



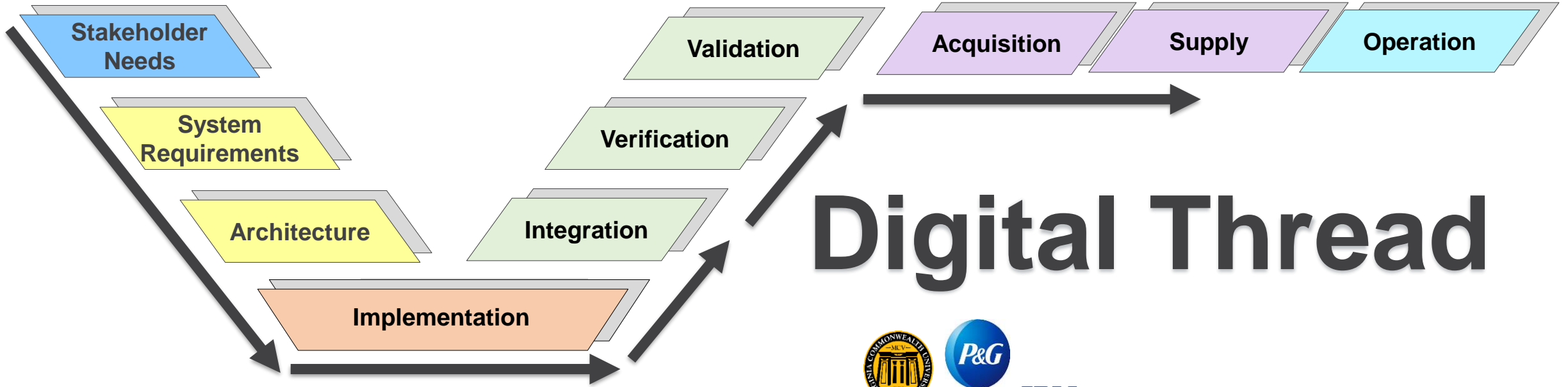
2022
Annual **INCOSE**
international workshop
HYBRID EVENT
Torrance, CA, USA
Jan 29 - Feb 1, 2022

Premier Systems Engineering Workshop

Uber for MBSE



Agenda:



Digital Thread

- Problem
- Solution
- Pilot

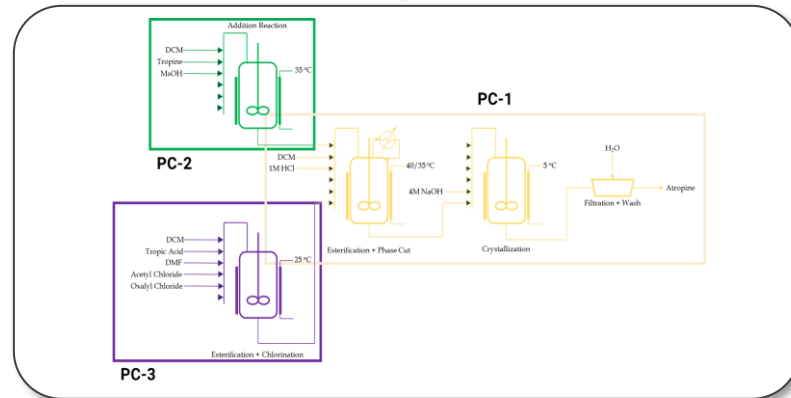
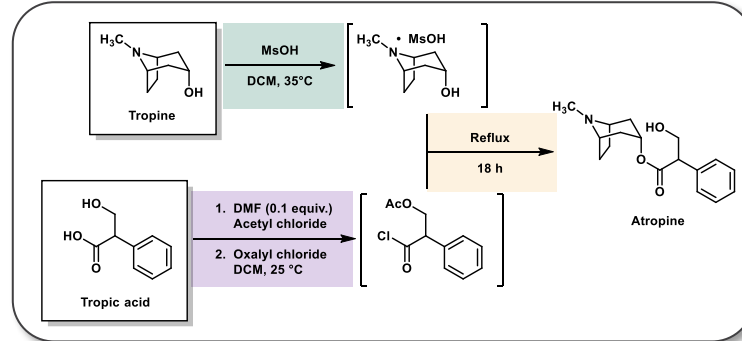


The problem...

>1300 Strategic Off-Patent API



Manufacturing Requirements



Contract Manufacturers



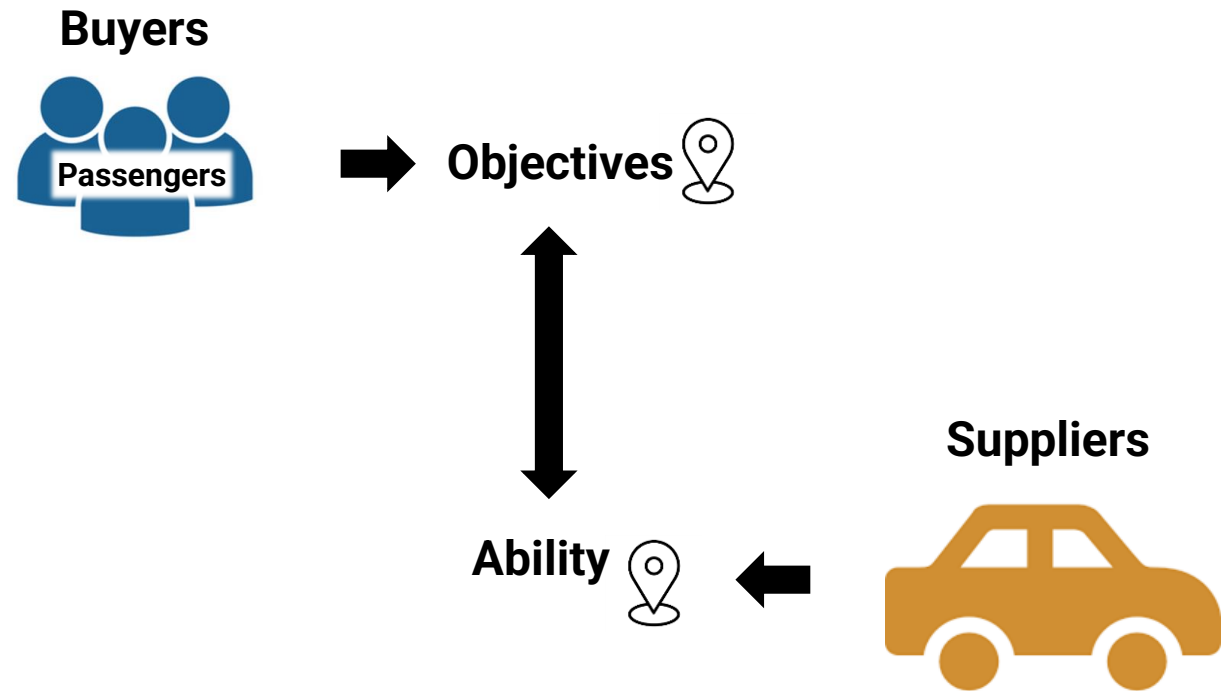
Contract Manufacturing Organization (CMO)
CMO = cGMP manufacturer
 12 CMOs, 27 sites
 14 Toll Manufacturers, 23 sites

Would an Uber Approach Help?



Uber

Mission: Provide transport solutions that mutually benefit both buyers and suppliers in a rapidly changing environment.

