Analysis of the Advantages of and Barriers to Adoption of Smart Manufacturing for Medical Products – Focus on Response to Emerging and Pandemic Threats such as SARS-CoV-2

MxD 20-19-01 – FDA OCET Project - Executive Summary

ISSUED 30 JUNE 2021

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Index

Project Overview

The Initiative

The COVID-19 pandemic has revealed that existing manufacturing structures, with a small number of facilities fed by long and complex supply chains, can be disrupted. Such events elevate risk and create shortages in the U.S.

The FDA and industry have a responsibility to accelerate the adoption of advanced and smart manufacturing technologies to strengthen the nation's public health infrastructure.

Attribution: Paraphrased from Accelerating the Adoption of Advanced Manufacturing Technologies to Strengthen Our Public Health Infrastructure 01/15/2021

Project Summary

PROBLEM STATEMENT

- The SARS-CoV-2 pandemic has exposed gaps in the U.S. manufacturing supply chain and has reinforced the need to adopt and accelerate the implementation of digital technologies which improve supply chain resilience, reduce time to market, or increase manufacturing capacity for medical diagnostics, therapies, and vaccines.

GOALS & OBJECTIVES

- Deepen the 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.

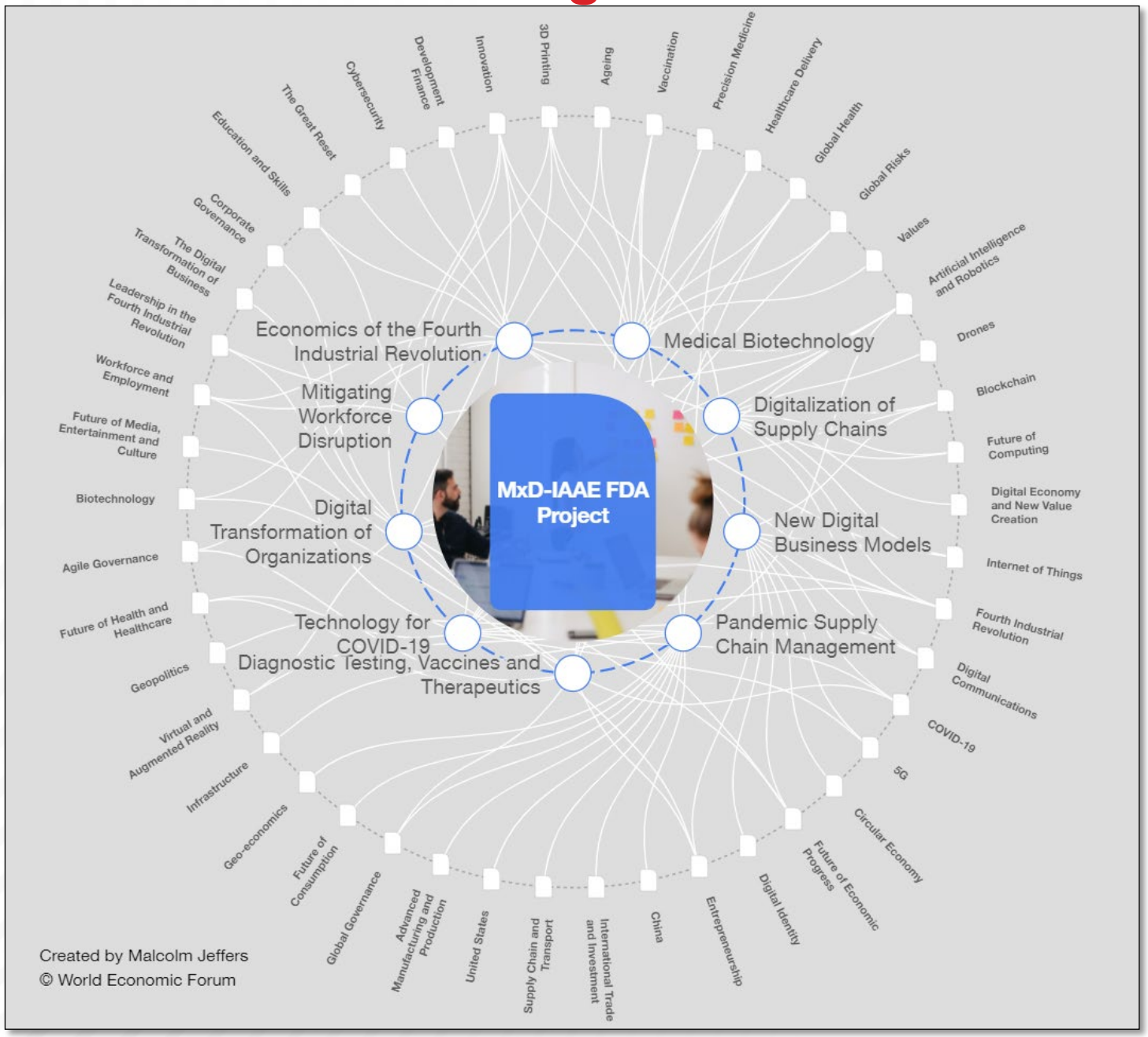
KEY ACTIVITIES

- **Under this project the MxD and IAAE project team performed site-level evaluations of nine manufacturers plus one corporate-level manufacturer evaluation,** interviewing representatives for the following areas:
  - Business process factors
  - Technology factors
  - Regulatory factors
  - People factors

DELIVERABLES

- The final report with all detailed findings and analysis.
- This Exec Summary slide deck is for distribution within FDA, MxD, IAAE, and to the public.
- Findings from all participating manufacturers showing only de-identified data.
- An infographic, for FDA review and internal promotion as well as public use by the project team and BioPhorum following approval.

Context of Technologies and Themes



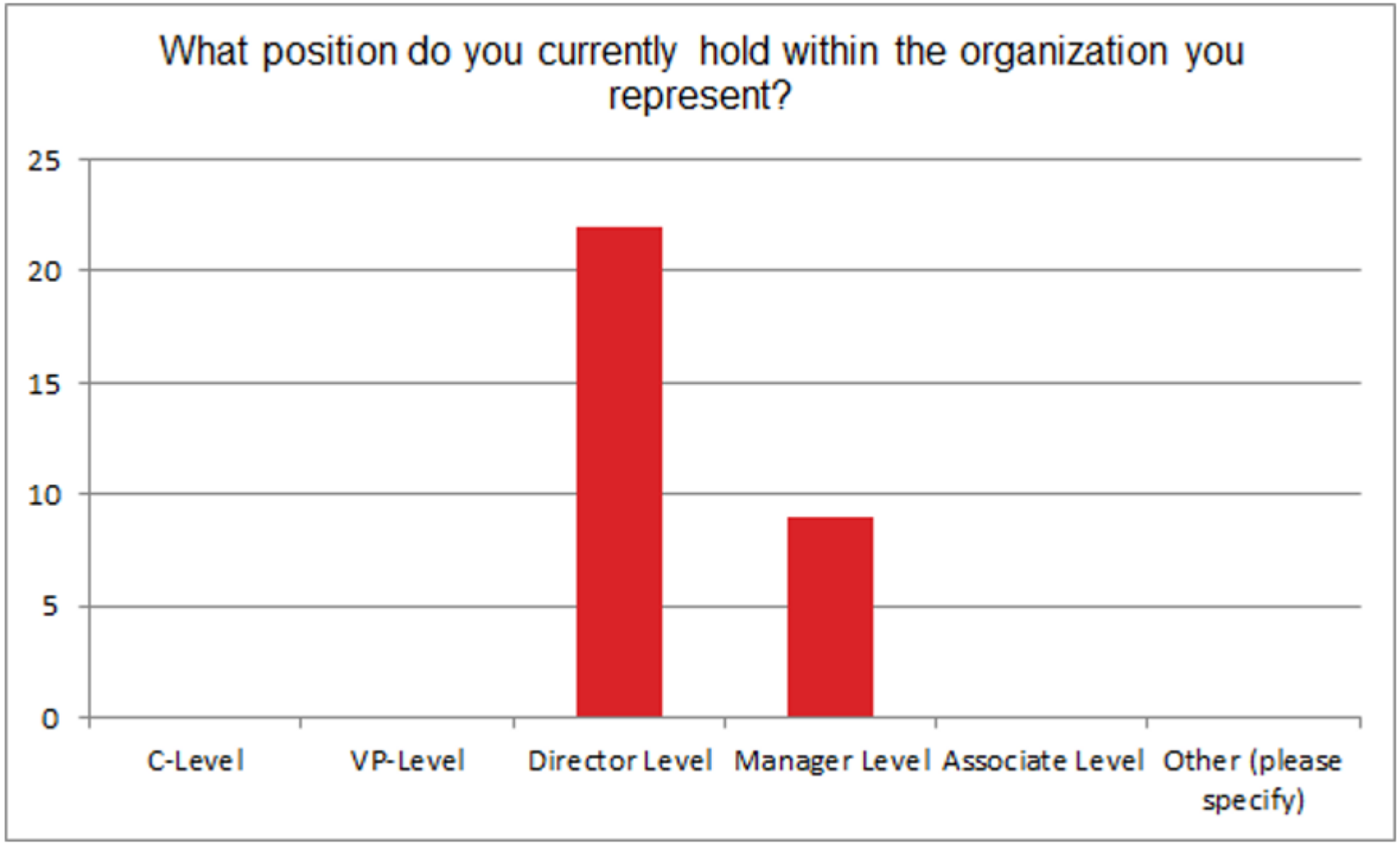
The transformation map shown opposite illustrates some of the primary themes in view under this project.

