ISPE®

2020 ISPE

BIOTECHNOLOGY

Virtual Conference

Assessing Artificial Intelligence Capabilities in Manufacturing Operations

Bill Whitford - Strategic Solutions Leader

DPS

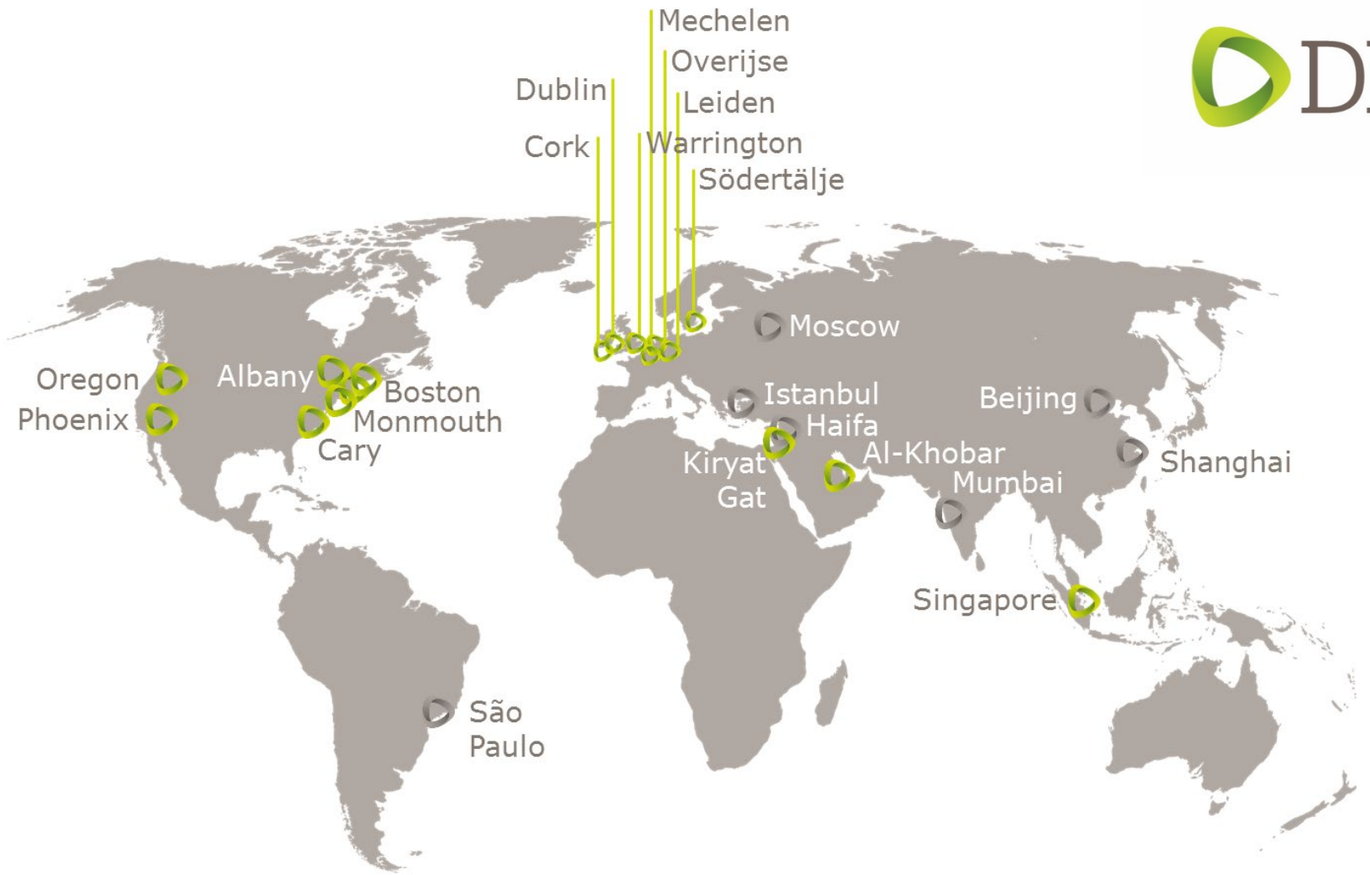
DPS Group

DPS Group

- A leading global Architectural, Engineering and Consulting Company
- Advanced therapeutics focus
- 2000 People in 15 offices worldwide

DPS Offices

Alliance Partners



Introduction

Artificial Intelligence in Operations

AI (or machine intelligence) in manufacturing

- Equipment enabled by advanced computer algorithms
- Enables advanced assessment, prediction and control

We know of AI as in

- Alexa, robotics
- Driverless cars
- Machine vision and translation

Industry 4.0 now addressed in pharma manufacturing

- AI in operations is becoming more important

Xavier AI Initiative has released a new diagnostic

- *AI in Operations Maturity Model*

Xavier Health administers the AI in Operations sub-team of the Xavier AI Initiative

Artificial Intelligence in Biomanufacturing

Cell-based production of

- Protein biologicals
- ATMPs (e.g., cell and gene therapies)
- Vaccines

Biomanufacturing is actually behind others

- Highly regulated
- Very conservative
- New technologies

DPS Group goals and participation

- To enable good AI practices in biomanufacturing
- Bill Whitford has been a team member from start

FOCUS ON... MANUFACTURING

The Era of Digital Biomanufacturing

William Whitford

The digital revolution in manufacturing began with an explosion in monitoring, analytics, and new computing capabilities. Combined with such advances as artificial intelligence (AI), automation, and robotics, they are changing our concepts of manufacturing in general — from product development and factory operations to materials supply. This evolution also connects product and process designers and leaders in manufacturing engineering. Digital manufacturing (DM) isn't a dream or a concept on some advanced developer's design table; it's occurring now and will change industry forever (1, 2).

For many years, manufacturing plants have been generating more and better data than ever before. But some companies have begun harnessing the resulting sea of information to gain valuable insights that can lead to

WHAT IS DIGITAL MANUFACTURING?