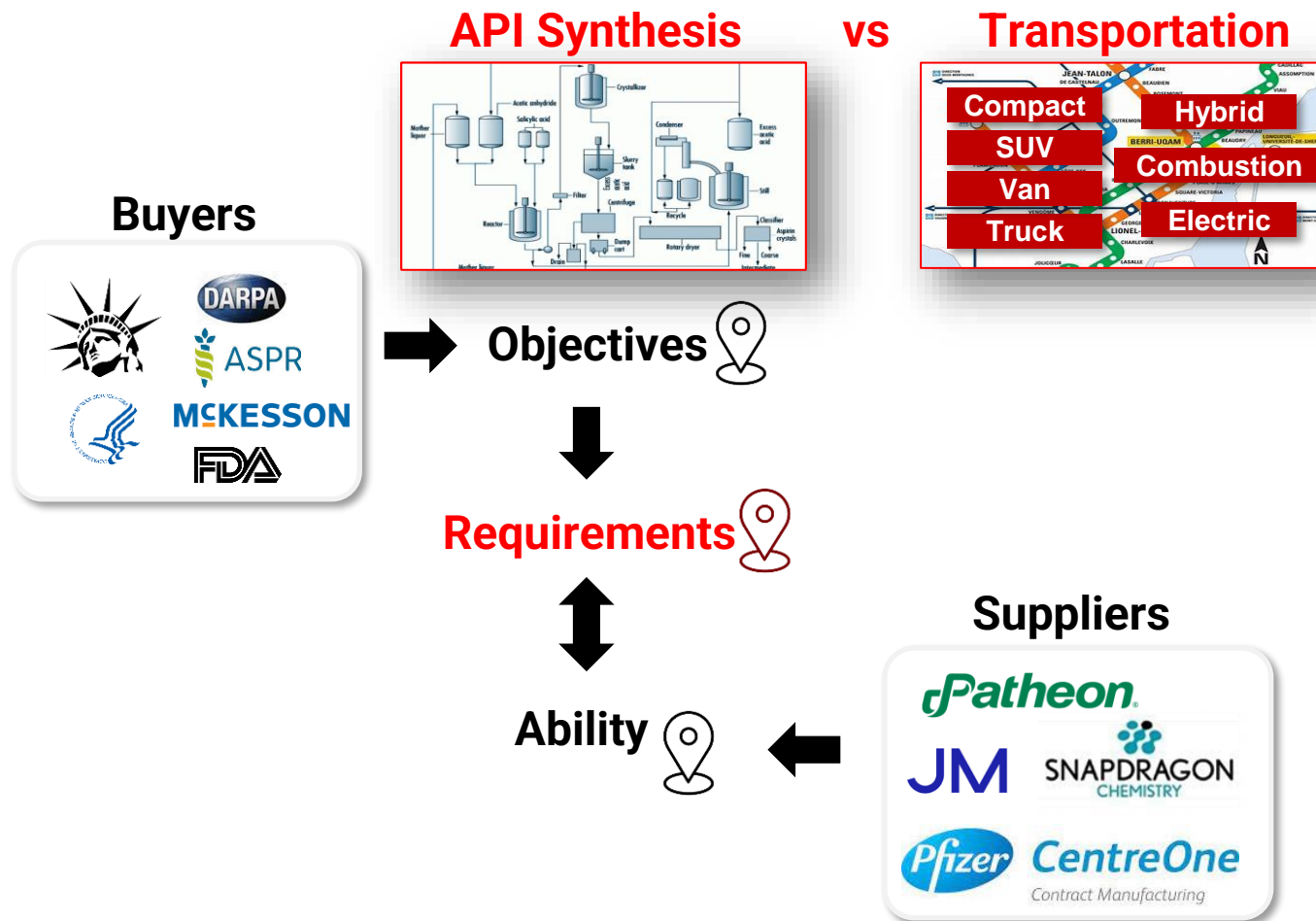


Uber for Chemical Supply Chain

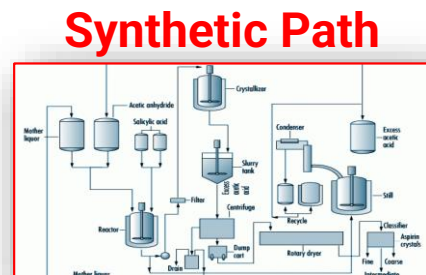


Atropine (antidote); Albuterol (bronchodilator; #10 prescription); Ciprofloxacin (antibiotic); Propofol (anesthetic); Midazolam (anesthetic); Ceftriaxone (antibiotic; part of penicillin/ceflosporin derivatives). Famotidine (antacid); Neostigmine (muscle strengthener; used with atropine); Lisinopril (ACE inhibitor; #1 prescription)

Mission: Provide **transport** manufacturing solutions that mutually benefit both buyers and suppliers in a rapidly changing environment.



Uber for Chemical Supply Chain



Buyers

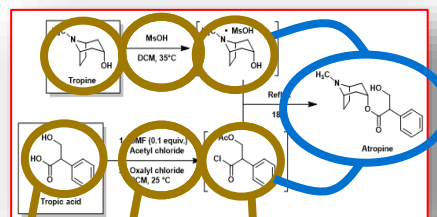
Objectives 📍

Requirements 📍

Ability 📍

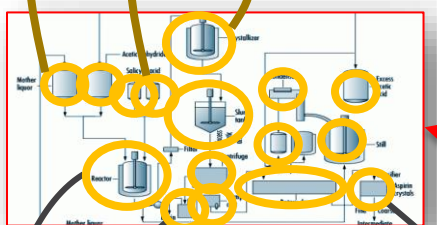
Suppliers

Transformations



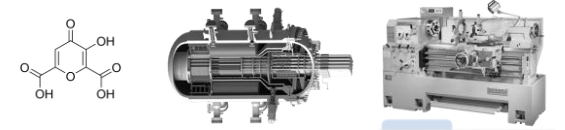
Objective

Types of Things



Instances of Things

Item ID	Description	Quantity	Unit	Location	Status
101	Acetic anhydride	1000	kg	Warehouse A	In Stock
102	Sulphuric acid	500	kg	Warehouse B	In Stock
103	Crystallizer	1	unit	Plant 1	Operational
104	Reactor	1	unit	Plant 1	Operational
105	Distillation Column	1	unit	Plant 1	Operational
106	Filter	1	unit	Plant 1	Operational
107	Slurry tank	1	unit	Plant 1	Operational
108	Condenser	1	unit	Plant 1	Operational
109	Excess reagent acid	1	unit	Plant 1	Operational
110	Sill	1	unit	Plant 1	Operational
111	Classifier	1	unit	Plant 1	Operational
112	Agitate crystal	1	unit	Plant 1	Operational
113	Filter	1	unit	Plant 1	Operational
114	Course	1	unit	Plant 1	Operational
115	Crystallizer	1	unit	Plant 1	Operational
116	Reactor	1	unit	Plant 1	Operational
117	Distillation Column	1	unit	Plant 1	Operational
118	Filter	1	unit	Plant 1	Operational
119	Slurry tank	1	unit	Plant 1	Operational
120	Condenser	1	unit	Plant 1	Operational
121	Excess reagent acid	1	unit	Plant 1	Operational
122	Sill	1	unit	Plant 1	Operational
123	Classifier	1	unit	Plant 1	Operational
124	Agitate crystal	1	unit	Plant 1	Operational
125	Filter	1	unit	Plant 1	Operational
126	Course	1	unit	Plant 1	Operational
127	Crystallizer	1	unit	Plant 1	Operational
128	Reactor	1	unit	Plant 1	Operational
129	Distillation Column	1	unit	Plant 1	Operational
130	Filter	1	unit	Plant 1	Operational
131	Slurry tank	1	unit	Plant 1	Operational
132	Condenser	1	unit	Plant 1	Operational
133	Excess reagent acid	1	unit	Plant 1	Operational
134	Sill	1	unit	Plant 1	Operational
135	Classifier	1	unit	Plant 1	Operational
136	Agitate crystal	1	unit	Plant 1	Operational
137	Filter	1	unit	Plant 1	Operational
138	Course	1	unit	Plant 1	Operational
139	Crystallizer	1	unit	Plant 1	Operational
140	Reactor	1	unit	Plant 1	Operational
141	Distillation Column	1	unit	Plant 1	Operational
142	Filter	1	unit	Plant 1	Operational
143	Slurry tank	1	unit	Plant 1	Operational
144	Condenser	1	unit	Plant 1	Operational
145	Excess reagent acid	1	unit	Plant 1	Operational
146	Sill	1	unit	Plant 1	Operational
147	Classifier	1	unit	Plant 1	Operational
148	Agitate crystal	1	unit	Plant 1	Operational
149	Filter	1	unit	Plant 1	Operational
150	Course	1	unit	Plant 1	Operational

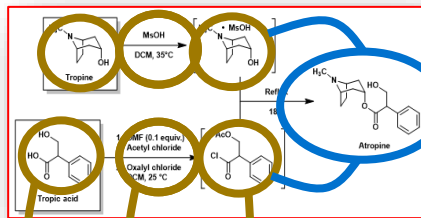


Agenda:



