

ON DEMAND PHARMACEUTICALS

Industry Development of Advanced Manufacturing: On Demand Pharmaceuticals

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funded by the U.S.
Government. The views and
conclusions contained in this
document are those of the
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the official policies,
either expressed or implied,
of the U.S. Government.



MINI BUT **MIGHTY**

Disclaimers:

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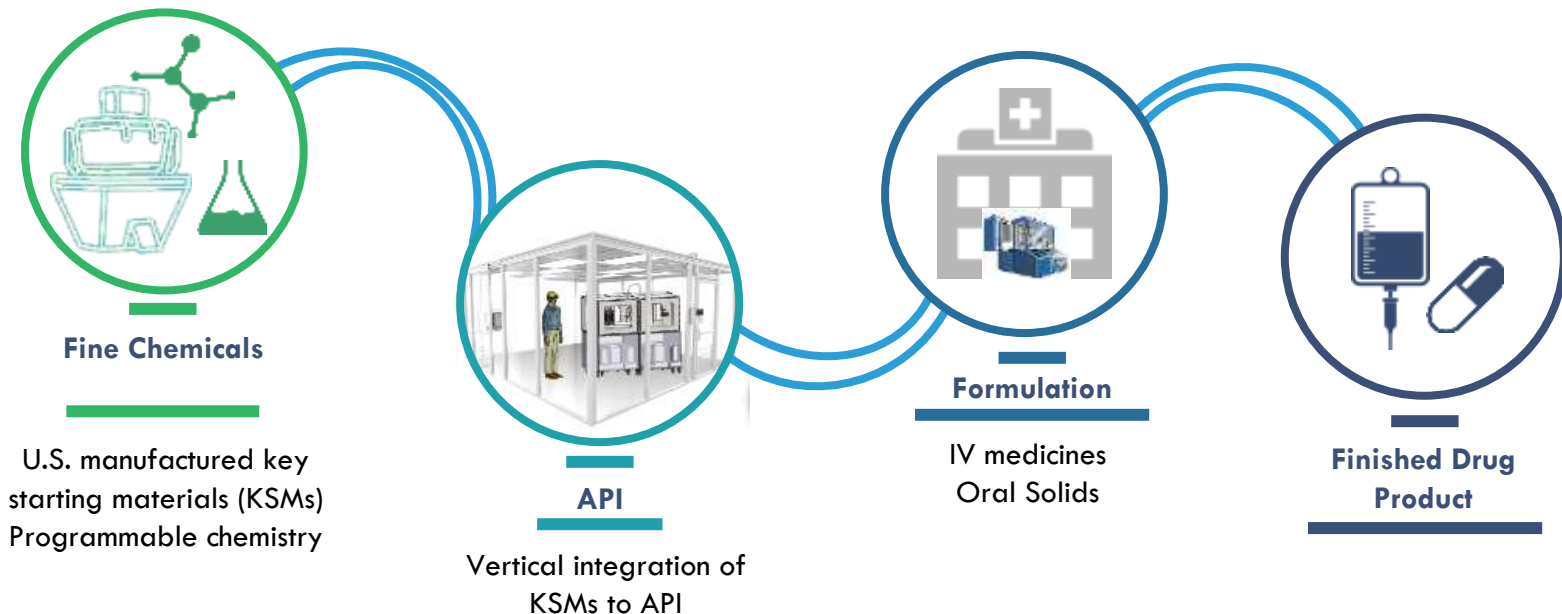
ODP at a Glance

Dr. Ling conceived of the idea of Pharmacy on Demand while treating an injured soldier in Afghanistan. The soldier suffered from a traumatic brain injury and the medicine he needed was unavailable. Dr. Ling had the medicine flown in from Germany and the young soldier went on to make a full recovery.