- Explosion in monitoring, analytics, and new computing capabilities
- Artificial intelligence, automation, and robotics operating now
- From product development to materials supply to factory operations
- Connectivity among operations, design engineers, and academic leaders
- Small-molecule drug manufacturers exploiting for continuous processes

Program / Team / Leads

Xavier Health AI Initiative

- Leading innovation with FDA officials and pharmaceutical industry professionals
- To protect patient safety, increase product confidence, and promote business success.

AI In Operations Team

- Formed Oct 2019 to optimize AI in manufacturing
- Sub-teams: AI in Development and Roadmap for AI
  - AID produced two use-cases with valuable lessons
  - RAI produced the *Maturity Level Characterization* matrix

AI in Operations (AIO) team

- Toni Manzano (Bigfinite) Team Lead

AI Development (AID) sub-team

- Lacey Harbour Smith (Lima Corporate) Co-lead
- Sundar Selvatharasu (Sierra Labs) Co-lead

Roadmap for AI (RAI) sub-team

- Cynthia Ipach (Compliance Insight) Co-lead
- Kip Wolf (X-Vax Technology) Co-lead

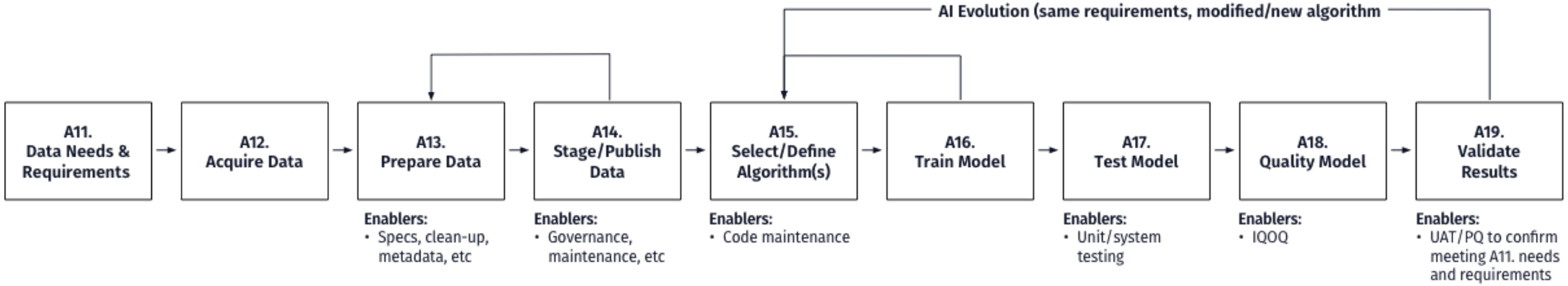
Standardized Process Flow

Implementation of AI in operations

Level 0 (Macro Level)

Implement AI Solutions

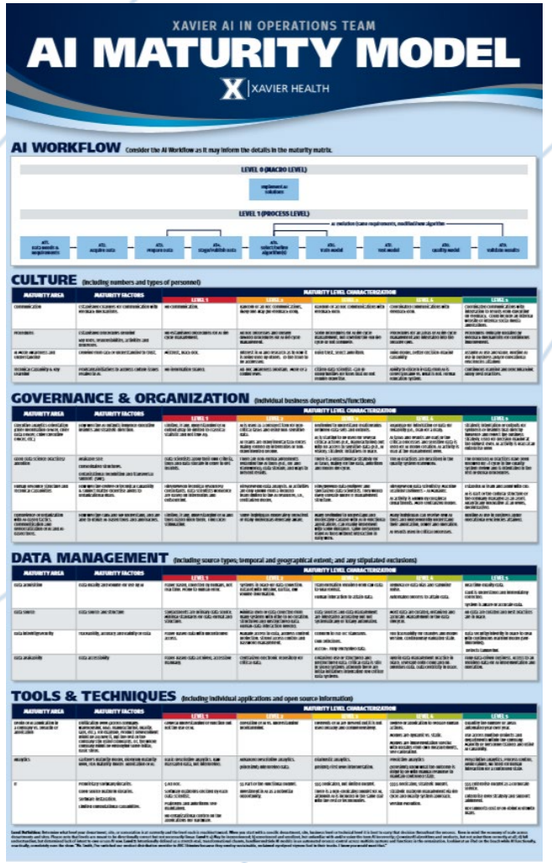
Level 1 (Process Level)



Maturity Level Characterization (MLC)

- Model assesses the
  - People
  - Departments
  - Activities
- Practical AI capability to
  - Understand
  - Implement
  - Operate
- In AI empowered
  - Tools
  - Processes
  - Structures

- 4 MLC *Dimensions or Drivers*:
  - Culture
  - Governance and Organization
  - Data Management
  - Tools and Techniques
- Each *Driver* sub-divided into:
  - 3 - 4 Areas / Factors
- Total matrix includes:
  - *Standard Process Flow* (at top)
  - 19 functional rows
  - 7 functional columns



Maturity model

Culture

Including numbers and types of personnel

MATURITY AREA	MATURITY FACTORS	MATURITY LEVEL CHARACTERIZATION				
		LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
Communication	Established channels for communication with feedback mechanisms.	No communication.	Random or ad hoc communications, likely one-way (no feedback loop).	Random or ad hoc communications with feedback loop.	Coordinated communications with feedback loop.	Coordinated communications with integration to results from executing on feedback. Could include an internal website or internal social media applications.
Procedures	Established procedures defining key roles, responsibilities, activities and processes.	No established procedures for AI life cycle management.	Ad hoc processes and loosely defined procedures for AI life cycle management.	Some procedures for AI life cycle management, not covering the full life cycle or not complete.	Procedures for all areas of AI life cycle management and integrated into the broader QMS.	Procedures regularly updated by feedback mechanisms for continuous improvement.
AI Mode Awareness and Understanding	Evolving from lack of understanding to trust.	Mistrust, black box.	Interest in AI and research as to how it is being used by others. ID the issue to be addressed.	Build trust, select algorithm.	Build model, better decision-making capability	Assume AI use and value. Routine AI use in business and/or operational efficiencies attained
Technical Capability & Key Learning	Programs/initiatives to address culture issues related to AI.	No information shared.	Ad-hoc awareness program. More of a coding level.	Citizen data scientist—can ID opportunities for tools that do not require expertise.	Ability to discern if data from AI is correct/usable vs. what is not. Formal education system.	Continuous learning and benchmarking. Apply best practices.