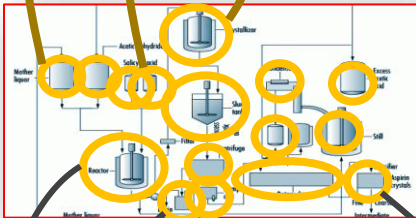
- Problem
- Solution
- Pilot

Transformations




Objectives

Types of Things

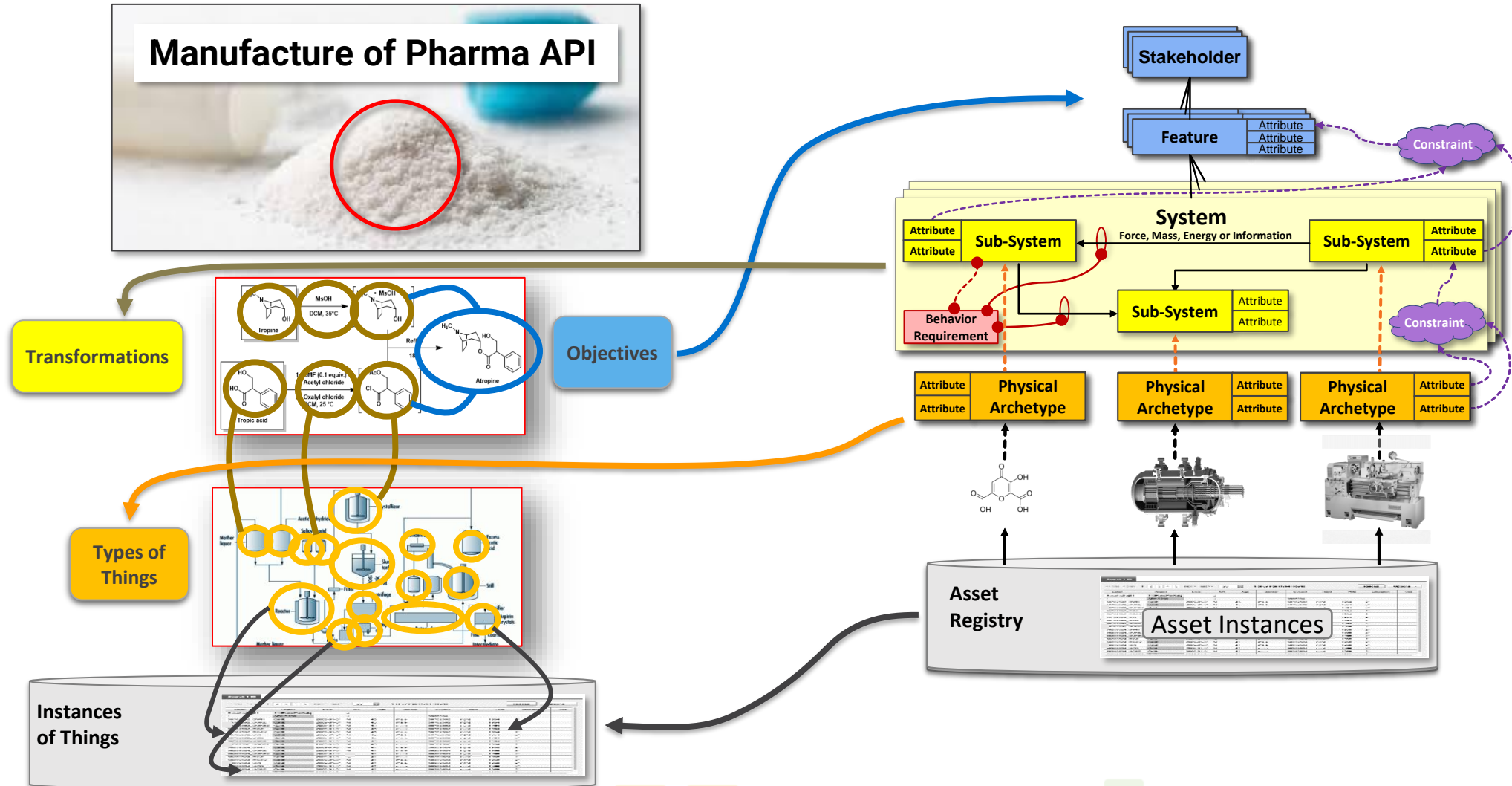


Instances of Things



ID	Name	Type	Status	Location	Created	Modified
1	Reactor 1	Reactor	Active	Plant A	2022-01-10	2022-01-15
2	Distillation Column 1	Distillation	Active	Plant A	2022-01-10	2022-01-15
3	Storage Tank 1	Storage	Active	Plant A	2022-01-10	2022-01-15
4	Reactor 2	Reactor	Active	Plant B	2022-01-10	2022-01-15
5	Distillation Column 2	Distillation	Active	Plant B	2022-01-10	2022-01-15
6	Storage Tank 2	Storage	Active	Plant B	2022-01-10	2022-01-15

Minimalistic, Formal "Systems Model"



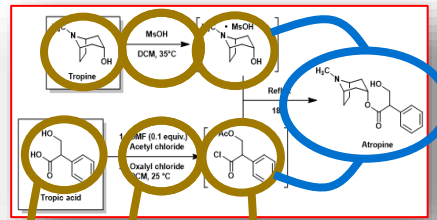
Minimalistic, Formal “Systems Model”



Manufacturer	U.S. Sites / Locations
Albemarle Fine Chemistry Services	2 / MI, PA
AMPAC Fine Chemicals (AFC)	3 / CA, TX, VA
Patheon	3 / SC*
Seqens PCI Synthesis	1 / MA
Sterling Pharma Solutions	2 / NC, WI
Pfizer CentreOne	Multiple / MI*
Snapdragon Chemistry	1 / MA
Johnson Matthey Ph	1 / MA
Abbvie	1 / IL
Evonik	1 / IN*
Millipore Sigma	3 / MO, WI
Lonza	1 / NJ
AMRI	5 / IL, MO, NY, WI
Bachem Americas	2 / CA
Cambrex	1 / IA
Recro Gainesville	1 / GA
Regis Technologies	1 / IL
Siegfried	1 / NJ
Ortec	3 / SC
Hovione New Jersey	1 / NJ

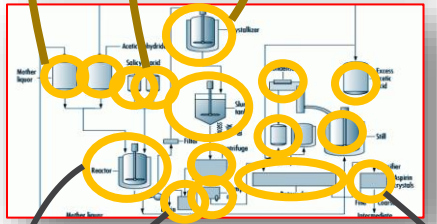
Best estimate:
50-60% of US CMO sites
(non-domestic CMOs excluded)

