

Digital Asset Performance Management Due Diligence

LCE Life Sciences

September 2022

LCE Overview

Do the right thing the right way.

Honesty and integrity in everything we do.



Headquarters in
Charleston, SC

~600+ employees
in 10 U.S. offices



Supporting our industrial
clients for more than 35 years



Founded in 1976
and employee owned



Recognized as a
Best Place to Work
in South Carolina
since 2005



Global delivery
experience and success



Supporting our military
for more than 45 years,
pioneering online diagnostics

LCE Life Sciences Experience



- 20+ Years of pharmaceutical and medical device industry consulting experience
- Established Corporate Reliability Programs in major life sciences corporations
- Tactical Reliability Engineering support in many large and small organizations
- Asset Management, Reliability Engineering, and Maintenance training for hundreds of life sciences industry clients
- LCE actively participates in ISPE Good Practice Guide development and organizational activities



Specific ISPE & Life Sciences Industry Organization Involvement:

- ISPE Annual & Regional Conference Educational Sessions
- ISPE Drug Shortage Prevention Guidance Committee
- ISPE Asset Management Good Practice Guide Committee
- ISPE Maintenance Good Practice Guide Committee
- ISPE Maintenance Training Program Committee
- Articles published in Pharmaceutical Engineering and Pharmaceutical Manufacturing Magazines
- SMRP Pharmaceutical & Biotech SIG Member
- LCE Life Sciences Reliability Network

Asset Performance Management Due Diligence Background

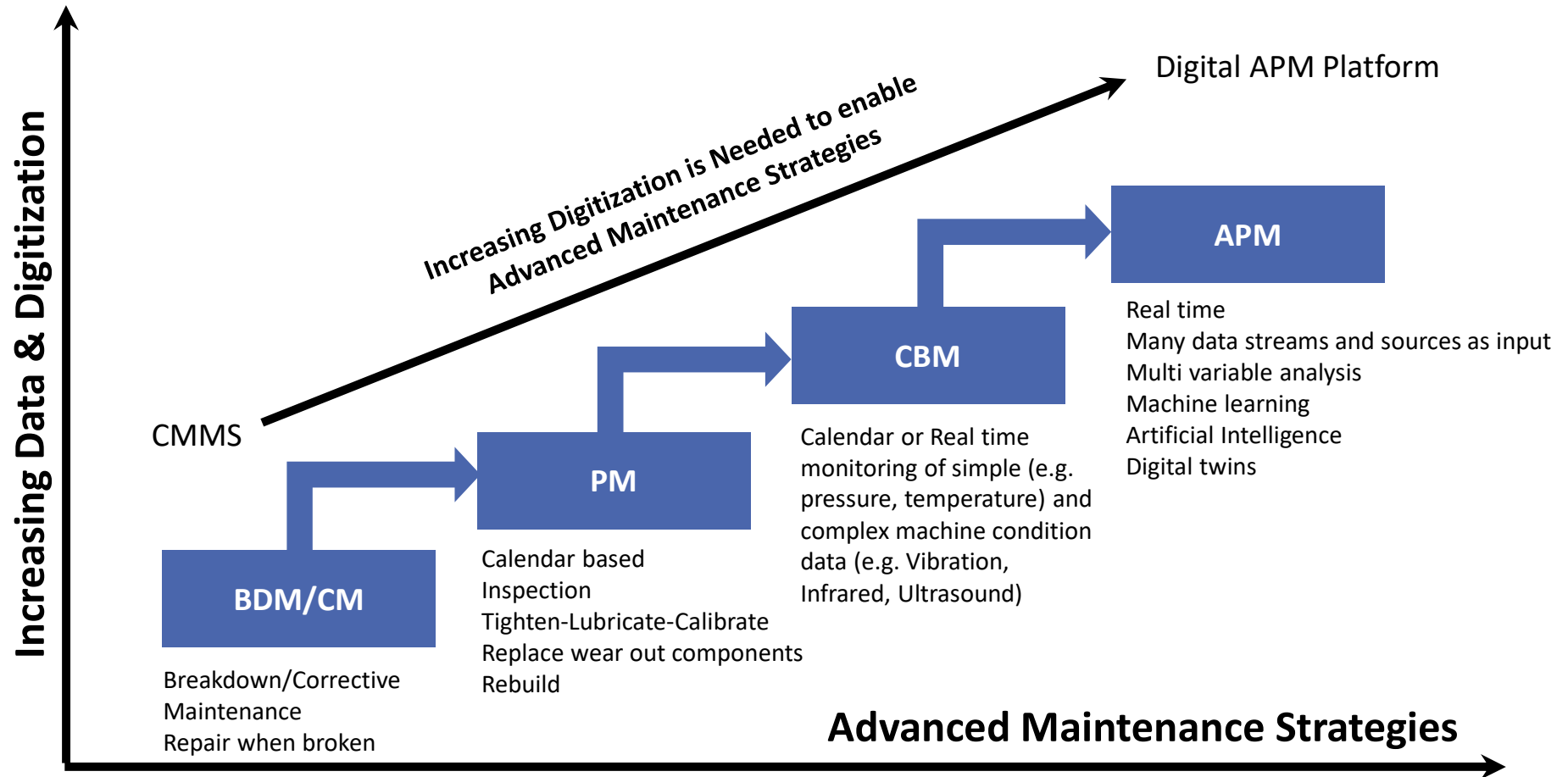
- A large multi-national pharmaceutical company has partnered with LCE to conduct due diligence for an Asset Performance Management platform to support their global operations
- LCE is conducting a wide market assessment during September 2022 to develop a 'short list' of viable solutions and service providers
- In late September & October 2022, the selected short list of APM service providers will be invited to participate in a RFP and detailed evaluation where additional client details and system requirements will be provided