Governance & Organization

Individual business departments / functions

MATURITY AREA	MATURITY FACTORS	MATURITY LEVEL CHARACTERIZATION				
		LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
Executive analytics orientation (Chief Information Officer, Chief Data Officer, Chief Executive Officer, etc.)	How well the AI outputs influence executive insights and strategic direction.	Limited, if any, understanding of AI output (may be limited to classical statistic and not true AI).	AI is used as a prospect tool for non-critical tasks and using non-sensitive data. AI Teams are experimental task forces mainly formed by internships or non-experimented people.	Beginning to understand relationships between data sets and outputs. AI is starting to be used for several critical actions (e.g., manufacturing) but with no access to sensitive data (e.g., AI Vision). Strategic initiatives in place.	Roadmap for integration of data for reliability (I.e., plan for a plan). AI tasks and results are part of the critical processes and sensitive data is used for AI model creation. AI activity is lead at the management level.	Strategic integration of outputs for synthesis of insights that directly influence and reflect the business strategy. Used for decision making at the highest level. AI activity is lead at an enterprise level
Good Data Science practices/ adoption	Available SOP. Consolidated structures. Organizational recognition and transversal support (SME).	Data scientists apply their own criteria, tools and data storage in order to get insights.	There are non-formal agreements regarding the AI tools (e.g., IDE and frameworks), data storage, and ways to present results.	There is a departmental strategy for AI tasks, mainly for the data, algorithm and model life cycle.	The AI practices are described in the Quality System framework.	The proposed AI practices have been followed for >1 cycle in the Quality System review and is integrated in the rest of global procedures.
Human Resource Structure and Technical Capabilities	How well the degree of technical capability & subject matter expertise aligns to organizational goals.	Hire/develop technical resources/ consultants. Data scientists workforce are based on internships and outsourcing.	Hire/develop data analysts. AI activities are only known from a reduced team limited to the AI resources, I.e., centralized model,	Hire/develop data engineer and specialized data scientists. They would likely operate under IT management structure.	Hire/develop data scientists/ Machine Learning Engineers + AI Manager. AI activity is known by collateral departments. More centralized model.	Establish AI team and along with CIO. AI is part of the cultural structure of the company managed as an asset. Analytically innovative at all levels, decentralized.
Competence of organization with AI-based tactics. Commoditization and democratization of AI and AI-based tools.	How well the rank and file understand, and are able to utilize AI-based tools and approaches.	Limited, if any, understanding of AI and tools based upon them. Find Excel stimulating.	Some individuals moderately proficient or many individuals generally aware.	Many beginning to understand and moderately capable with AI in functional applications. Can readily implement with some guidance. Same personnel using AI tools without interaction in daily work.	Many individuals can receive new AI tools and independently understand their application, power and operation. AI results used in critical processes.	Routine AI use in business andor operational efficiencies attained.

Data Management

Including source types; temporal and geographical extent; and any stipulated exclusions

MATURITY AREA	MATURITY FACTORS	MATURITY LEVEL CHARACTERIZATION				
		LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
Data acquisition	Data quality and volume for use by AI	Paper based, collected by humans, not real time. Prone to human error.	Systems in place for data collection. Dataset with missing, partial, low volume information.	Transformation required from raw data to final format. Human interaction to attain data.	Removal of data bias and sampling noise. Automated process to attain data.	Real time quality data. Fault is understood and immediately corrected. System is aware of accurate data.
Data source	Data source and structure	Spreadsheets are primary data source. Minimal standards for data format and structure.	Minimal level of data collected from many systems with little to no curation. Structured and unstructured data. Human-data interaction needed.	Data sources and data management are integrated accurately but not systematically or totally automated.	Most data are curated, organized and accurate. Management of the data lifecycle.	All data are curated and best practices are in place.
Data integrity/security	Traceability, accuracy and validity of data	Paper-based data with uncontrolled access.	Manage access to data, address content protection. Strong access control and password management.	Conform to ISO IEC standards. FAIR principles. ALCOA+. Fully encrypted data.	Full traceability for changes and model version. Continuously validated state.	Data security/integrity in place to deal with continuous learning model (self-improving). Detects tampering.
Data availability	Data accessibility	Paper-based data archived, accessible manually.	Centralized electronic repository for critical data.	Organized use of structured and unstructured data. Critical data is still in siloed systems although there are initial initiatives integrating *non critical* data systems.	Hybrid data management practice in place. Leverage both cloud and on-premises data. Data centricity in place.	Fully data-driven business. Access to all required data for AI implementation and operation.

