



ACCELERATING
INNOVATION

Session ID: 6-1191

**Getting your automation project
approved by the CFO**

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Vision

Our vision is a world in which access to life-changing therapies transforms human health.

Mission

Our mission is to advance and accelerate therapeutics.

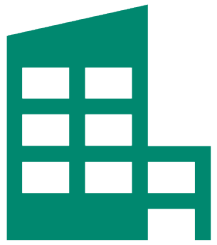
Christopher Sandusky • Director, Automation Solutions -
Product & Lifecycle Mngt March 2024



1

What is return on invested capital (ROIC), and why does it matter?

What is ROIC (return on invested capital)



Return on invested capital (ROIC)

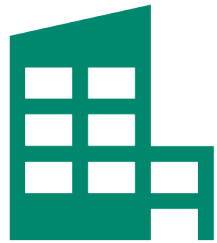
A calculation used to assess a company's efficiency at allocating the capital under its control.¹



Weighted average cost of capital (WACC)

A firm's average cost of capital, weighted to reflect that different sources of capital, like common stocks and bonds, carry different return expectations.¹

What is ROIC (return on invested capital)



Return on invested capital (ROIC)

A calculation used to assess a company's efficiency at allocating the capital under its control.¹

$$\frac{\text{Net Operating Profit After Tax}}{\text{Average invested capital}} = \text{ROIC}$$



Weighted average cost of capital (WACC)

A firm's average cost of capital, weighted to reflect that different sources of capital, like common stocks and bonds, carry different return expectations.¹

$$\text{Company health ratio or (\%)} = \text{ROIC} / \text{WACC}$$

Note: Anything over 10% is considered strong

$$\frac{\text{ROIC}}{\text{Cost of capital}} < 1 = \text{unsustainable business model}^1$$

2

What is BioPhorum?

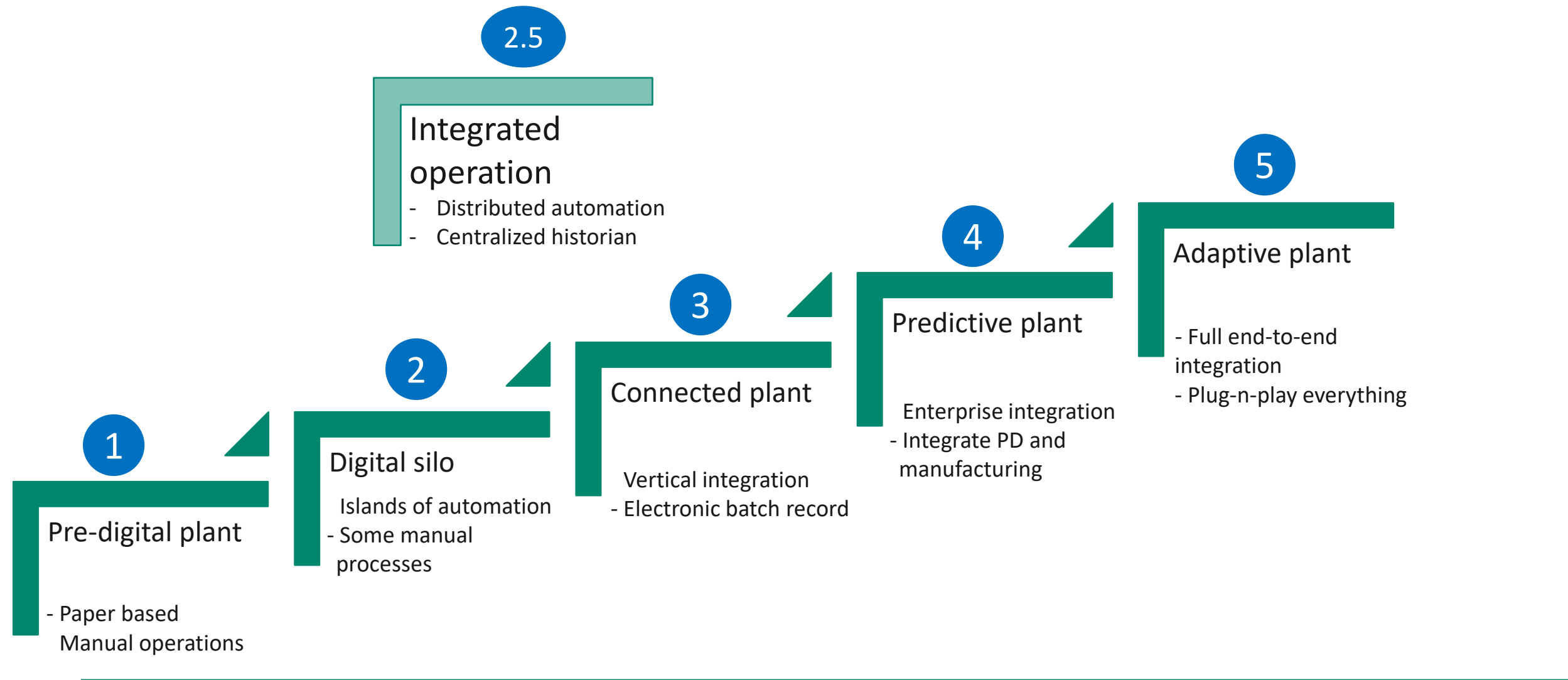
BioPhorum

- Founded in 2008 – brings leaders and SMEs together to collaborate
- 7,500 active subject-matter experts
- Ten technical forums transforming the industry through over 110 initiatives