Transformations



Objectives

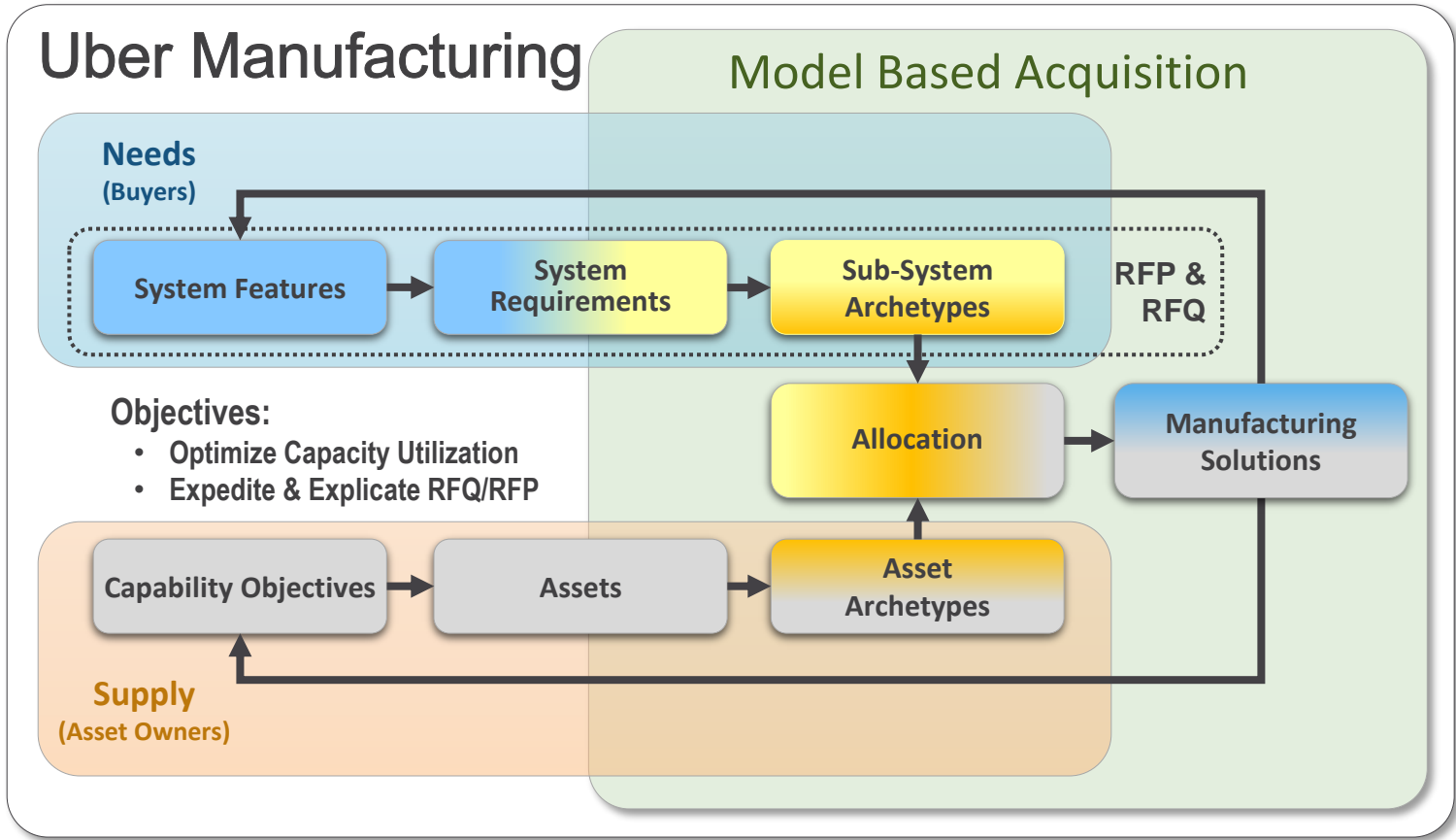
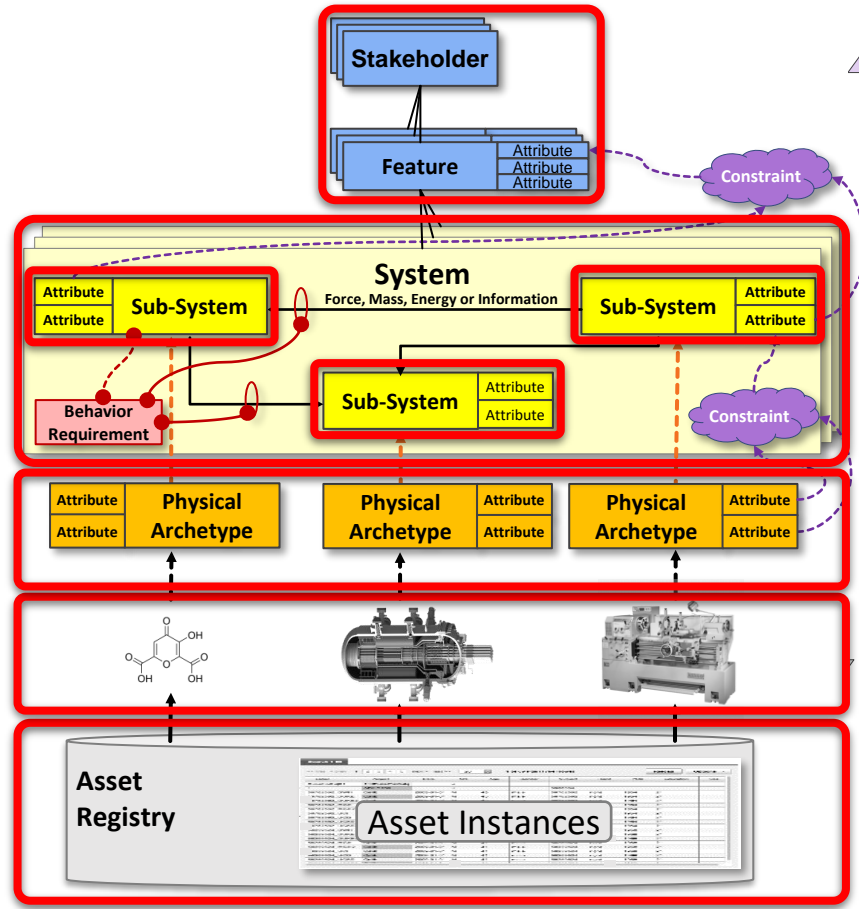
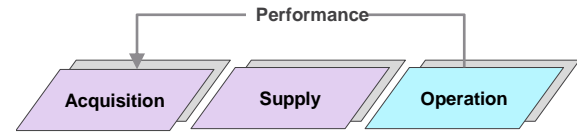
Types of Things



Instances of Things

Asset Registry

Minimalistic Solution “Activity System”



Agenda:



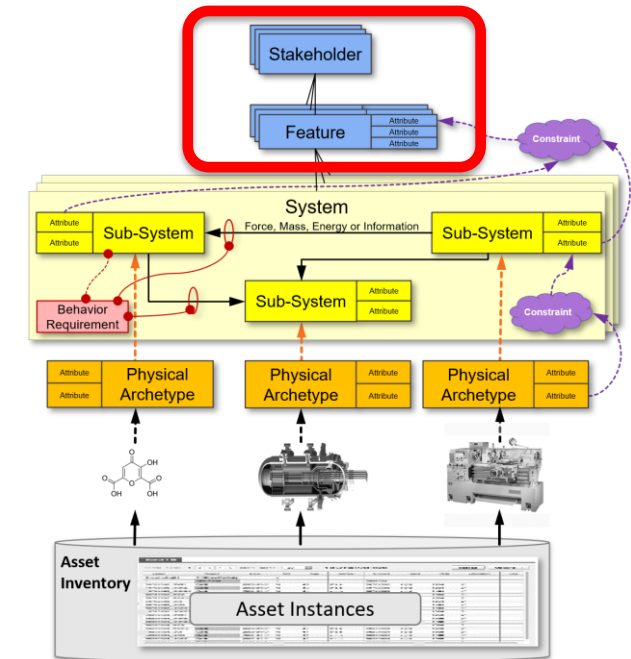
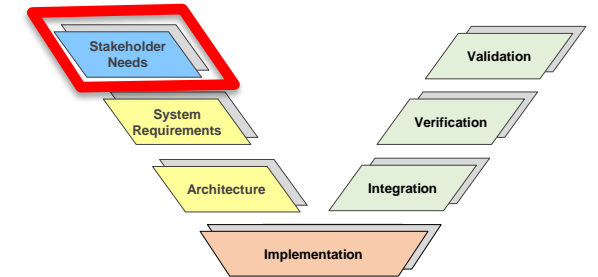
- Problem
- Solution
- Pilot

Translate Objectives to Systems Model



System Features:

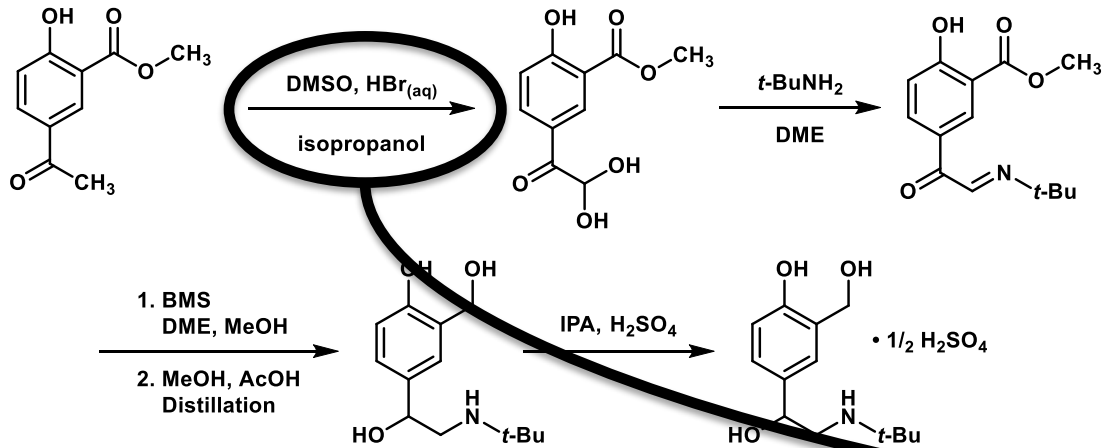
- xx,xxx KG(n) of API(n) over time(n)
- API(n) may not use manufactures in region X or Y
- Minimize cost of API(n)
- API(n) Must use “> x site” and “> y supplier”



