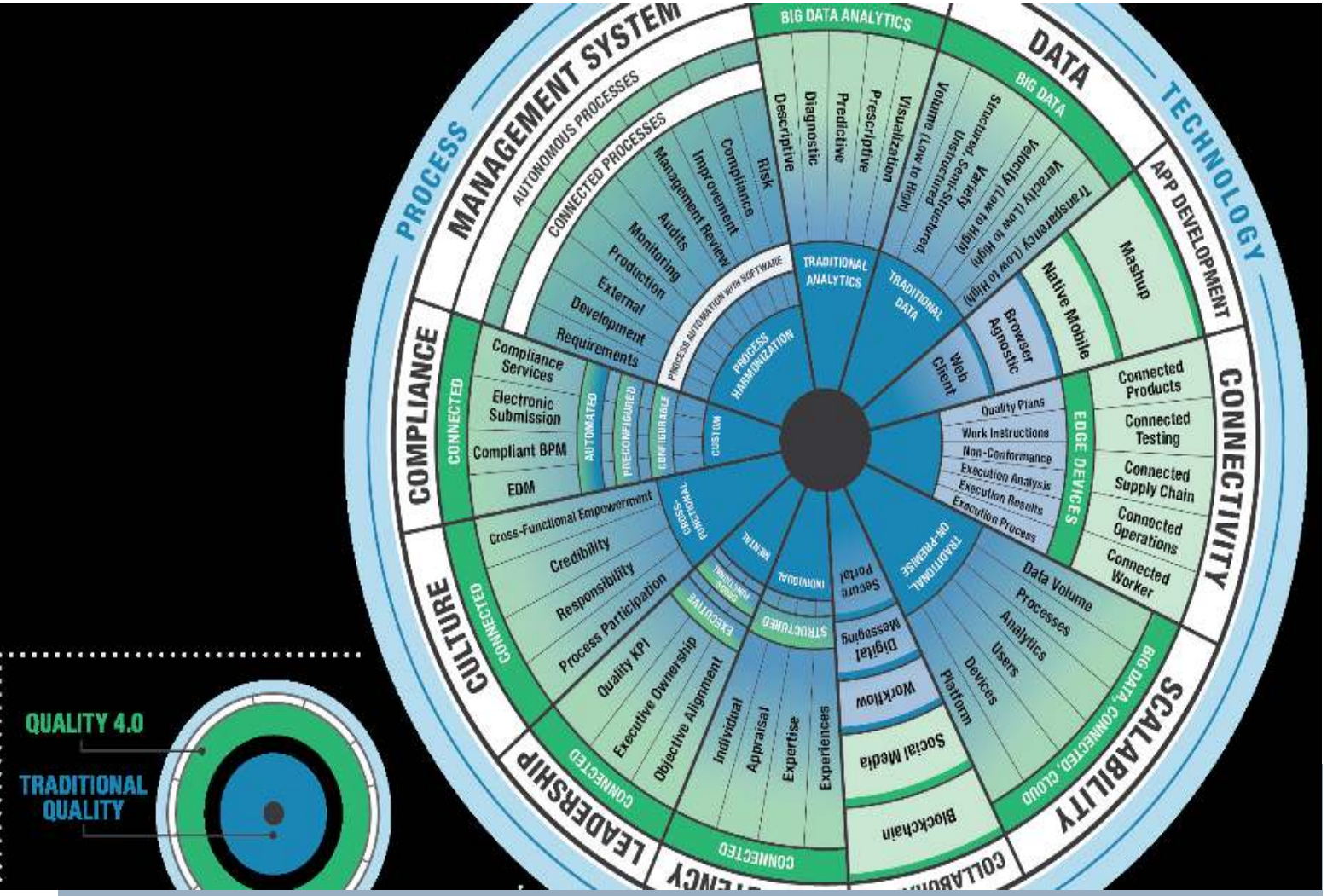
AstraZeneca

AZ Digitalization Journey and Adoption of Quality 4.0

High Level Introduction and Deployment Overview

May 2022



What is the concept of Quality 4.0

Quality 4.0 is a framework to assist with the digitalisation of quality management and the impact of that digitalisation on quality technology, processes and people

So far, there are identified 11 axes of Quality 4.0, which companies can use to educate, plan and act

Using this framework, it can be identified how Quality 4.0 can transform existing capabilities and initiatives

Quality 4.0 does not replace traditional quality methods, but rather builds and improves upon them.