“Our mission is to create an environment where the global biopharmaceutical and device industry can collaborate and accelerate rate of progress – for the benefit of all.”¹

Many biomanufacturers are at DPMM¹ Level 2 and may not realize or be able to quantify the benefits of increasing digital maturity



3

**Where digital and
sustainability intersect**

Taking advantage of digital technologies

Three men won the Noble Prize for Chemistry in 2024 for AI designed proteins. However, manufacturing those into a therapeutic will require years of trial-and-error experimentation, mountains of paper, many millions of dollars, and a decade to come to market.



A six-month breakthrough turns into a ten-year delivery with thousands of patients waiting – but the digital technology exists.

Many companies were planning to evaluate and/or test digital bioprocessing control, monitoring in 2023(1)

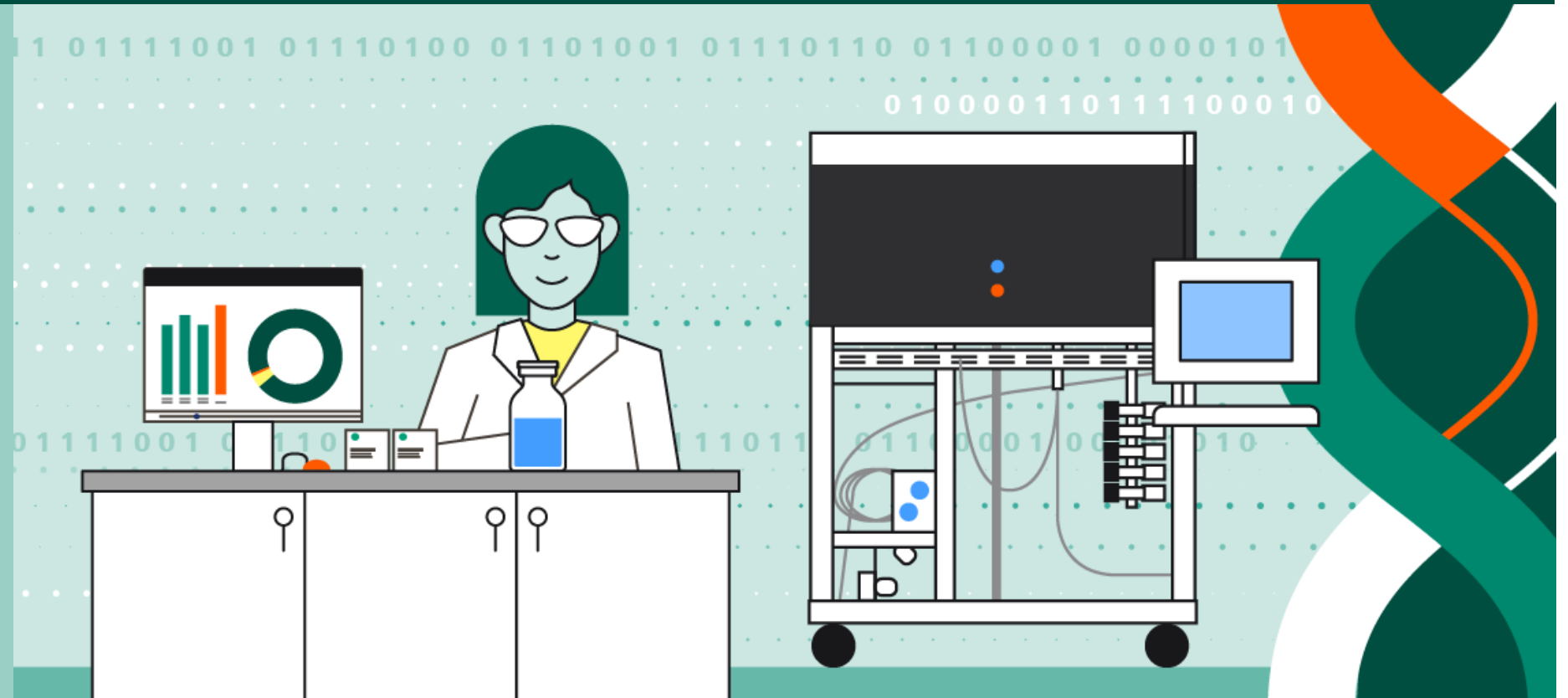


1. 2024 21st Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production. BioPlan Associates. April 2024. Accessed March 2025. <https://www.bioplanassociates.com/21st/>

