Analysis of the Advantages of and Barriers to Adoption of

SMART MANUFACTURING FOR MEDICAL PRODUCTS

An industry study by MxD and IAAE between February and June 2021 funded by FDA Office of Counterterrorism and Emerging ThreatsA

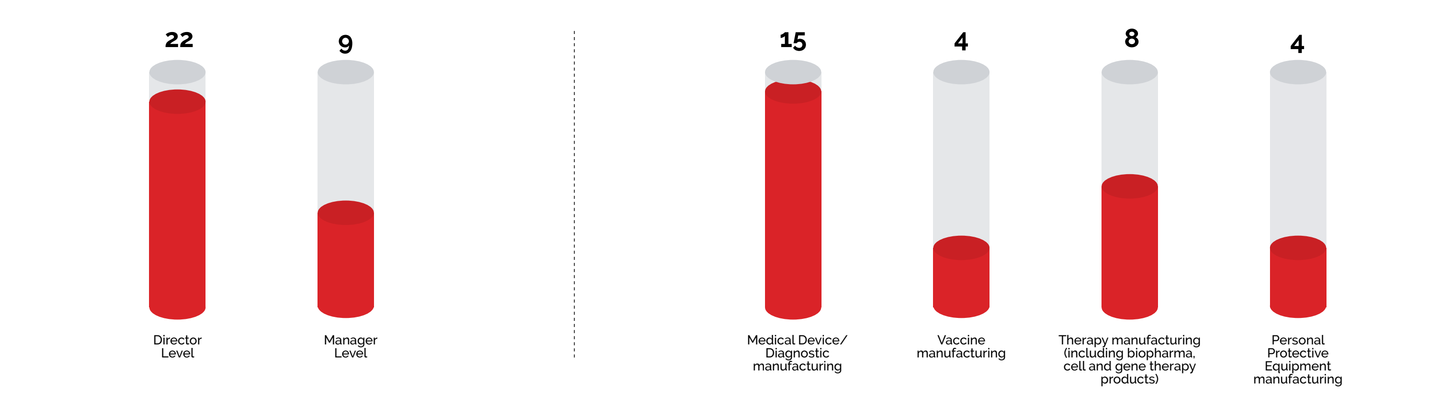
PROJECT SUMMARY

Project Objectives
Gain an inital baseline to deepen FDA's understanding of the factors that impact a manufacturer's decision to invest in and adopt digital technologies by illuminating both perceived and demonstrated barriers from technical, business, and regulatory perspectives, and related cybersecurity considerations.

Key Activities
Detailed evaluations at nine US-based, FDA-regulated pharma sites covering:
Business process factors
Technology factors
Regulatory factors
People factors

DeliverablesA
Project report and de-identified data for distribution within FDA
Project exec summary and infographic for limited distribution

> **"The reality is that it isn't enough to just respond to the current pandemic. The FDA and industry have to accelerate the adoption of advanced and smart manufacturing technologies to strengthen the nation's public health infrastructure."**
>
> Stephen M. Hahn, M.D., Former Commissioner of Food and Drug Administration, 2019-2021



31 participants represented the US-based sites of 9 different manufacturers. While the sample size of manufacturers was limited, most sites were represented by several participants, the majority in director level roles, and each participant completed a survey and two separate interviews with the project team.

BARRIERS TO TECHNOLOGY ADOPTION (REAL AND PERCEIVED)

This engagement was seen by the manufacturers interviewed to be a very welcome initiative coming from FDA.

REAL BARRIERS

Respondents were asked to rank in priority from top to bottom the factors that, in their opinion, most hinder digital transformation at their site.

- Legacy systems
- Insufficient funding
- Competing priorities of senior executives
- Organizational silos
- Lack of specific skills and talents
- Conflicting corporate strategies
- Business Technology (including IT) and business misalignment
- Regulation and compliance challenges
- Cybersecurity and privacy requirements
- Risk-adverse culture
- Lack of change management best practice

Obstacles to Digital Transformation, Business Process respondents (n=7)

LIKELY PERCEIVED BARRIERSA

The misunderstanding that a corporate approach to Operational Excellence is sufficient and does not need to be complemented by best practices and expertise from the disciplines of change management and human performance.

The technology gap is sometimes a psychological one. Lack of understanding of technologies or the inability of experts to adequately explain technologies can cause individuals to be more reluctant to adopt/trust new technology Whether this is a real or perceived barrier is most likely person and culture dependent and may be reduced with education, training, and skills.

The perception that regulation may be a limitation. Regular engagement of regulators and internally presenting the value of proposed changes can mitigate this.

That new expertise depends on the infusion of talent through new hires. Capability building through technical training and educational programs empower internal talent. In a labor market that is already not producing enough talent to hire, this perceived barrier could be detrimental to the long-term success of the organization and lead to challenges with talent retention.