These themes, in the context of regulated pharmaceutical manufacturing, were carefully considered in both surveys and interviews with participants.

Identification Framework

Secuing participation from manufacturers from each quadrant		
Scale	**Higher Digital Maturity Starting Point**	**Lower Digital Maturity Starting Point**
Large	• Raw material supplier • **Vaccine developer (1)** • **Diagnostic/Device manufacturer (1)** • **Therapy developer (2)** • **PPE producer (1)** • Distribution/demand prediction company	• Raw material supplier • Vaccine developer • **Diagnostic/Device manufacturer (1)** • Therapy developer • PPE producer • Distribution/demand prediction company
Mid- and Small Size	• Raw material supplier • Vaccine developer • Diagnostic/Device manufacturer • **Therapy developer (1)** • PPE producer • Distribution/demand prediction company	• Raw material supplier • Vaccine developer • **Diagnostic/Device manufacturer (1)** • **Therapy developer (1)** • PPE producer • Distribution/demand prediction company

Seniority of Respondents



Seniority of participants (N = 31)

A total of 31 participants from 9 different site-level manufacturers participated on this project between the 22nd of February and the 30th of June 2021.

Executive Summary Findings

BioPhorum Assessment

- The project team utilized the BioPhorum Digital Plant Maturity Model (DPMM), used with permission, as a basis for the assessment.
- It enables an assessment of a plant against five maturity levels within each dimension as shown in the table below.

Maturity level	Level name	Description
1	pre-digital plant	manual, paper-based processes
2	digital silos	'islands of automation'
3	connected plant	high level of automation, integration and systems standardization
4	predictive plant	integrated plant network, pervasive real-time predictive analytics
5	adaptive plant	'plant of the future', autonomous, self-optimizing, plug-and-play

- The assessment tool gives a neutral assessment of the current state and facilitates discussion on a desired future state.
- Both summary and detailed dashboards are shown next.

BioPhorum Maturity Model Summary

BioPhorum Digital Plant Maturity Mode							
Dimensions 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

Topic	Project team conclusion
DPMM analysis	While there were individual companies that indicated a higher maturity progressing through Levels 2 and 3, the overall picture is that the 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. More scoring detail is given in the slide below for each Level. Emerging = Partially describes the Plant at this Level; Mature = Fully describes the Plant at this level OR Plant matured past this level

BioPhorum Maturity Model Detail

BioPhorum Digital Plant Maturity Mod								
Dimensions of Maturity		Trend	Level 1 Pre-Digital Plant	Level 2 Digital Silos	Level 3 Connected Plant	Level 4 Predictive Plant	Level 5 Adaptive Plant	Score
Business Capabilities	Manufacturing Execution & Process Automation	UP	88%	60%	25%	14%	2%	1.9
	Lab Execution & Quality Management	UP	70%	59%	31%	17%	1%	1.8
	Manufacturing Support	UP	54%	34%	25%	7%	1%	1.2
	Production Planning & Supply Chain	UP	50%	40%	20%	8%	0%	1.2
Enabling Dimensions	People & Culture	UP	60%	60%	40%	23%	4%	1.9
	Business Insights & Analytics	UP	49%	36%	26%	7%	1%	1.2
	Systems Interoperability & Governance	UP	87%	69%	37%	17%	1%	2.1
	IT Security & Operations	UP	88%	85%	67%	31%	12%	2.8
Business Capabilities			66%	48%	25%	12%	1%	1.5
Enabling Dimensions			71%	63%	43%	20%	5%	2.0
Total Score			68%	55%	34%	16%	3%	3.5

Level of Digital Mastery

What does each quadrant indicate?

- **Beginners**
  - Management skeptical of the business value of advanced digital technologies
  - May be carrying out some experiments
  - Immature digital culture
- **Tech Wanderers**
  - Many advanced digital features in silos
  - No overarching vision
  - Underdeveloped coordination
  - Digital culture may exist in silos
- **Conservatives**
  - Overarching digital vision, but may be underdeveloped
  - Few advanced digital features, though traditional digital capabilities may be mature
  - Strong digital governance across silos
  - Active steps to build digital skills and culture
- **Digital Masters**
  - Strong overarching digital vision
  - Excellent governance across silos
  - Many digital initiatives generating business value in measurable ways
  - Strong digital culture

