



*“On-Demand Manufacturing of Pharmaceuticals”*

Compact Factory for Drugs on Demand:  
*Technology, Implementation, and Impact*

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Feb 28, 2020



Access to Medications affected by High Costs of  
Drugs and Shortages



**Rethink**

Manufacturing Process and Supply Chain  
Distribution

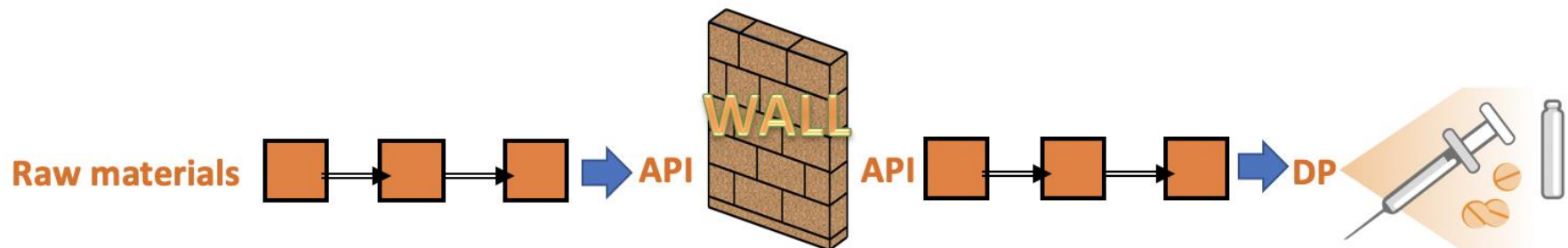
# The Underlying Problem: Batch Manufacturing of Pharmaceuticals