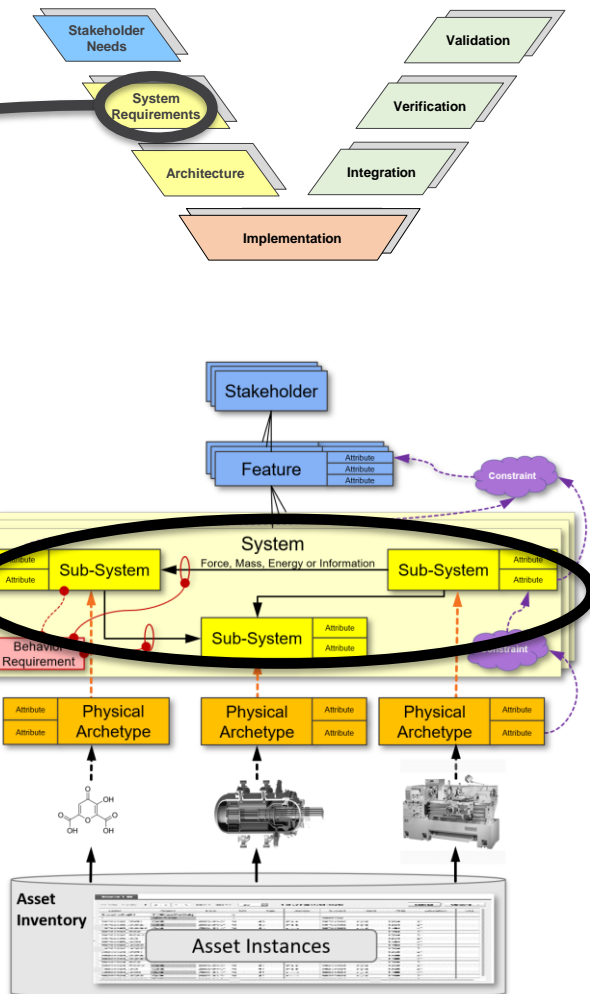
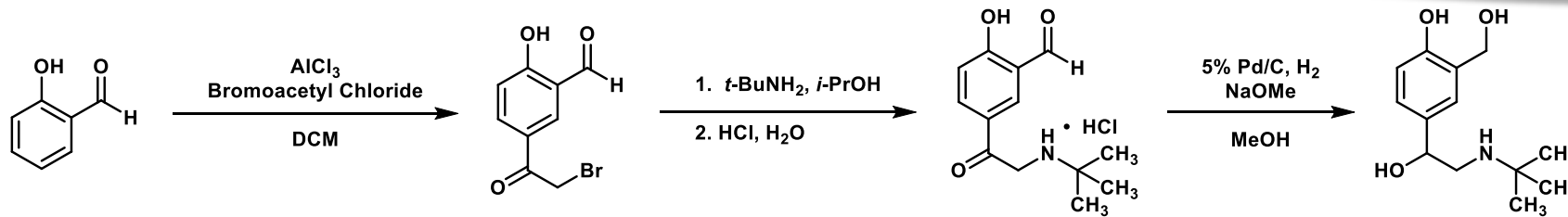
System Requirements



Albuterol Route 1



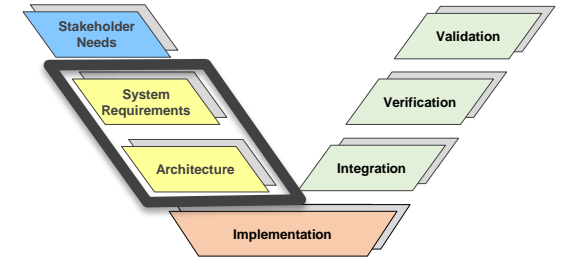
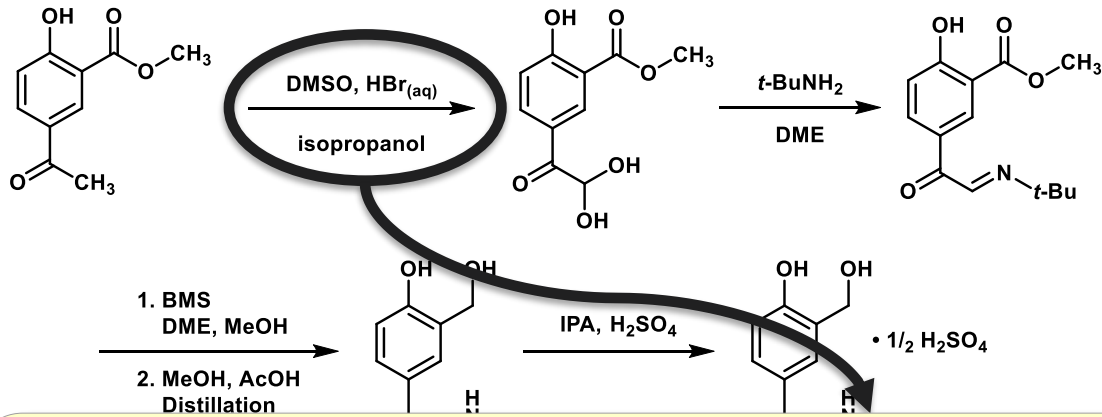
Albuterol Route 2



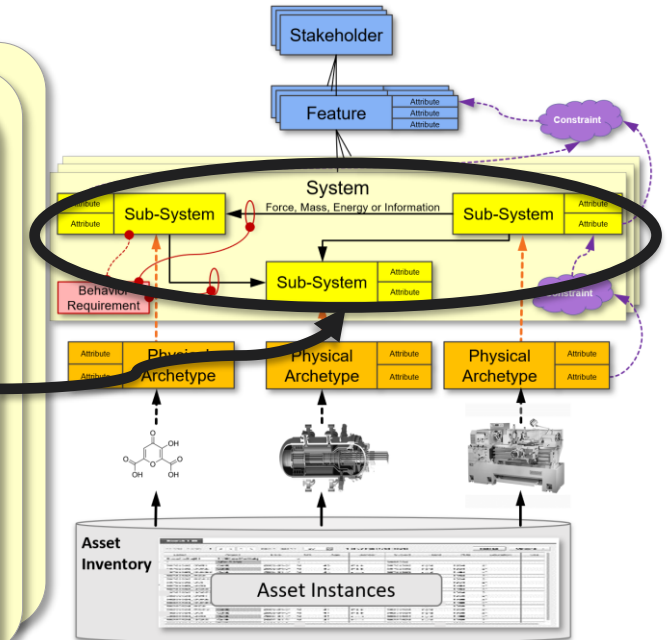
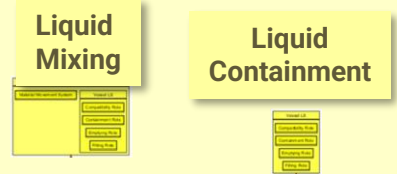
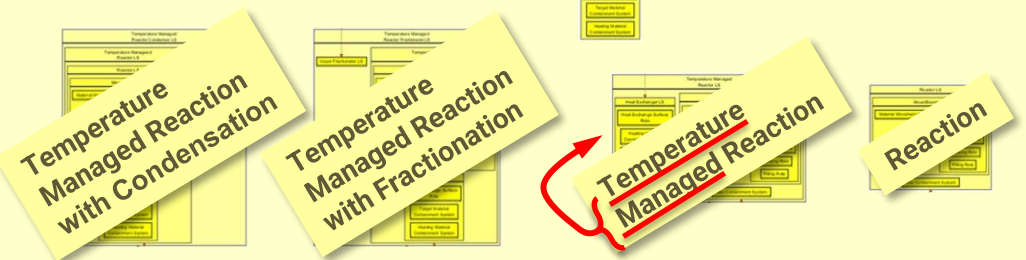
Decomposition to Functional Archetypes



Route 1



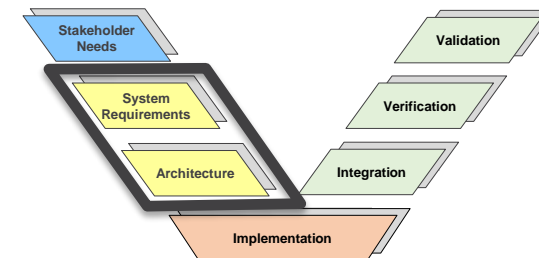
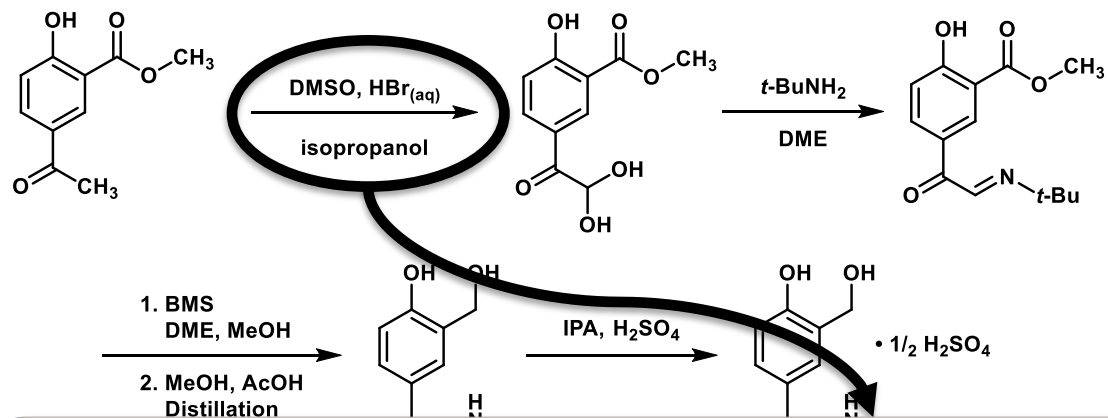
Sub-System



