Transforming lives through science, innovation and collaboration

How to be a QP in a Digital World

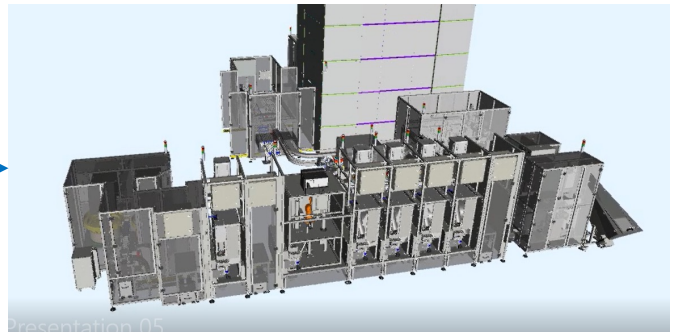
Trinity College Dublin – QP Forum – 13 May 2025

Peter Deegan

Independent Consultant

– Digitalisation and Automation

Digital Learning – a unique perspective



PACE Innovation Project

- Digital Quality Lead
  - Digital QP data review
  - Automated GMP line

GMP and QP Training Tutor

- Digital QP Career Path
  - CPD roadmap for QPs in the digital age

30+ years in Pharma
- EU GMP Qualified Person
- PQS - Operations, R&D
- Training
- Regulatory Affairs (data and submission standards)
- Digitalisation specialisation

Authorised training partner Ireland
- GMP / GDP / Lead Auditor and technical training

Digital Competence

New knowledge, new skills, new language

IT Systems
ML/DL/AI
Data Architecture
Cybersecurity

Validation
Agile
Automation

Quality Verification
Process re-design
Mapping technologies e.g. BPMN

Leadership
Active digital champion
ICHQ10 1.5.3
Business acumen

PQS Guardian
Vs just bx sheet

Futurist
Horizon-planning
Disruptor
Business acumen

Analytics
Methodologies
Interpretation

Failure Tolerance
Repeat human-error high frequencies
Business acumen

The Just-in-Time QP White Paper 2017

(Author: Peter Deegan, ReMediES project)

- QA / QP review is a highly manual process
  - Human expertise to know the data
  - Know how, know where (semantic memory)
  - Large clerical component
  - Manual login – read – copy – paste – logout - repeat
- Regulatory texts written in 'human-workflow' prose
  - 1.(vi) "Records are made, manually and/or by recording instruments"
  - 4.7 "Handwritten entries should be made in clear, legible, indelible way"
- No mention of 'data', just 'documents'

- IT systems are designed by humans for humans
  - Paper on Glass 'Human-eye-readable'
  - Data architecture bespoke for the applications, not the workflow
    - Companies must change their operating model to 'fit' the application
    - Data architecture mis-match
  - Data embedded in documents
  - Multi-document / data consolidation
    - Human request to only open 1 document
      - Effectively a clone of many
    - e.g. PSF

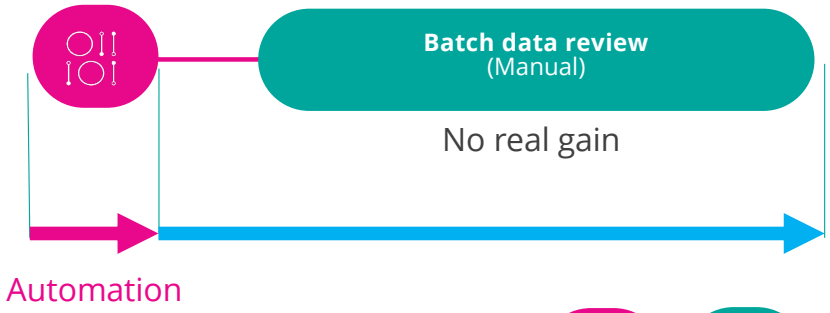
ReMediES
RE-configuring MEDIcines End-to-end Supply

Automation/Digitalisation Drivers in Pharma

WHY?

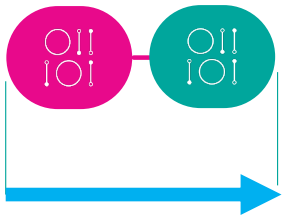
Today: Make to Campaign (just in case) and store to be ready

Automation: fill and label patient bottles "just in time"
– still need to have a stock as bottles can't be QP released in real time



Digitalisation: Ability to release product "just in time"

- Pre-flight registration verification
- MES automated GMP verification
- Batch record automated verification
- QP 'Real-time release'