**Active Pharmaceutical Ingredient (API)**



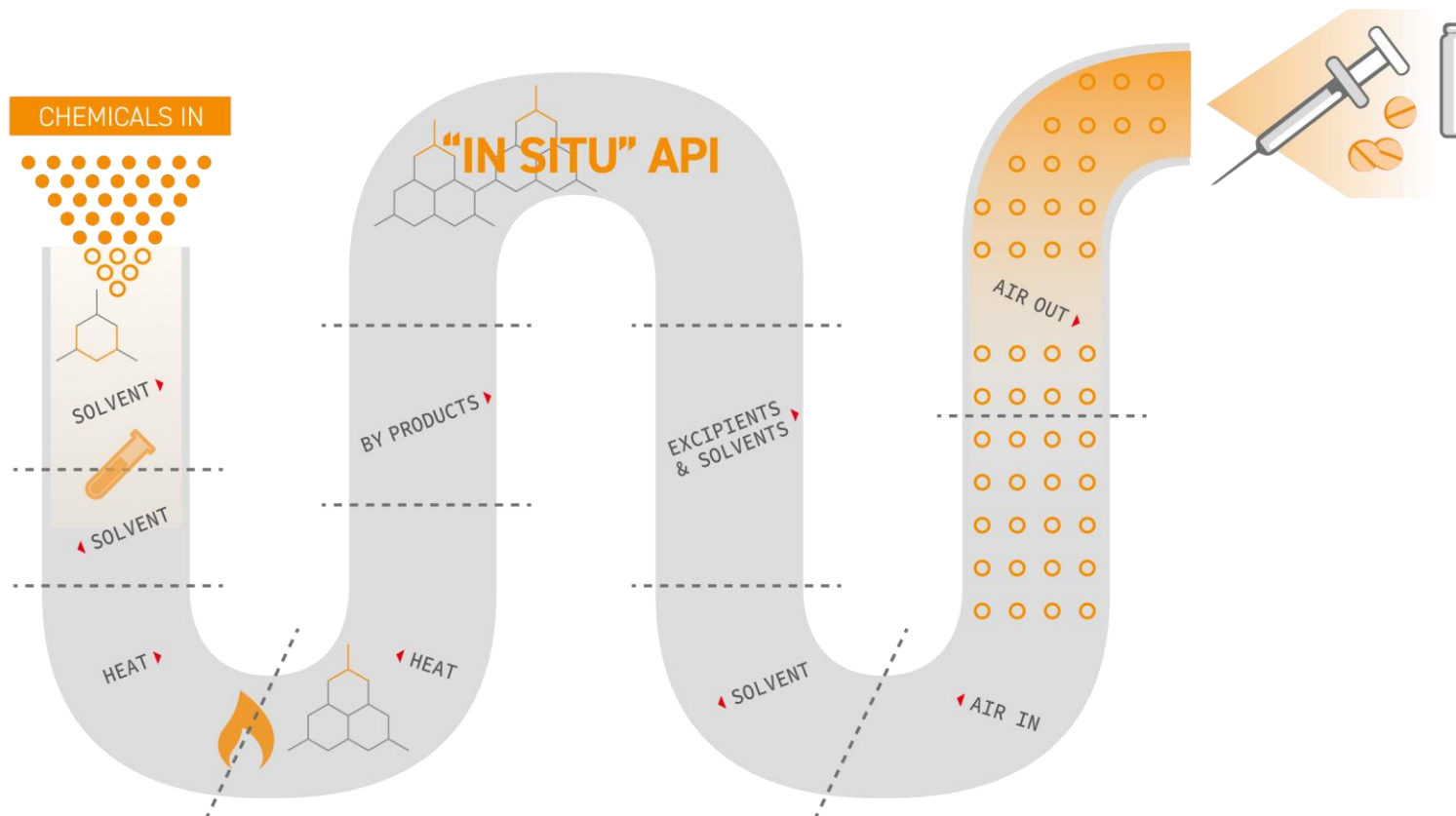
**Drug Product (DP)**



**Multiple, disconnected batch steps**

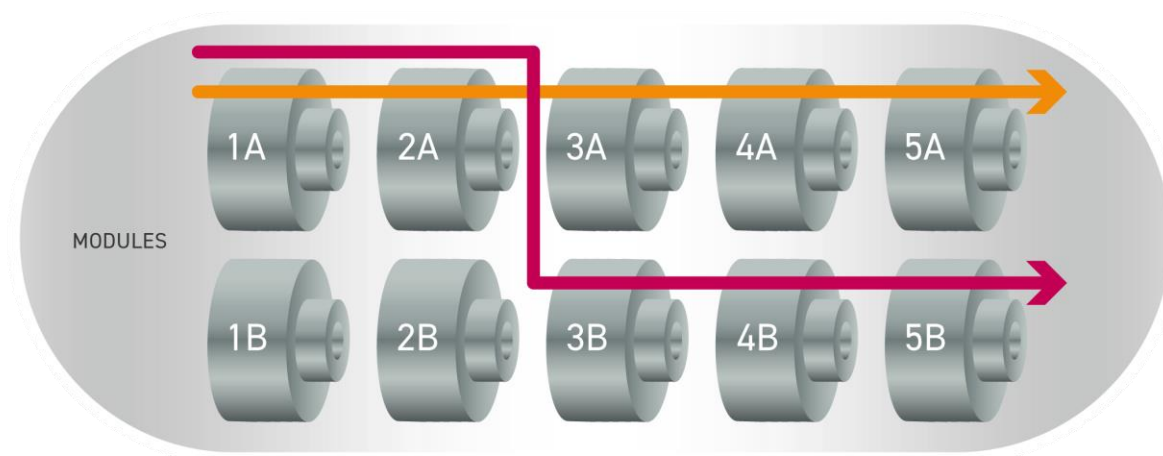
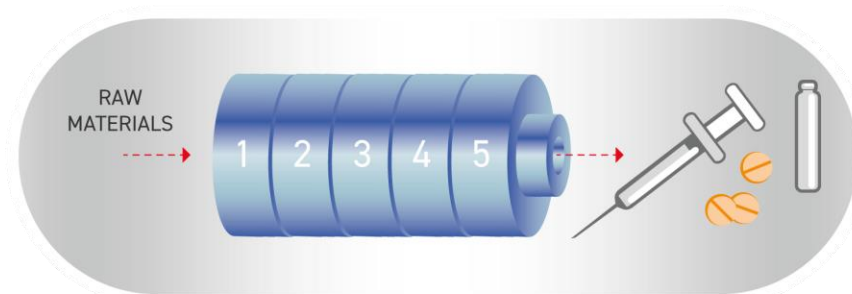
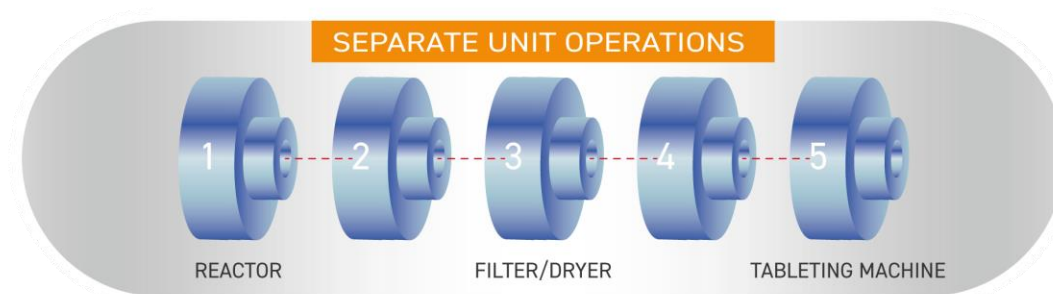
# Our Solution:

## Integrated Continuous Manufacturing (ICM)

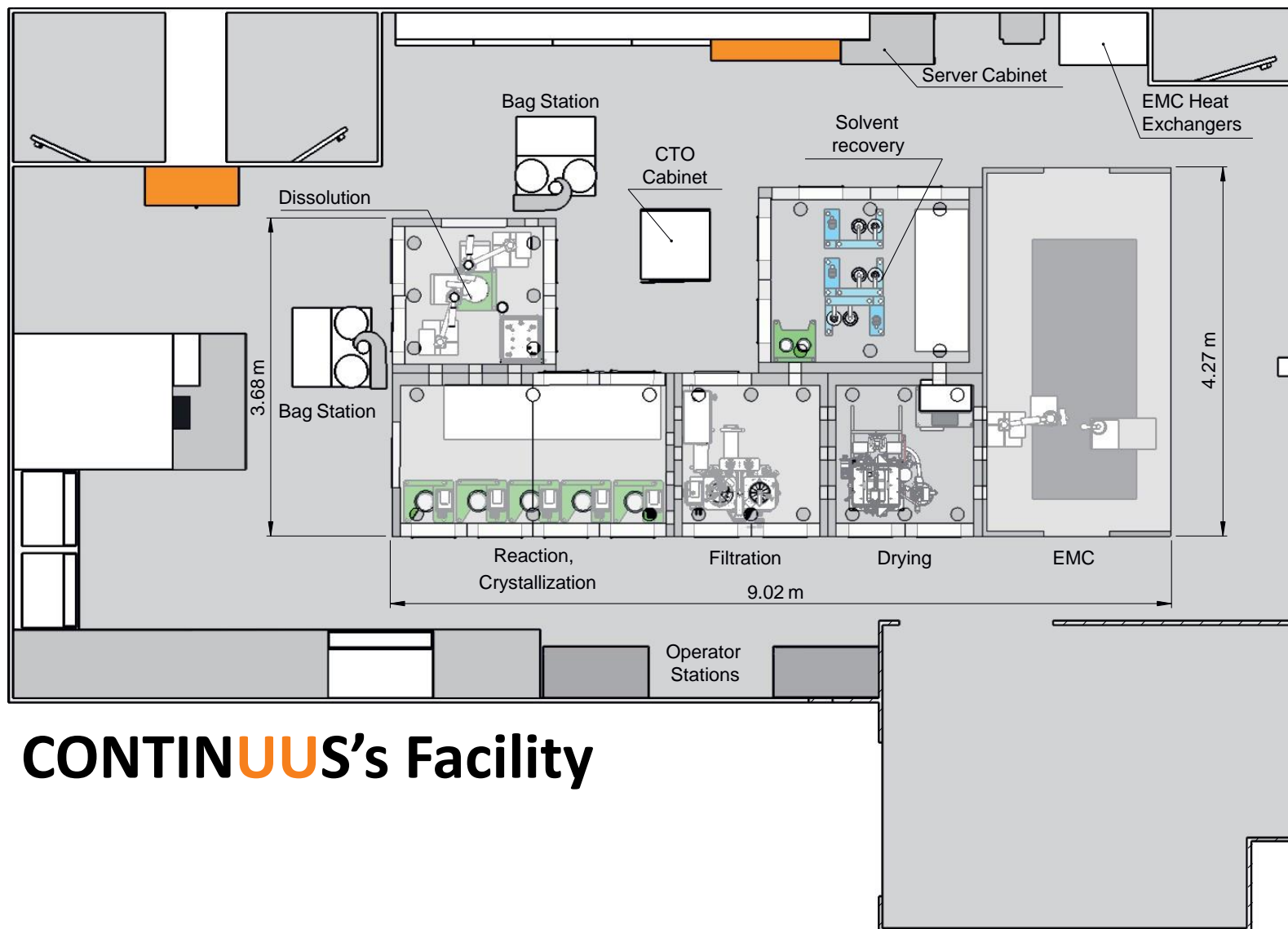


***Continuous Flow - End to End Integration - System Approach - Integrated Control Strategy***

# ICM: *How it works*



# ICM Facility Floor Plan



## CONTINUUS's Facility

# ICM Plant is Operational

nature

Subscribe



A drug-making facility built from bespoke parts takes up no more space than a boxing ring. Credit: Studio Baraldi sas

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## Mini-factory churns out drug cheaply and at a furious pace

A small, fully automated assembly line can produce 4,800 tablets an hour and could make drugs more widely available.



# Commercial Business Case Study



All Target Product Profiles were met



Cost reduction vs batch is 30%-35%



Reduction in # of unit operations 80%-85%



Reduction in solvent usage > 60%



Energy savings is 50%-60%



Footprint reduction ~ 90%



Lead-time from months to < 48hr

*High volume generic drug*





# Supply Chain Advantages



## Development

- Shorter development times
- Reduced scale-up from development to manufacturing
- Fast to market



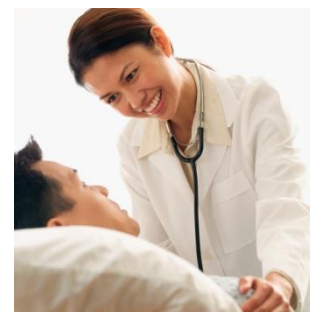
## Manufacturing

- Reduced lead time
- Decreased COGS
- Greater flexibility during launch
- Small footprint
- Decreased inventory



## Sales/Distribution

- Regional manufacturing and distribution network
- Increased responsiveness to change in demand