Our Objectives



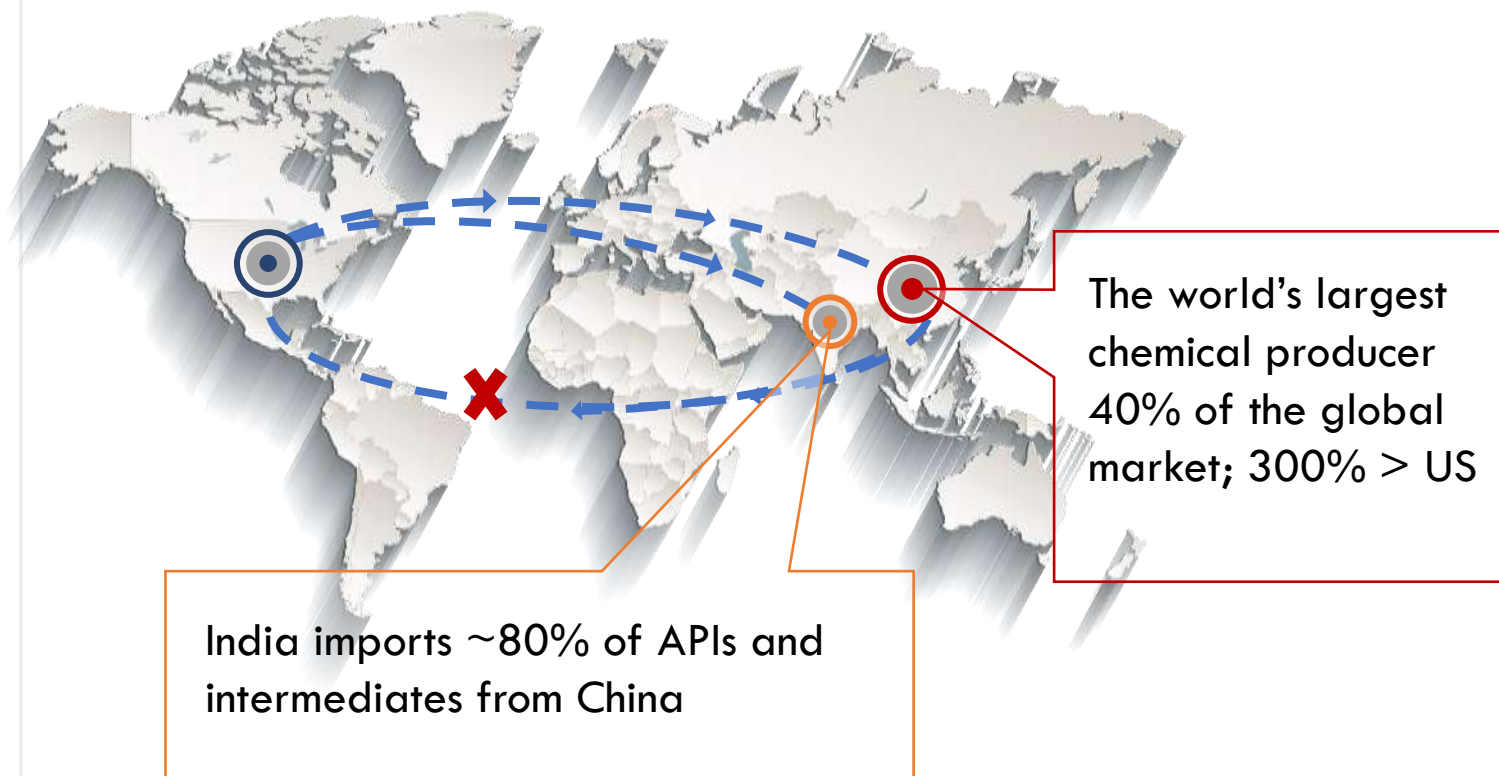
Funded by
DARPA + HHS



Rapid Acceleration :

- 45,000 ft² HQ with cGMP suites
- A growing team
 - R&D
 - Manufacturing
 - Quality
 - Regulatory
 - Operations
- 16 precursors
- 21 APIs (active pharmaceutical ingredients)
- 5 tablets
- 3 sterile injectables

The Current Ecosystem → Aging Facilities, Off-shore Manufacturing, Quality Issues, and Challenging Market Dynamics



