop informatics-based models to create a real-time digital regulatory approval framework for qualification of pharmaceuticals produced in agile pharmaceutical manufacturing platforms.

WHY IS THE EIT OFFICE IMPORTANT?

The EIT Office advances the development, deployment, and on-shoring of manufacturing capacities for Key Starting Materials, Drug Substances and Drug Products that enable population-scale fill/finish and agile and distributed cGMP compliant production of pharmaceuticals and supportive care fluids. These manufacturing capacities will help strengthen supply chain resilience, grow the bioeconomy, and deploy increasingly agile, renewable and sustainable pharmaceutical resources capable of immediately responding to surges in demand caused by public health emergencies.