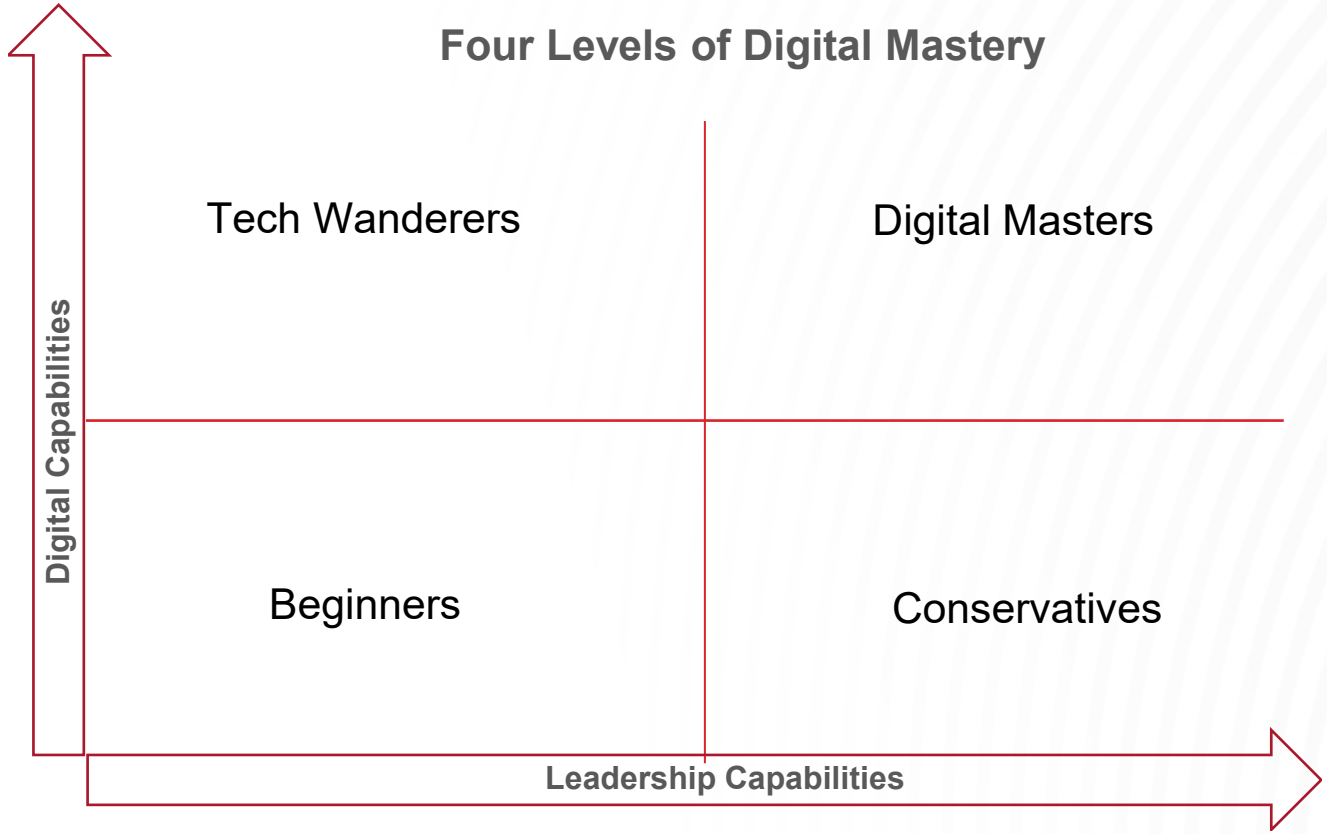


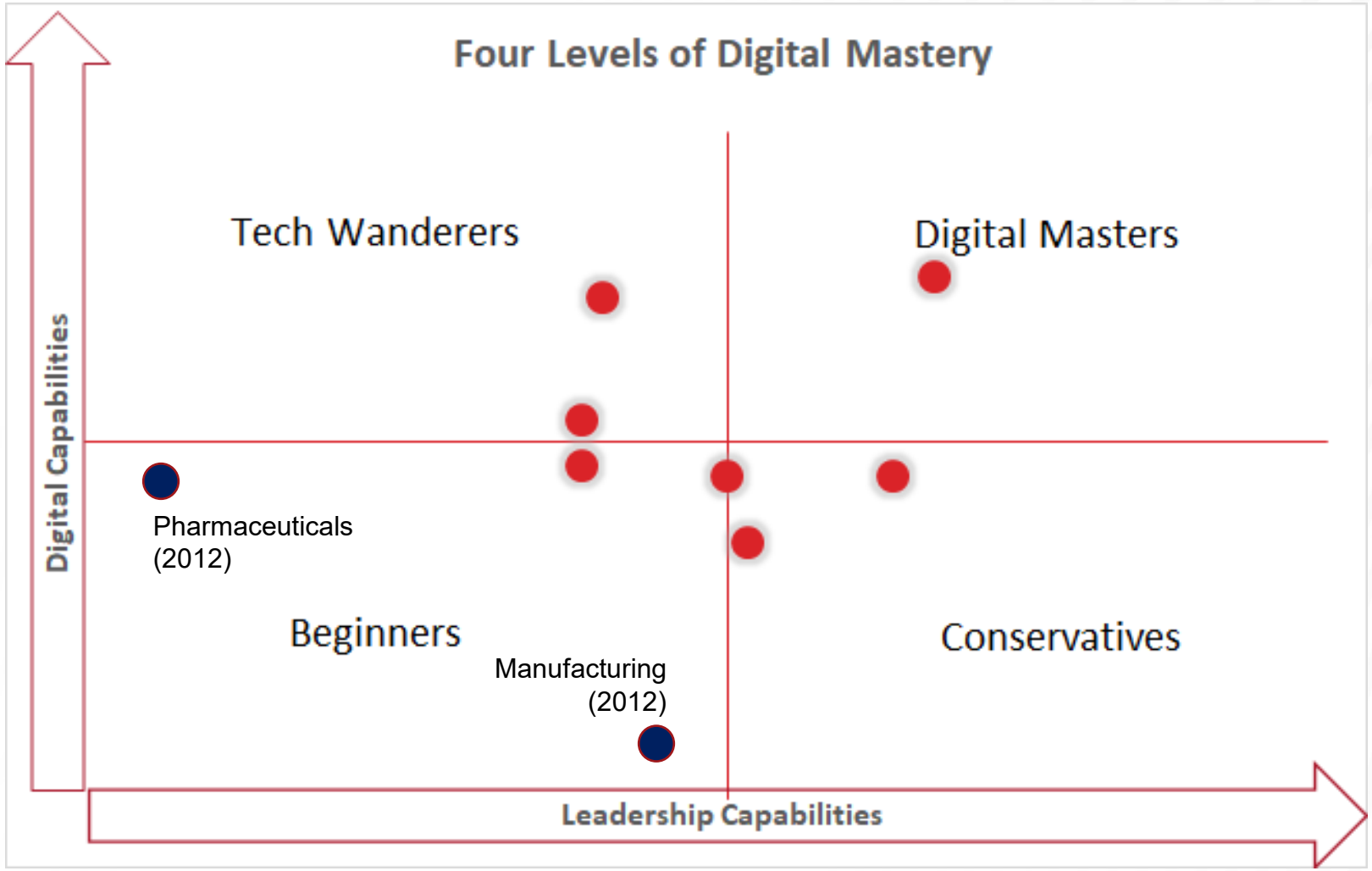
Chart and Text Source: Leading Digital, by Westerman, George; Bonnet, Didier; McAfee, Andrew. Harvard Business Review Press. Used with permission of the publisher.

Level of Digital Mastery – Results and Analysis

The figure shows the level of digital mastery identified for whether each manufacturer is a beginner, conservative, tech wanderer, or digital master with respect to digital capabilities and leadership capabilities.

Based on responses to survey questions under the category of Business Process factors it was determined that very few manufacturers were in the quadrant of Digital Masters.

Detailed recommendations were given to each manufacturer in a site-specific report.



Level of digital mastery (all participating manufacturers that completed business process surveys) (n=7)

Digital Transformation Compass – Results and Analysis

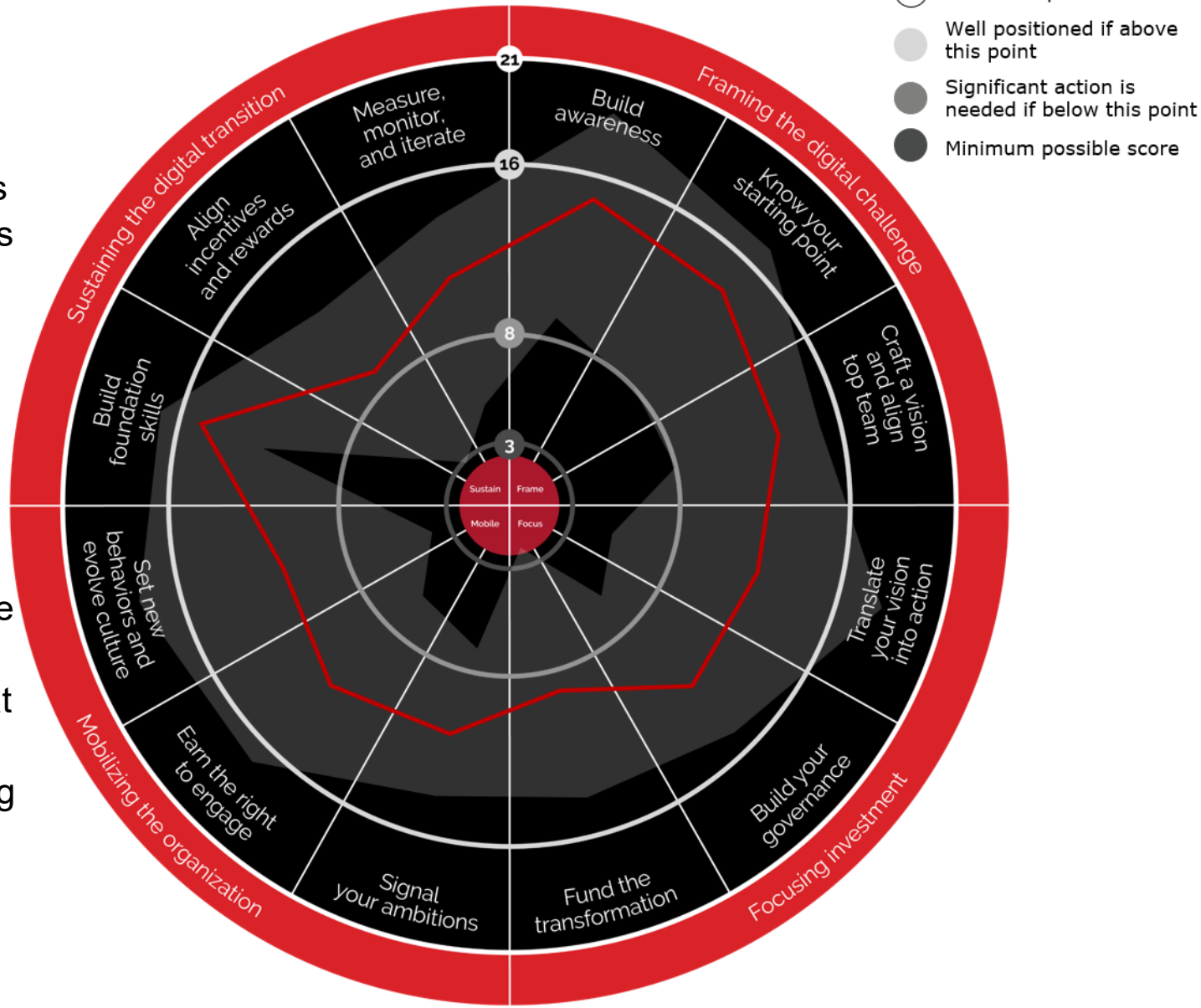
The digital transformation compass is a tool used to visualize how an organization is framing, focusing, mobilizing, and sustaining its digital transformation.

Each manufacturer who completed the business process survey received a specific digital transformation compass chart based on their survey responses.

The figure below shows the average score line in red. The maximum and minimum points are also shown by the gray shading.

Some observations:

1. On average, all metrics of digital transformation score weakly. While some orgs scored over 16 in one or more categories, no single organization scored over 16 for all categories (i.e., the line indicating what is necessary for solid digital transformation.)
2. Not a single manufacturer scored above 16 indicating continued opportunity for improvement.
3. The two broader areas that manufacturers are struggling the most with digital transformation would seem to be ‘Mobilizing the Organization’, and ‘Sustaining the Digital Transition’.