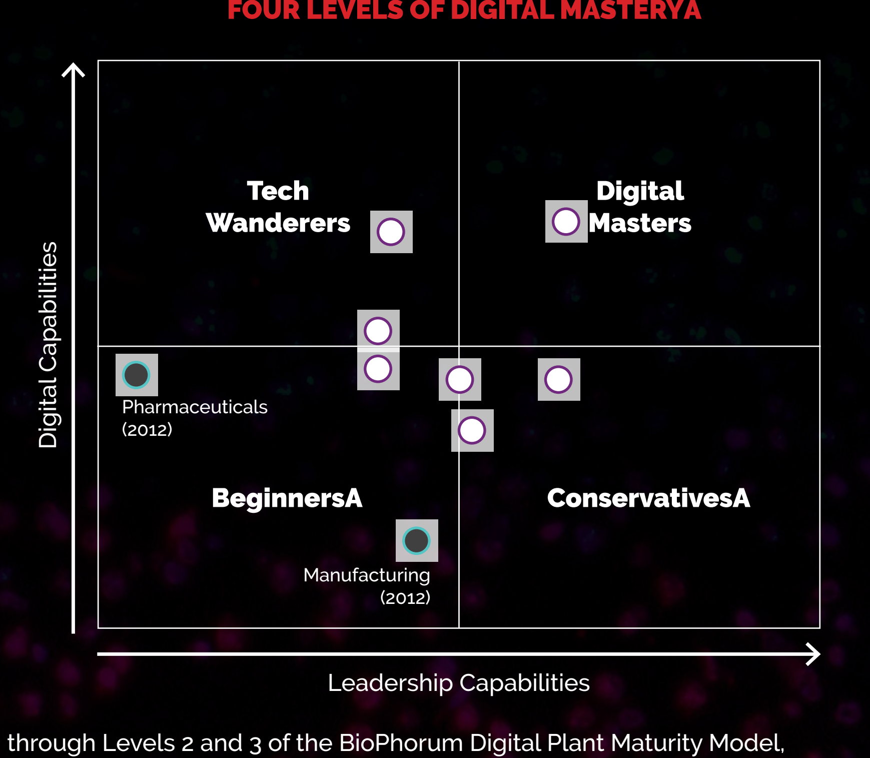
WHAT WE EXPECTED TO FIND

The levels of digital mastery of pharmaceutical manufacturers were found to have broadly improved when compared to a similar assessment done a few years ago which placed the pharmaceutical industry firmly in the Beginners quadrant. Such progress is likely due to the emphasis placed on digital transformation in recent years, and likely further accelerated by the pandemic.

Project team findings under MxD-IAAE FDA OCET study 22FEB21 – 23JUN21 (n=7)

Source: Leading Digital, by Westerman, George; Bonnet, Didier; McAfee, Andrew. Harvard Business Review Press. Level of digital mastery (all participating manufacturers that completed business process surveys) (n=7). Used with permission of the publisher

FOUR LEVELS OF DIGITAL MASTERYA



Several individual companies are progressing through Levels 2 and 3 of the BioPhorum Digital Plant Maturity Model, shown in the table below. However, the overall picture is that the majority of manufacturers assessed are only starting to emerge into levels 2 and 3, and many are still highly reliant on paper-centric processes at Level 1.

BioPhorum Digital Plant Maturity Model

Emerging = partially describes my plant
Mature = fully describes my plant OR plant matured past this level

	Dimension of Maturity	Trend	Level 1 Pre-Digital Plant	Level 2 Digital Silos	Level 3 Connected Plant	Level 4 Predictive Plant	Level 5 Adaptive Plant
Business Capabilities	Manufacturing Execution & Process Automation	UP	Mature	Emerging	Emerging	None	None
	Lab Execution & Quality Management	UP	Emerging	Emerging	Emerging	Emerging	None
	Manufacturing Support	UP	Emerging	Emerging	Emerging	None	None
	Production Planning & Supply Chain	UP	Emerging	Emerging	Emerging	None	None
Enabling Dimensions	People & Culture	UP	Emerging	Emerging	Emerging	Emerging	None
	Business Insights & Analytics	UP	Emerging	Emerging	Emerging	None	None
	Systems Interoperability & Governance	UP	Mature	Emerging	Emerging	Emerging	None
	IT Security & Operations	UP	Mature	Mature	Emerging	Emerging	None

Source: Digital Plant Maturity Model Summary across manufacturers assessed (n=9); DPMM used with permission of BioPhorum

Level 1 | Pre-digital plant: manual, paper-based processes
Level 2 | Digital Silos: 'islands of automation
Level 3 | Connected plant: high level of automation, integration and systems standardization
Level 4 | Predictive plant: integrated plant network, pervasive real-time predictive analytics
Level 5 Adaptive plant: 'plant of the future, autonomous, self-optimizing, plug-and-play

WHAT WE DID NOT EXPECT TO FIND

01
International regulatory complexity is outstripping efforts to harmonize - "We can't even agree on how to write the word 'harmonize'".

02
You will face significant challenges when introducing new terms for old things (that is, standardization can change vocabulary or ontologies, which can lead to resistance)

03
Some sites have fully embraced and successfully implemented new technologies, such as cloud computing, AR/VR, and RPA and many manufacturers have very mature digital transformation programs that have existed for more than 15 years!