The framework is used to interpret the current state and identify what changes are needed to move to the future state

Quality 4.0 brings into focus the data required to monitor quality performance

What is Quality 4.0

- Our quality profession started during the middle of the second industrial revolution, when methods were needed to ensure that assembly lines ran smoothly
- It was about assessing manufacturing errors against specifications, that the workers knew how to engage in the process and that costs were controlled.
- As industrial production matured, those methods grew to include the design of processes which were built to produce to specifications
- In the third period, organisations started to include the concepts of human capabilities and active engagement in quality - TQM, Lean, and Six Sigma etc.
- Manufacturing quality concepts were adapted into research

- There was also the key event of the invention of the digital processor, leading to most of our current CSV auditing and more recent data integrity requirements
- Then there was Cloud Computing….

- How our quality methodology and QMS will now evolve in an adaptive, environment with Artificial Intelligence (AI) is largely still open, still unregulated and that is the basis of the Quality 4.0 debates

Change and Compliance Oversight

We are still waiting for the legal, international framework for AI-governance to be issued - current CSV and GxP regulations will have to change.

The FDA is “actively developing a new regulatory framework to promote innovation” in the AI space….. at least fourteen AI-embedded medical devices have been approved in the US since January 2017

It will take time to create a mechanism that protects individuals and society without blocking the paths to promising new technologies

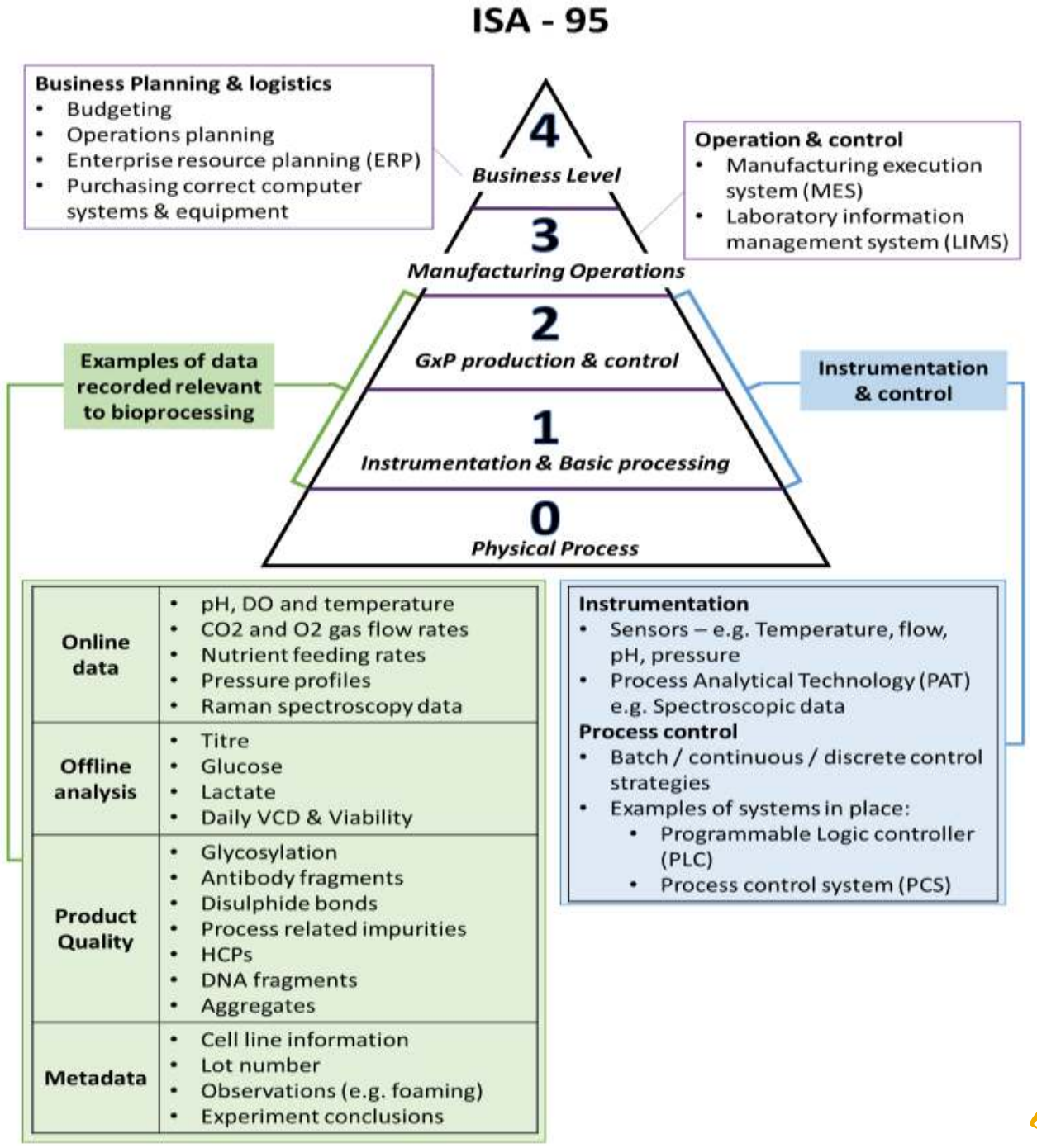
How do we audit AI? What is our internal guidance?
Big Data Analytics, transfer, manipulations and storage?