Digital transformation compass – Average across all manufacturers who completed business process surveys with max and min scores shown at top and bottom of each segment (n=7)
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.

Word Cloud of Subject Matter

The word cloud below shows the terms that had most prevalence across interviews for all four categories of business process, technology, regulatory, and people.

Notice that the words illustrate that the subject matter covered was very much in line with intended conversations and context.

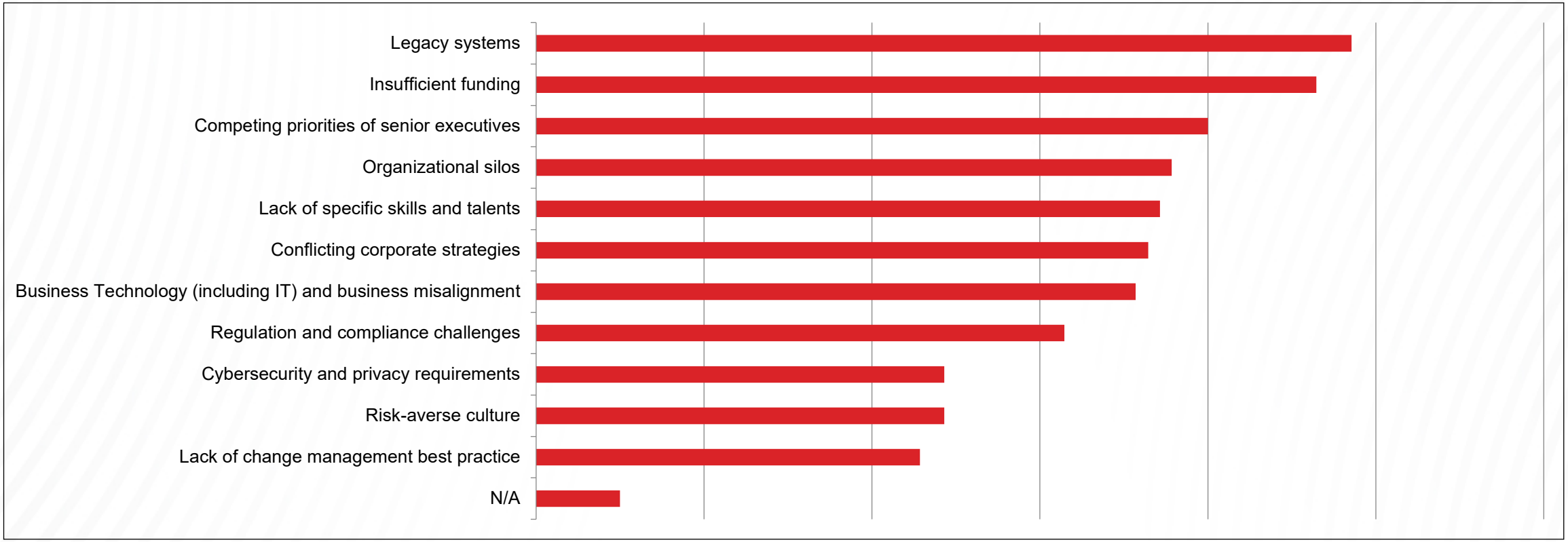
Word clouds for each of the four categories are available in the full report.

Number of Data Sets Available/Included: 24/24

Selection of Key Findings

Selection of Key Survey Findings – Business process factors

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



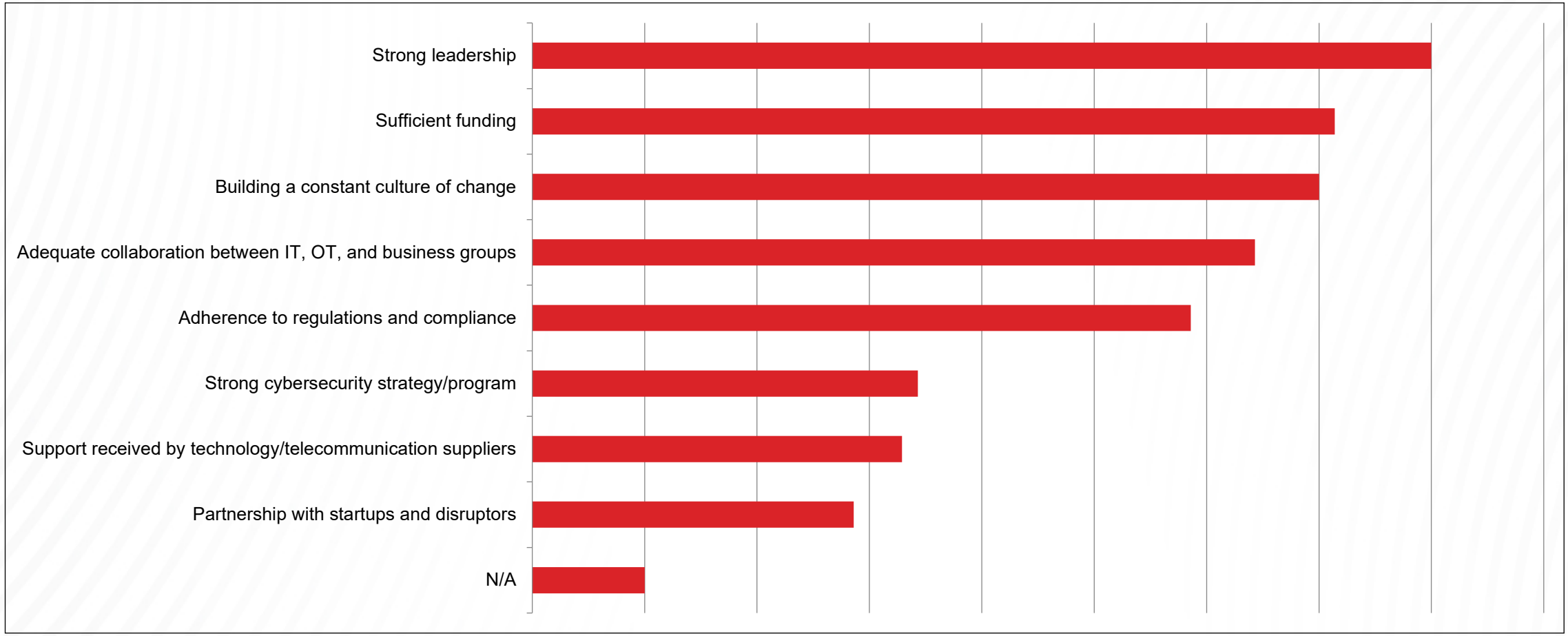
Project team analysis

There was a consistent thread across most respondents when it came to legacy systems, insufficient funding, and competing priorities of senior executives as challenges to better digital transformation successes. One could see the correlation between the three despite the order they were presented in. It was felt that in the business systems the ERP systems were expensive to implement and to upgrade without significant cost and disruption. Most respondents commented that the have several legacy systems and anticipate the maintenance of these and future systems to cause legacy issues on an ongoing basis.

Note: These are the responses of the participants or syntheses of their comments.

Selection of Key Survey Findings – Business process factors

Ranking of the most important factors for successful digital transformation at your site (n=7)