## Patient Care

- Reduced chance of drug shortages
- Improved product quality globally

***Throughout the supply chain, ICM adds significant value***

# *Implementation*

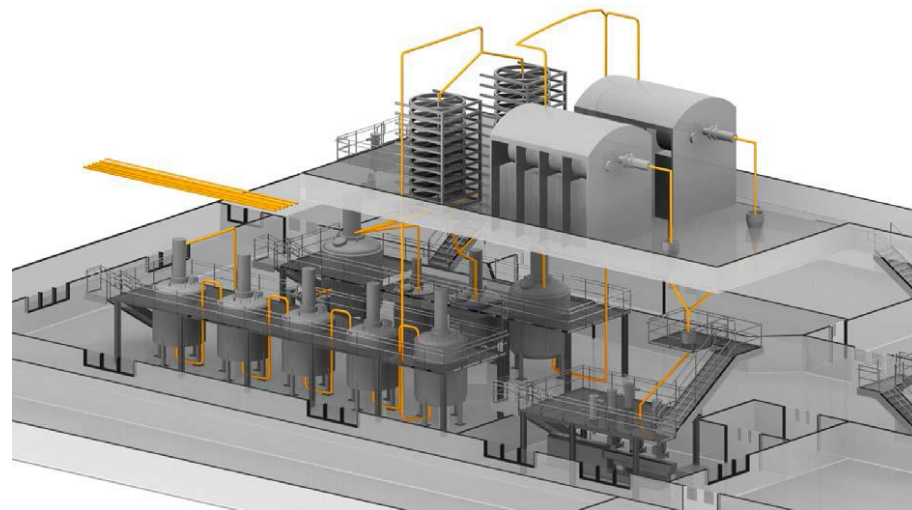
# Transition Phase

✓  
Process  
Development

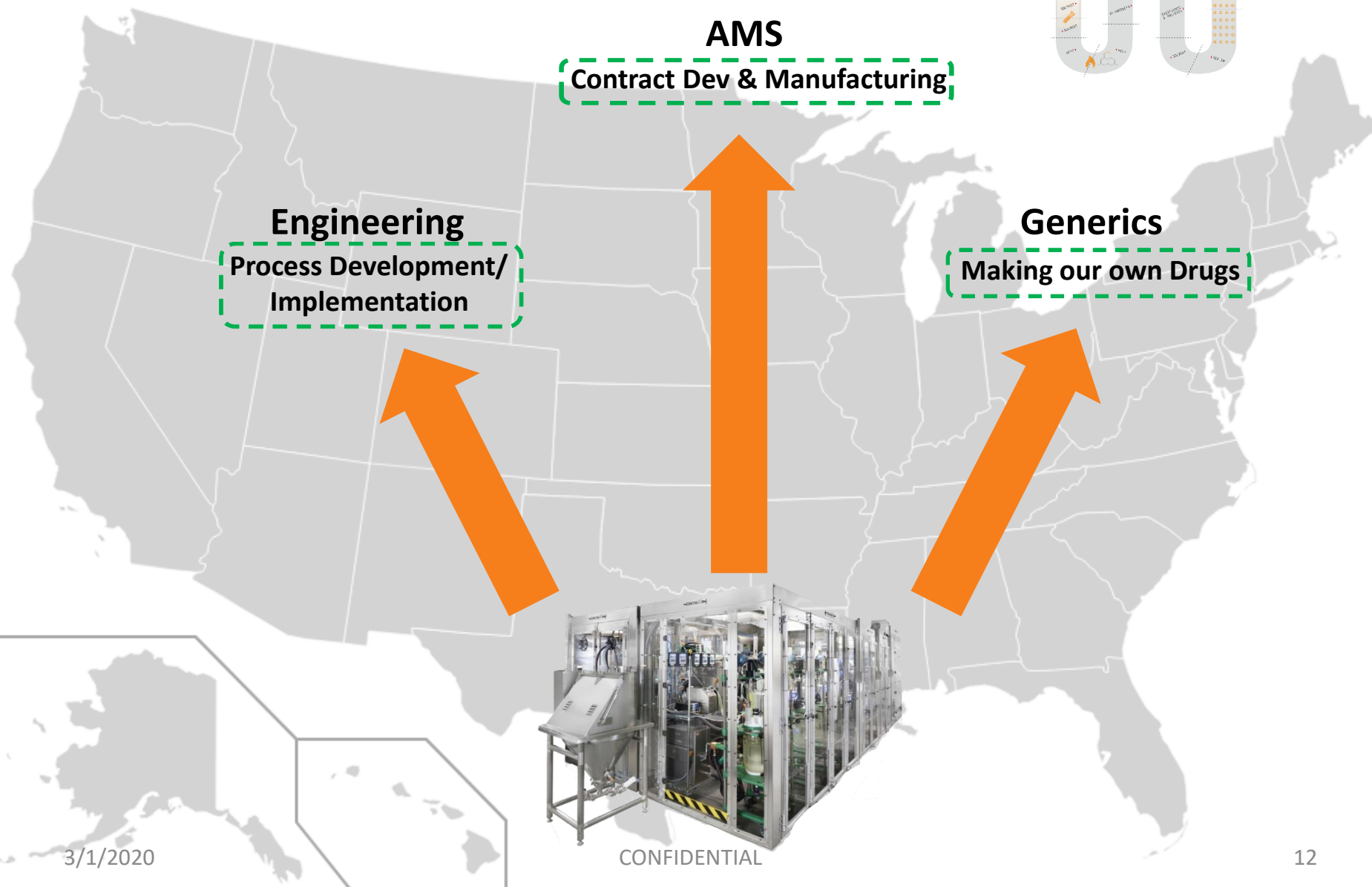
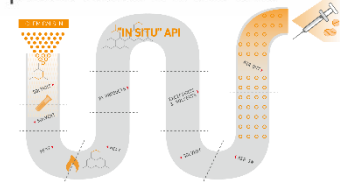
Ready in 3 years



✗  
Commercial  
Manufacturing  
(cGMP capability)



