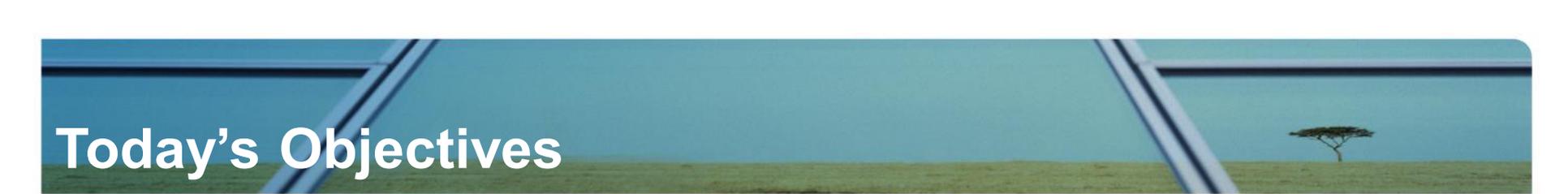


PDP Access Group

Terminology, use, and value of COGS to PDPs

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Today's Objectives

- *Provide an understanding of COGS terminology*
- Provide examples of manufacturing complexity
- Discuss the value and limitations of COGS assessments to PDPs

Terminology

COGS & Price Definitions

- Cost of Goods Sold (COGS):
 - The direct costs attributable to the production of the goods sold by a company

- Product Price:
 - The price charged to ‘customers’
 - Price is not related to COGS, except in commodity markets where the price of the product has dropped to its lowest price (e.g. BCG vaccine, generic antibiotics)

Terminology

COGS Estimates

- COGS are generally estimated including:

Direct costs to produce a product



'Traditional' global health estimates

Direct costs to produce a product +
R&D costs required to develop the product for the global health markets



More recent global health estimates

Direct costs to produce a product +
R&D costs required to develop the product for the global health markets +
Indirect costs related to distribution and sales force costs

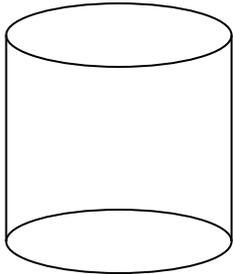


Not generally included in global health estimates
(not always relevant to public sector markets, e.g., vaccines)

Terminology

COGS Components & Definitions

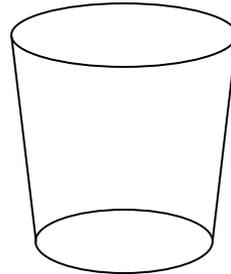
Capital Costs (Fixed, one-time costs)



Includes, but not limited to:

- Buildings
- Equipment and instrumentation
- Installation of piping, HVAC, equipment, etc.
- Critical utilities
- Clean rooms
- QC labs
- Warehousing & cold storage
- Validation

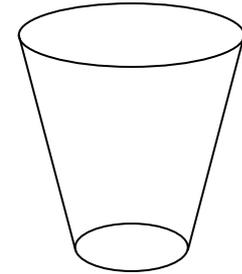
Semi-Variable Costs (Fixed & variable costs)



Includes, but not limited to:

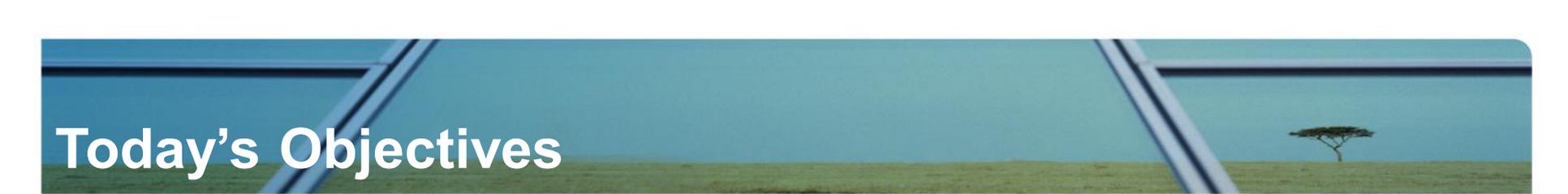
- Direct labor
- Indirect labor
- Quality system costs
- Indirect materials (e.g., gowning, gloves)
- Regulatory compliance
- Environment, health & safety
- Maintenance, metrology & technical support
- Utilities

Variable Costs (related to product production)



• Such as:

- Raw materials
- Consumables
- Waste

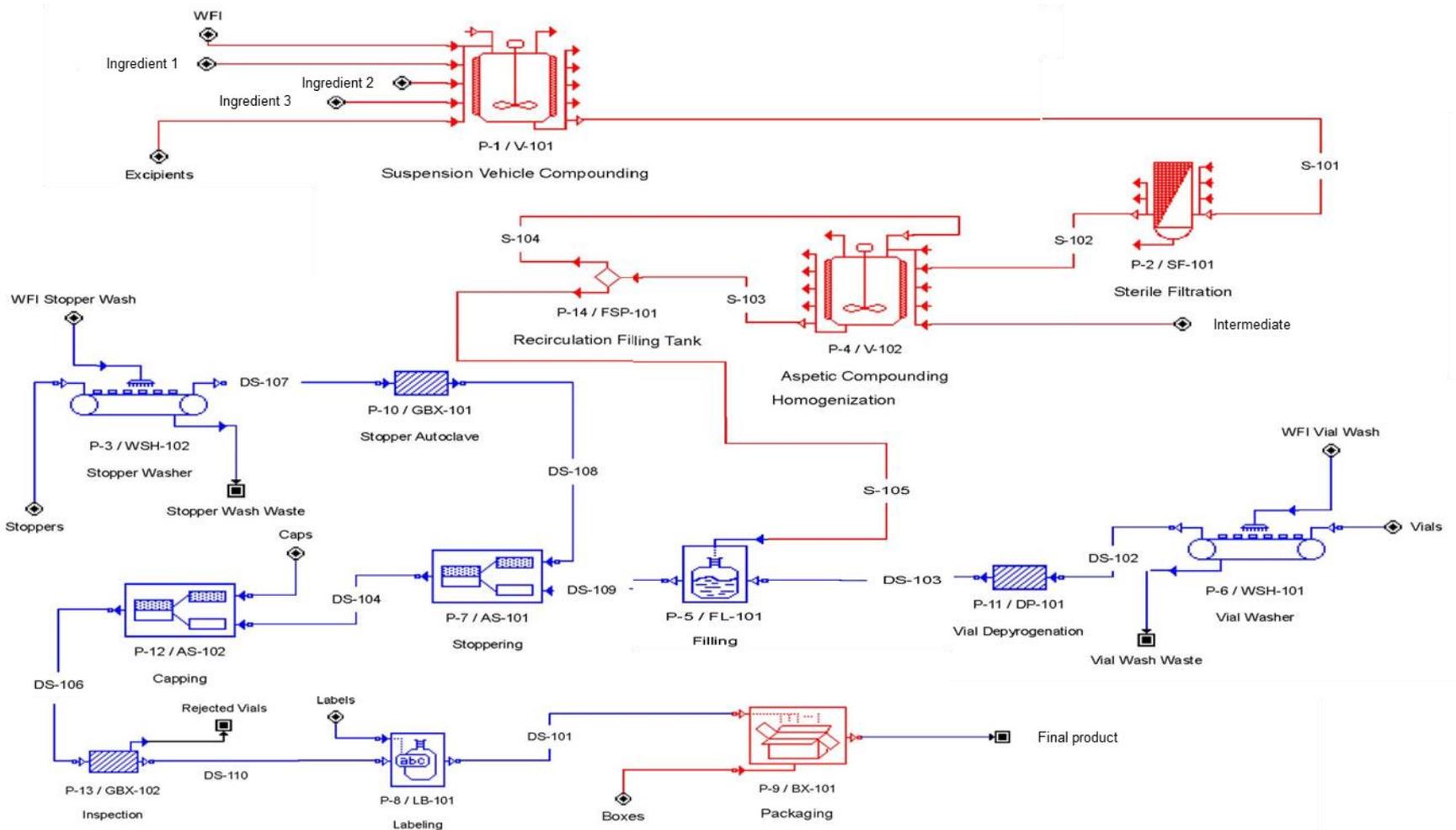


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- ***Provide examples of manufacturing complexity***
- Discuss the value and limitations of COGS assessments to PDPs