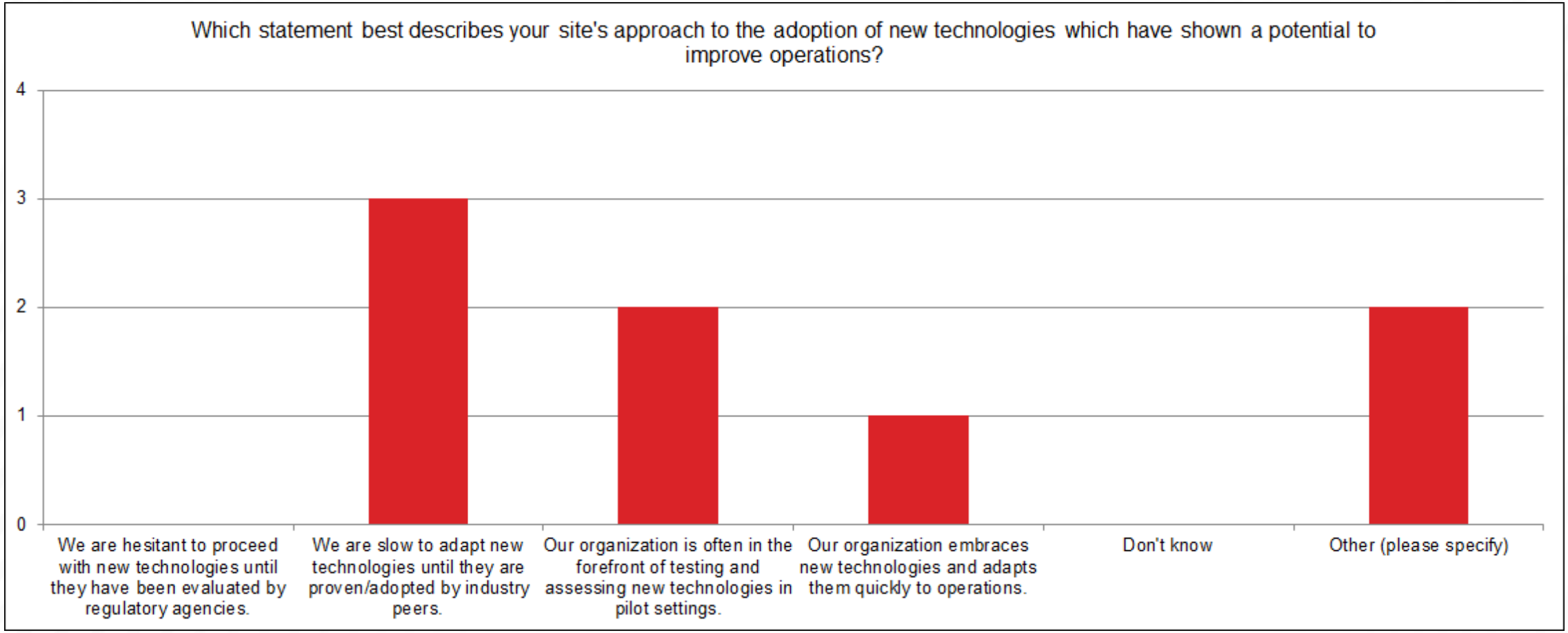
Project team analysis

Evidence was obtained that those companies who had strong management and a mandate from either the C-suite level or VP sponsorship made the most progress. Typically, the strong leadership went with a solid strategy, good communication of the need for digital transformation, and adequate funding as shown.

Note: These are the responses of the participants or syntheses of their comments.

Selection of Key Findings – Technology factors

Describe your site's approach to the adoption of promising new technologies (n=8)



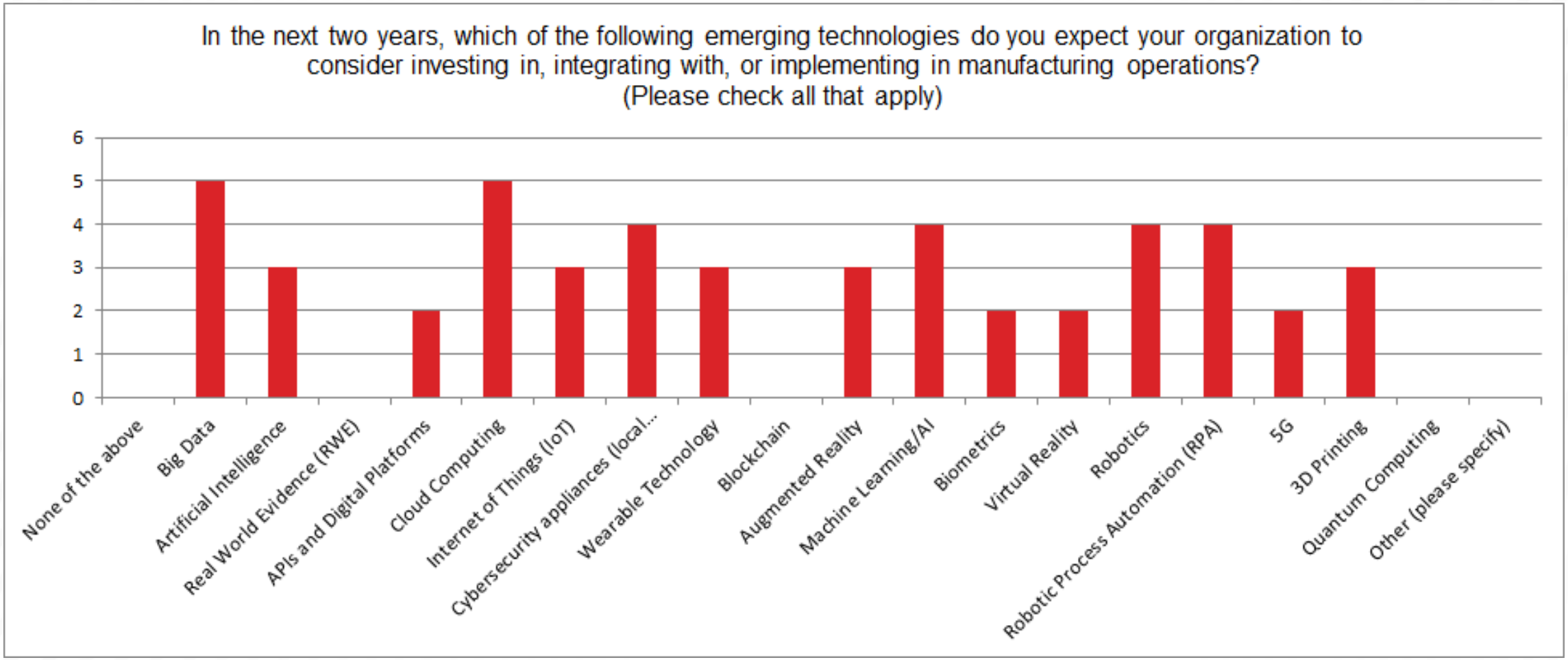
Project team analysis

This chart indicates the number of participating manufacturers responding given the choices below when asked to best describe their site's approach to the adoption of new technologies which have shown a potential to improve operations. In general, new technologies are being considered, evaluated, and employed in manufacturing, but barriers exist.

Note: These are the responses of the participants or syntheses of their comments.

Selection of Key Findings – Technology factors

Indicate which emerging digital technologies are being considered over the next two years at your site (n=8)



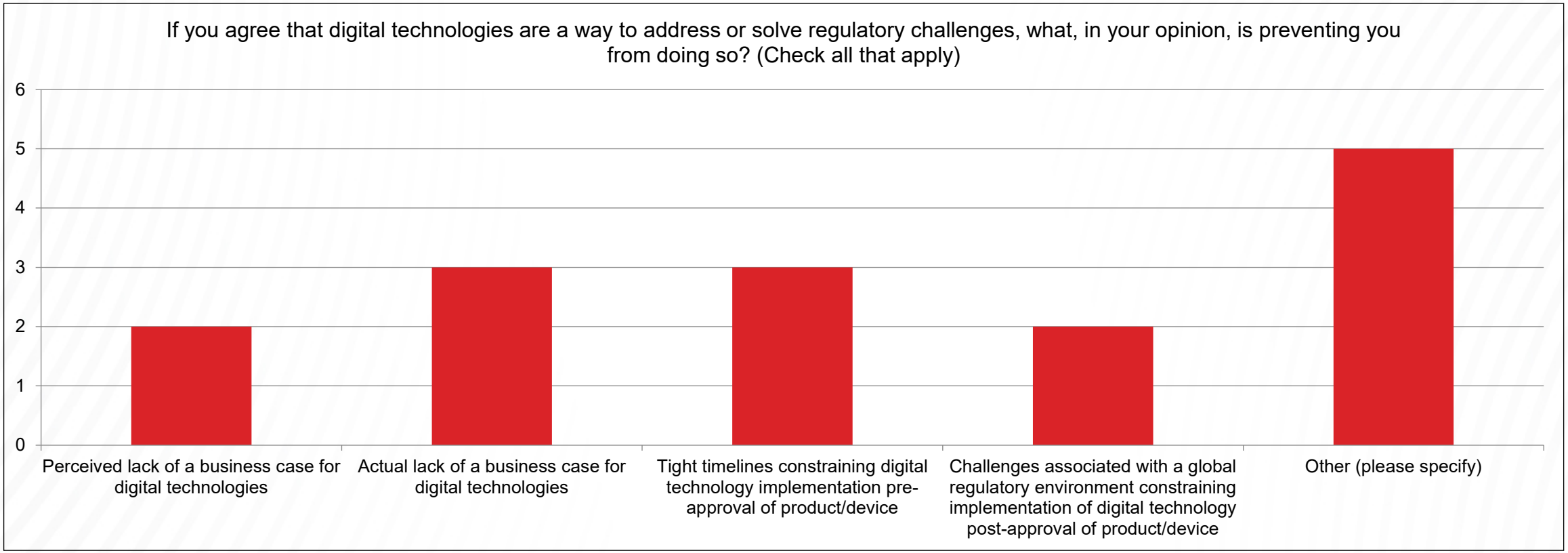
Project team analysis

This chart indicates the number of participating manufacturers responding given the choices below when asked to best describe which of these emerging technologies are being considered for investment, integration, and implementation at their site. Cloud computing and Big Data are the most-often cited, but other technologies, such as ML/AI and Robotics, are being considered by many companies.

Note: These are the responses of the participants or syntheses of their comments.