The QMS and our auditing techniques or methodologies will need to focus on data governance, data confidentiality, data integrity, availability, systems quality assurance and accountability

Ensuring data integrity within the biopharma sector as it moves towards Industry 4.0

GMP manufacturing – Sources of risk to data integrity

- GMP manufacturing data sets are prone to data integrity risks if not managed appropriately
- Different datasets from multiple sources links to the need for standardisation of data processing



AZ Digitalisation Vision

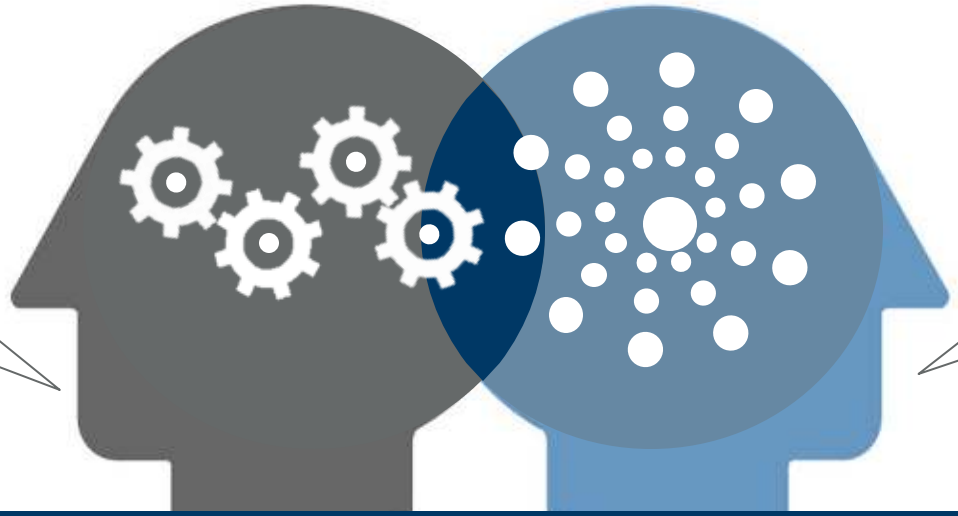
Mode 1

Industrialising existing operations

Mode 2

Enabling digital transformation

"We deliver to our customers in the most efficient & effective manner possible



"We work hand in hand with our customers to explore and deliver new possibilities"

Operational Excellence
"Run IT Brilliantly"

The shift to value
"Digitise everything we do"