Tools & Techniques

Including individual applications and open source information

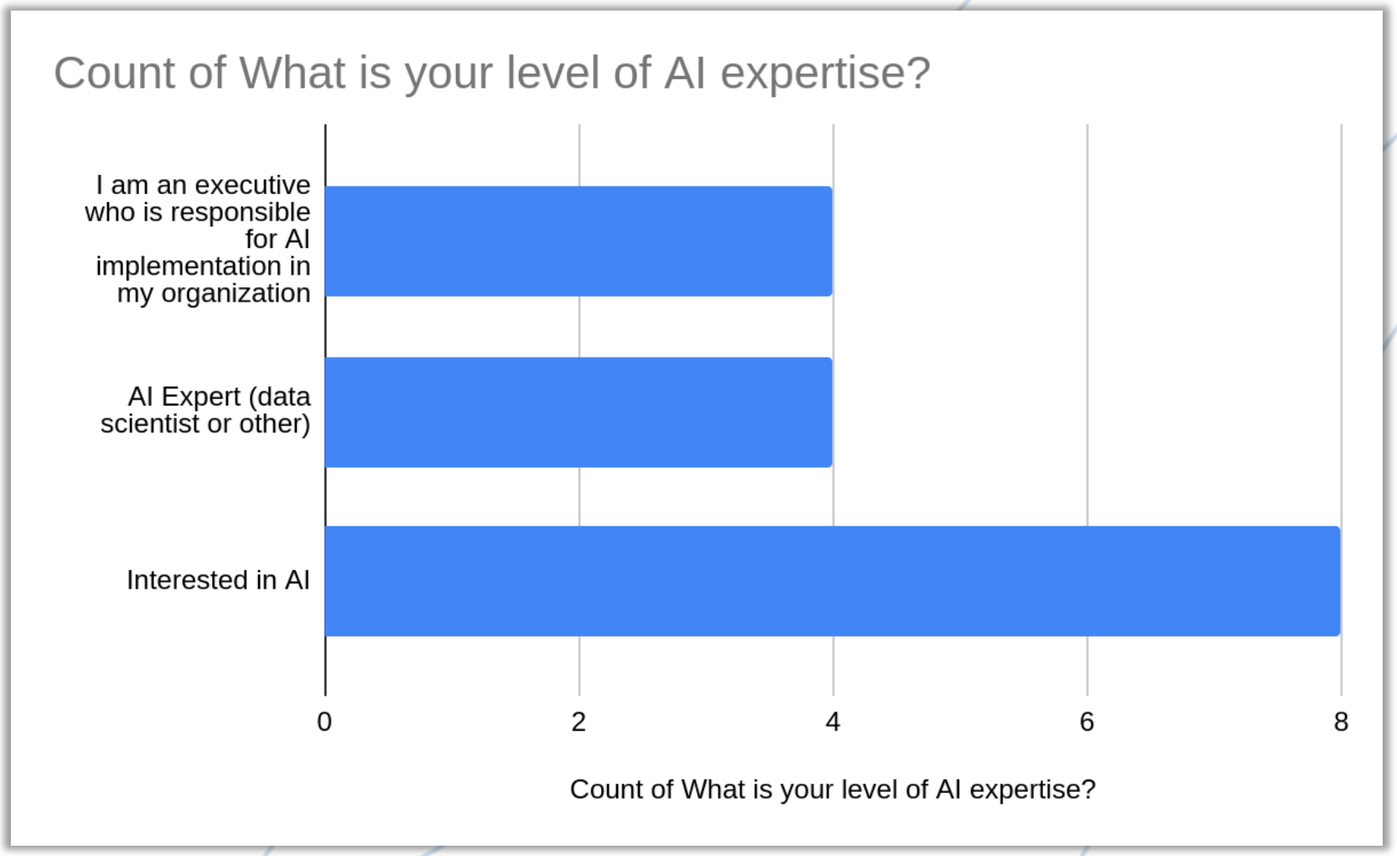
MATURITY AREA	MATURITY FACTORS	MATURITY LEVEL CHARACTERIZATION				
		LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
Depth of AI application in a company vs. breadth of application	Digitization level (across company: warehousing, R&D, manufacturing, quality, labs, etc.). For example, Product Development might be all over it, but the rest of the company still using clipboards. Or, the whole company might be employing some initial, basic steps.	General understanding of function but not the use of AI.	Operation of AI vs. understanding programming.	Elements of AI are present but it is not used broadly and comprehensively.	Degree of application to replace human actions. Models are dynamic vs. static. Models are implementation specific with updates from own measurements, self-calibrating.	Quantify the number of areas automated year over year. Use across multiple projects and departments within the company. Majority of personnel trained and using AI capability.
Analytics	Gartner's maturity model, bioforum maturity level, FDA maturity model Application of AI.	Basic descriptive analytics. Raw massaged data, not interpreted.	Advanced Descriptive analytics. (Hindsight) Interpreted data.	Diagnostic analytics. (Insight) First level interpretation.	Predictive analytics (Foresight) Know what the outcome is going to be with manual response to maintain controlled state.	Prescriptive analytics, Process control, Avoid failure, No need for human interaction for a controlled state.
IT	Proprietary software/libraries. Open source platform libraries. Software installation. Limited computational capabilities.	$ Ad Hoc. Software platforms decided by each Data Scientist. Platforms and algorithms self-maintained. No organizational control on the applications nor hardware.	$$ Part of the functional budget. Investment in AI as a potential opportunity.	$$$ Dedicated, but limited budget. There is a non-dedicated budget for AI, although AI is included in the same bag with the rest of technologies.	$$$$ Dedicated, strategic budget. Strategic platform management via life cycle and quality system approach. Version evolution.	$$$ Enterprise budget as a corporate service. Enterprise level strategy and support alignment. ROI supports cost of on-going AI growth plans.

Survey of candidate users

Selected responses from the pilot application

MLC reviewed by 16 volunteers

- From Xavier Health AI Initiative
- 13 from industry
  (med device, Rx, biopharm, healthcare)
- 3 from consulting or academic / university