Selection of Key Findings – Regulatory factors

Barriers to using digital technologies as a way to address of solve regulatory challenges (n=8 due to one group who skipped this question due to previous question being “No”)



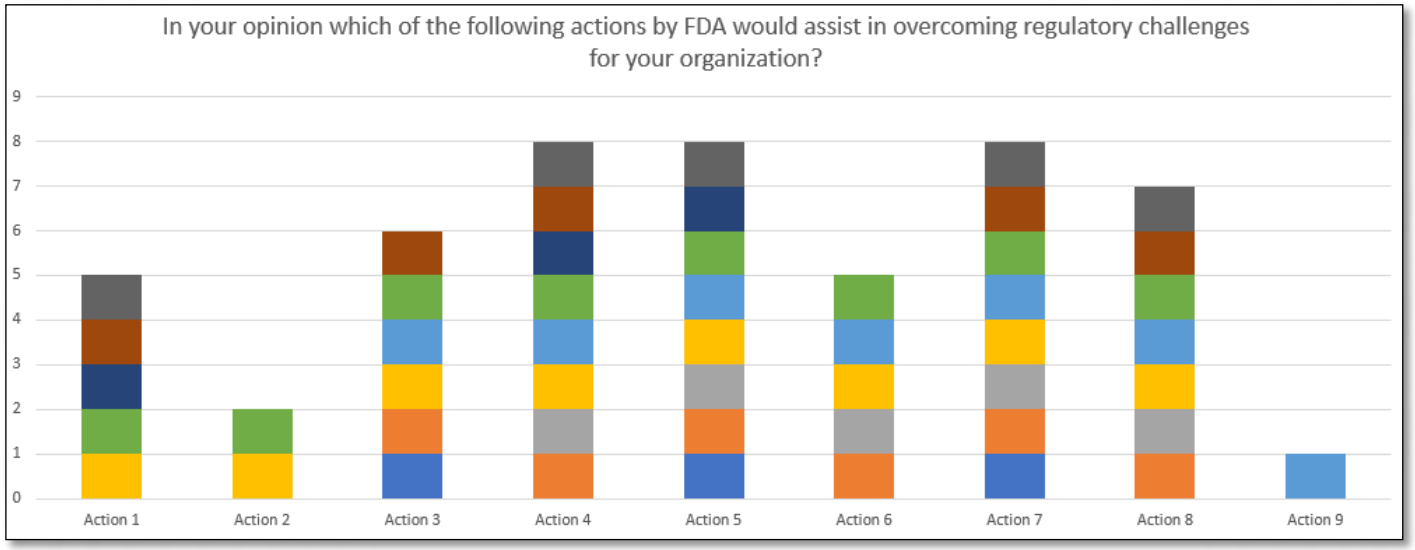
Project team analysis

Other = “Head Count to be able to implement”, “Capability to implement effective solution. Limited support during stand up”, “Costs”, “We need more expertise in our company to implement these with a pragmatic way of getting them in place. Need to use off the shelf solutions, not re-invent solutions”, “Money”. For the manufacturers who agreed that digital technologies are a way to address or solve regulatory challenges, these barriers were identified for their organizations.

Note: These are the responses of the participants or syntheses of their comments.

Selection of Key Findings – Regulatory factors

Manufacturers responded to a list of suggested actions from a 2020 National Academies report (N=9; Other = FDA employees to be more consistent in both inspections and guidance)



Action 1: Work with the industry to distinguish regulatory language from descriptions of scientific or engineering principles and practices (e.g., the term 'control').
Action 2: Communicate innovation value proposition in the context of the pharmaceutical supply chain, financials, and operations.
Action 3: For FDA to give greater presence in FDA's discussions of new control approaches and innovations relating to concepts of "people, process, and technology" and related business processes such as stage gating and change management.
Action 4: Become familiar with condition-based monitoring approaches and provide incentives for their use.
Action 5: That inspection staff have the expertise to understand the technologies and best practices in their application.
Action 6: For FDA to influence standards for modularization that have integrated sensing and control technologies.
Action 7: For FDA to become more aware of the trend towards greater use of expert-system digitized work instructions.
Action 8: Relating to innovations in sensing, modeling, ML applications, and advanced control, for FDA to issue focused guidance on cGMP implementation and expectations for their management.
Action 9: Other

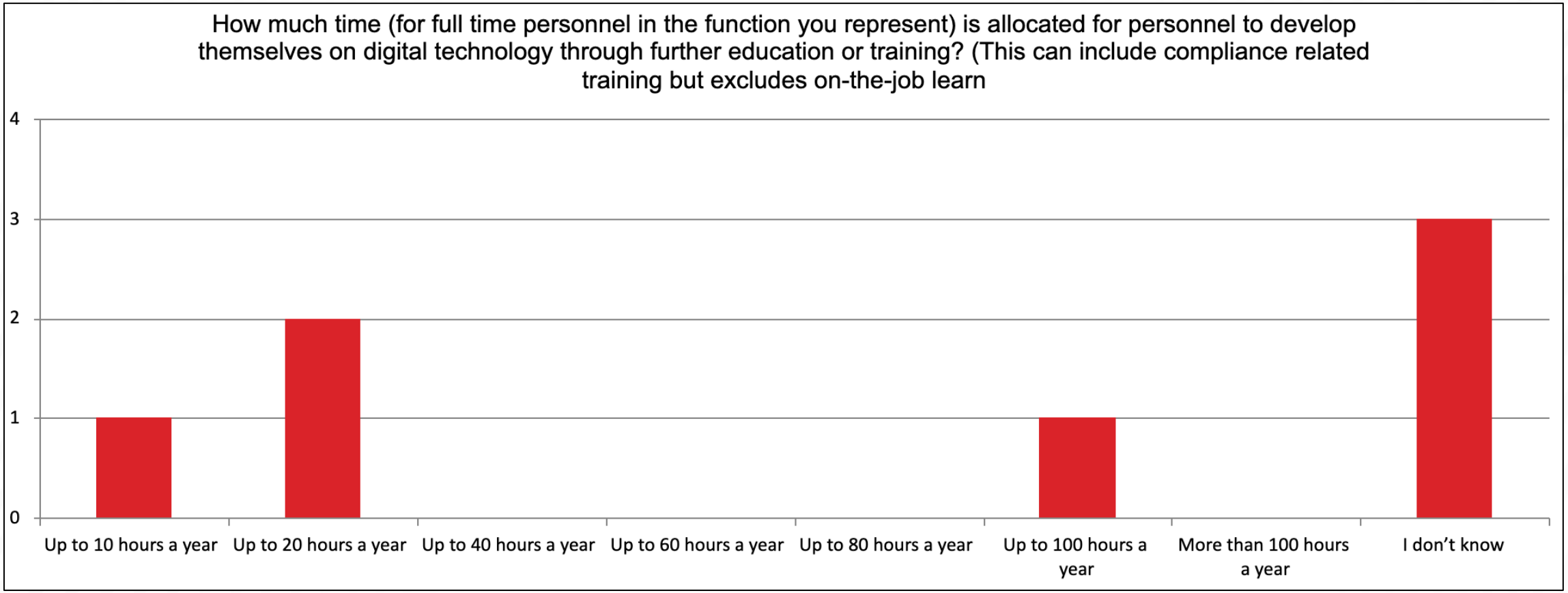
Project team analysis

The project team conducting this study decided to build upon work carried out during 2020 by reflecting back these suggested actions to each of the nine site-level regulatory factors interviewees, noting the participants agreement or disagreement, and related clarifications on each suggestion.

Note: These are the responses of the participants or syntheses of their comments.

Selection of Key Findings – People factors

Hours/year to develop on digital technology through further education and training (n=7)