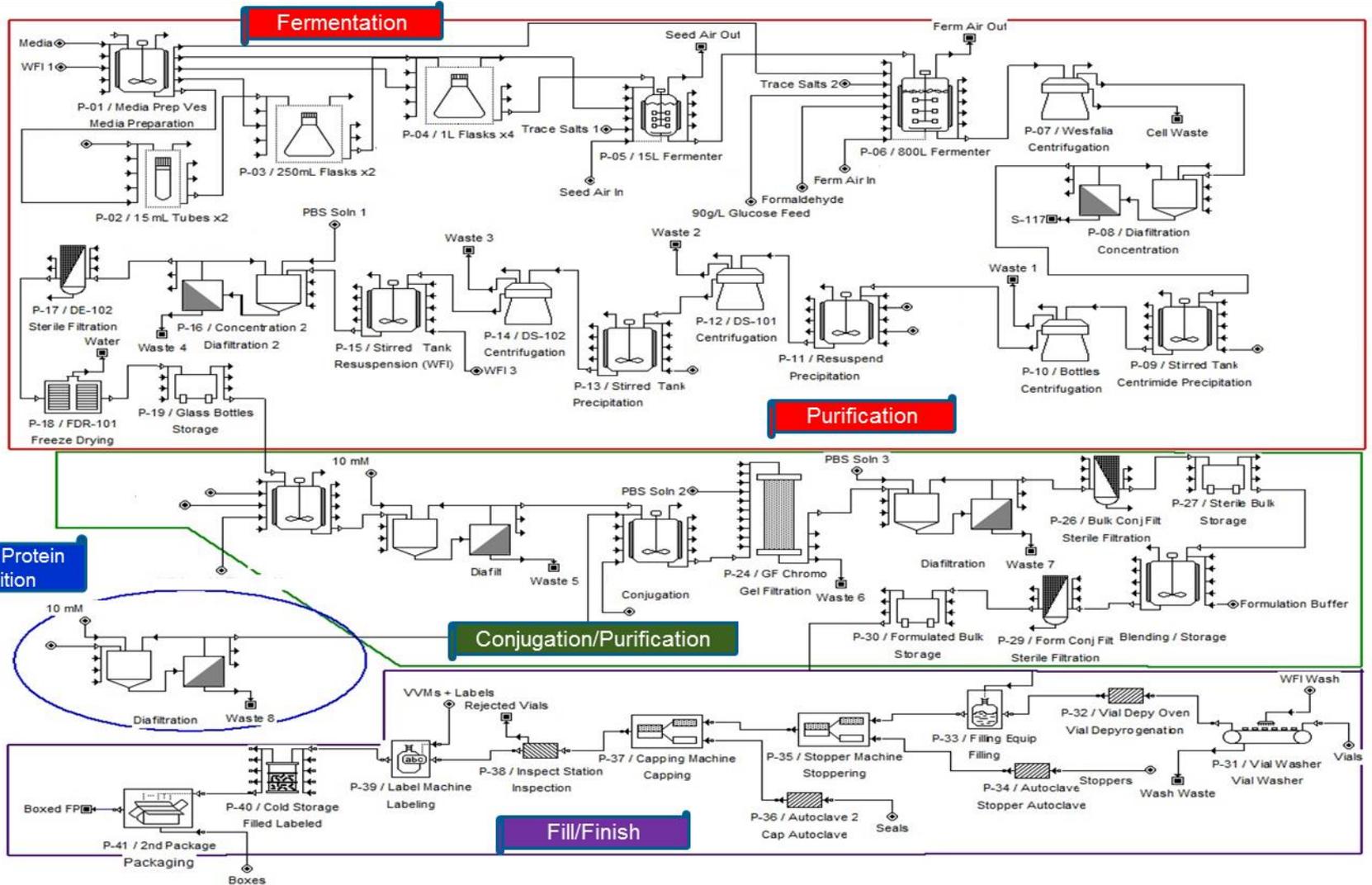
Manufacturing Complexity

Small Molecule Example in Vials



Manufacturing Complexity

Conjugated Vaccine Example in Vials



Manufacturing Complexity

General Principles

- COGS influenced by:
 - Number of manufacturing steps (e.g., a 7 step manufacturing process is much less costly than a 15 step manufacturing process)
 - Yields (e.g., lower yields require more starting materials, labor)
 - Sterile facilities for manufacturing steps (e.g., increases facility & labor costs)
 - Primary packaging (e.g., tablets cost less than taste-masked rapid-dissolving tablets; multi-dose vials cost less than single dose vials)
 - Plant utilization (e.g., greater the plant utilization, lower the COGS)