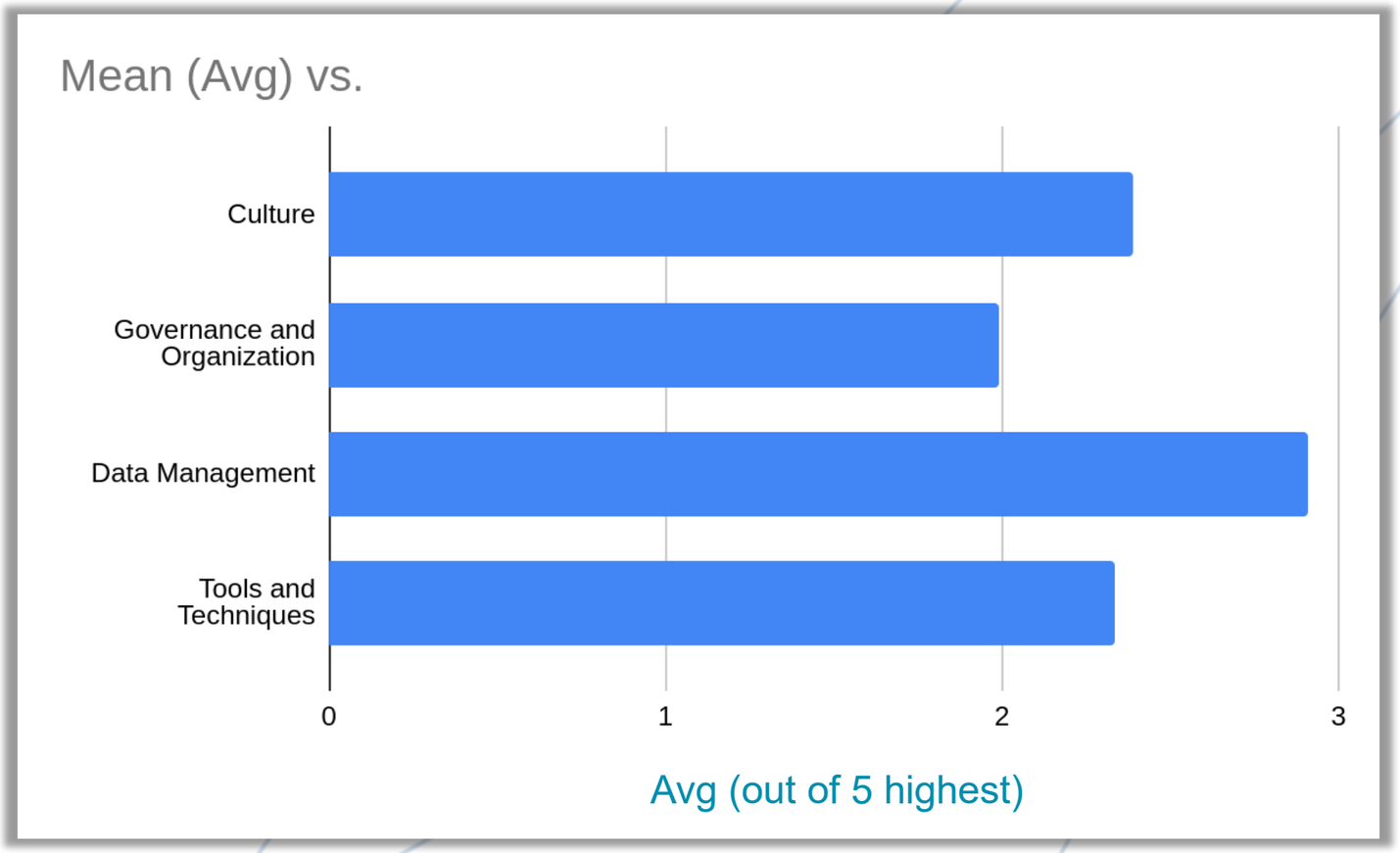
XAVIER HEALTH

Mean maturity by the 4 process drivers

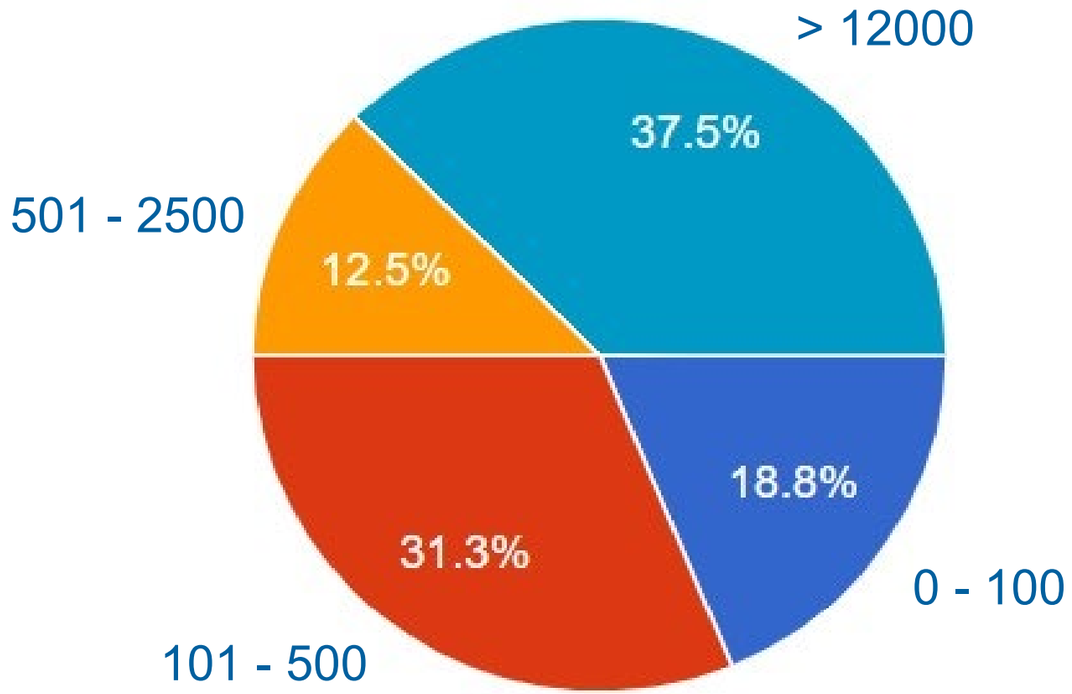
Volunteer's assessment of their organization's status

Many felt

- A cross-functional team is required to address this accurately
- This evaluation is best applied per team or department rather than "company"
- A point-to-point study was more valuable than "averages" of a group