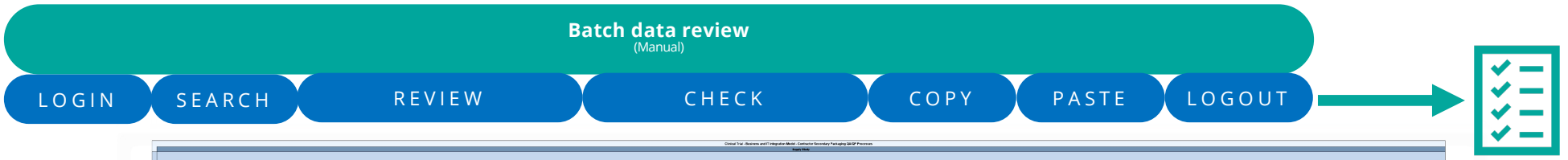


As-is Data Flow map

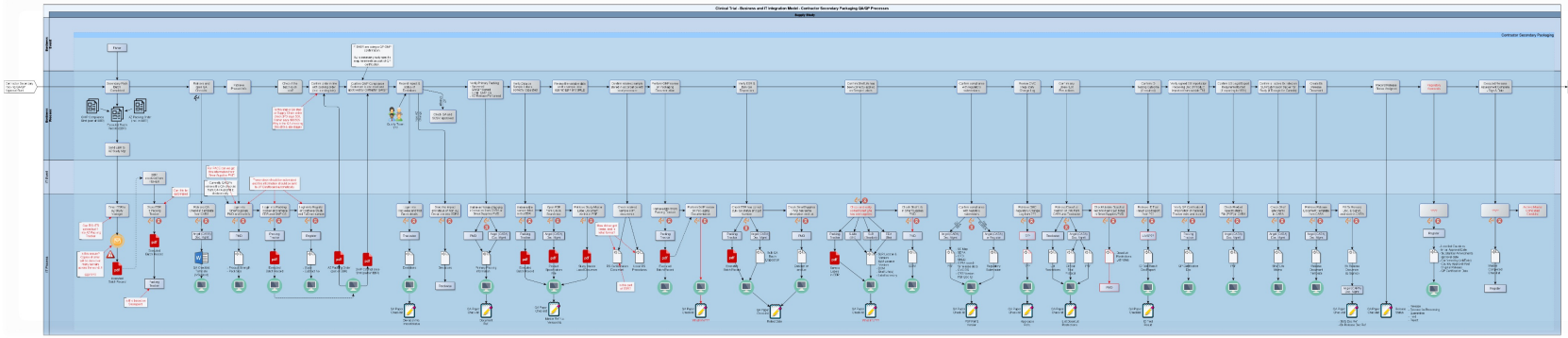
- Secondary packing (UK)

Systems analysis of all of the steps a QA batch reviewer has to take for each batch review.

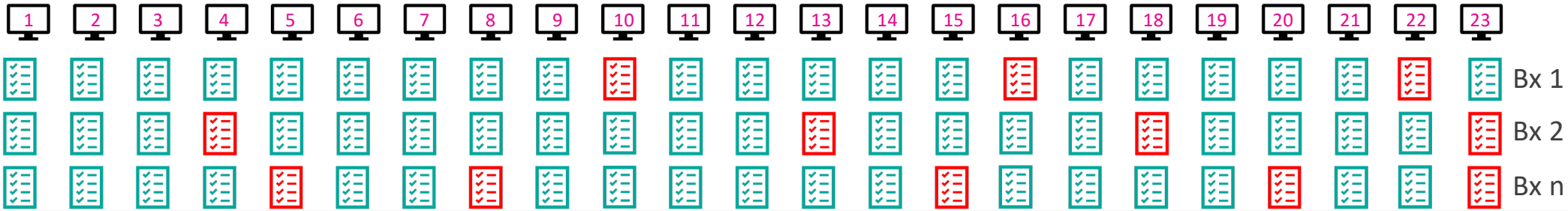
- All steps are manually done – logging in to each system, viewing, copying and pasting data into a manual checklist



(Systems Analysis conducted as part of PACE project)



