MANAGING A COMPLEX SUPPLY CHAIN USING E2E DIGITALIZATION SOLUTIONS

ELECTRONIC DATA SOLUTIONS FOR THE BIOPHARMA INDUSTRY

February 2024

OAGi

Arizona State University

NIST

AGENDA

INTRODUCTION

PHARMA 4.0 INDUSTRY DRIVERS

SUPPLY CHAIN CHALLENGES

EDATA USE CASES & SOLUTIONS

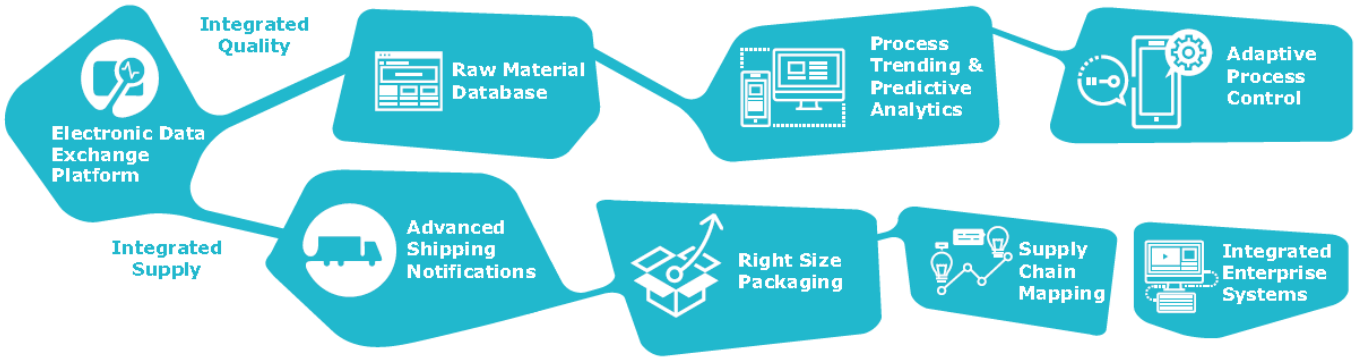
SUMMARY – Q&A

INTRODUCTION

STEPHEN WING, HEAD OF ANALYTICAL & LOGISTICAL SERVICES

MilliporeSigma

eMERGE™ eData Platform



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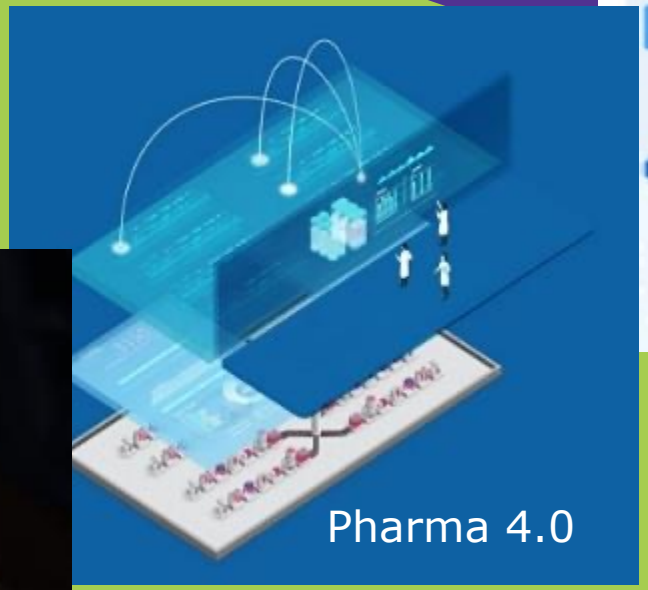
eMERGE™ Program
Main Industry Drivers

Customers Want to Simplify & Optimize Business Processes



Designation: E3077 – 17$^{\varepsilon 2}$

eCoA Plus

Standard Guide for
Raw Material eData Transfer from Material Suppliers to Pharmaceutical & Biopharmaceutical Manufacturers[1]