9/10

prescriptions taken by
Americans are generics

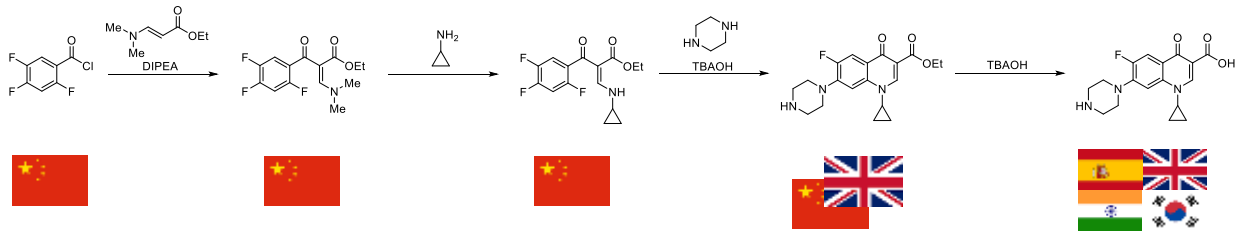


85%

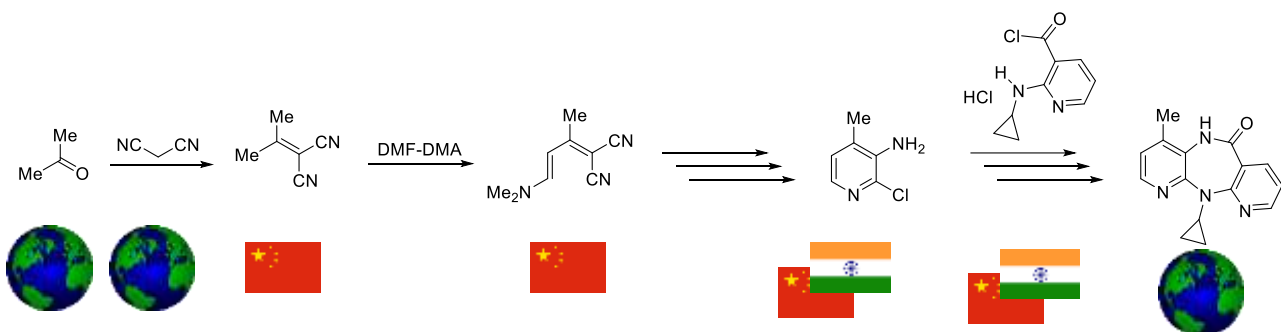
are **vulnerable** to supply
chain disruption if trade with Asia
were interrupted