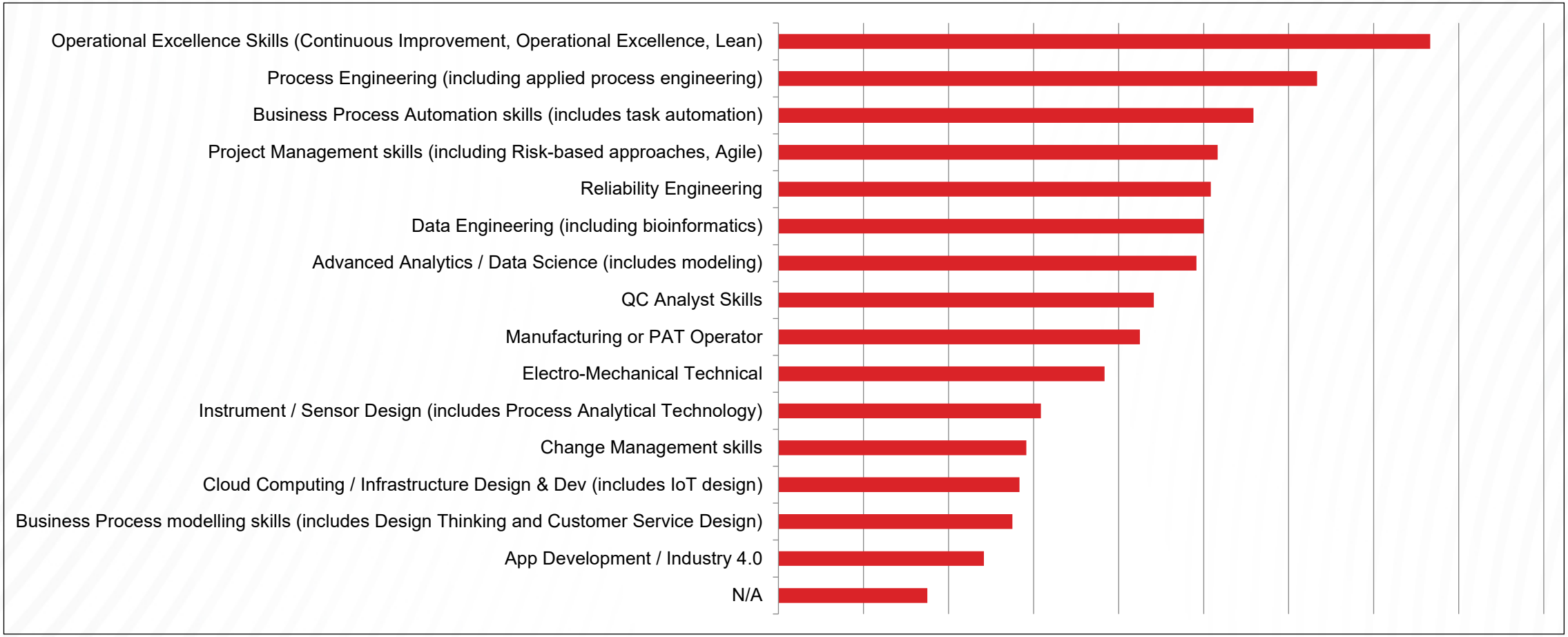
Project team analysis

The responses to the survey question above were illuminating. The majority of manufacturers shared that personnel within their department/function either have less than 20 hours a year to develop themselves on digital technology through further education and training, or that they don't know how many hours they have for such development. One manufacturer responded, 'Up to 100 hours a year', a figure shared as a lead indicator by digital master industry leader Novartis, who did not participate under this engagement.

Note: These are the responses of the participants or syntheses of their comments.

Selection of Key Findings – People factors

Skills currently being given the most focus relating to developing people at sites (n=7)



Project team analysis

Based on follow-on interview discussions the top eight skills shown above are the skill groupings being given the most focus across all medical product manufacturers evaluated.

Note: These are the responses of the participants or syntheses of their comments.

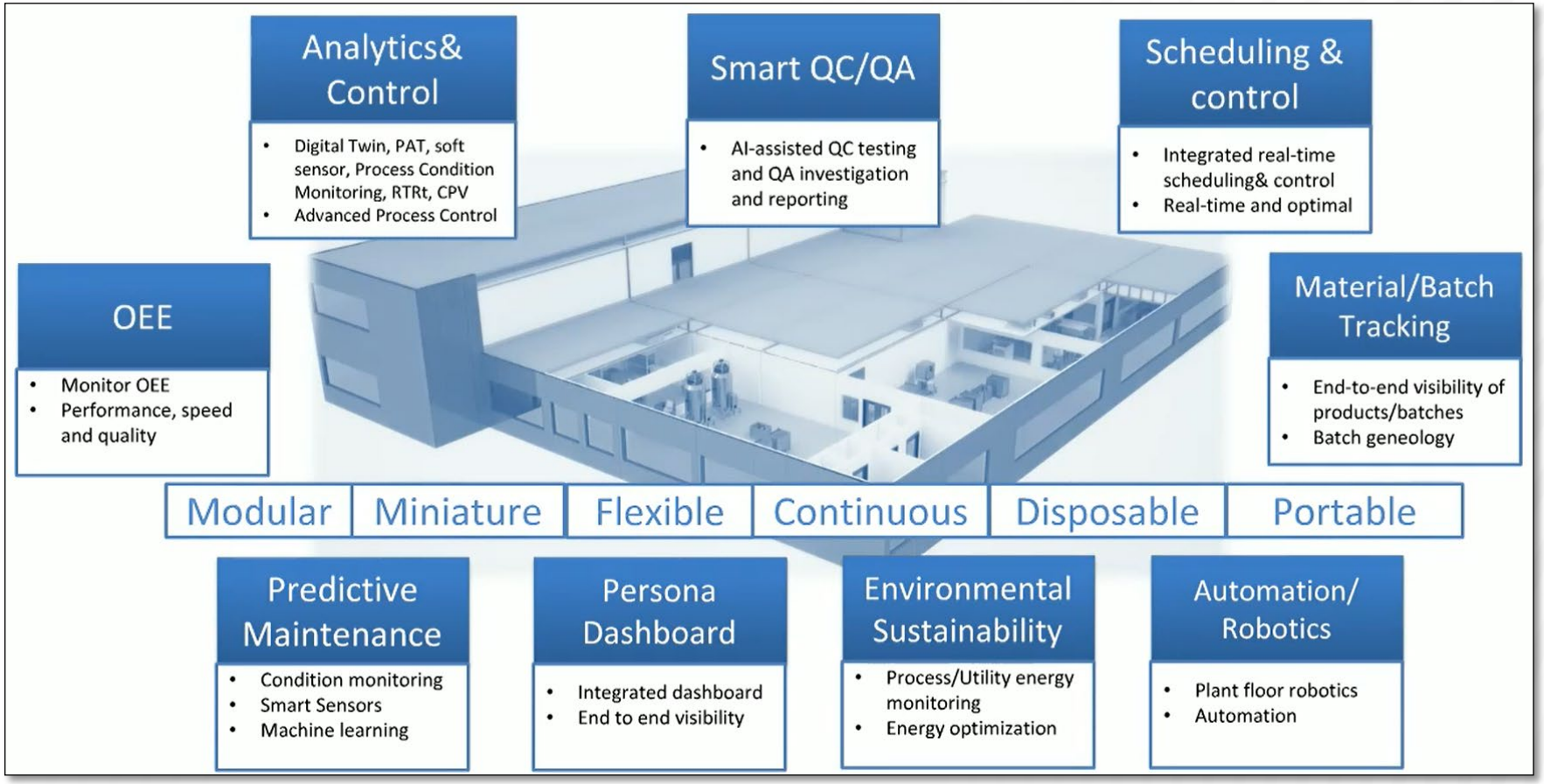
Analysis of Advantages of Adoption of Smart Manufacturing for Medical Products

Analysis of Advantages to Adoption of Smart Manufacturing

This figure illustrates a vision of the future for digitalizing pharmaceutical manufacturing operations.

The business processes, technology factors, regulatory factors, and people factors discussed all helped to reveal the current state at the sites evaluated, as well as the desire of many to enhance their digital maturity levels through the adoption of smart manufacturing.

The points in the table below made by medical device manufacturers, vaccine manufacturers, therapeutic manufacturers etc. should not be taken as complete list to be followed by any one of these manufacturer types as each sub-sector has different needs and opportunities and each company is at a different stage of digital maturity.



'Digital Manufacturing Capabilities – From Hype to Reality' as pictured in webinar 'IIoT and AI for Digitalizing Pharmaceutical Manufacturing Operations: From Hype to Reality' by Jun Huang, Regeneron (ex-Pfizer) (https://biopharma-asia.com/webinars/iiot-and-ai-for-digitalizing-pharmaceutical-manufacturing-operations-from-hype-to-reality/)

Analysis of Advantages to Adoption of Smart Manufacturing

Category	Analysis Statement (Selection only)
BUSINESS PROCESS	• Implementation of sensor technologies, edge computing, and cloud computing in the future will generate meaningful data that can be quickly analyzed and made available on demand. • Proper use of the data along with newer practices (Process Analytical Techniques) and procedures should move the site towards a more continuous manufacturing approach versus the existing batch approach which in theory should allow an increase in product yield. • Faster analysis of production data using software algorithms will in the future allow quicker release of the product based on improved "Report By Exception" methods. • More accurate access to data and the increased understanding of such data will allow site leadership to make informed decisions more quickly, leading to more efficiencies at the site.
TECHNOLOGY	• Adoption of data analytical tools, data lakes, and cloud-based applications can assist Manufacturing and Regulatory in meeting new requirements for data integrity, compliance monitoring, and deviation avoidance. • Increased consistency in data and higher level of data integrity as the result of automated data collection and audit software. • Potential to eliminate some manual manufacturing steps and manual data collection steps, improving accuracy, saving effort, and reducing costs. • Enabling other advanced manufacturing techniques, such as automated product release. • Increased use of technologies (such as AR/VR) can help ensure manufacturing consistency and continuity even when disruptive events such as a pandemic limits access by on-site production personnel. • Adoption of a digital transformation roadmap for technology can drive standardization across sites and controlled adoption of new technologies. • Provide the incentive to improve and expand the digital infrastructure required for future technology implementations, including IIoT, RPA, AR/VR, and Machine Learning.