Functional Archetypes Encode Knowledge

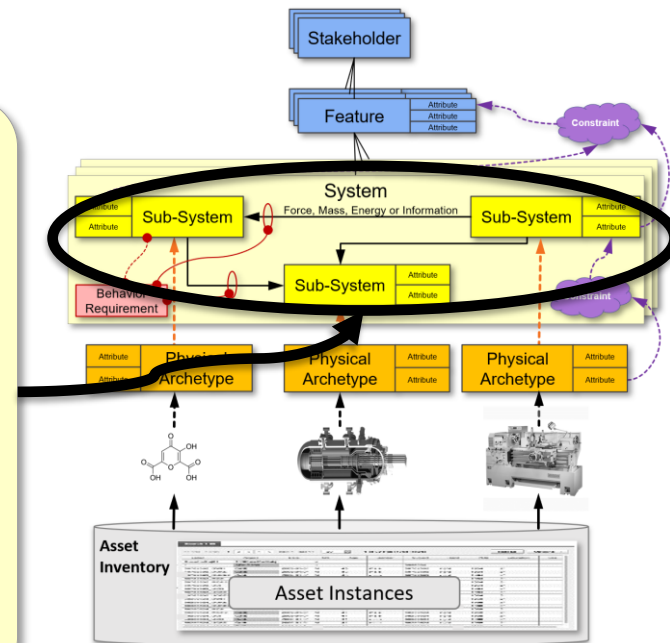


Route 1

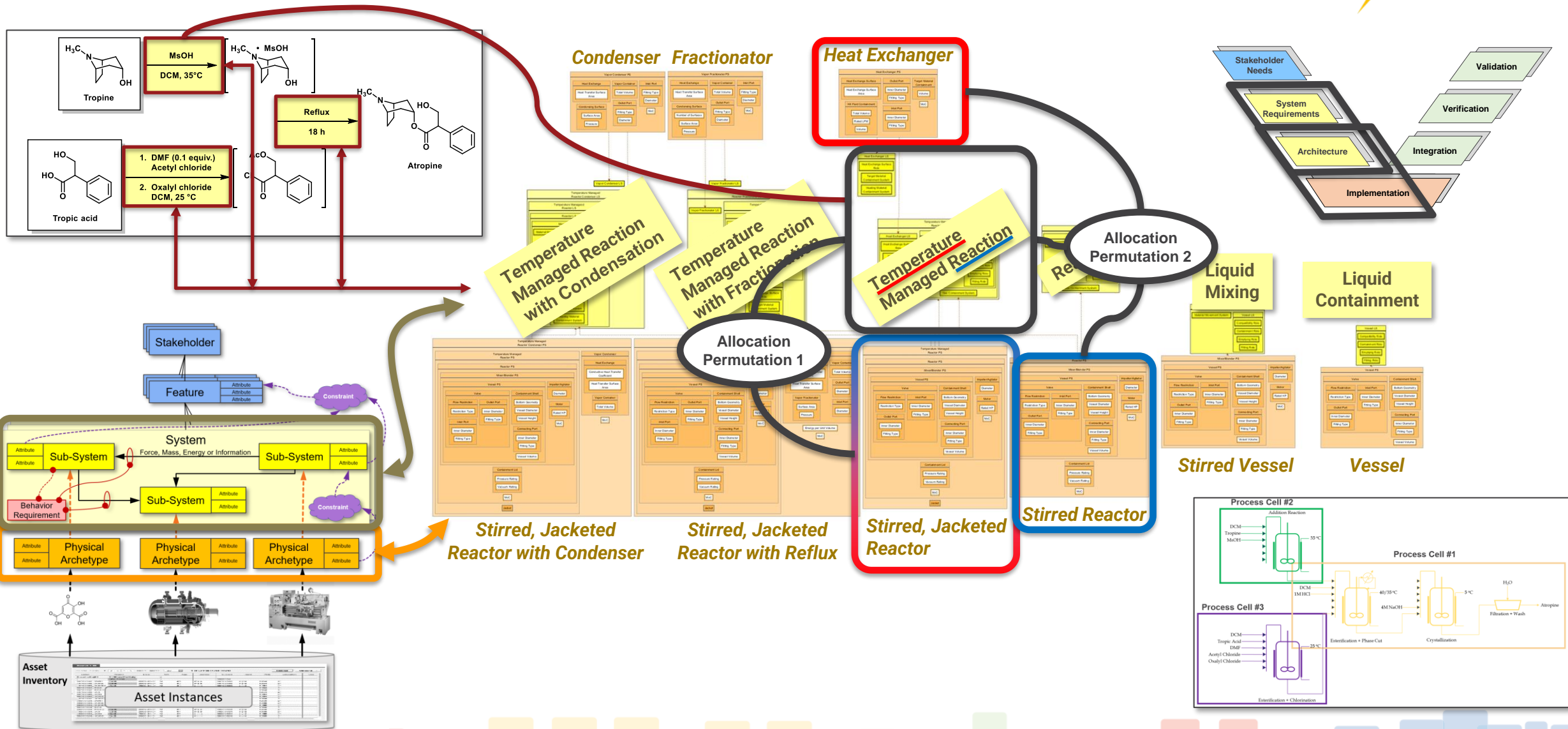


Temperature Management Sub-System

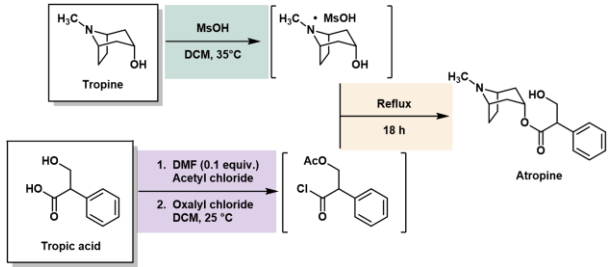
Equation	Output (s)
$\Delta T_{B6.3} = \frac{\ln(1 - (T_{B6.3} - T_{B6.2}) / (T_{H2O} - T_{B6.2})) m_{HCl} C_{p,HCl}}{hA}$	374.8651086
Specific Variable	Specific Output
T B6.2 (C)	35
T B6.3 (C)	5
T H2O B6.3 (C)	-5
m Total Aqueous (kg) B6.3	20.654
m Aqueous PC2 (kg) = m (Tropine + Methanesulfonic Acid)	3.360741816
m Aqueous PC3 (kg) = m (DMF + Tropic Acid + Acetyl Chloride + Oxalylic Acid)	5.054
m HCl B1.9 (kg)	12.23871962
Re	$Re = \frac{\rho D_r D_r}{2\mu}$ 376443.0046
Pr	$Pr = \frac{\mu C_p}{k_T}$ 10.19875
Nu	$Nu = \frac{h D_r}{k_T} = (constant) Re^m Pr^n$ 8899.23283
h	$h = \frac{Nu k_T}{D_r} = (constant) Re^m Pr^n$ 5255.452459
Impeller Rotational Rate Q (1/s)	$Q = \frac{P_i}{\rho N_p D_r^3}$ 2.964513812



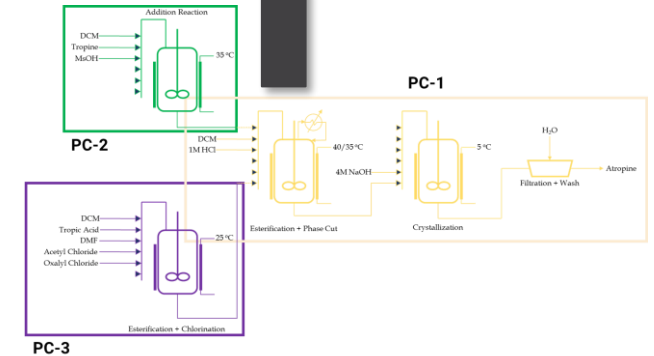
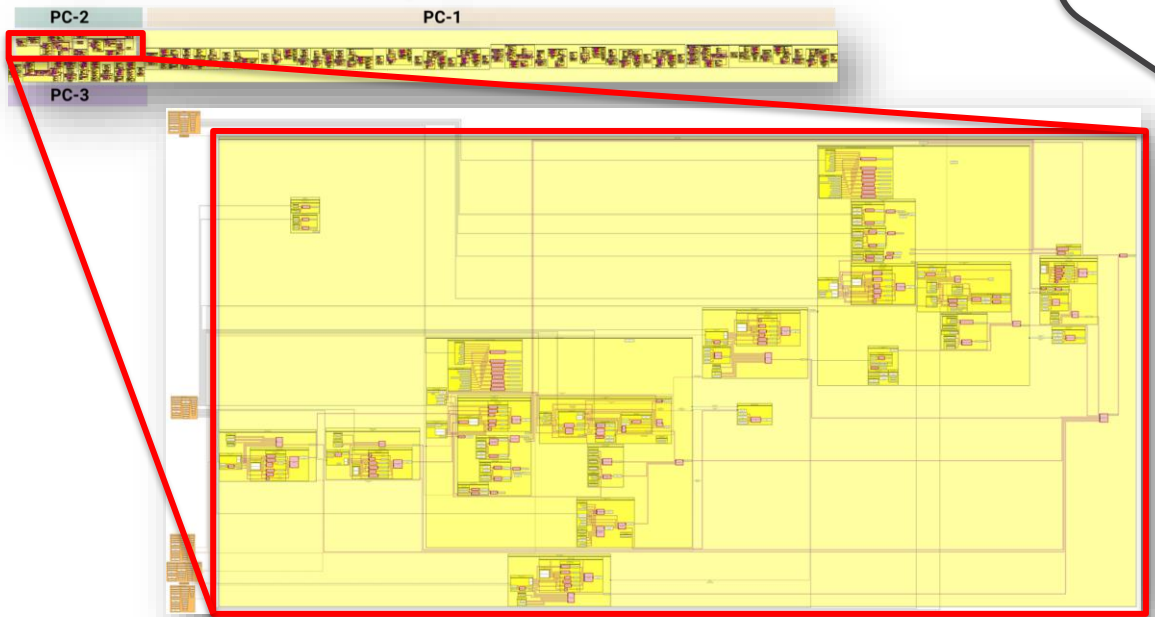
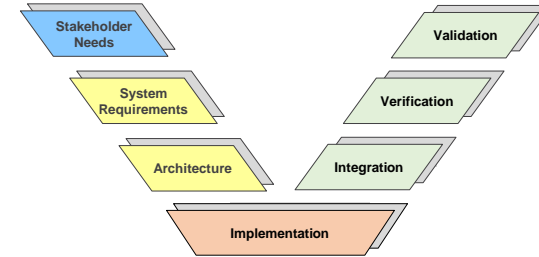
Allocatable Physical Archetypes



