HORIZON CONTROLS GROUP


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# 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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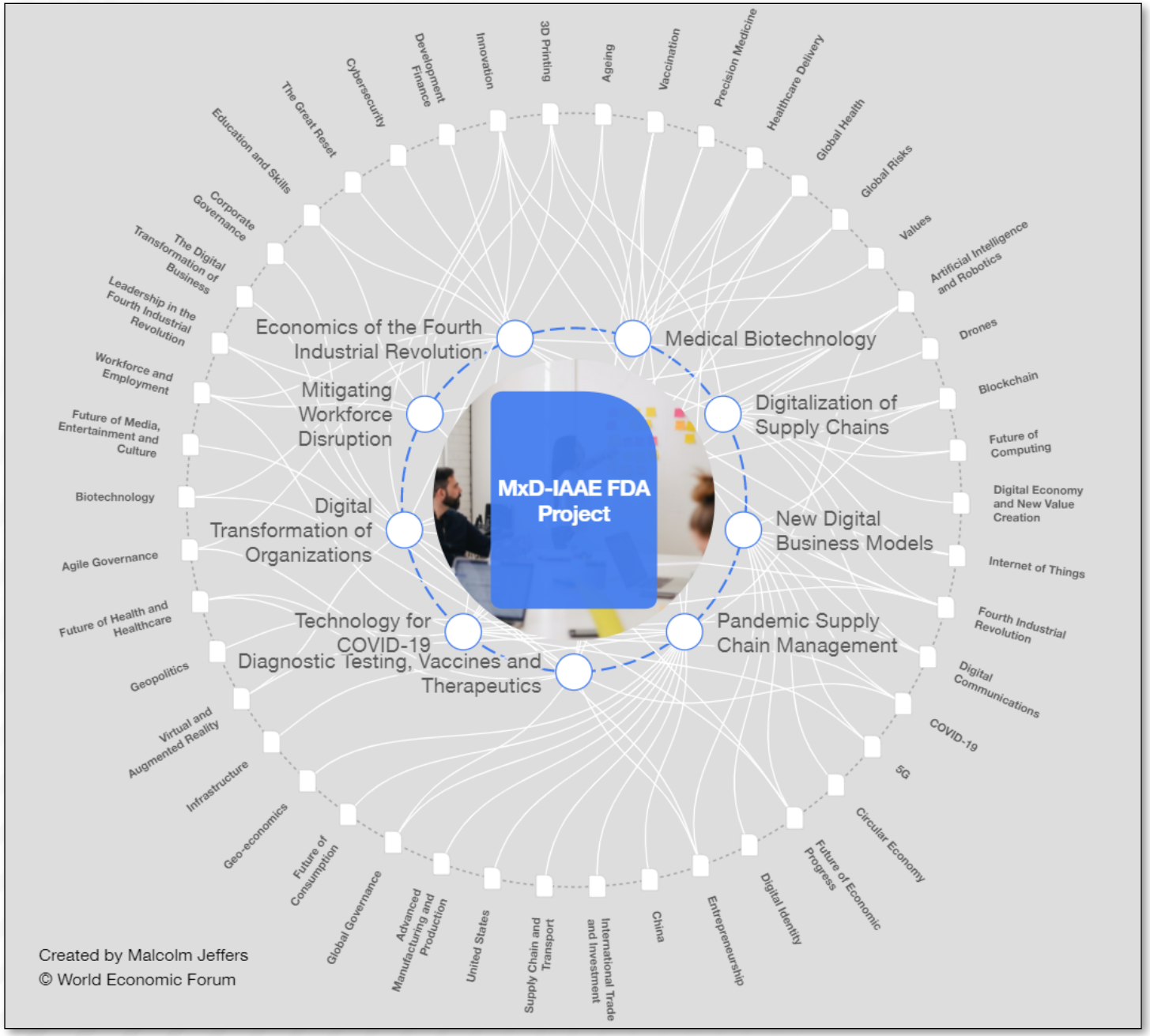
# Context of Technologies and Themes




The diagram 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.

- Artificial Intelligence and Robotics
- Blockchain
- Future of Computing
- Industry 4.0
- Global Governance
- Virtual and Augmented Reality
- Leadership in the 4th Industrial Revolution
- The Digital Transformation of Business
- Cybersecurity
- Innovation

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# Level of Digital Mastery – Results and Analysis