Data enablement is a fundamental building block for increased digital maturity

“Data is the DNA of digital transformation.”*

- Data enablement is the automatic electronic capture of process, raw material, and machine data for conversion into knowledge
- Addresses deficiencies including:
 - Data access and visualization
 - Data context
 - Data retrieval
 - Data quality/accuracy
 - Data formats
 - Data analysis



*BioPhorum Operations Group. Digital technologies roadmap. July 2022. <https://www.biophorum.com/download/digital-technologies/>

4

**Who is BIOPHARMA SERVICES
LIMITED (BPS)?**

BIOPHARM SERVICES LIMITED (BPS) is a global leader in modeling biopharmaceutical manufacturing costs

23

Years in Business

>40

Years of Modeling Experience

600+

Professional Users

100%

Supply Chain Coverage

Configure:

- Choose from unit operations Knowledge Base
- Apply industry-averaged costs
- Modify parameters and determine impact

Analyze:

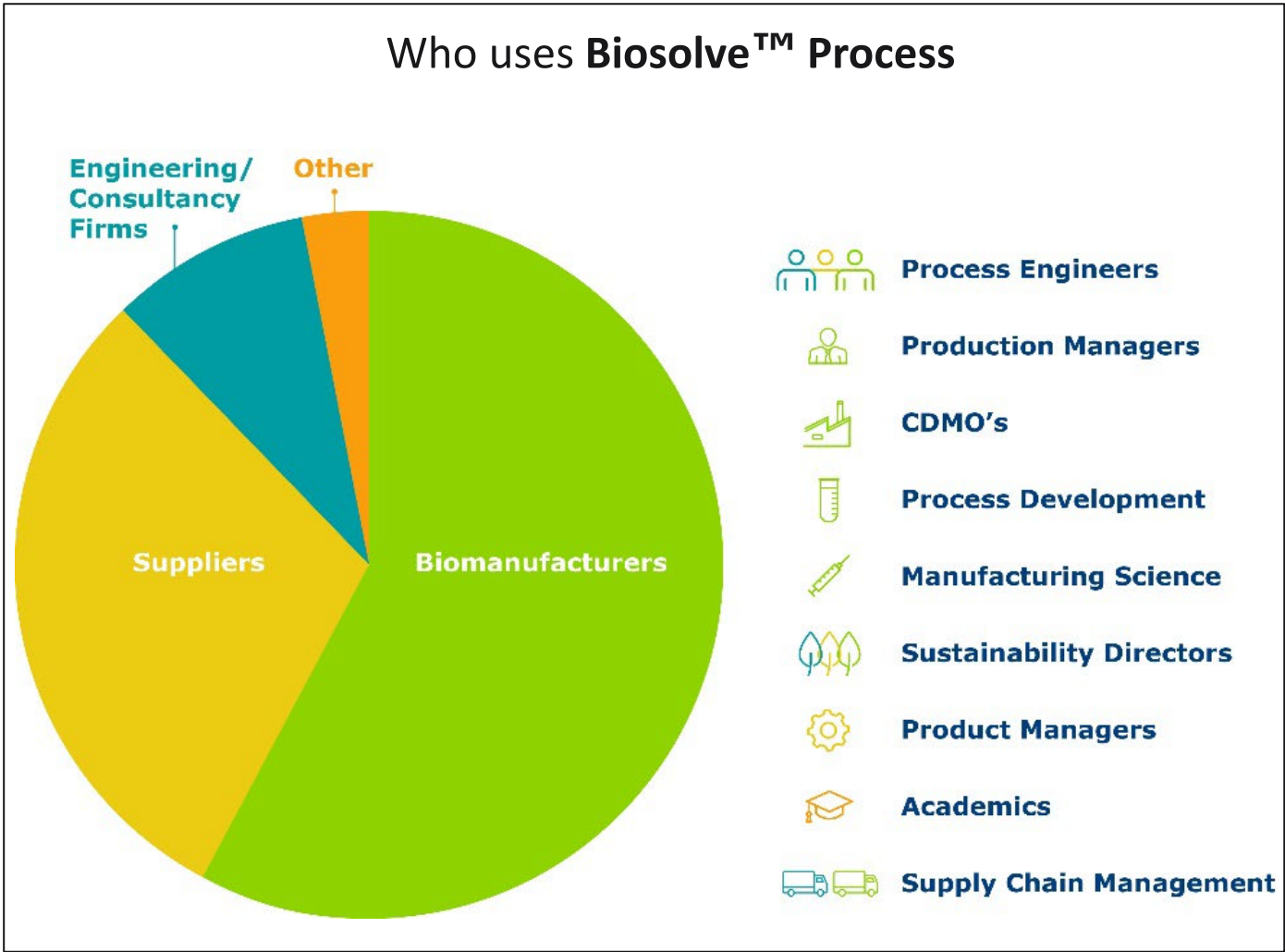
- Develop business cases
- Mitigate risk
- Avoid surprises

Scale:

