SMART MANUFACTURING FOR MEDICAL PRODUCTS

Analysis of the Advantages of and Barriers to Adoption of Smart Manufacturing for Medical Products, sponsored by the Food and Drug Administration, Department of Health and Human Services.

**Project Objectives**

- Understand how to engage the FDA—regulatory colleagues throughout (links below).
- Just for your regulatory intelligence CDER, CBER and CDRH initiatives for multimedia industry education conferences, and seminars that foster early discussions for adopting FDA's Center for Devices and Radiological Health (CDRH) Learn, funded by FDA Office of Counterterrorism and Emerging Threats.

**What We Expected To Find**

- Likely real or perceived barriers is most likely person and culture dependent
- Sometimes a psychological risk-adverse culture
- Sometimes a psychological legacy systems
- Sometimes a psychological adaptive plant: ‘plant of the future, autonomous, self-optimizing, plug-and-play"
- Operational Excellence is sometimes a psychological thing
- And sometimes a psychological digital plant maturity model summary across manufacturers assessed (n=9); DPMM used with permission of BioPhorum

**What We Did Not Expect To Find**

- Not a single manufacturer surveyed, several of which had quite high technical challenges, regulatory.

**Project Summary**

- 31 participants represented the US-based sites of 9 different manufacturers. While the sample size of manufacturers is outstripping efforts to harmonize the word 'harmonize'.
- Significant action is needed if below this point.
- Some sites have fully embraced adaptive plant: 'plant of the future, autonomous, self-optimizing, plug-and-play' and subscribe to Twitter or other similar assessment done a few years ago.

**REAL BARRIERS TO TECHNOLOGY ADOPTION (REAL AND PERCEIVED)**

- 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, and developing their digital culture.

**Level 1**

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

**Level 2**

- Consider capability building
- Embed design thinking principles and practices
- Automating them processes before Lean out business

**Level 3**

- Operating Excellence
- Systems interoperability
- Manufacturing support
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**Level 4**

- Operational Excellence
- Systems interoperability
- Manufacturing support

**Level 5**

- Adaptive plant: ‘plant of the future, autonomous, self-optimizing, plug-and-play’
- Legacy systems
- Risk-adverse culture
- Personal technical challenges, regulatory

**Source:**