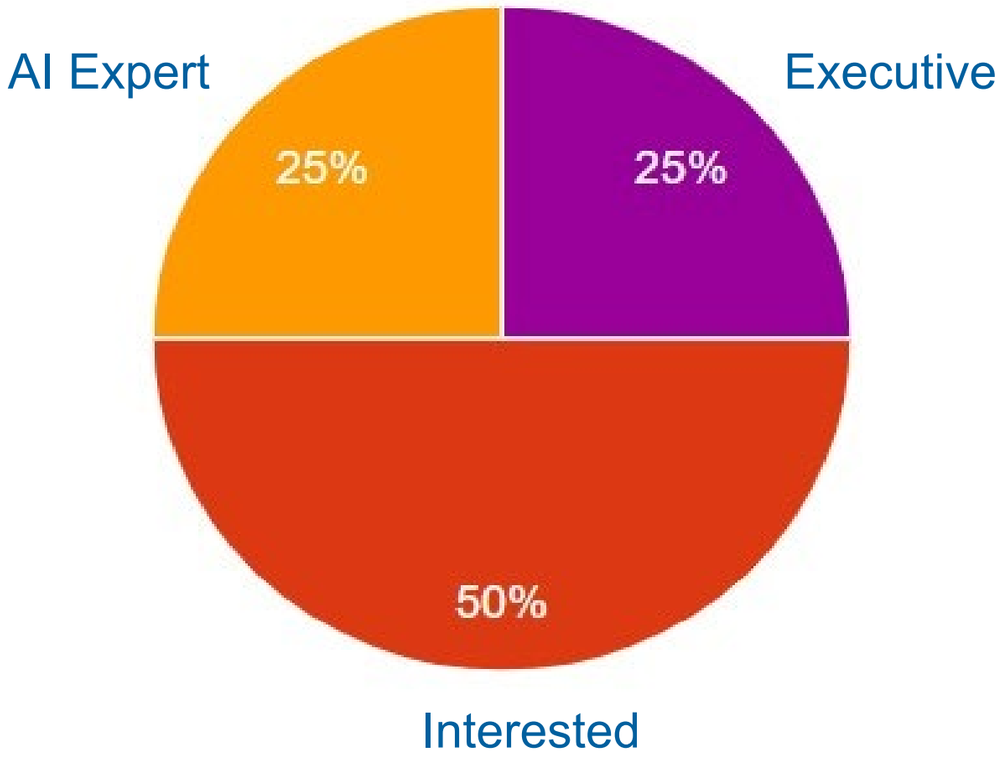


What is the size of your organization (employees)?



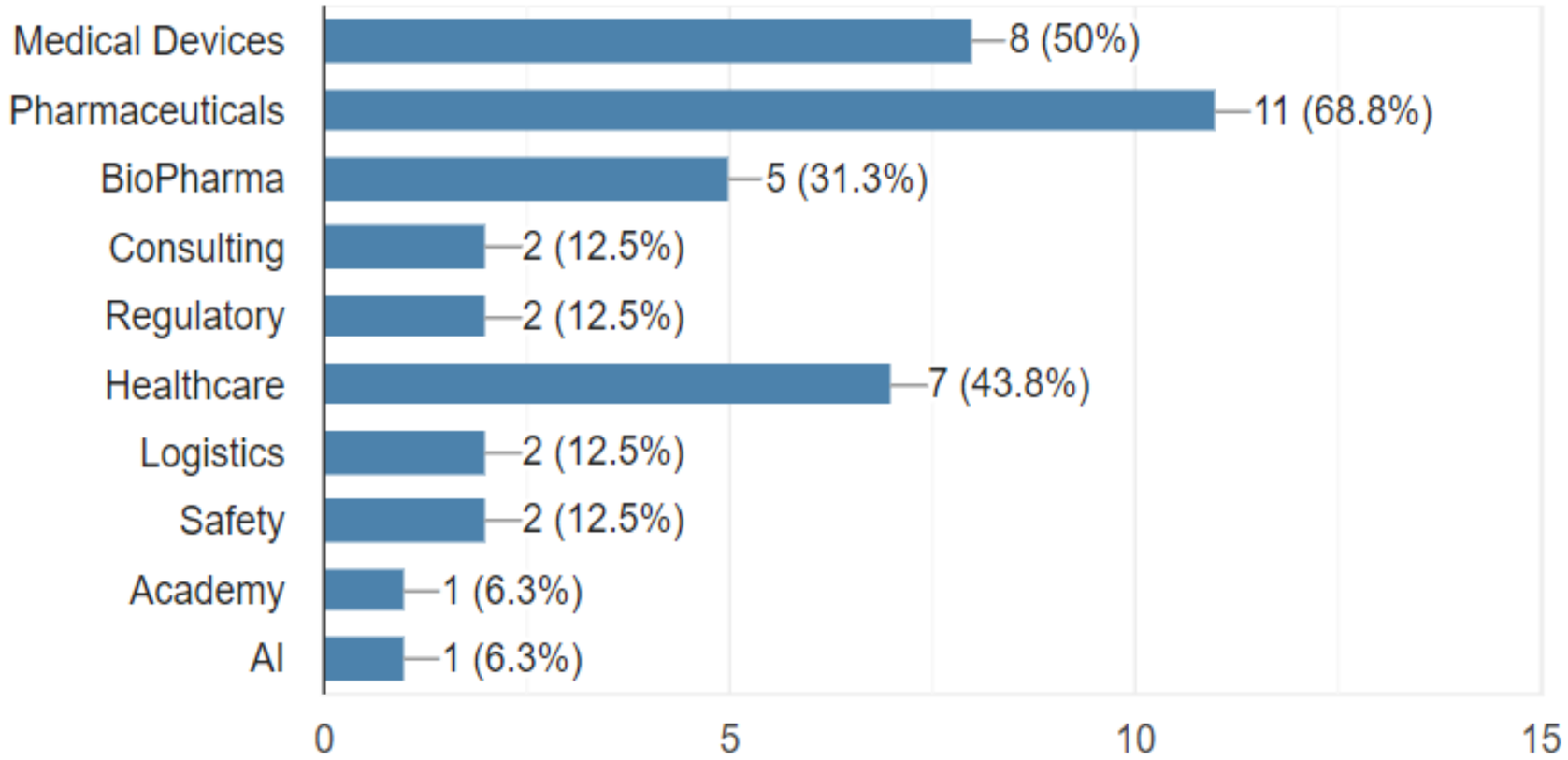
	0 – 100
	101 – 500
	501 – 2500
	2501 – 7500
	7501 – 12000
	> 12000

What is your level of AI experience?