Supply Chain Challenges Overview
Supporting Customers Across the Entire Purchasing Journey

- Different Business Processes
- Various Systems and Tools
- Different Functions and People
- Various Data Requirements

Digitization Goals – Right Data | Right Time | Right People → Improve Process Efficiencies

Biopharmaceutical Production Systems
Digital Transformation Landscape & Opportunities

Key Business Partners

Key Suppliers

Contract Manufacturing Organizations (CMO)

FDA U.S. FOOD & DRUG ADMINISTRATION

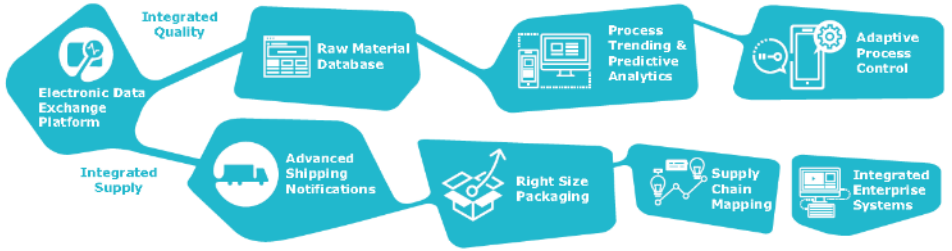
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Commercial Business Operations