National Security: High Foreign Dependency

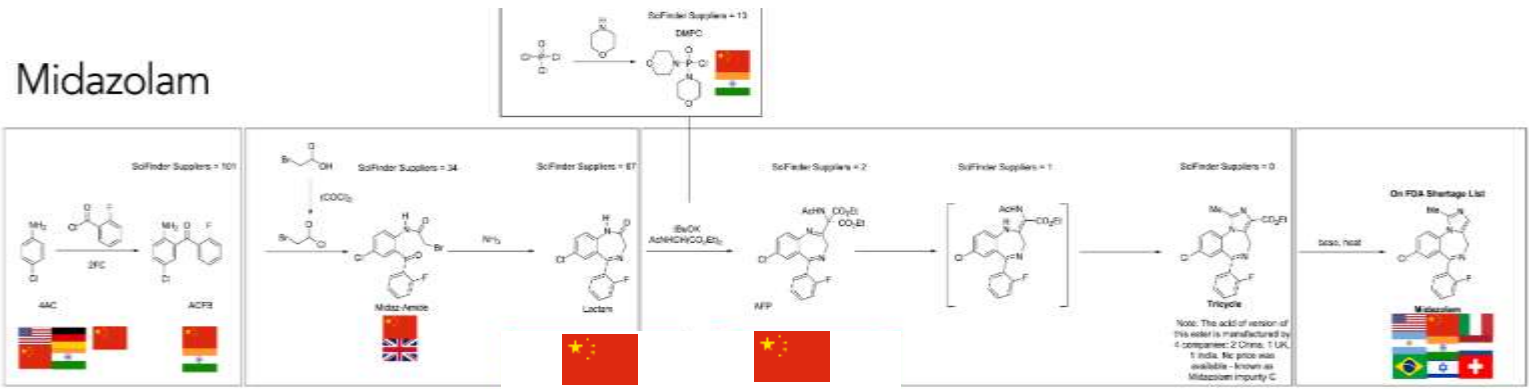
Ciprofloxacin



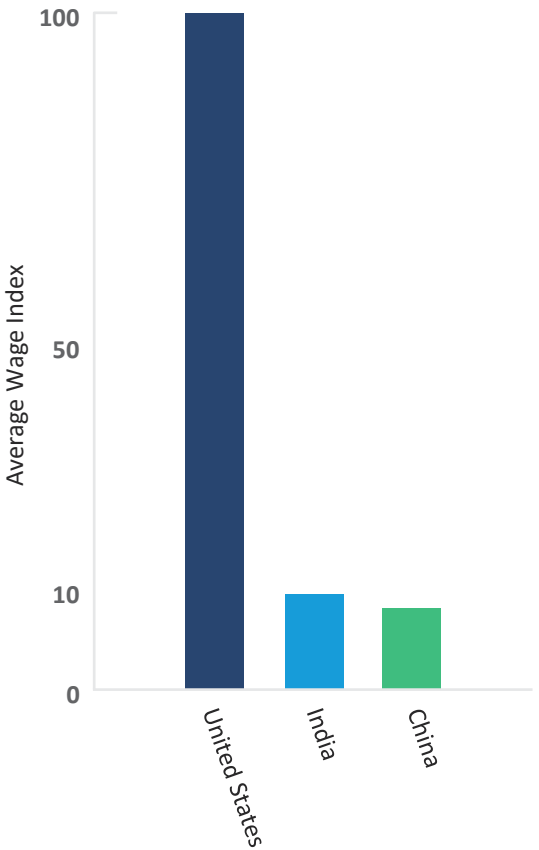
Nevirapine



Midazolam



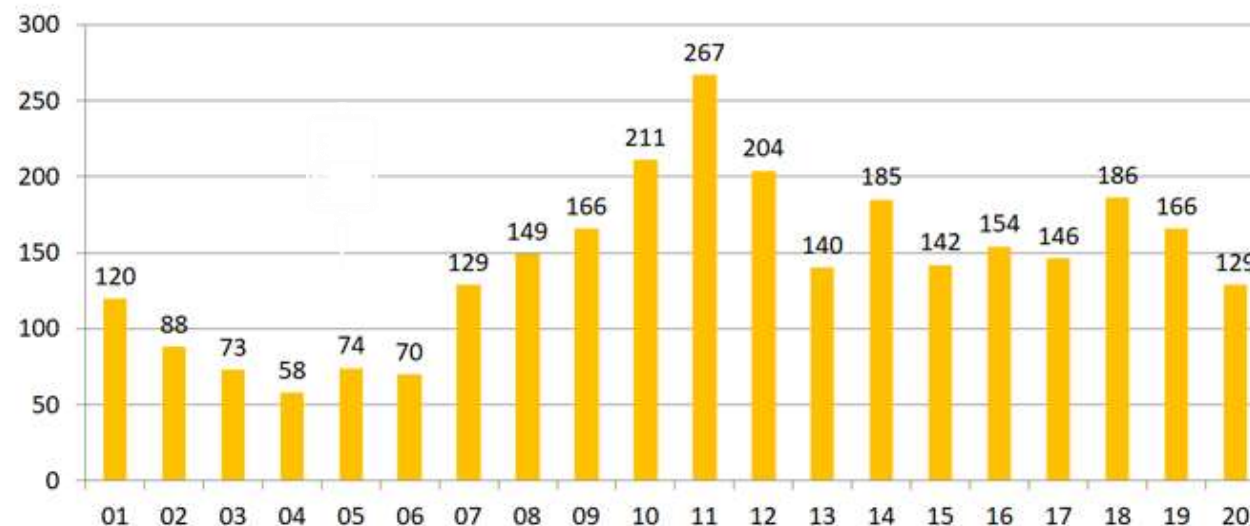
Wages to Make KSMs & API



Patients Lives at Risk: An Old Problem in Need of New Solutions

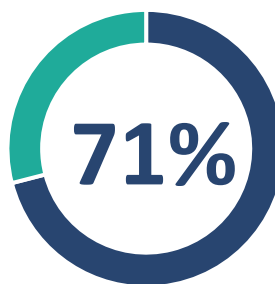


National Drug Shortages: New Shortages by Year (2001 to 2020)

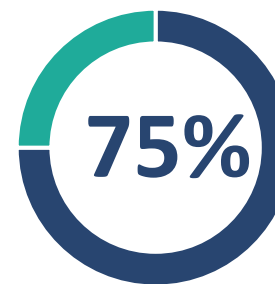


ASHP - University of Utah Drug Information Service
<https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics>