# Different Business Models



# Manufacturing Operations Model

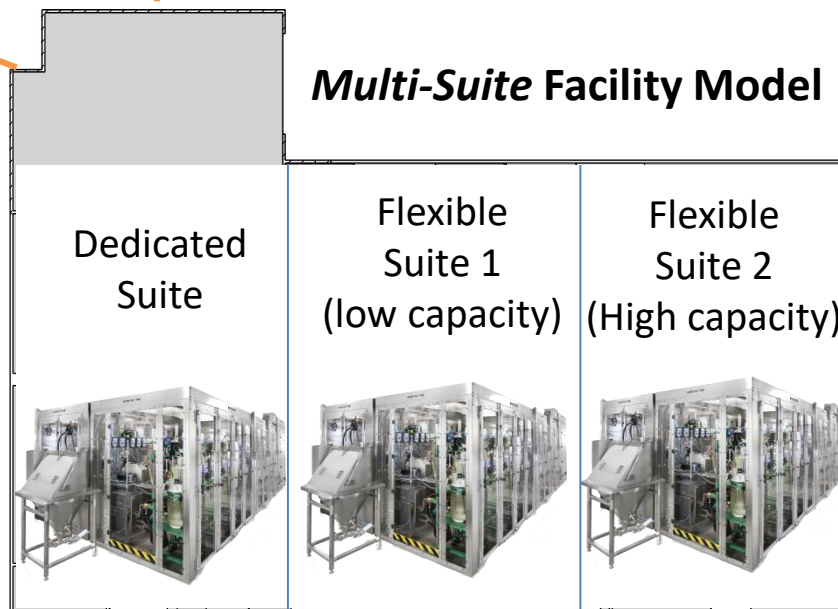
***MoP line at client-owned  
location e.g. Pharma Facilities***



***MoP line at point of care,  
e.g. Pharmacies***



## ***Multi-Suite Facility Model***



# Manufacturing Operations Model

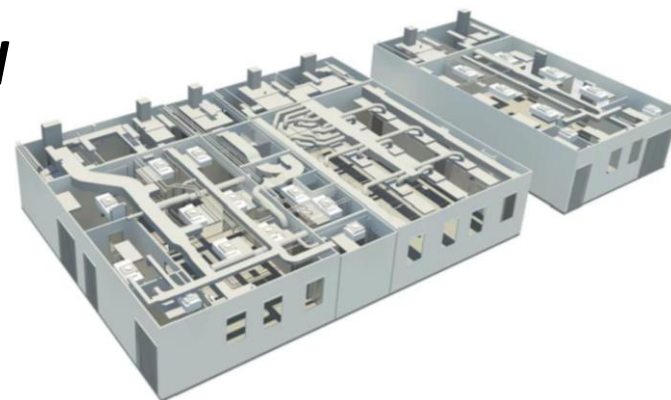
## ***Multi-Suite Facility Model***

- Project/Client that do not have facility infrastructure
- Projects for long term operations



## ***Mobile Pharmaceuticals (MoP) Model***

- Projects that requires high mobility across facilities





# MoP - Mobile Pharmaceuticals Concept

## Site Readiness:

- Pre-equipped with necessary utility & power /back-up infrastructure
- UPS
- BAS