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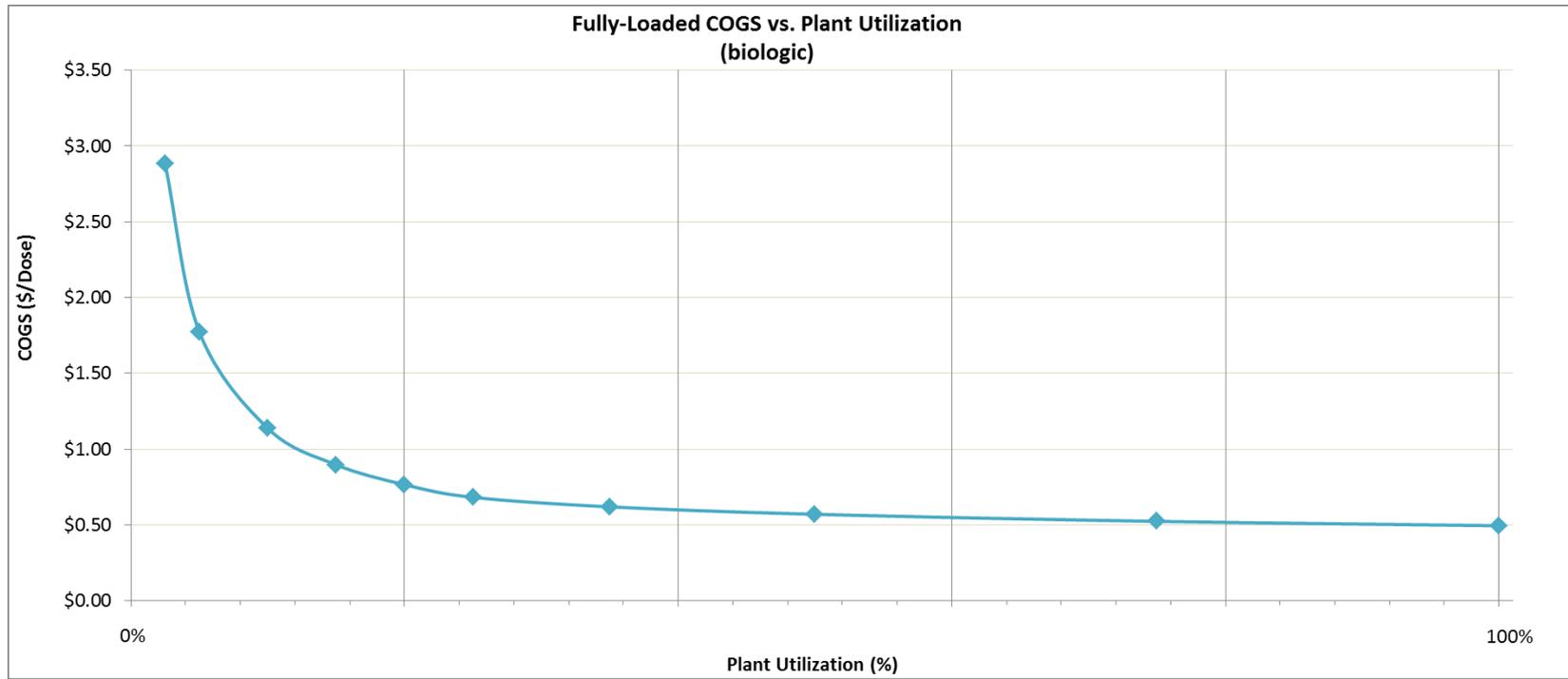
COGS Value & Limitations

COGS Value

- PDPs may need to develop an ‘investment case’ for their vaccine and drug development candidates for donors and countries
 - Include supply & demand forecasts and estimates of health impact and cost-effectiveness
 - COGS estimates inform price forecasts needed for these analyses
- Utilizing COGS to inform price forecasts requires an understanding of the relationship between COGS and plant utilization
 - Suppliers estimate their market share and build their production capacity based on what they believe they can sell to in their markets (e.g., public/private, HIC, MIC, LIC)
 - COGS drop to lowest cost when plant utilization is high, so suppliers are very motivated to produce enough of their products to reach high plant utilization where their margins are optimal

COGS Value & Limitations

COGS vs. Plant Utilization



- At ~5% of plant utilization, estimated COGS are ~6 times higher than at 100% of plant utilization
 - Influences the higher prices seen as suppliers enter a global health market
- Much harder to forecast early market price than lowest market price

COGS Value & Limitations

COGS Limitations

- COGS are highly proprietary and generally protected by suppliers
 - COGS likely assessed differently by suppliers, and often higher than global health estimates, when discussions have occurred (e.g., PCV AMC analyses)
 - Supplier discussions have improved the way global health organizations estimate COGS, but they are still estimates
- Price forecasting not necessarily related to COGS
 - Estimating market entry price is very challenging and there is no good ‘guidance’, especially for novel vaccines or drugs (suppliers price what the market will bear)
 - Easier in established markets because suppliers are motivated to be competitive and try to achieve greater market share (greater volume = lower COGS & hopefully price)
 - Reasonable to forecast a higher entry price which can decrease over time, especially as volume increases and suppliers have time to build additional markets which will increase plant utilization (e.g., private sector markets, high and upper middle income country markets)