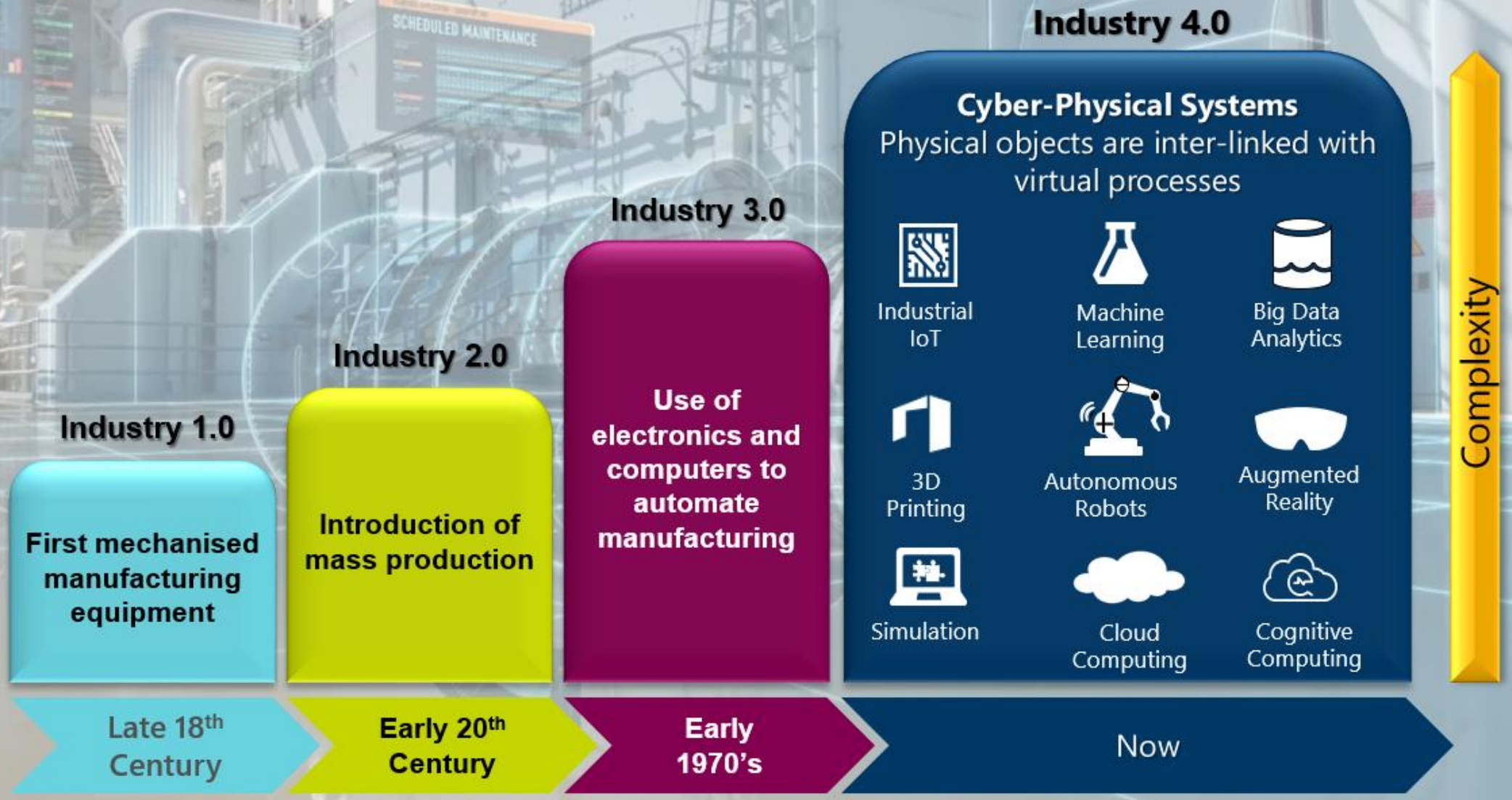
Value Engineering
"Innovate to Win"

Doing the same things but better

Doing new things that add value

Doing things that provide competitive advantage

The Fourth Industrial Revolution



Introduction to GVLMS

GVLMS Mission

GVLMS has being launched across all AZ operations sites.

Transition from a paper based validation process to a Global Validation Lifecycle Management System that is scalable and enables users to apply standardised and simplified processes to manage validation.

Using a Disruptor to Standardise?