	New in my understanding of AI
	Interested in AI
	AI Expert (data scientist or other)
	AI End User
	I am an executive responsible for AI implementation in my organization

What your organization's manufacturing activity?
[Check all that apply]



Area / Department where you will apply the ML

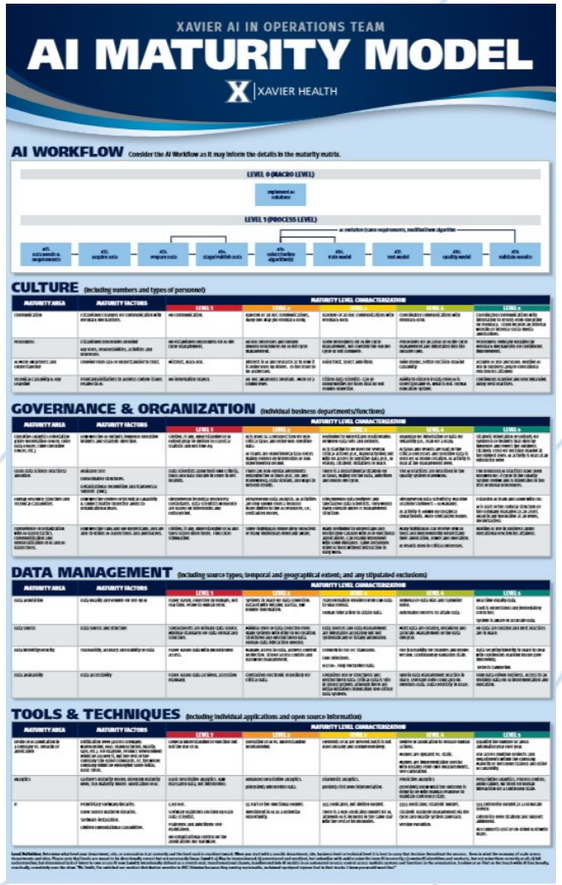
- SaMD
- Manufacturing
- Product, R&D, Operations, QA
- Drug Manufacturing
- Operations
- Product development, manufacturing
- Manufacturing and logistics
- Product Development, Manufacturing Improvement, Contract & Document Analysis
- Manufacturing / Process Control
- Quality

ML: Machine Learning

Data Management: Acquisition

#1 of 15 rows of *Maturity Areas / Factors*

- Describes of degree of competence
- Assigns “Level” or status
- Provides vision of next step and final stage

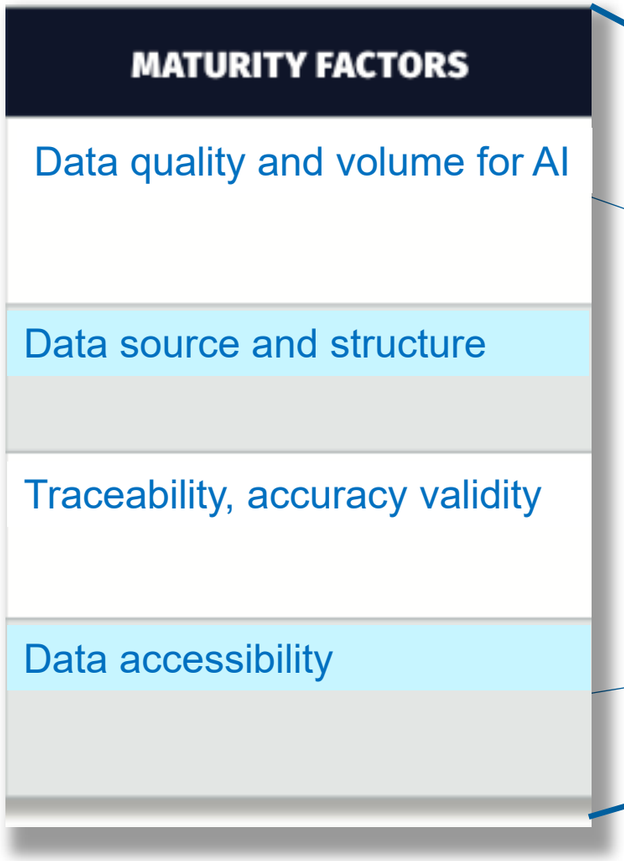


Rating Section

MATURITY LEVEL CHARACTERIZATION

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
Paper based, collected by humans, not real time. Prone to human error.	Systems in place for data collection. Dataset with missing, partial, low volume information.	Transformation required from raw data to final format. Human interaction to attain data.	Removal of data bias and sampling noise. Automated process to attain data.	Real time quality data. Fault is understood and immediately corrected. System is aware of accurate data.

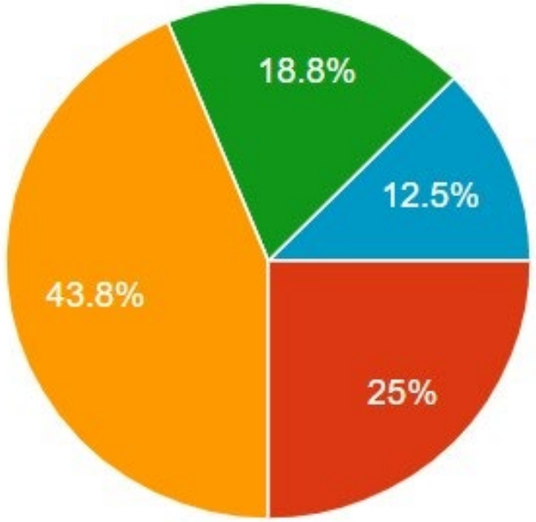
Data Management (the four MLC factors)



MATURITY AREA	MATURITY FACTORS	MATURITY LEVEL CHARACTERIZATION				
		LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
Data acquisition	Data quality and volume for use by AI	Paper based, collected by humans, not real time. Prone to human error.	Systems in place for data collection. Dataset with missing, partial, low volume information.	Transformation required from raw data to final format. Human interaction to attain data.	Removal of data bias and sampling noise. Automated process to attain data.	Real time quality data. Fault is understood and immediately corrected. System is aware of accurate data.
Data source	Data source and structure	Spreadsheets are primary data source. Minimal standards for data format and structure.	Minimal level of data collected from many systems with little to no curation. Structured and unstructured data. Human-data interaction needed.	Data sources and data management are integrated accurately but not systematically or totally automated.	Most data are curated, organized and accurate. Management of the data lifecycle.	All data are curated and best practices are in place.
Data integrity/security	Traceability, accuracy and validity of data	Paper-based data with uncontrolled access.	Manage access to data, address content protection. Strong access control and password management.	Conform to ISO IEC standards. FAIR principles. ALCOA+. Fully encrypted data.	Full traceability for changes and model version. Continuously validated state.	Data security/integrity in place to deal with continuous learning model (self-improving). Detects tampering.
Data availability	Data accessibility	Paper-based data archived, accessible manually.	Centralized electronic repository for critical data.	Organized use of structured and unstructured data. Critical data is still in siloed systems although there are initial initiatives integrating *non critical* data systems.	Hybrid data management practice in place. Leverage both cloud and on-premises data. Data centricity in place.	Fully data-driven business. Access to all required data for AI implementation and operation.