## cGMP Requirements:

- Floor quality
- Air filtration
- Contamination
- Airlock
- Other

## Utility Hookups:

- Gases
- Liquids
- Power
- CIP agents

## Lighting & Enclosure Controls

## Control:

- Wiring
- Electrical Panels
- PLC's
- Main Station
- Server

## Air Handling & Containment:

- HVAC
- HEPA Filters
- Scrubbers
- Other

## Waste:

- Collection
- Disposal

Material Inflows

Material Outflows

## Environmental Controls:

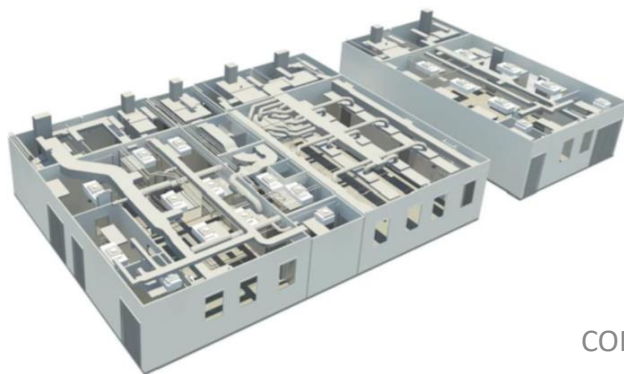
- Temp.
- Humidity
- Other

Spill Containment

Unit Ops

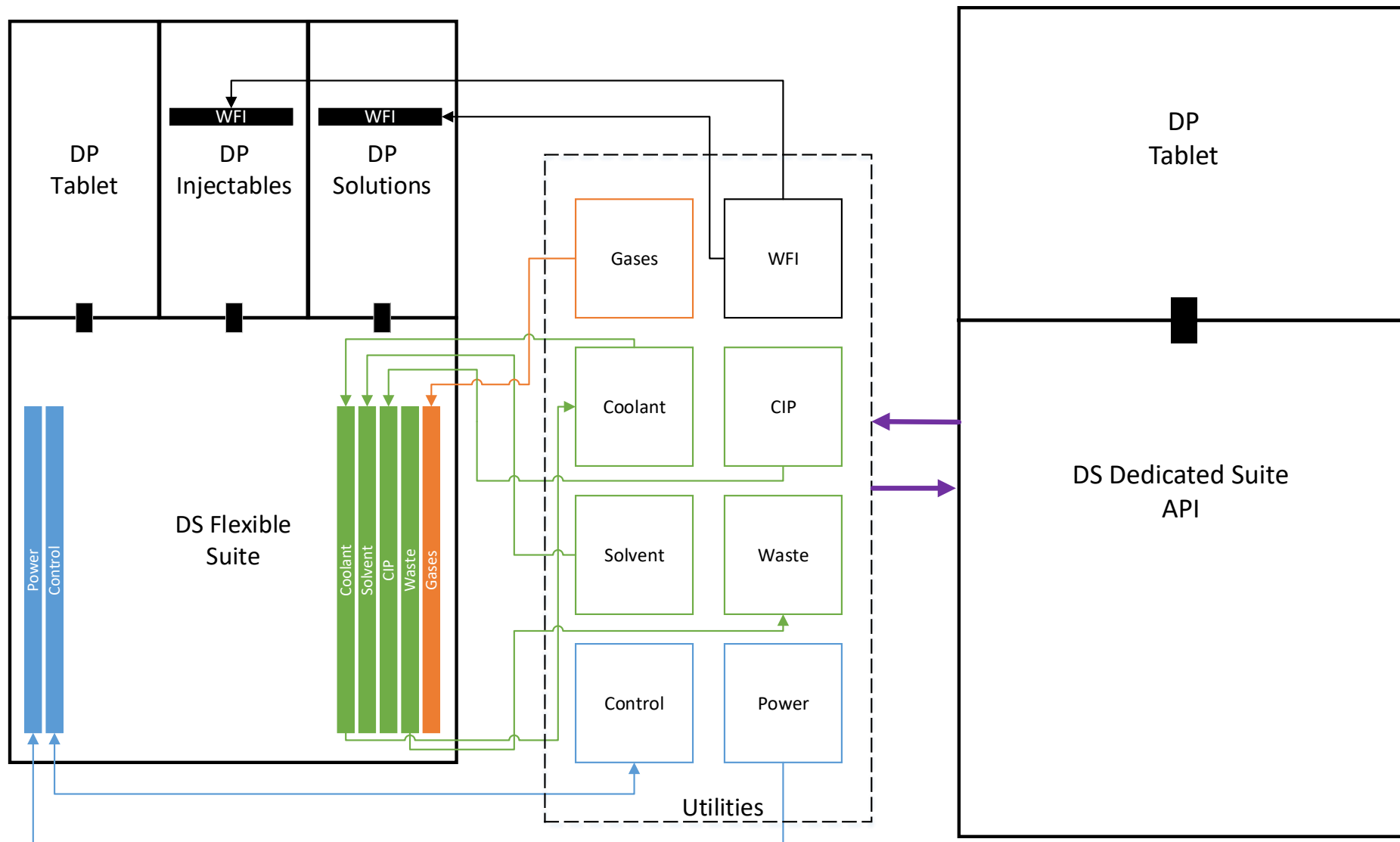
## Alarms

- LLE
- Solvent Conc.
- Air Flow
- Other



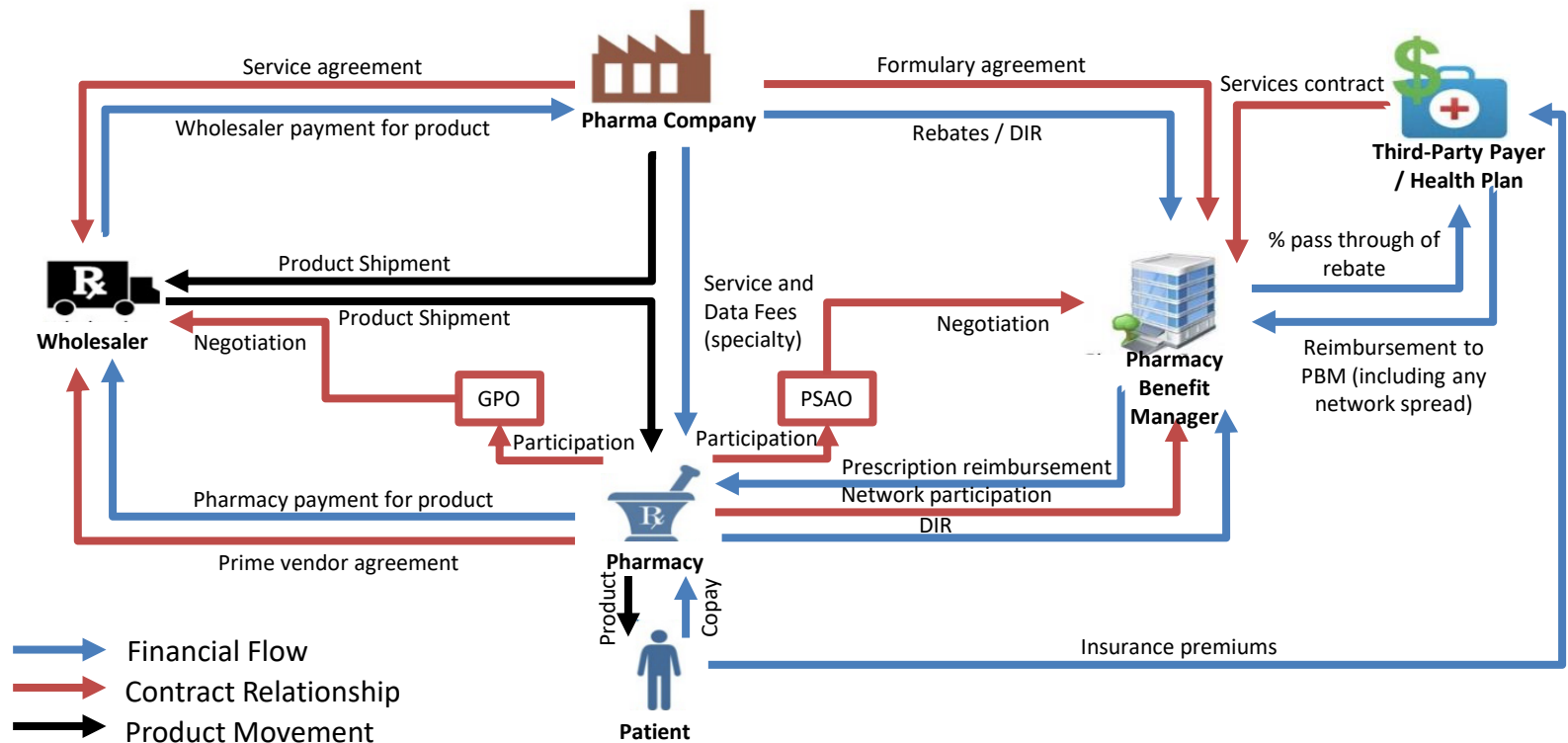
*“Deployable MoP plants that connect to clients’ existing utility infrastructures”*