- Easily scale unit operations
- Evaluate production capacity
- Estimate scale-up costs

Report:

- Visualize data
- Prepare bills of material
- Determine Process Mass Intensities



Gain supply chain insights during tech transfer

Minimise cost of bioprocessing

Minimise your process' environmental impact

5

Analysis of the COGS and ROIC for a manufacturing plant's digital maturity

Companies struggle to justify the initial capital costs associated with enabling higher digital plant maturity

Problem statement

- Increased digital maturity is beneficial
- Difficult to quantify benefits of digital maturity
- Hard to justify investment in digital technologies



Solution

- BIOPHARM SERVICES LIMITED's Biosolve™ software models
- Modeling makes the value of increased digital maturity more tangible:
 - Increased throughput
 - Increased yield
 - Reduced labor requirements
 - Reduced total cost of ownership
 - Increased speed-to-market
 - Reduced risk

mAb – monoclonal antibody

BIOPHARM SERVICES LIMITED’s Biosolve™ software evaluates total cost of ownership required to achieve a higher digital plant maturity

Cost contributors	Assumptions to adapt model for higher DPMM
Capital costs	Increased to reflect incremental automation costs
Labor ¹	• Engineering and general/logistics labor reduced for DPMM level 2.5² and 3.0³ as some manual tasks and inefficiencies are eliminated • Second person verification eliminated at DPMM 3.0 due to introduction of MES and ERP • QA labor reduced from 2 to 1 resource for DPMM level 3.0 due to use of full eBR • De-skill resources - error-proof procedures require lower skilled/more junior resources with less training time
Facility utilization	Increased from 70% to 80% to 90% from level 2.0 to 2.5 to 3.0 as fewer manual operations improve facility management (operational tasks and time management), which enable optimal resource utilization while facility assets are better utilized with increased productivity

¹ Note the model does not include labor costs associated with increased automation staffing, if any
 Note: All above data are assumptions and are inputs into the DPMM model. Other(s) data and assumptions might be similar or different depending on other(s) circumstances and experiences.

² DPMM level 2.5 represents addition of a Distributed Control System (DCS) and in-line sensors

³ DPMM Level 3.0 represents level 2.5 plus addition of MES system, and integration with ERP to provide electronic batch records

Definitions: MES – Manufacturing Execution System, DPPM – Digital Plant Maturity Model, ERP – Enterprise Resource Planning, eBR – Electronic Batch Record, QA – Quality Assurance

BIOPHARM SERVICES LIMITED’s Biosolve™ software evaluates total cost of ownership required to achieve a higher digital plant maturity

Cost contributors	Assumptions to adapt model for higher DPMM
Batch failure rate	Fewer operator errors and failures to meet spec ¹ results in: - Reduced rate from 1.2% (level 2.0) to 0.25% (levels 2.5 and 3.0 for commercial manufacturing) - Reduced rate from 1.2% to 0.19% (levels 2.5 and 3.0 for clinical manufacturing)
QA batch release time	- Reduced by 50% from level 2.0 to 2.5 and 50% from level 2.5 to 3.0 due to easier access to more accurate electronic data from a single source - Reduced by addressing quality events in real time versus at the end of the batch
Deviations	- Deviations per batch were reduced from 1.5 to 1.0 to 0.5 for DPMM level 2.0. 2.5 and 3.0, respectively - Personnel required to investigate deviations was reduced from 2 for DPMM level 2.0 and 2.5 to 1 for level 3.0 due to fully electronic batch records