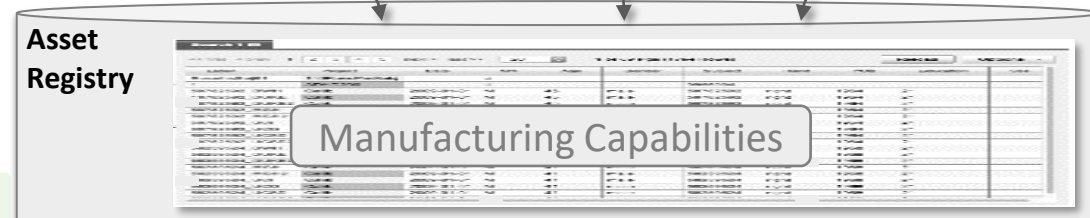
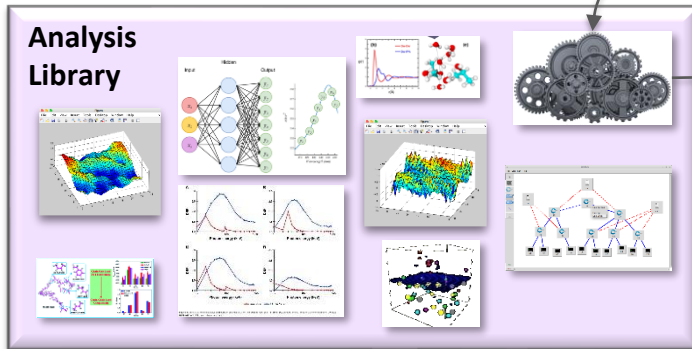
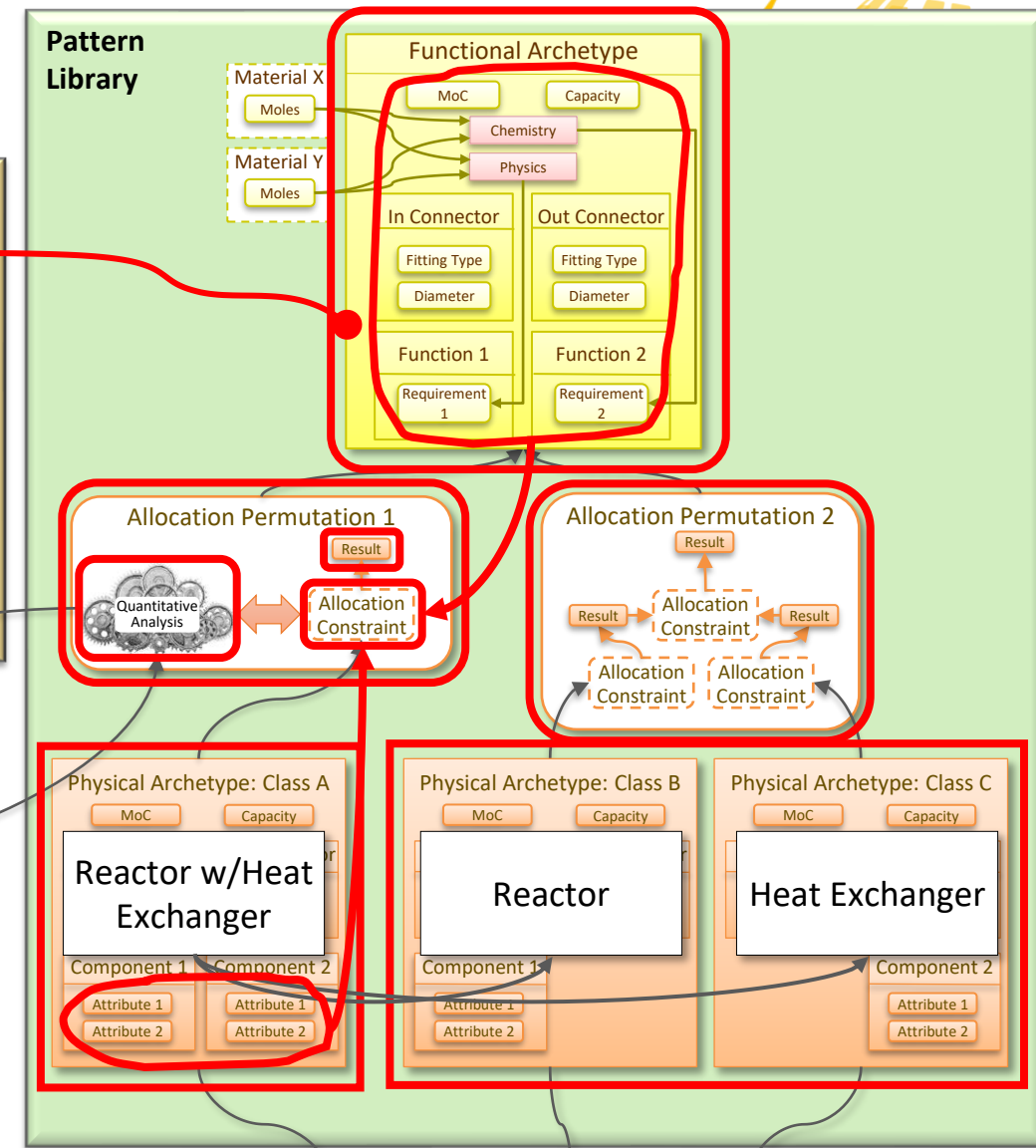
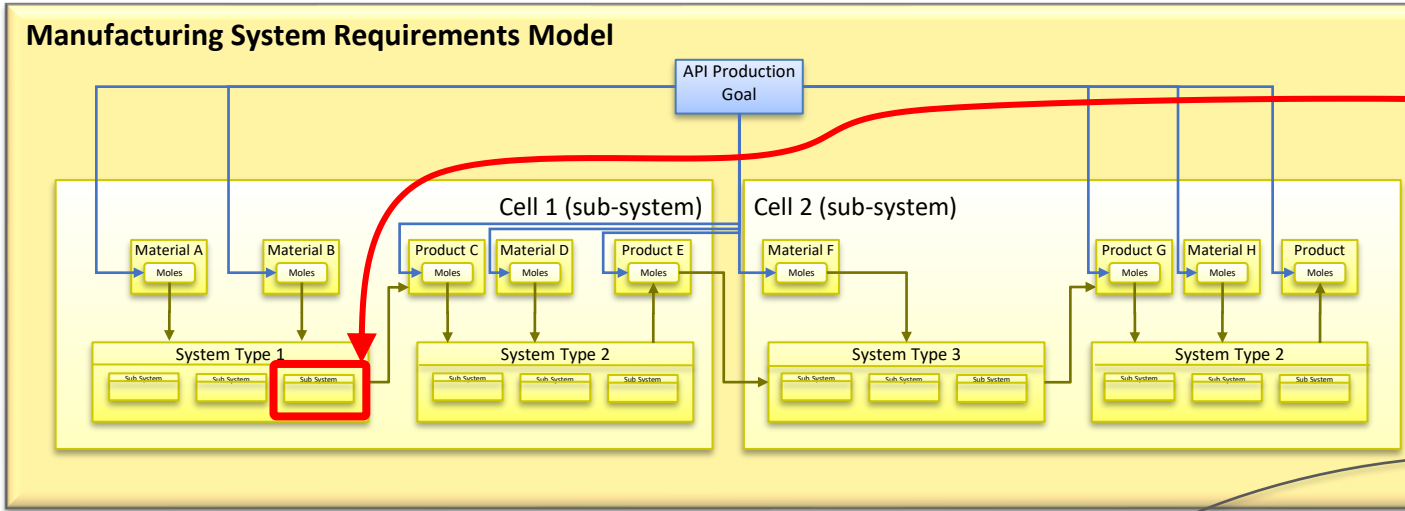
The Manufacturing System is Complex