# Multi-Suite Facility Concept



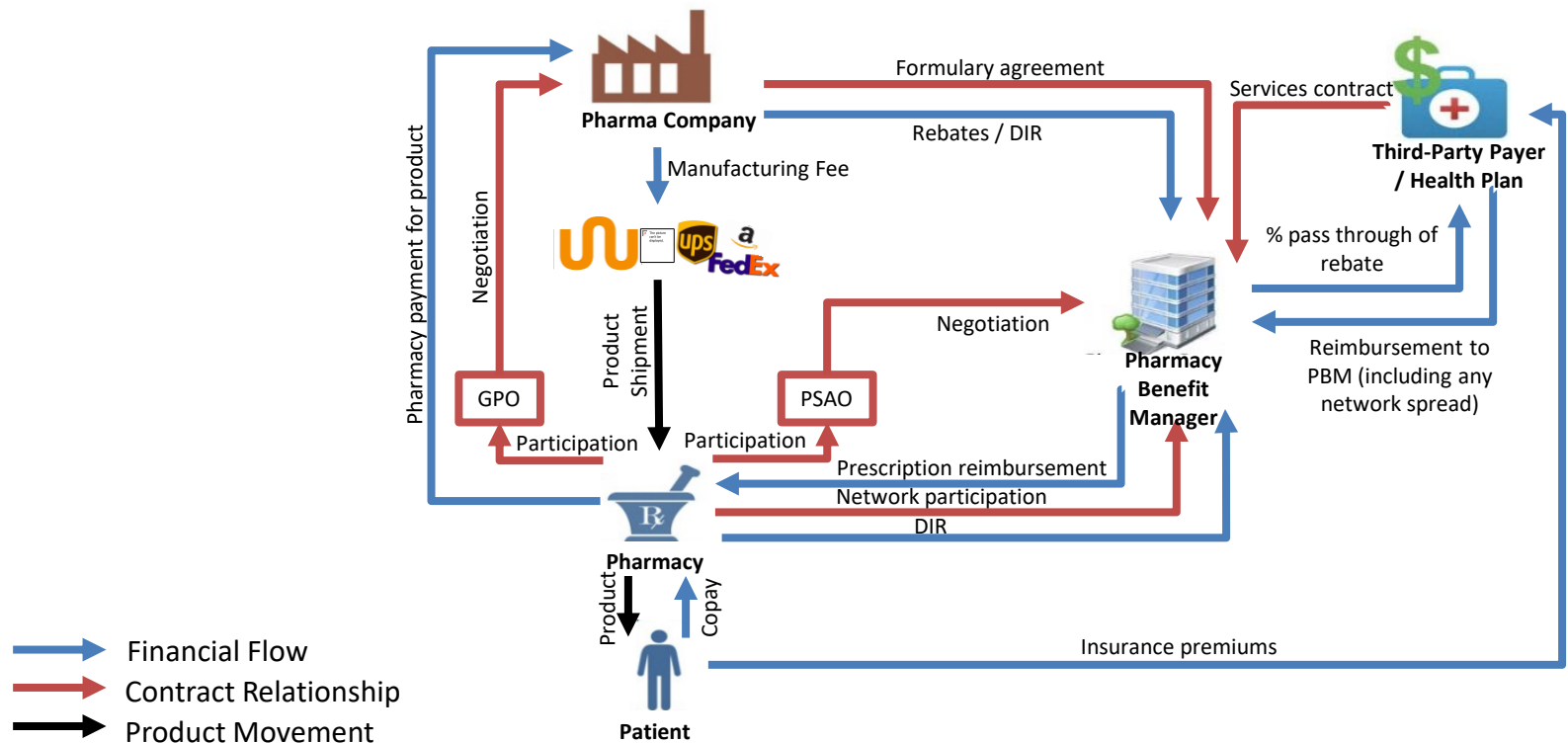
# *Impact*

# U.S. Drug Distribution and Reimbursement System: *Current Status*

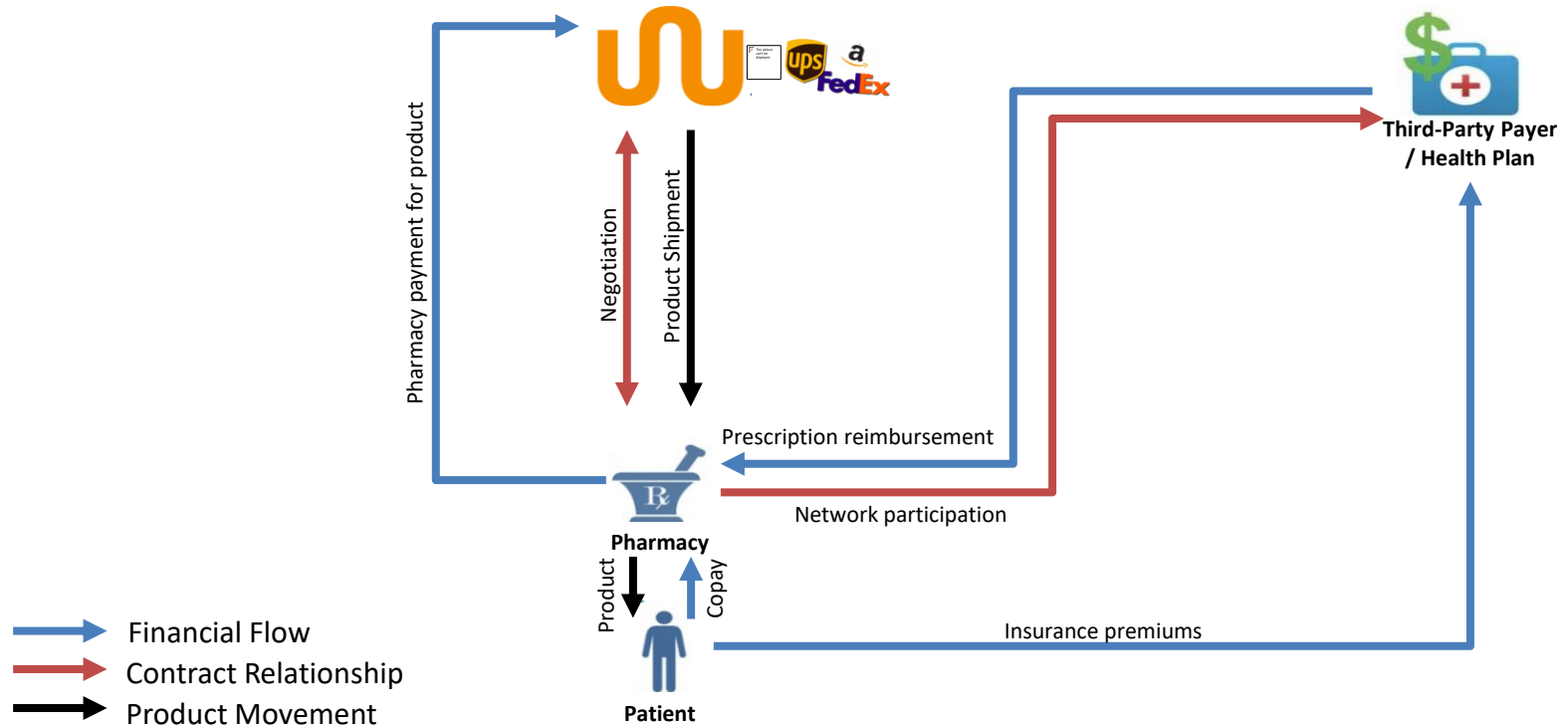


Source: Drug Channel Institute

# U.S. Drug Distribution and Reimbursement System: *with ICM for Brand Name Drugs*



# U.S. Drug Distribution and Reimbursement System: *with ICM for Generics*





# Conclusions

## ICM will transform pharmaceutical manufacturing

- Fully automated process with built-in quality
- Miniaturized plant with modular, interchangeable unit operations for many different drugs
- "On-demand"* manufacturing: lead time ~ 30 h
- Cost reductions ~ 30-50% versus batch

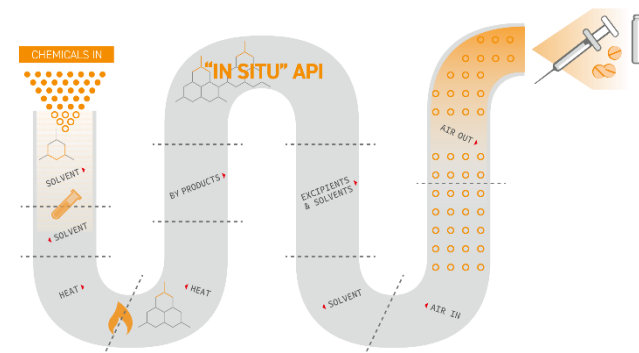
## Status and Impact of ICM Process

- ICM pilot plant is operational – Commercial in 3 years
- Enable novel Manufacturing Operations models
- Streamline drug distribution and reimbursement system

3/1/2020

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pharmaceuticals



*Thank you!*

*The CONTINUUS Pharmaceuticals Team*

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