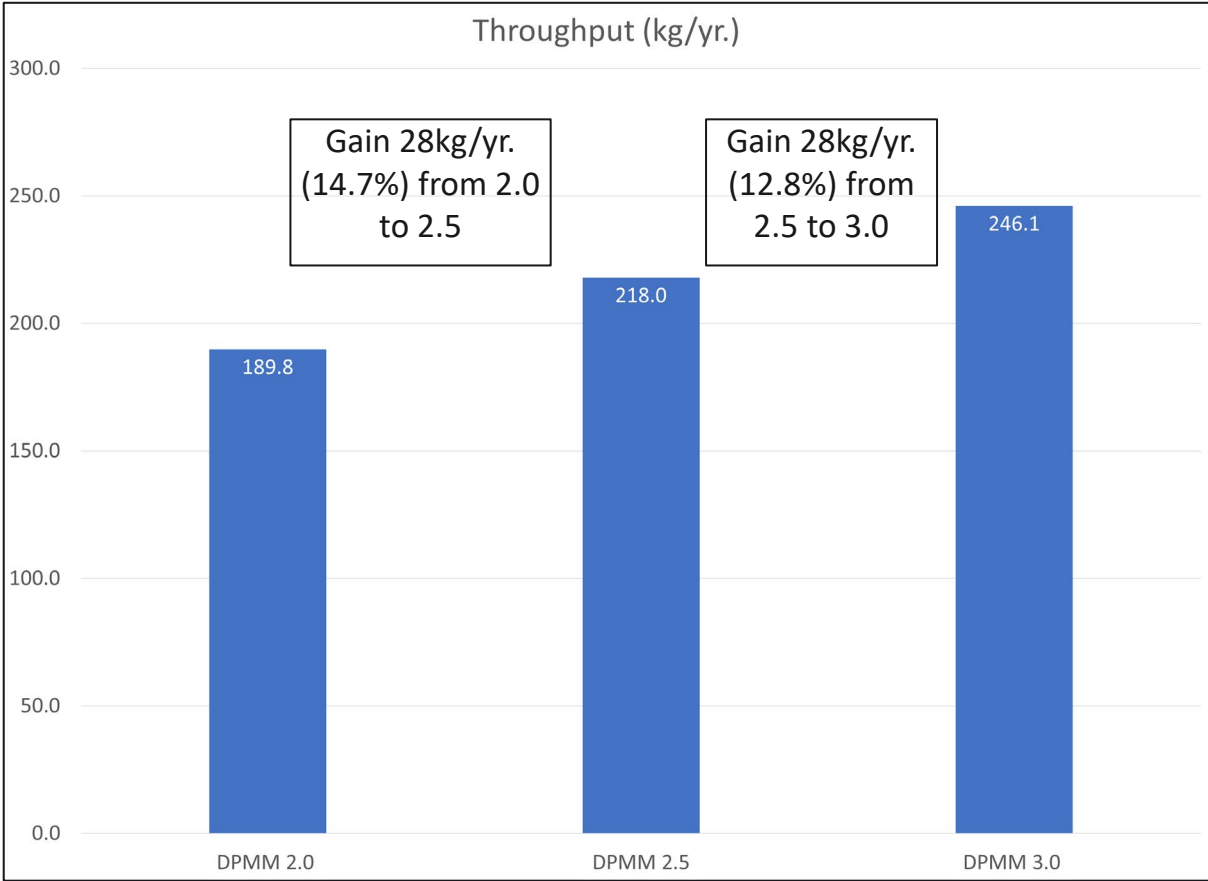
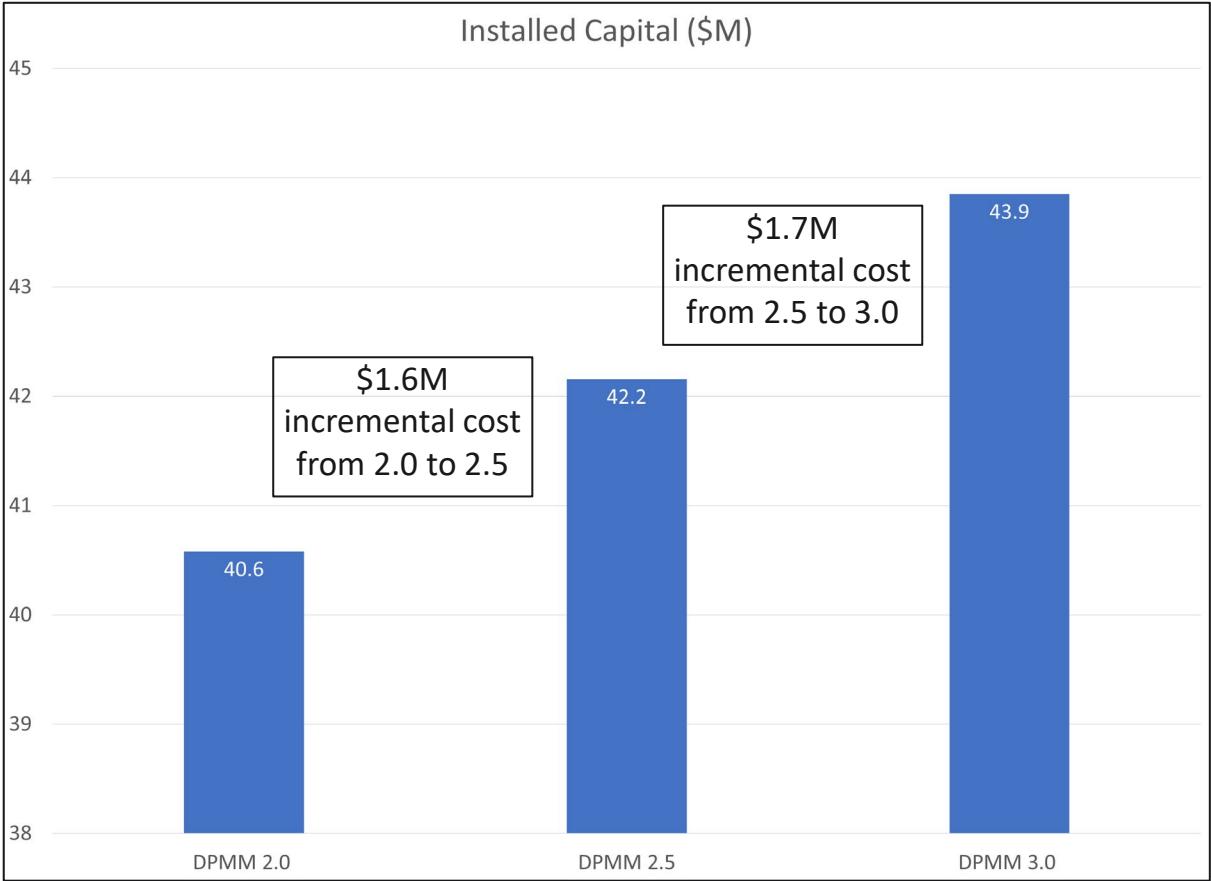
1. Bioplan Associates, “17th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production,” April 2020: <https://bioplanassociates>