Responses to Factor #1

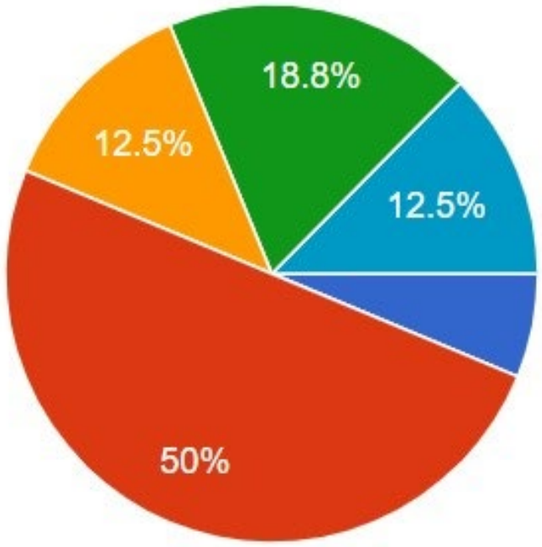
Data quality and volume for use by AI



L1	Paper-based, collected by humans, not real time
L2	Systems in place for data collection. Dataset with missing, partial, and/or low volume information
L3	**Transformation required from raw data to final format. Human interaction to attain data**
L4	Removal of data bias and sampling noise. Automated process to attain data
L5	Real time quality data. Fault is understood and immediately corrected. System is aware of accurate data
	N/A

Responses to factor #2

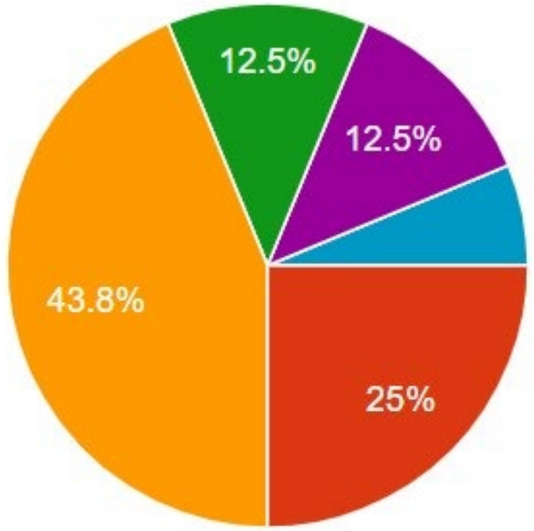
Data source and structure



L1	Spreadsheets are primary data source. Minimal standards for data format and structure
L2	**Data collected from many systems with no curation. Structured and unstructured data. Human-data interaction needed**
L3	Data sources and data management are integrated accurately but not systematically or totally automated
L4	Most data are curated, organized and accurate. Management of the data lifecycle
L5	All data are curated, and best practices are in place
	N/A

Responses to factor #3

Traceability, accuracy, and validity of data

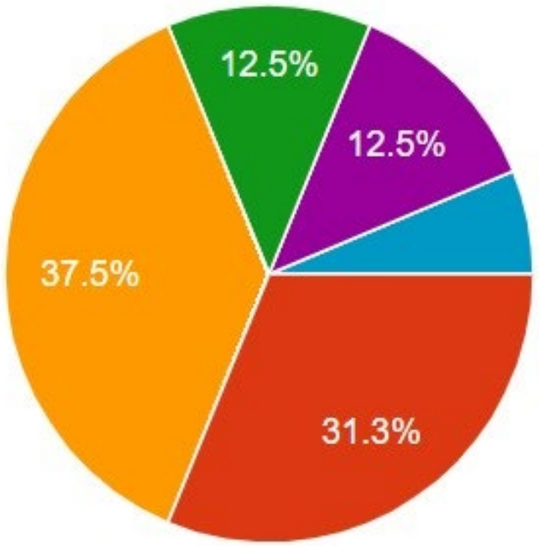


L1	Paper-based data with uncontrolled access
L2	Manage access to data, address content protection. Strong access control and password management
L3	**Conform to ISO IEC standards. FAIR principles. ALCOA+. Fully encrypted data**
L4	Full traceability for changes and model version. Continuously validated state
L5	Data security/integrity in place to deal with continuous learning model (self-improving). Detects tampering
	N/A

ALCOA+ Attributable, Legible, Contemporaneous, Original and Accurate

Responses to factor #4

Data accessibility



L1	Paper-based data archived, accessible manually
L2	Centralized electronic repository for critical data
L3	Organized use of structured and unstructured data. Critical data in siloed systems
L4	Hybrid data management practice in place. Leverage both cloud and on-premises data. Data centricity in place
L5	Fully data-driven business. Access to all required data for AI implementation and operation
	N/A

Conclusion

Conclusion

- Xavier Health's AI in Operations has released its ***AI in Operations Maturity Model***
- It measures the functional AI capability of an organization in defined operations or categories
- Designed for employment in
  - diverse teams / units
  - degrees of formality
  - levels of stringency

For more information on the model visit www.xavierhealth.org/aio-team

For more information on DPS Group visit - www.dpsgroupglobal.com

ISPE®

2020 ISPE

BIOTECHNOLOGY

Virtual Conference

Thank you!

DPS

Bill Whitford

Strategic Solutions Leader

DPS Group

www.@dpsgroupglobal.com