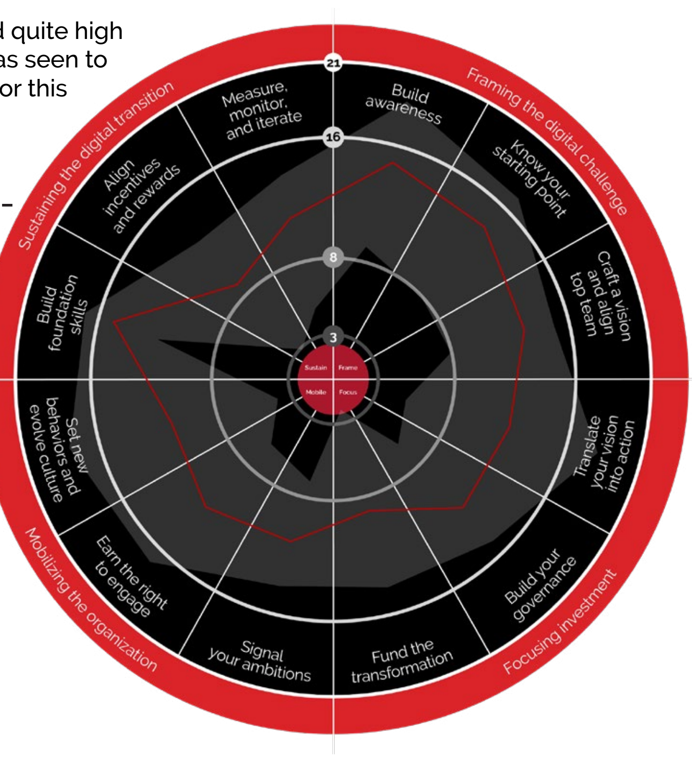
04
The manufacturers surveyed provided a broad, but shallow representation of the larger pharmaceutical and biopharmaceutical industry. Each still have a significant way to go with respect to how they are framing, focusing, mobilizing, and sustaining their digital transformation.
Not a single manufacturer surveyed, several of which had quite high levels of digital maturity, had a strong score in all the areas seen to be necessary for comprehensive digital transformation. For this a manufacturer would have needed to score above the circle score of 16 in the image below.

Digital transformation compass

Average across all manufacturers who completed business process surveys with max and min scores shown in gray shading for each segment

Project team findings under MxD-IAAE FDA OCET study, 22FEB21 – 23JUN21 (n=7)

- (21) Maximum possible score
- (16) Well positioned if above this point
- (8) Significant action is needed if below this point
- (3) Minimum possible score



Source: Leading Digital, by Westerman, George; Bonnet, Didier; McAfee, Andrew. Harvard Business Review Press. Part III Digital Transformation Compass used with permission of the publisher.

THREE AREAS MANUFACTURERS CAN BETTER FOCUS THEIR ENGAGEMENT WITH FDA

01
Avail of the webinars, podcasts, conferences, and seminars that FDA make available or attend, not just for your regulatory intelligence teams but for quality and regulatory colleagues throughout your organization.

02
Understand how to engage the FDA for early discussions for adopting advanced technologies through CDER, CBER and CDRH initiatives like the ETT, CATT, and CfQVIP (links below).

03
If applicable, access CDRH Learn, FDA's Center for Devices and Radiological Health (CDRH) web page for multimedia industry education and subscribe to Twitter or other channels to stay informed on new media releases.

SEVEN WAYS MANUFACTURERS CAN ADVANCE THEIR DIGITAL TRANSFORMATION AGENDA

- **01** Think digital evolution instead of single transformation
- **02** Lean out business processes before automating them
- **03** Embed design thinking principles and practices into projects
- **04** Invest in organizational change management and change leadership capabilities for a healthy digital culture
- **05** Organize and empower passionate people for success
- **06** Consider capability building via an academy approach*
- **07** Cybersecurity is necessary and essential to modernization

If your organization would like to connect with the MxD team reach out via the Web.A > MxD

***Similarly, to connect with the IAAE® team reach out via LinkedIn.A** > IAAE®

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Source: Accelerating the Adoption of Advanced Manufacturing Technologies to Strengthen Our Public Health Infrastructure 01/15/2021
> FDA Office Counterterrorism and Emerging Threats
> FDA Center for Biologics Evaluation and Research (CBER) Advanced Technologies Program (CATT)
> FDA Center for Drug Evaluation and Research (CDER) Emerging Technology Program (ETT)
> FDA Center for Devices and Radiological Health (CDRH) Learn
> FDA Center for Devices and Radiological Health (CDRH) Case for Quality Voluntary Improvement Program (CfQVIP)
> National Academies of Sciences, Engineering, and Medicine 2021. Innovations in Pharmaceutical Manufacturing on the Horizon: Technical Challenges, Regulatory ssues, and Recommendations. Washington, DC: The National Academies Press

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