Transactional Processes

Logistical Processes

Analytical Processes

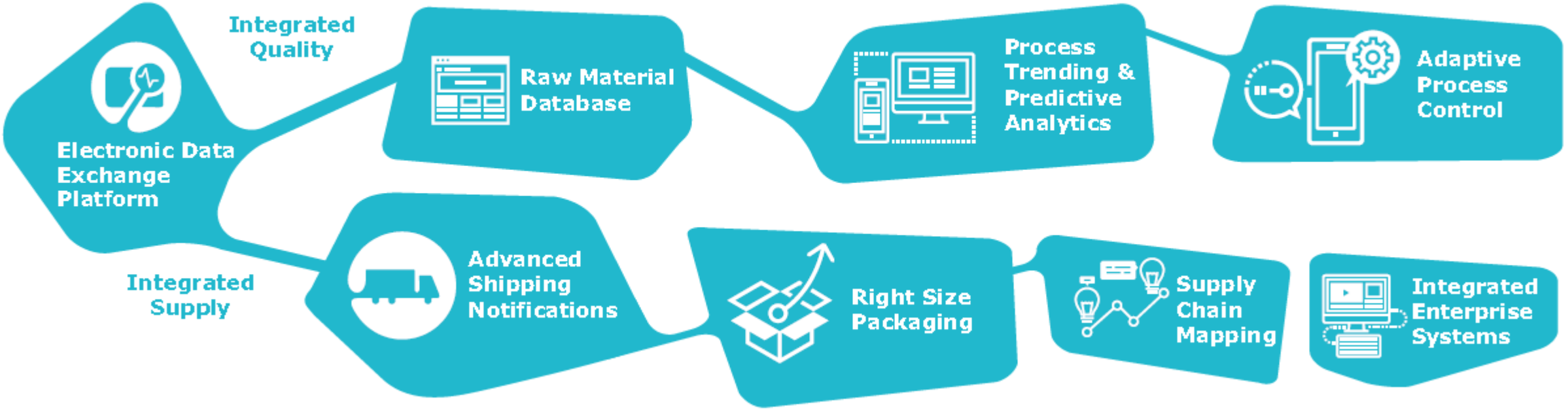


eMERGE™ Program Benefits

Customers

Concurrent Digital Transformation to Accelerate the Journey

eMERGE™ Program Vision



Industry Landscape & Standards
Industry eData Standard

Sample eData XML File Structure

Standard E3077-17* from American Standards for Testing and Materials (ASTM)

```
<ASTMeDataXchange xmlns="https://www.astm.org/e55edataxchange.html">
  <FileInformation version="1.0">
    <EndUserSystemVersion>1</EndUserSystemVersion>
    <FilePartyEmail>email address</FilePartyEmail>
    <DataPartyEmail>email address</DataPartyEmail>
    <GenerationDate>2017-12-10</GenerationDate>
    <GenerationTime>16:59:06</GenerationTime>
    <ContentRevision>7</ContentRevision>
  </FileInformation>
  <Comments>Materials from Multi-Manufacturers</Comments>
  <MaterialDataGroup>
    <MaterialData MaterialDataLotID="L0">
      <QualitySignature>PCKV</QualitySignature>
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      <ProductName>40% GLUCOSE HTST TREATED</ProductName>
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      <QuantityUOM>EA</QuantityUOM>
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        <MaterialParameter>
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          <Description/>
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          <UnitOfMeasure/>
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          <MeasurementValue/>
          <MeasurementText>Conforms</MeasurementText>
          <MeasurementTestLot/>
          <SpecificationNumber/>
          <Specification>Complete</Specification>
          <SampleLocation/>
        </MaterialParameter>
      </MaterialParameters>
    </MaterialData>
```