2. DPMM – Digital Plant Maturity Model

3. Note: All above data are assumptions and are inputs into the DPMM model. Other(s) data and assumptions might be similar or different depending on other(s) circumstances and experiences.

Increasing digital maturity requires higher automation costs but results in additional annual throughput

Increased digital maturity leads to increased number of batches and higher production

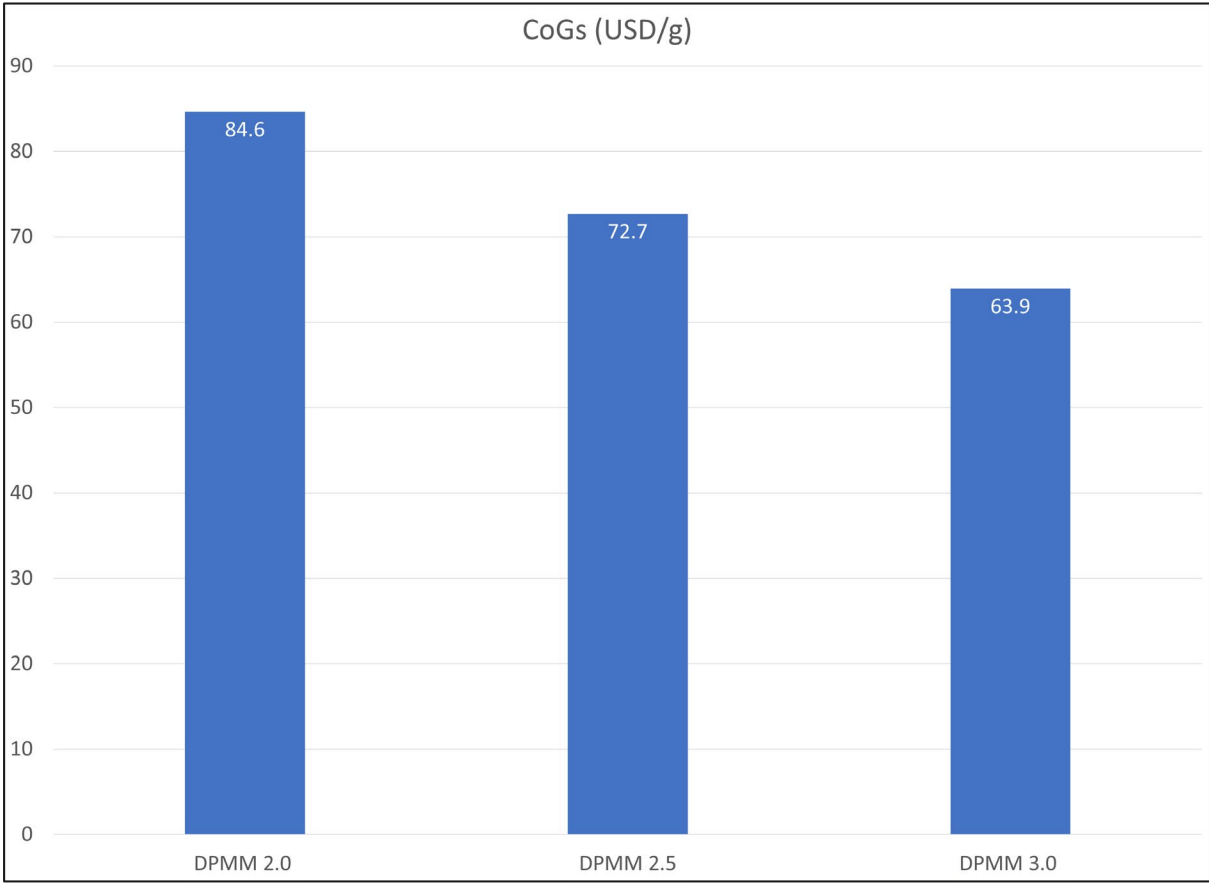
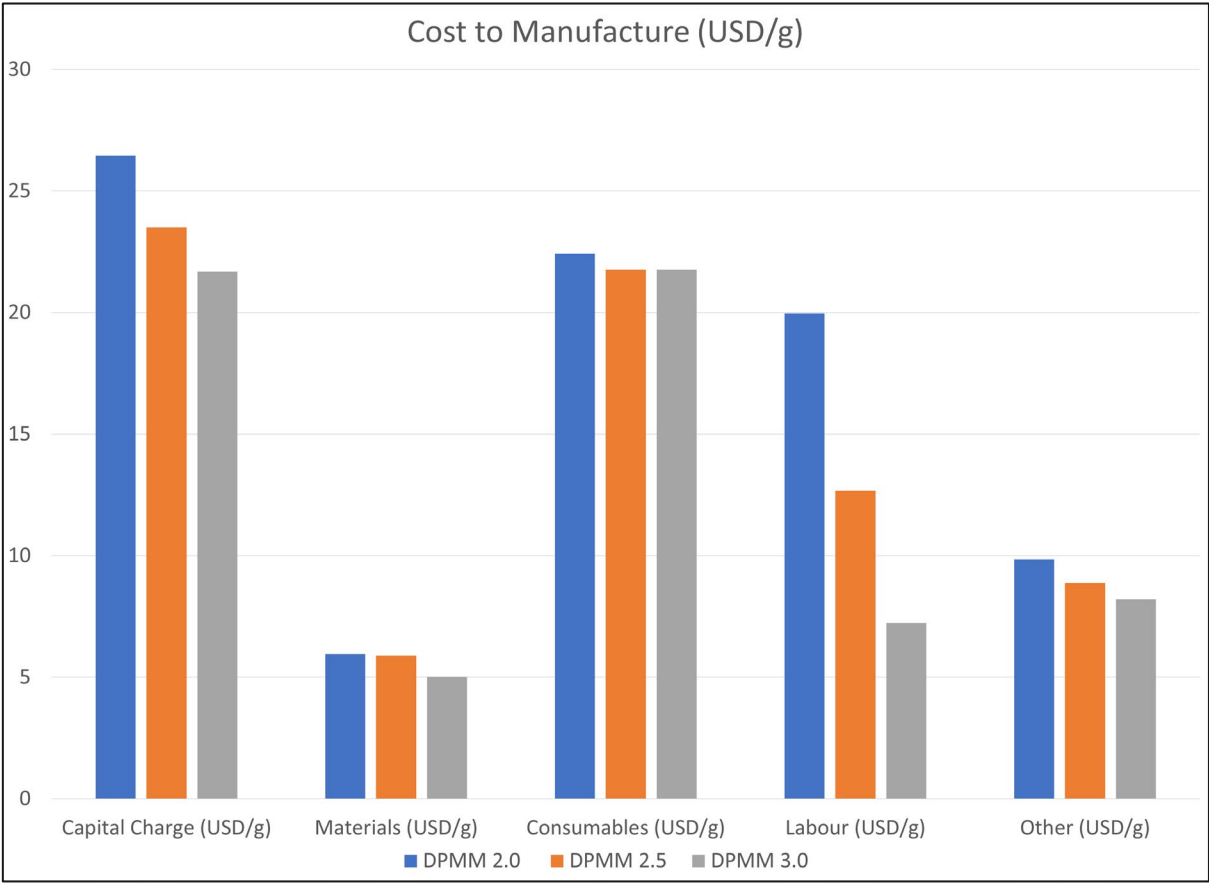