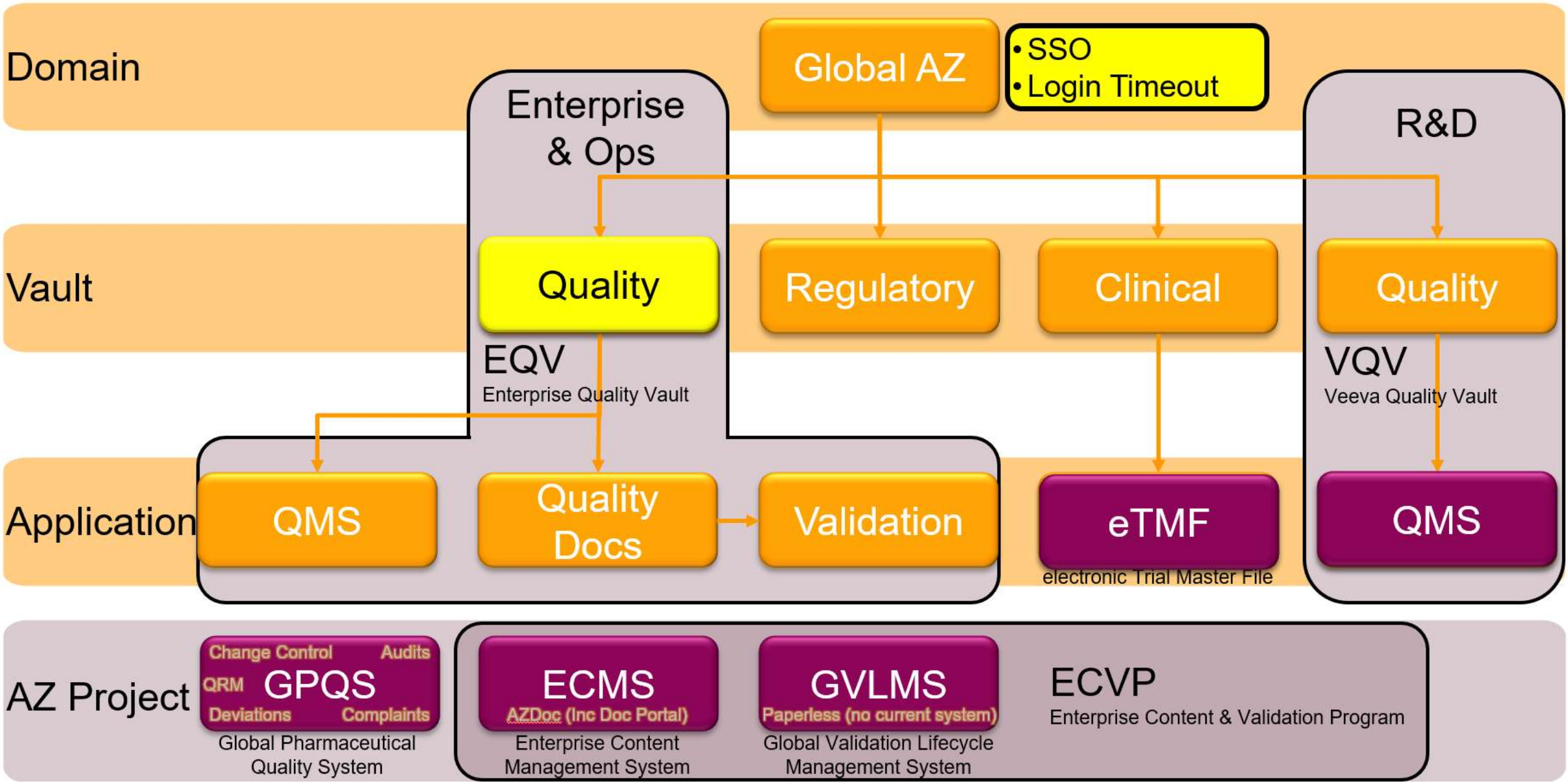
- Great Opportunity to use best practice approach through collaboration with all sites
- Lean Enablement

Why did we move to a new system?

To meet the needs of an enterprise with a system that:

- Contributes to AZ's Digital Vision
- Is Scalable and Efficient
- Performs Faster
- Is Cloud based and intuitive
- Enables internal and external collaboration
- Can be updated seamlessly and continuously with new features and functionality
- Allows mobile device access
- Is integrated within our PQMS

What is GVLMS, ECMS and EQV?



Key Benefits

Simplified & standardised processes, templates and content across the Qualification & Validation business process

Simple & intuitive system, with a modern look and feel

Improved **compliance** – with compliant scheduling tools for periodic review and & requalification

Efficiency savings wrt to documentation generation time & effort; removal of archiving

Global visibility with automated reports & dashboards for KPIs and metrics

Globally-managed common procedural documents and training materials to **reduce burden** on sites/functions

Standardised & simplified Business Process & Practices + **Standard Content (User requirements & Test Scripts)** + **One Global IT system** = **Standardised, efficient and compliant approach for Qualification & Validation**

What does GVLMS do?

GVLMS Users & Entity Structure

- GVLMS is being launched across all AZ operations sites.
- GVLMS includes a representation of our Equipment Structure within the system; this is called the “entity structure.”