Data Security Signature

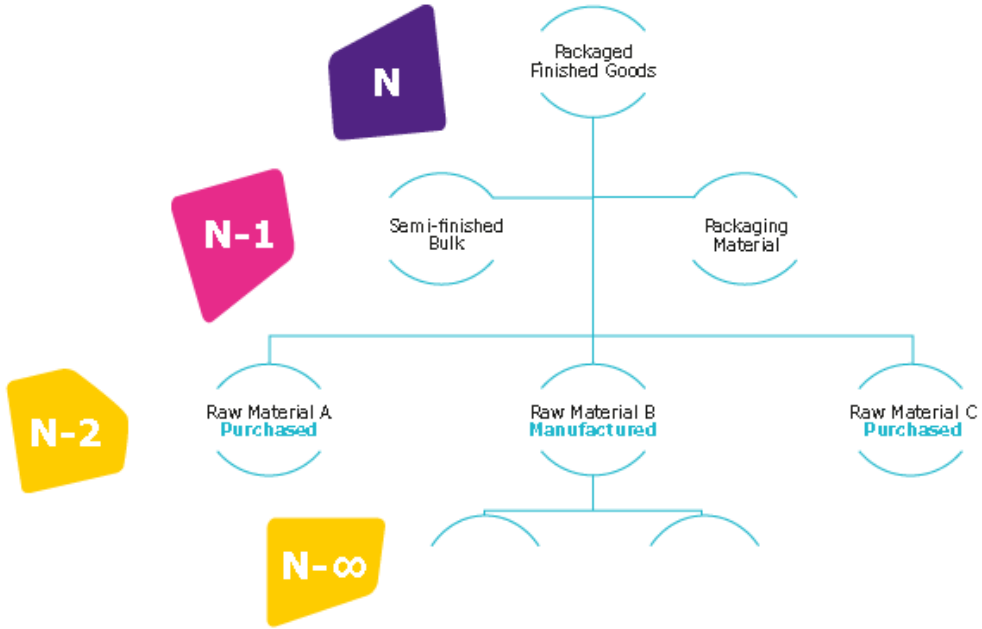
Genealogy / Supplier Data

Measurement Parameters

Inspection Plans

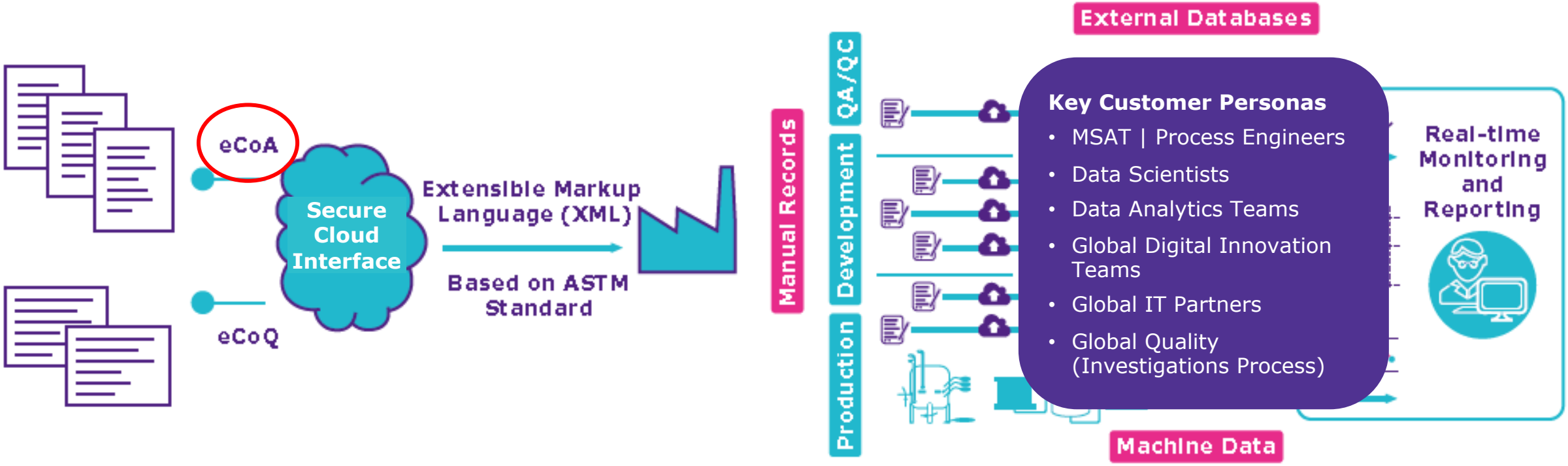
QC Results

Multi-Level Data Fields



* Standard Guide for Raw Material eData Transfer from Material Suppliers to Pharmaceutical & Biopharmaceutical Manufacturers