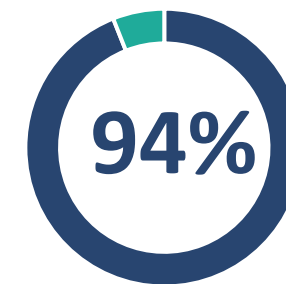
Hospital Pharmacy Survey



unable to provide
patients with the
recommended drug



patient treatments have
been delayed



rationing or restricting
drugs in short supply

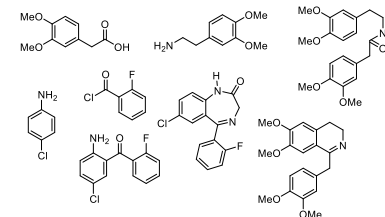
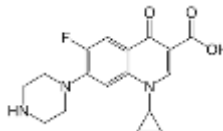
8.6m hours of additional labor

\$359m annual spend by hospitals on
shortage mitigation
strategies

<https://www.ismp.org/resources/drug-shortages-continue-compromise-patient-care>

ISMP. ISMP survey on drug shortages for hospital pharmacy directors or their designees only. *ISMP Medication Safety Alert!* 2017;22(17):5-6.

Global Supply Chain Capabilities Under One Roof



Making Equipment	Making Drug Products	Making API	Making Precursors	Virtual/Digital QA & Production Control
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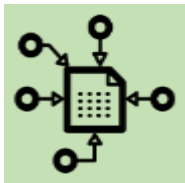
Rapid prototyping → GMP

QbD, PAT/APCs, RTRT

Automation / Programming

Modularity / Plug and play

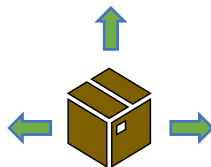
- Site monitoring/support
- Virtual QA
- Distributed QMS



IT Infrastructure and
Cyber



Integrated Project &
Lifecycle Mgmt.



Warehousing, Storage, &
Distribution



QMS - Documents,
Records, Controls, QA



QC Lab (Device
and Product)

Rapid Progression – Integrated, Multidisciplinary Workflows

Organic Chemists
Chemical Engineers
Analytical Scientists
Formulation Scientists
Electromechanical Engineers
Automation Engineers
Machining Engineers
Data Scientists and Statisticians

QA Scientists
QC Scientists
Qual/Validation Engineers
Regulatory Scientists
Manufacturing Experts
Operations and Admin