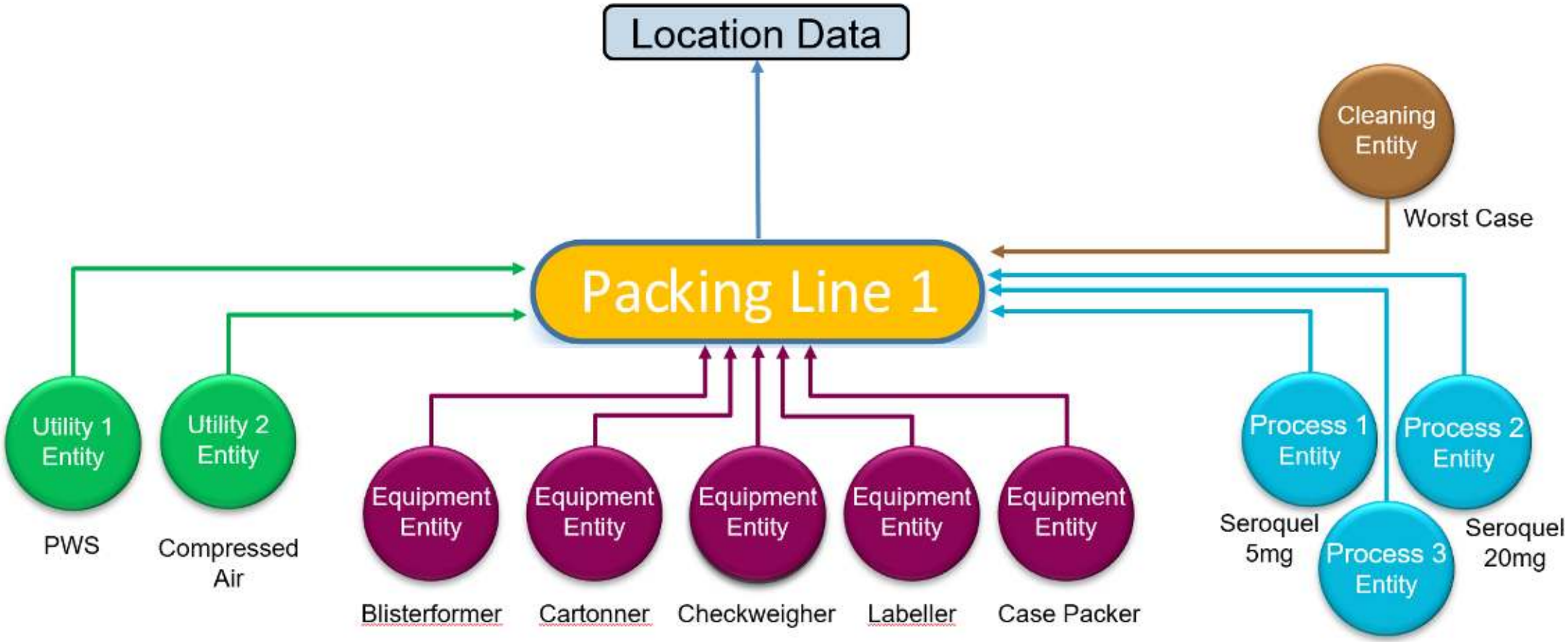
What is an Entity?

- An “entity” is an object that represents something that will be Qualified or Validated.
- Entities can be:
  - ***Tangible***, e.g. A piece of Manufacturing Equipment or Utility Equipment to be Qualified (this info is linked to equipment in SAP)
  - ***Intangible***, e.g. A Process to be Validated.

Use of Entities in GVLMS

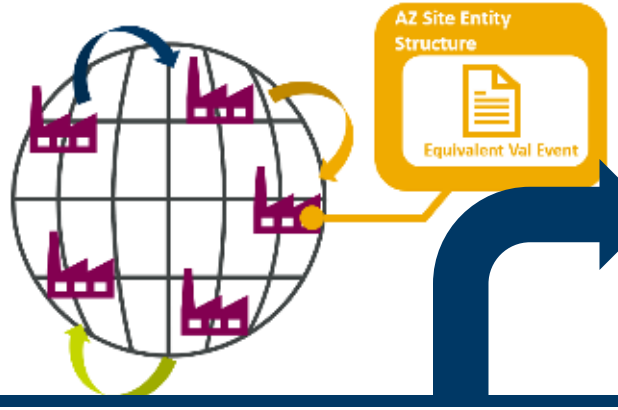
- The entity structure in GVLMS gives us a real-time reflection of the status of all of the “things” we validate and Qualify (this is the “entity lifecycle”). Managing this helps us standardise how we Validate and Qualify different types of entities.
- The entities will link to other parts of the EQV; giving full traceability to all actions performed throughout its operational lifecycle.
- GVLMS will deliver the current entity structure that becomes the platform for all future works.