Note: These are the responses of the participants or syntheses of their comments.

Analysis of Advantages to Adoption of Smart Manufacturing

Category	Analysis Statement (Selection only)
REGULATORY	• The advantages include automated batch releases, including real-time release with little or no human involvement are clear. • Introducing new technology should reduce Corrective Actions and Preventative Actions (CAPAs) ultimately. • One manufacturer shared that adopting technologies such as Electronic Batch Records would greatly strengthen their regulatory position and adherence. • The 'sweet spot' for the implementation of new technology is seen to be when bringing in new equipment, and before ordering the new equipment, to assess the best-in-class technology for where it can bring improvements with respect to OE and MVDA. • Knowledge management is also a key focus – that is, how to access more information, more easily and robustly. Knowledge Management at the Process and Product Development stages, the foundation of the process, is seen as key. Much time is wasted looking for data and checking what studies were performed. Having a strong KM approach at these early stages would be foundational and an enabler for the other activities (e.g., Tech Transfer, Manufacturing etc.).
PEOPLE	• Due to COVID-19 many manufacturers have also used conferencing software for team collaboration for performance evaluations, qualification of trainers, and training. • For one manufacturer AR/VR technology applications are being investigated for gowning and certain standard practices such as pH balances, but the ROI is not yet clear. • For another manufacturer AR digital aids would provide a lot of value for cases such as line clearance and assembly feedback to decrease quality risks and would be of huge benefit and hugely powerful. • VR tools have been used within the Drug Product building for vial fills. AR tools are being explored within Drug Substance. • There may be an opportunity for technology that can assist with process risk mitigation.

Note: These are the responses of the participants or syntheses of their comments.

Analysis of Barriers to Adoption of Smart Manufacturing for Medical Products

Analysis of Barriers to Adoption of Smart Manufacturing

Category	Real barrier (Selection only)	Likely Perceived barrier (Selection only)
BUSINESS PROCESS	• Disruption to business continuity when upgrading or replacing legacy systems. • Level of effort to migrate from overly complex paper based QMS system.	• There are no adequate education or other training materials available through external providers that can equip personnel to better understand automation or how to carry out data analysis for business requirements. • Excessive number of audits in a given year.
TECHNOLOGY	• Resource constraints are a barrier not only to initial design work but also to ongoing support of the systems. New technologies require new skills and expertise, and time and head count limitations make this a balancing act. • Shortcomings in communication between support groups, like R&D and process development, and manufacturing so that digital strategies can be considered earlier in the development process.	• Tech transfers for new systems coming from R&D do not always consider the disparate systems at the target manufacturing sites that may cause a distinct and separate learning curve during the installation at each site. • In the past, OEM interfaces (or lack thereof) were a barrier to collecting machine operating data; those challenges have largely been met through cultivating relationships with the right vendors, but the perception persists.

Note: These are the responses of the participants or syntheses of their comments.

Analysis of Barriers to Adoption of Smart Manufacturing

Category	Real barrier (Selection only)	Likely Perceived barrier (Selection only)
REGULATORY	• It was shared that change control has one of the longest lead times. It sometimes takes longer than other tasks such as the validation itself. A digital platform is currently being used, but the opportunity to simplify and lean out change control workflows exists. • Sometimes technology can be seen as an excuse to avoid re-thinking improvements to the science and supply-chain. Prematurely jumping to a technology conversation or excluding other elements of conversation that correctly position technology, may be a barrier.	• 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.
PEOPLE	• Availability of IT/automation personnel in the market to hire. • Less than 10 hours per year is allocated for personnel to develop themselves on digital technology through further education or training. If not increased in a highly focused manner, and in connection with business capabilities, this may become a real barrier to personnel development, long term competitiveness, and talent retention.	• The misunderstanding that a corporate approach to Operational Excellence is sufficient and that it does not need to be complemented by best practices and expertise from the disciplines of in change management and human performance. • That new expertise depends on the infusion of talent through new hires and not through capability building education or training programs for internal talent. In a labor market that is already seen as 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.

Note: These are the responses of the participants or syntheses of their comments.

Best Practice Recommendations to Manufacturers at Site and Org Levels based on MxD and IAAE experience

Best Practice Recommendations from MxD and IAAE teams

Category	Site-Level Opportunities for Manufacturer	Org-Level Opportunities for Manufacturer
BUSINESS PROCESS	• Continue the building of an innovative culture with a focus on learning. • Some participants in the study used incentives (simple and cost effective) to generate activism in the transformation to good effect. They ranged from call outs in meetings and company communications to novel gifts/presentations to digital badges and monetary incentives. • Consider the use of the Design Thinking approach to digital projects at the beginning of the effort for better alignment between stakeholders.	• Consider a Center of Excellence (CoE) for deployment of strategic projects and support after implementation (ERP, MES, Dig Twining). Network Operation Center (NOC), Manufacturing Operations Center (MOC) • Ensure robust understanding of newer technologies by Leadership Team to assist in the project investment approval, to ensure the third-party technology partnerships are good for the business and to create empathy when the sites are under pressure in the implementation of such projects. • Share lessons learned across the Organization as this may speed up implementation and lower risk.
TECHNOLOGY	• Our findings suggest the there is a considerable opportunity for the sites to use existing production data to develop production models and pattern recognition for increasing yield, increasing throughput, and decreasing variability. Technologies, such as digital twin, analytical tools, cloud data aggregation (data lakes), and MVDA, could yield significant benefits without any major process interruptions. • Even though not currently on most manufacturer's radar, anticipate the adoption of 5G for example, as the norm in business and plan for investments and projects to install the infrastructure. Many advantages in advancing digital transformation are expected here e.g., more powerful data analytics capabilities, enablement of enhanced manufacturing, edge computing and analytics, and faster mobile worker technologies (headsets, tablets etc., giving immediate access to data at the point of need).	• Strive to ensure interoperability and a common platform for maximizing value and impact of digital systems investment across the company. • Support a common digital transformation roadmap company-wide in order to prioritize needed projects that will raise each site to a common level of maturity. This will help support technology transfers and remove barriers to implementing common production methods and help support common data acquisition and analytics strategies.

Note: These are the responses of the participants or syntheses of their comments.

Best Practice Recommendations from MxD and IAAE teams

Category	Site-Level Opportunities for Manufacturer	Org-Level Opportunities for Manufacturer
REGULATORY	• Better knowledge management is a significant area of opportunity for tech transfer. It would be worth obtaining reports and guidance on Knowledge Management in the public domain. • Promote a culture of business case generation and review that doesn't prematurely reduce all business cases to P&L head count reduction and labor hours reduction but positively weighs other factors also. • An opportunity also exists to bring in a more suitable technology to assist with process validation. Some investment in change management and change leadership to enhance the digital culture at the site would likely go a long way towards the success of implementing such future systems and the related technology adoption by personnel.	• From a quality systems perspective continue to identify, fund, and implement global solutions (such as recent single enterprise calibration and equipment control cloud-based system that replaced separate systems) with ROI justification. • Possibly revamp any previous programs that supported knowledge transfer in a way that would be more sustainable and using modern media formats more suitable to newer hires would be valuable. (e.g., videos, VR, AR, etc.). • Ensure personnel understand the benefit of Value Stream Mapping and other such business and process mapping approaches that lean out processes before deciding whether to automate them.
PEOPLE	• A key concern for many sites is the limited time allocated for learning and skills development. Such development (truly aligned with business capabilities, roles, and role proficiencies) should rather be seen as a key talent retention and organizational competitive advantage in the future. • There is a significant opportunity for senior leadership to better shape and share a digital vision and lead (a seemingly eager workforce) forward.	• Suggest planning for the future and investing more in human performance expertise and focus. This discipline and related emphasis on 'making it harder to get it wrong, and easier to get it right' is becoming more significant with the increased interaction with and reliance on digital technologies for manufacturing. • Consider a more intentional academy approach to capability building at an organization level (e.g., digital manufacturing academy, or digital automation academy etc.). This can build upon learnings from program pilots. Note that leading companies allow for between 40 and 100 hours for personal development each year, not including compliance and on-the-job related training.

Note: These are the responses of the participants or syntheses of their comments.

References

References

- FDA Office of Counterterrorism and Emerging Threats
  - Accelerating the Adoption of Advanced Manufacturing Technologies to Strengthen Our Public Health Infrastructure
  - Center for Drug Evaluation and Research's (CDER) Emerging Technology Program,
  - Center for Devices and Radiological Health's (CDRH) Case for Quality,
  - Center for Biologics Evaluation and Research's (CBER) Advanced Technologies Program.
- MxD Manufacturing USA institute
- IAAE International Academy of Automation Engineering
- BioPhorum Digital plant maturity model assessment tool