2020



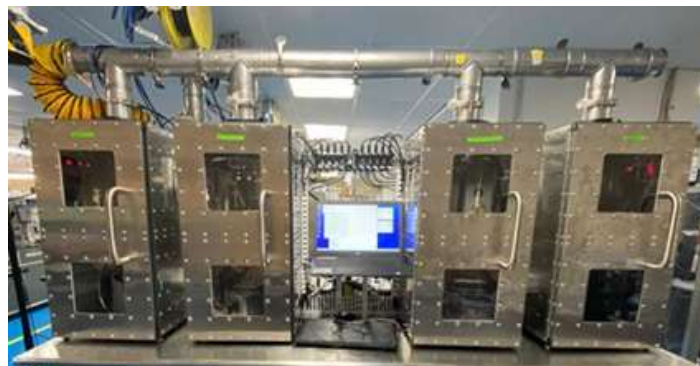
2021

Combatting the race to the bottom through science & technology

PoD: Automated, programmed, molecular systems



Precursor Production Systems



API Production Systems

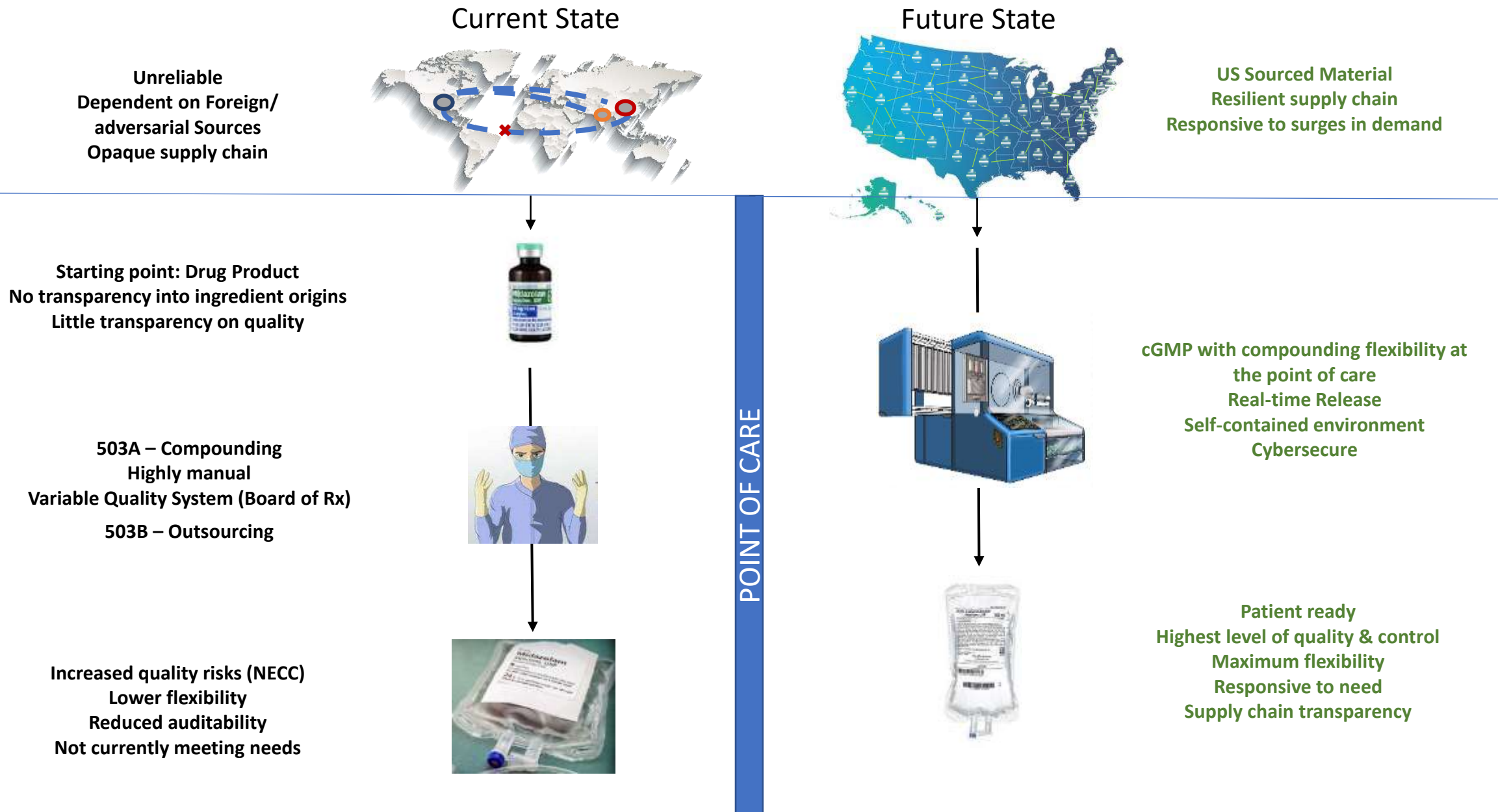


Purification Systems



US Sourced Material
Resilient supply chain
Responsive to surges in demand

Innovating a Patient-centric, Transparent, Ecosystem



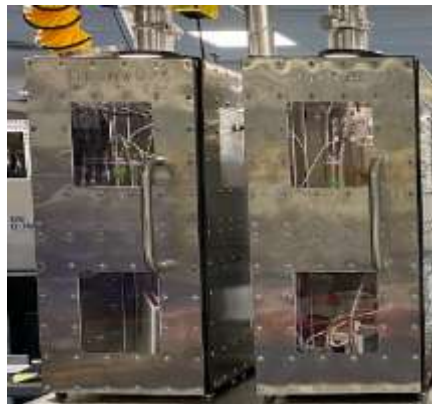
Revolutionizing Where and How Medicines are Made

Predictive Insights



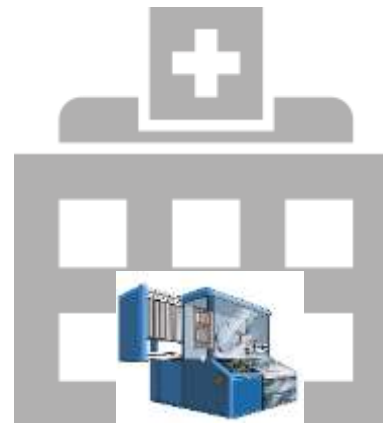
Proprietary Multilayer
Network Analysis

Agile, Rapid-Response Production Capability



- Programmable Chemistry
- Automation
- Process Analytical Technology

PoD at Point of Care



- Full automation
- Link with health records
- Personalized
- Improved safety
- Quality → every dose
- Cost savings