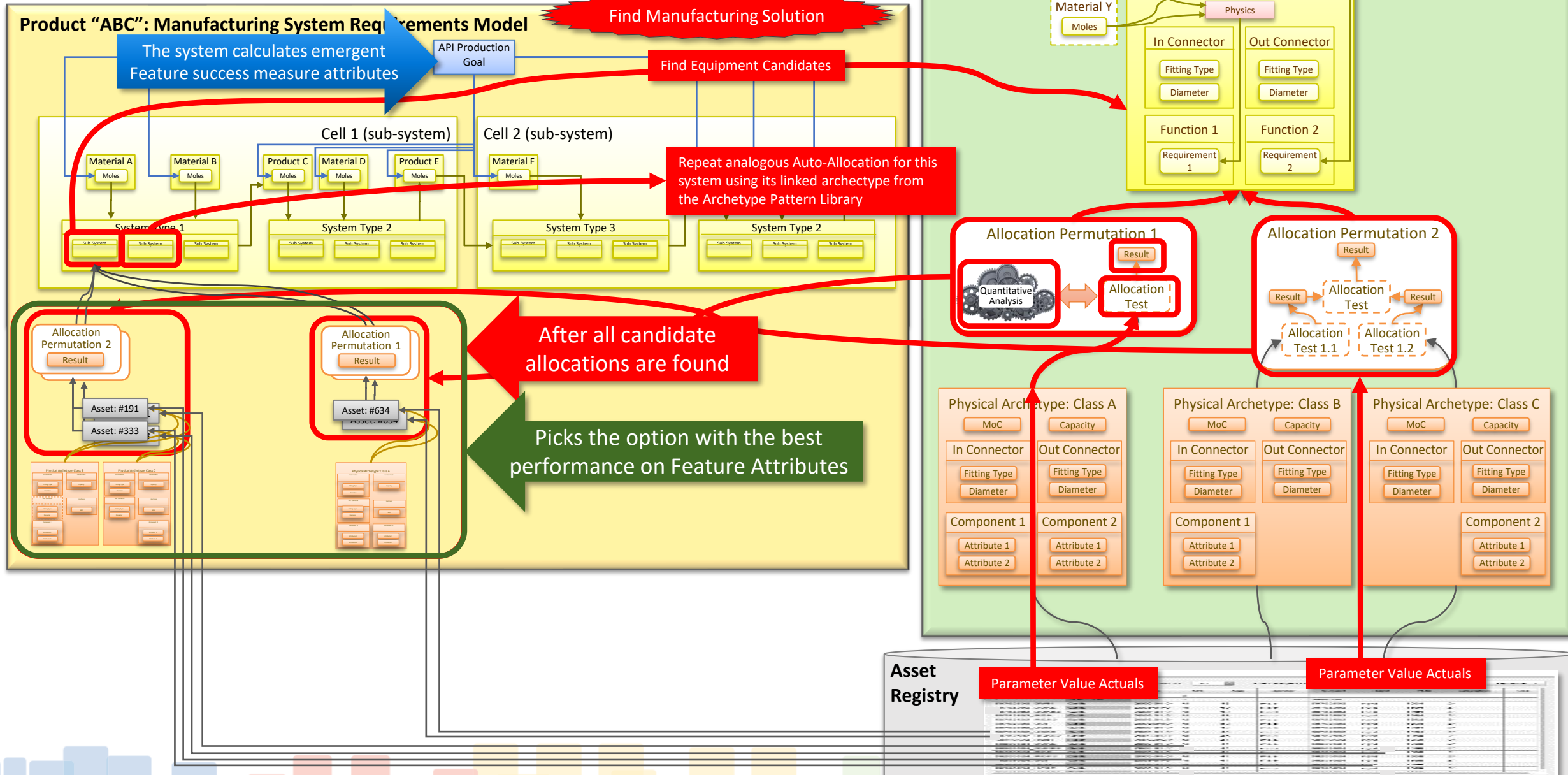
One solution:
System model size
> 5,000 nodes



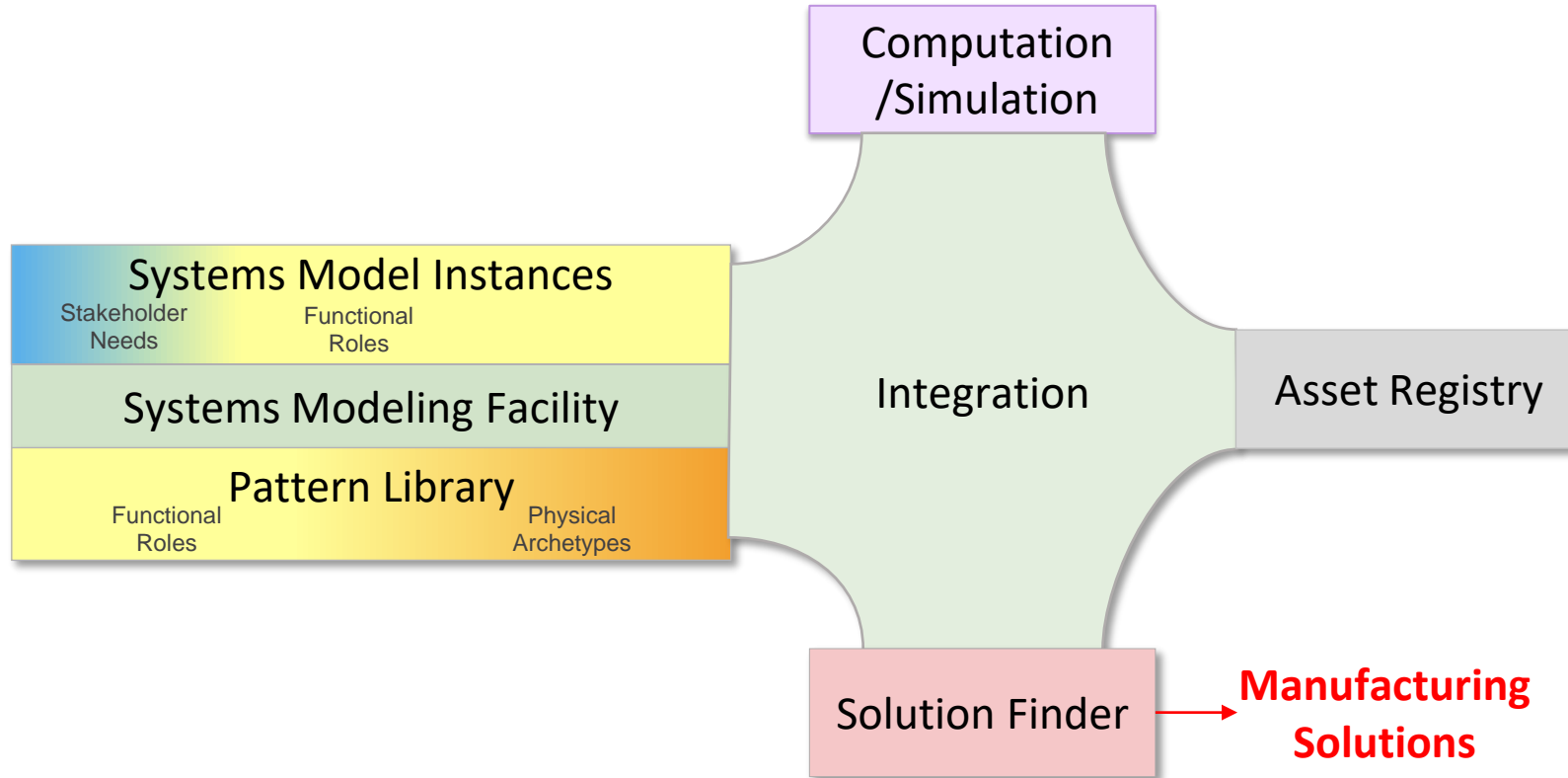
Putting it all together...



Putting it together: Solution Finding



Summary



Next Steps



- “Occam Systems Incorporated” to commercialize the solution
 - Simplify the modeling method
 - Improve model integrity checking
 - Re-platform to completely cloud infrastructure
- Seeking new pilots beyond chemistry
 - Verify extensibility of:
 - Business case
 - Method & automation
 - Increase the types of manufacturers in the Asset Registry



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Questions?

www.incose.org/iw2022/