Packing Line Example



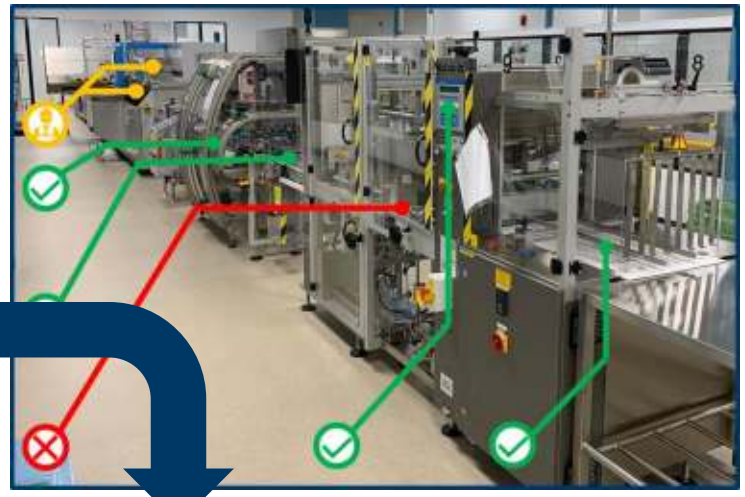
Each entity can be directly linked to other aspects of the EQV – i.e. Validation documentation; Deviations; Risks; Change Controls; Products; API and any other relevant documents.

GVLMS & EQV Tangible Benefits



A site validation entity structure means:

- A real-time readout of the Validated state for all of our GxP Systems and Processes
- Clarity on current state of equipment
- Reduced likelihood of errors / deviations

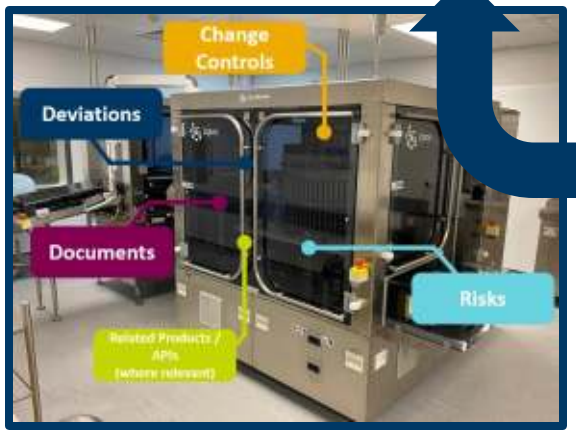


A shared Global Validation system means:

- Sharing of Validation strategy / documents between sites becomes a possible through the entity structure
- Configured system workflows standardise aspects of Validation planning and assessment
- A single shared platform for all Validation content (e.g. templates) that's accessible to all

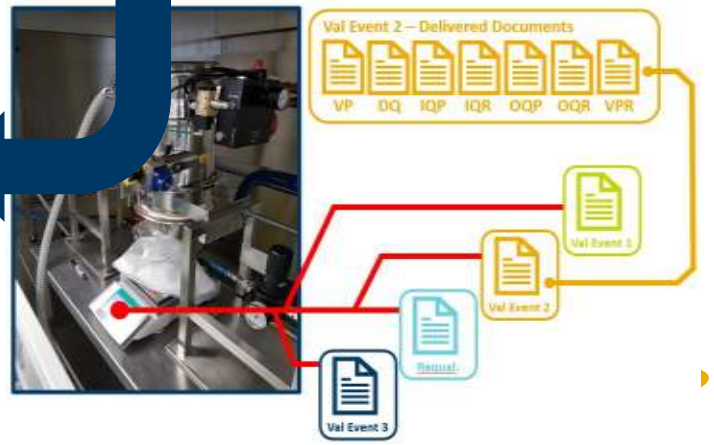
Having the full validation history linked to each entity means:

- From entity to any Validation document in a few clicks simplifies how we review and support audits
- Historic work can be easily leveraged for new equipment
- Users can see status of on-going projects