PoD Network Distributed Manufacturing



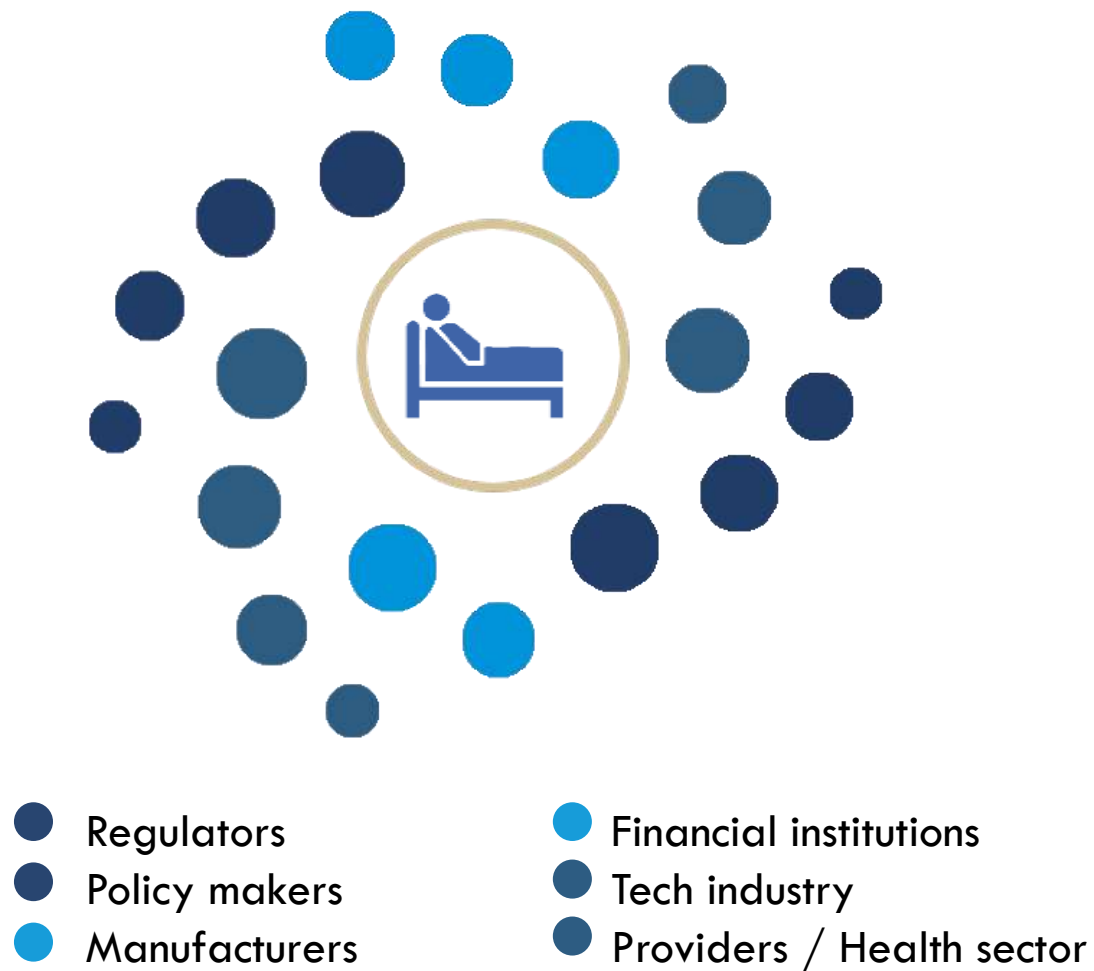
- Vertical integration
- Revolutionizes how medicines are sourced, manufactured, and distributed

ARBITRAGE

SPEED / RESILIENCE

SCALE

Mobilizing the Ecosystem: Advance 21st Century US Manufacturing Technology to Improve Patient Outcomes





Resilience & Responsiveness
protecting the warfighter



Access to high quality
essential medicines



Affordability
savings for our seniors



Reliability remediates
drug shortages