eMERGE™ Program
Customer Benefits – Process Analytics Use Case

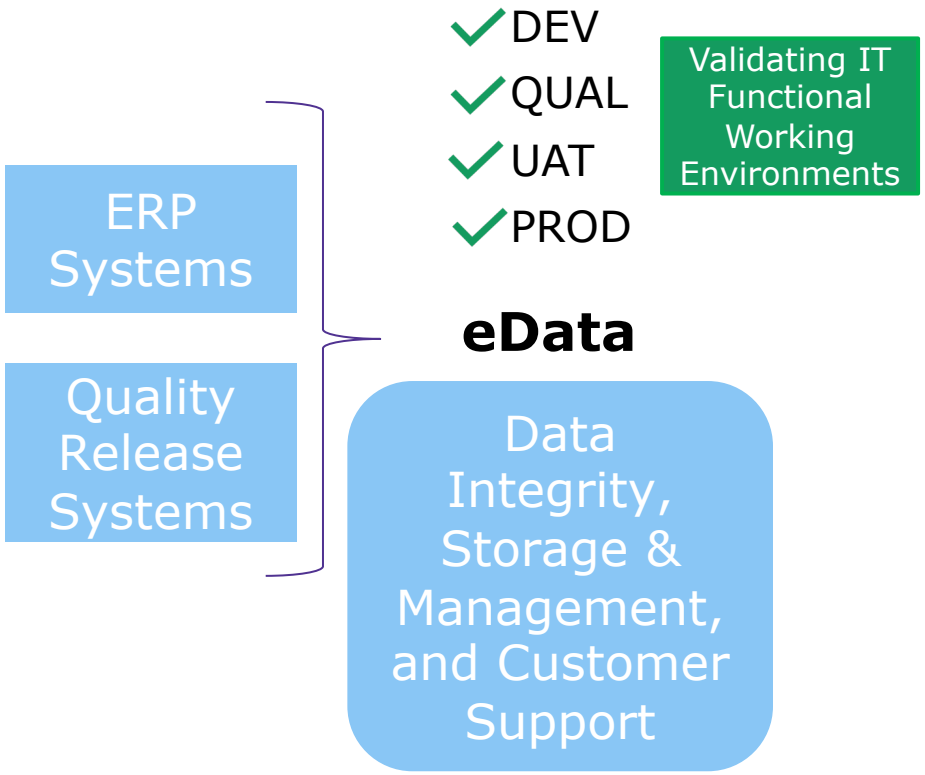


Improved Process Yield + Reduced Downtime = Increased Profitability

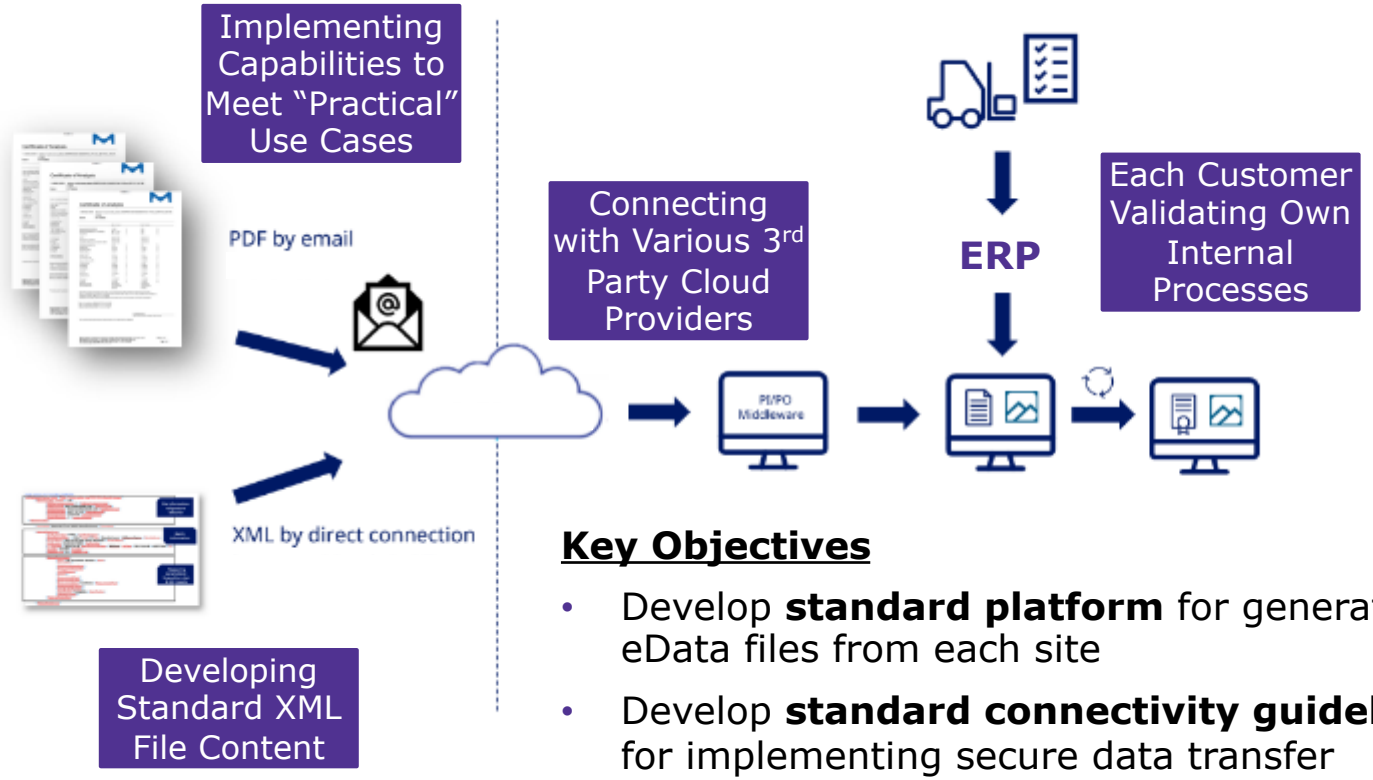
eMERGE™ Customer Collaborations

Customers are working with us to build an Industry Standard

Internal eData Readiness Development



Sample Pilot Customer Development Architecture



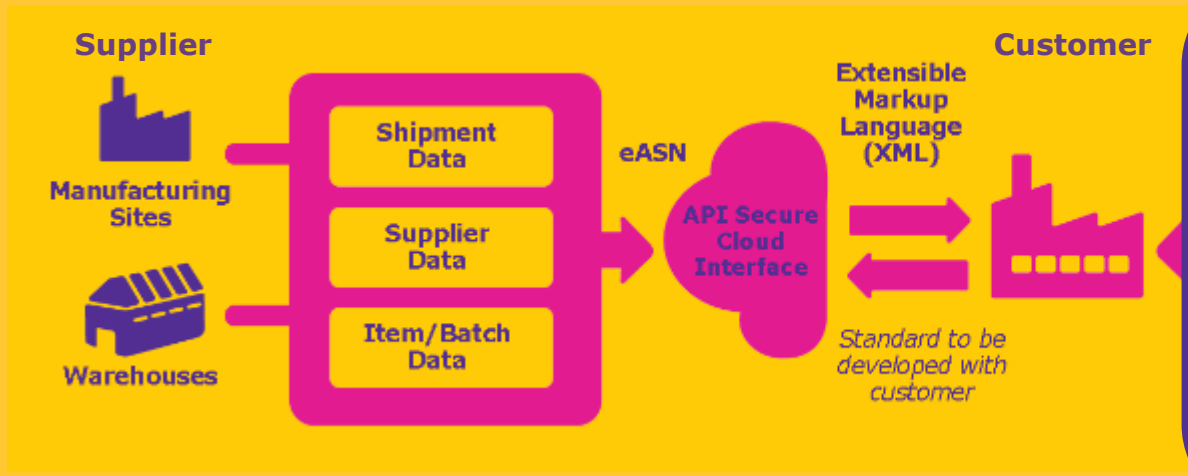
Key Objectives

- Develop **standard platform** for generating eData files from each site
- Develop **standard connectivity guidelines** for implementing secure data transfer
- Validate **Go-Live processes** for sharing production eData

eASN Initial Offering

Collaborate with customers to establish a Biopharma Industry Standard

E- Advanced Shipping Notification (eAsn)



Key Customer Personas

- Production Planning
- Procurement
- Receiving Dock / Department
- Incoming Quality
- Inventory Management
- Production Staging
- Manufacturing
- Process Quality

Improved Release Time + Available Inventory = On-Time Delivery

eMERGE™ Program
Customer Benefits – Logistics Analytics Use Case

Phase1: Basic eASN, focus on Delivery data for Digitalized Goods Receipts Process

Mandatory

- **Purchase order number**
- **Material number**
- **Customer's material number (only if provided)**
- **Line number**
- **Supplier Lot/Batch number**
- **Shipment number**
- **Date of shipment dispatch (Shipment Date)**
- **Estimated Delivery date**
- **Shipped Quantity**
- **Number of pallet**

Optional

- Packing list
  a) Description
  b) Weights (gross, net, total)
  c) Dimension
- # of material/box
- # of unit
- Delivery address
- Tracking
- Delivery type/shipment method
- Carrier
- Supplier name and address

Phase 2: Expand eData Capabilities, adding Quality data for Fast Quality Release

- Trusted weight (depends on EZ BioPack package)
- **Expiring date**
- **Original of Manufacture**
- **Country of Origin**
- **Date of manufacture**
- Temperature logger data

Phase 3: Adding additional Physical Capabilities for fast verification

- Barcode label
- License plate number
- Sampling

Must haves

Nice to haves

SUMMARY

BIOPHARMA SUPPLY CHAIN IS COMPLEX

Many custom solutions and processes driving inefficiencies

STANDARDIZATION IS THE KEY

Industry standards required for broader acceptance

COLLABORATION IS REQUIRED

Focus on working with key business partners

THIS IS A JOURNEY, NOT A PROJECT

Phased implementation with incremental benefits

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THANK YOU

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