Note: Output reflects commercial manufacturing (2 x 2000L, 5g/L), 25 – 27 – 31 batches

Note: The above data was generated using BIOPHARM SERVICES LIMITED’s Biosolve™ software and having it configured for our DPMM simulation / model. The above results are for modelling purposes only. Other(s) assumptions or input(s) can change the result of the model.

Additional throughput drives down manufacturing costs with labor reduction being primary driver

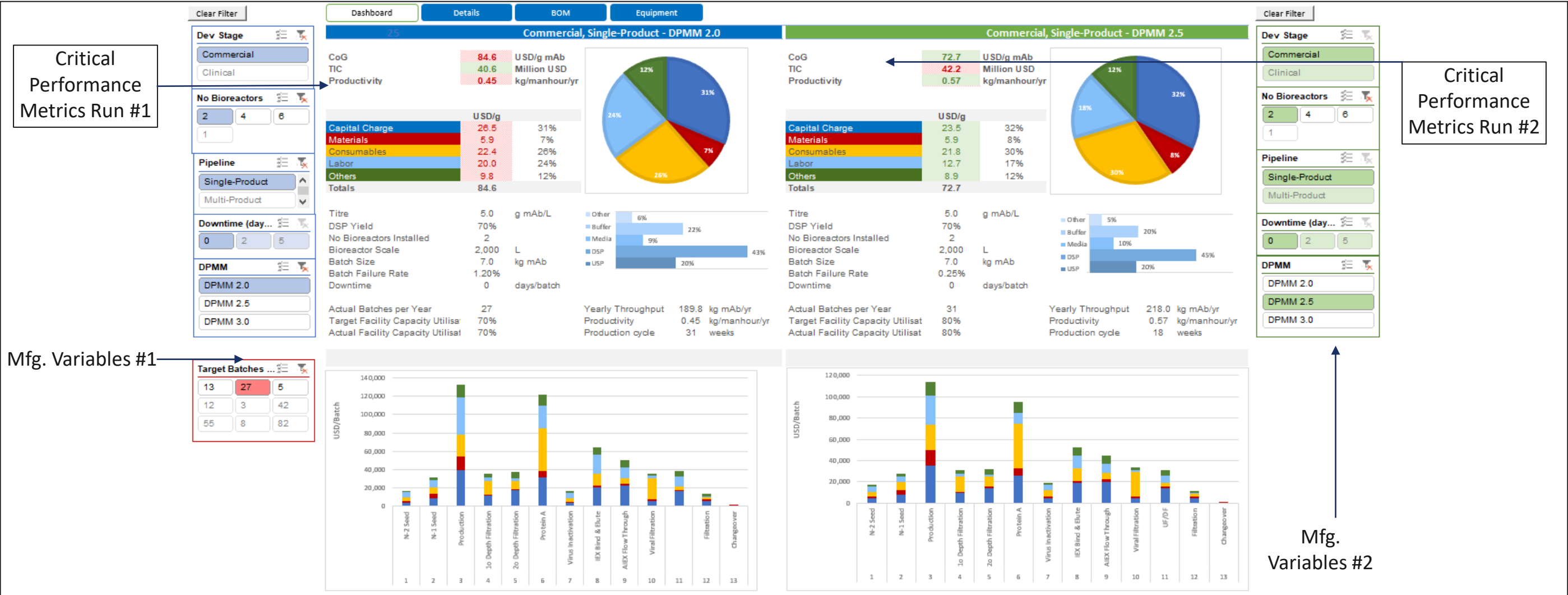
Increased digital maturity results in significantly lower cost of goods sold



Note: Output reflects commercial manufacturing (2 x 2000L, 5g/L), 25 – 27 – 31 batches

Note: The above data was generated using BIOPHARM SERVICES LIMITED’s Biosolve™ software and having it configured for our DPMM simulation / model. The above results are for modelling purposes only. Other(s) assumptions or input(s) can change the result of the model.

Side-by-side manufacturing comparison highlights difference in critical performance metrics



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Calculated ROIC

	DPMM 2.0	DPMM 2.5	DPMM 3.0
Capital	\$40.6M	\$42.2M	\$43.9M
Quantity of drug product	189.8KG	218KG	246.1KG
Selling price per gram	\$100	\$100	\$100
COGS \$/gram	\$85	\$73	\$64
COGS	\$16.1M	\$15.8M	\$15.7M
Revenue	\$18.9M	\$21.8M	\$24.6M
Net Operating Profit	\$2.9M	\$5.9M	\$8.8M
ROIC	7%	14%	20%

Note:

- The above did not account for taxes in the calculation
- Definitions of terms used: DPMM – Digital Plant Maturity Model, COGS – Cost of Gods Sold, ROIC – Return On Invested Capital
- The above table was created by C. Sandusky 2023
- The above data was generated using BIOPHARM SERVICES LIMITED’s Biosolve™ software and having it configured for our DPMM simulation/model. The above results are for modeling purposes only. Other(s) assumptions or input(s) can change the result of the model.

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Summary of benefits of digital maturity and considerations

Increased digital plant maturity can justify incremental automation costs

The introduction of advanced automation capabilities into a mAb process results in several advantages

Parameter	Unit of measure	Percent improvement DPMM level 2.5 vs. 2.0
COGS	(USD/gm)	Reduced up to 25%
Throughput	(kg/yr.)	Increased up to 25%
Productivity	(kg/man-hour/yr.)	Increased up to 50%

These advantages provide several benefits:

- Reduced scrap / sustainability
- Reduced labor
- Reduced deviations
- Reduced batch review time
- Increased facility utilization

Additional advantages not factored into model include:

- Improved regulatory compliance & audit results
- Greatly simplified and less costly manufacturing transfers
- Faster and less costly regulatory filings
- Amortize automation costs by using in future clinical and commercial campaigns

Typical project implementation approaches

Engineer, Procure, Construct

- Owner hires Engineering Firm and Construction firm separately
- Preliminary Budget and Schedule

- Typically, longest schedule
- Design is Bid out
- Managed by Construction
- Widely used approach

Design and Build

- Owner hires Design / Construction Firm
- Owner in the design process
- Budget and Schedule is set up front

- Typically, shorter than EPC
- Project built & managed by Design / Construction Firm
- Used based on project type

Productized Solutions

- Owner works with suppliers pre-engineered solutions
- Budget / schedule upfront
- Productized solution is configured

- Typically, shortest schedule
- Project is managed and delivered by supplier
- Used based on project type

Why engagements succeed?

Full executive sponsorship

A project needs executive sponsorship to succeed



Business value

The project finishes on time, and the business value is achieved



Culture

The company culture supports the change



Let's keep in touch

-  facebook.com/cytiva
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-  twitter.com/cytiva
-  youtube.com/c/cytiva

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Thank You