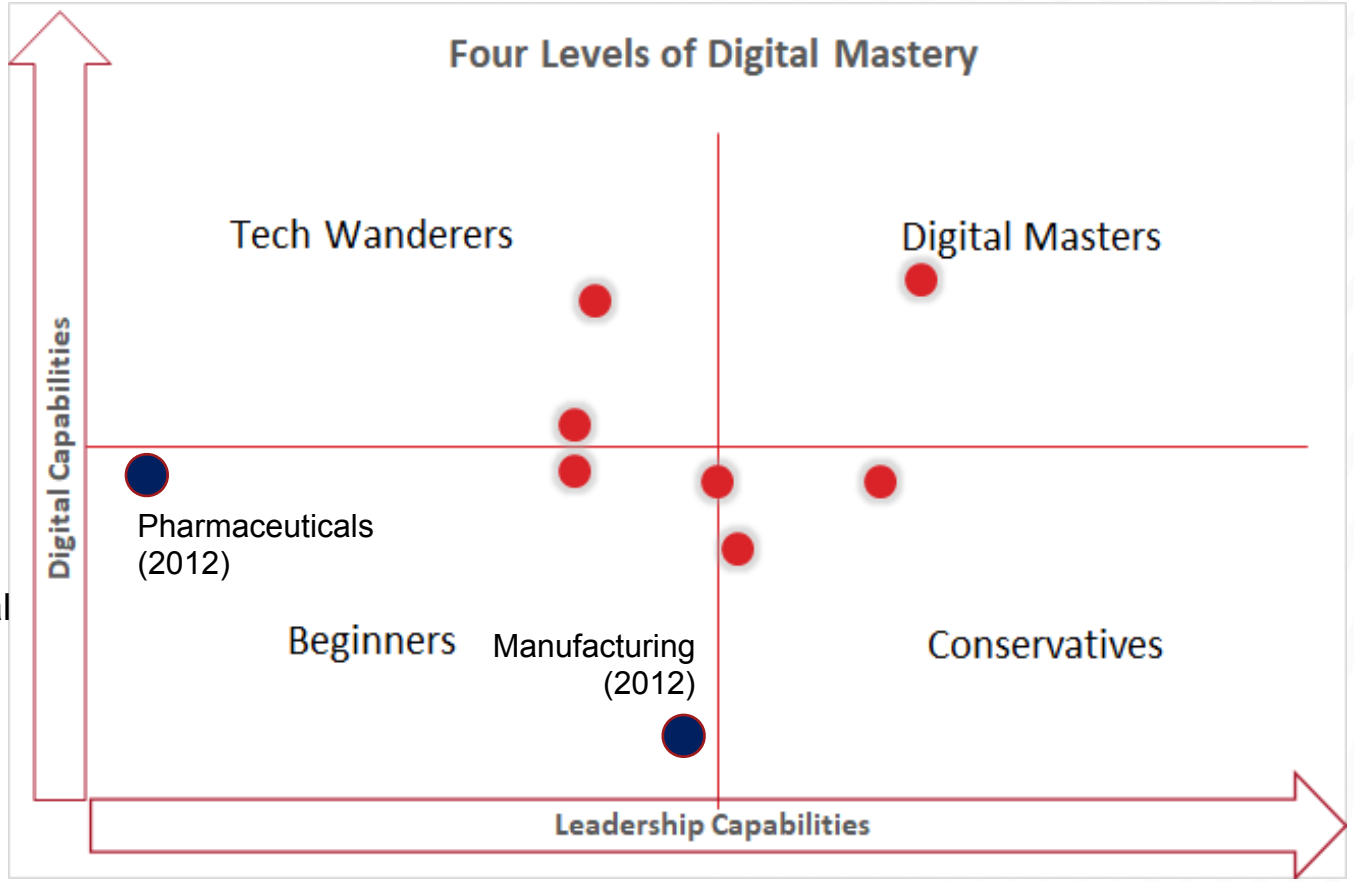
The figure shows the level of digital mastery identified for whether each manufacturer is a beginner, conservative, tech wanderer, or digital master with respect to digital capabilities and leadership capabilities.

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.

**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**
  - May have 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




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

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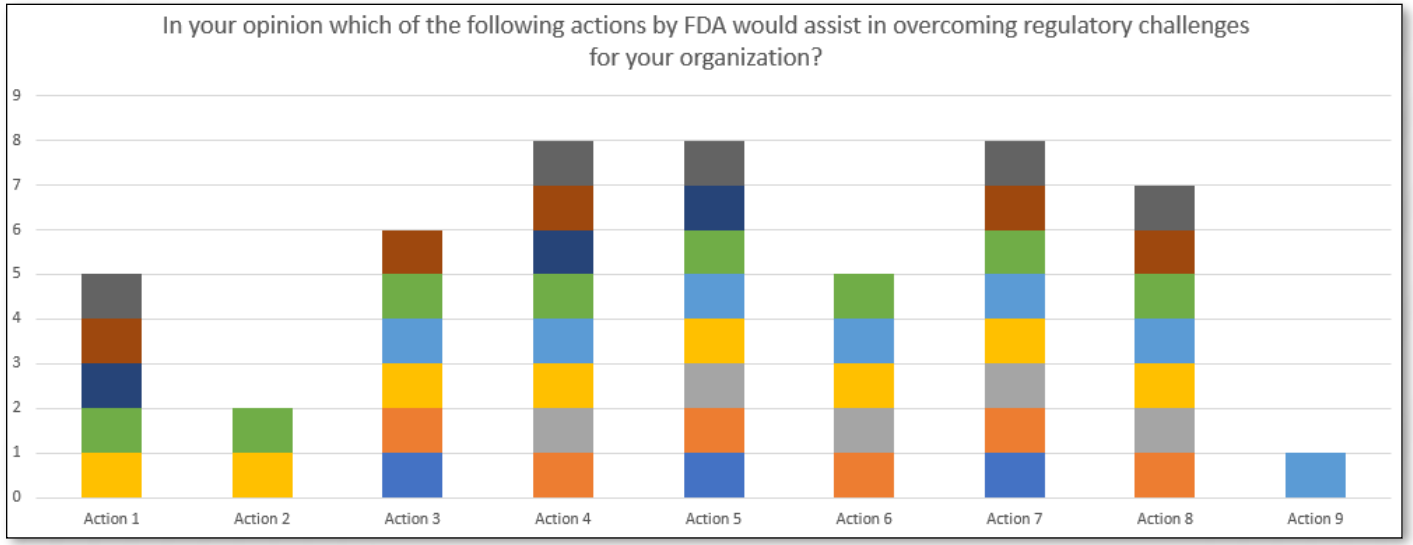
# Selection of Key Findings – Regulatory Factors

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.

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# Useful Links:

1. FDA-funded study (PDF, 2.2 MB), conducted by MxD and IAAE (MxD 20-19-01 – FDA OCET Project - Executive Summary)

   https://www.fda.gov/media/152569/download

2. Analysis of the Advantages of and Barriers to Adoption of Smart Manufacturing for Medical Products (infographic) (PDF, 760 KB)

   https://www.fda.gov/media/152568/download

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