LCE Points of Contact:

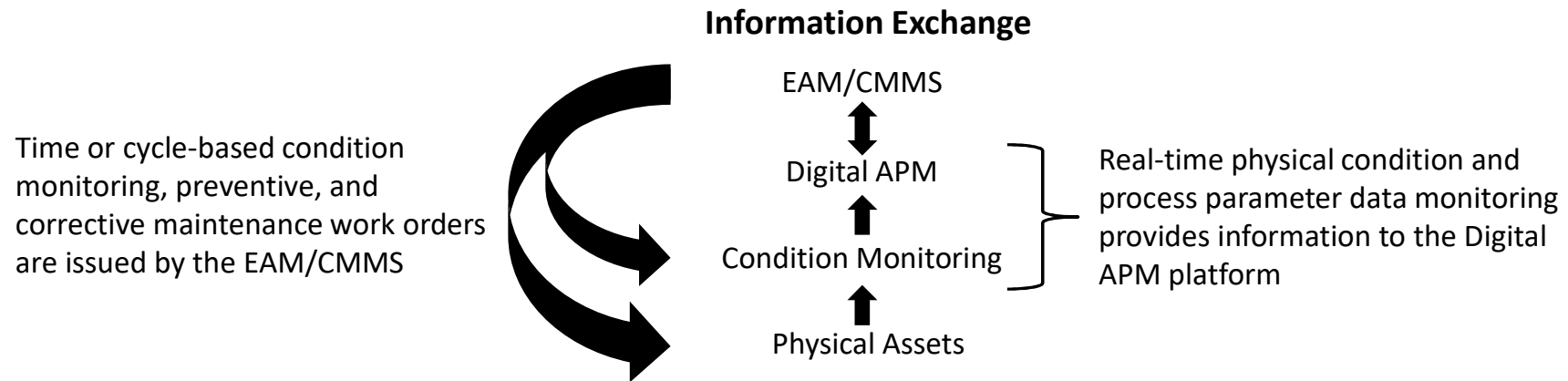
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Asset Performance Management Vision



Simplified Data Integration Concept



Notes:

- Data from other process control systems will need to be integrated into the Digital APM platform
- The client organization is currently implementing a data integration layer within their logical architecture that consolidates information from multiple data sources – this is on an AWS platform
- Data push/pull is required for APM interaction with the EAM/CMMS which is primarily SAP and IBM Maximo platforms

Desired Future State & High-Level Requirements

- A Global Digital APM platform, equipped with all the tools (e.g. machine learning / AI, Digital Twins) needed to develop proactive maintenance strategies, which can be scaled up, shared and leveraged across all manufacturing sites (30+ global locations)
- The APM Platform pulls structured and unstructured data from multiple data sources in operations through interfaces with Data Integration Layer, EAM/CMMS, third party systems (e.g. CBM – vibration monitoring), and if needed from field sensors directly
- APM processes are fully integrated with EAM/CMMS processes providing a seamless solution
- APM predicts, detects, and prescribes the maintenance interventions that are needed, well in advance, enabling planned maintenance work without impacting operations
- APM platform displays Asset Performance and Health in real-time including sustainability aspects such as energy use, which are viewable by all, and on various devices
- APM platform is secure, resilient and easily maintainable – needs to be a proven solution



APM Functional Concept Cleanroom Air Handling Unit



Unit Discharge Temperature
Unit Discharge Relative Humidity
Unit Discharge Airflow
Supply Fan VFD Frequency

Unit Supply Fan Vibration

Building Management System



Client or Vendor Cloud

APM

AI + Data Monitoring

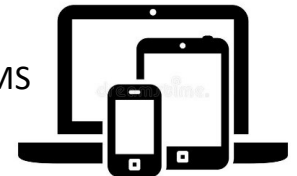
Vibration
Airflow
VFD Hertz

AI Determines Root Cause of Issue



Planned & Scheduled Corrective Work Order issued with work instructions to address root cause

EAM/CMMS



+Energy Management Optimization



Cleanroom Temperature
Cleanroom Relative Humidity
Cleanroom Differential Pressure

Data Historian



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