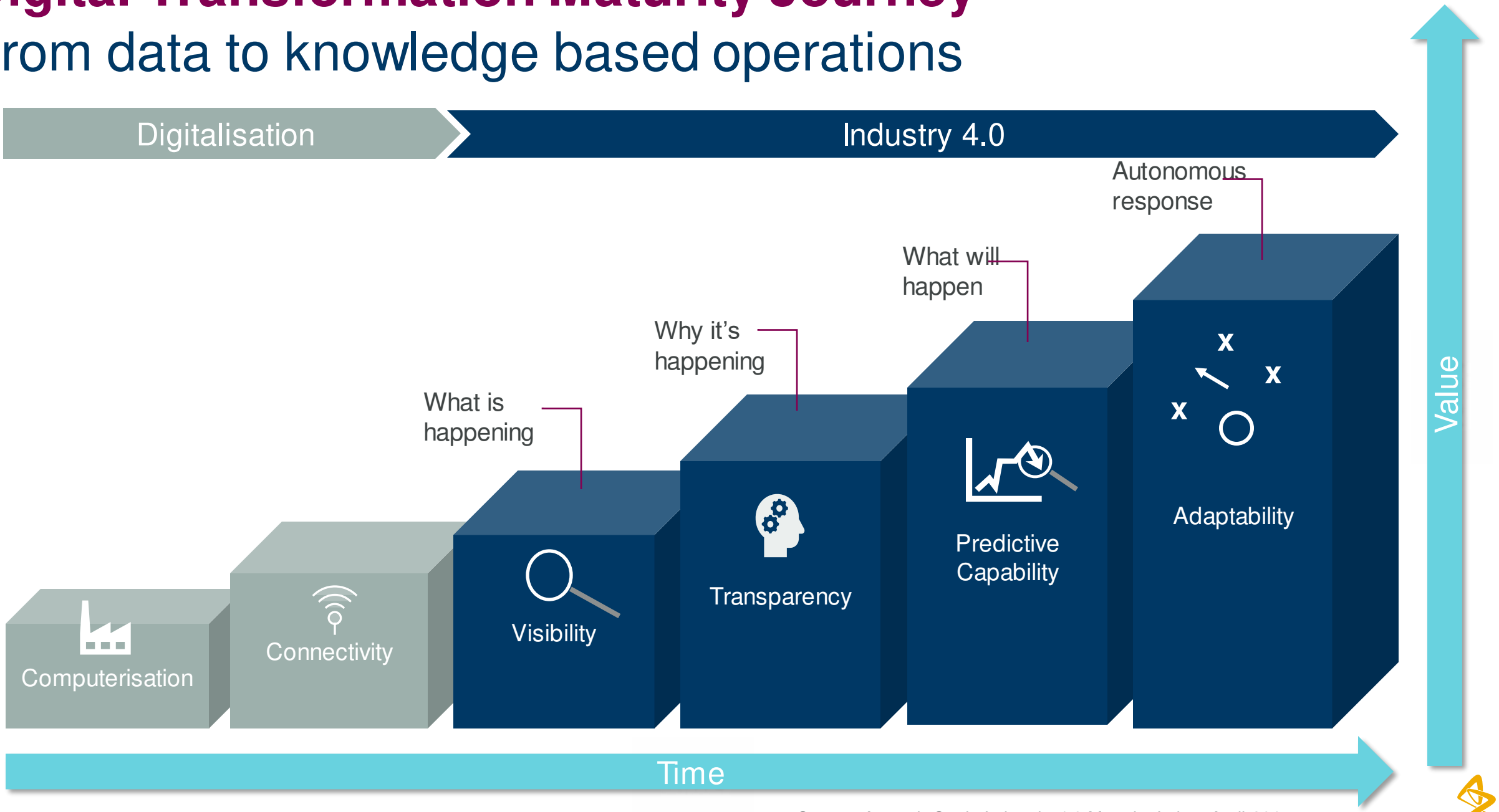
The Enterprise Quality Vault Platform means:

- An integrated platform for all Quality Systems
- Change controls; Documents; Risks; Deviations; Finished products can be linked to entities.
- A step change in Knowledge management capability
- Reduced data trawl workload for PQRs / investigations and Lifecycle review of equipment / processes



Digital Transformation Maturity Journey

From data to knowledge based operations



Source: Acatech Study Industrie 4.0 Maturity Index, April 2017

Summary

Industry 4.0 and AI are here

Quality 4.0 is happening today

To maintain a competitive edge, we need to deploy linked Quality analytics, data and connectivity strategies

We need to engage in our own continuing professional development to become familiar with the technologies of Industry 4.0 and have a readiness to engage with Quality 4.0.