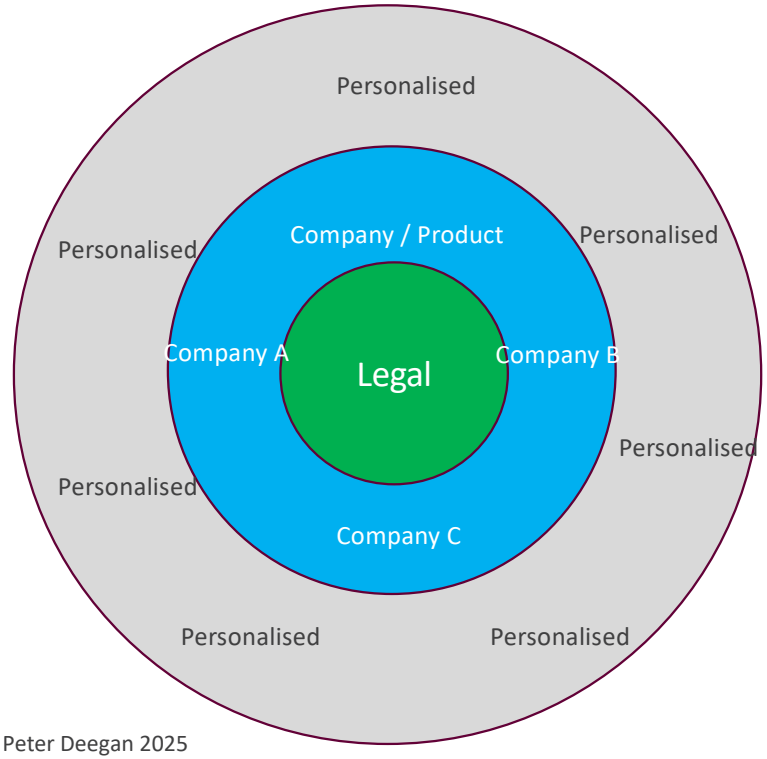
This process has hundreds of singular human checks per batch, but we start reviewing the same data again from the start for each batch iteration. Each time there is a new (and propagated) risk of human error



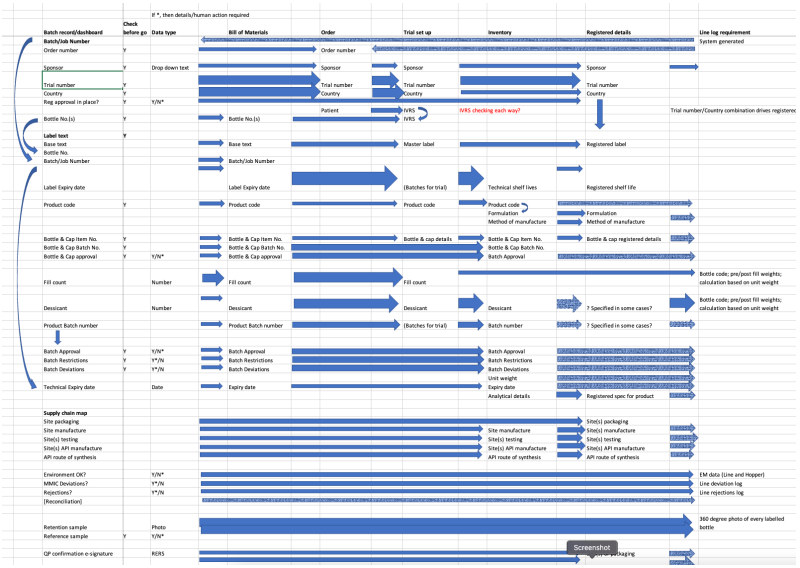
Data Standardisation

The project found that there is no standardised data listing or data architecture for the minimum legal checks to be done.

- Each MAH has different processes and different data checks
- Often, it's compounded by individual QP having personal preferences, so this becomes the 'norm'

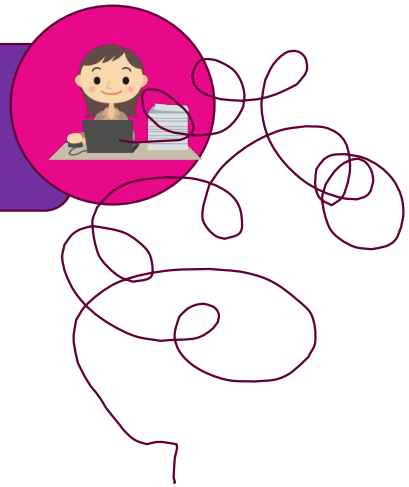


- The project has begun to create a QP Industry Standard Data Architecture.
- Standard Data Transfer mechanisms are being developed.



The Happy Path

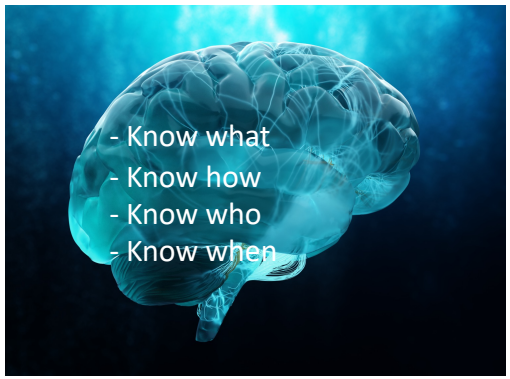
Step 1 → Step 2 → Step 3 → Step 4…



Problem

Step 4…

- Our procedures and processes generally describe positive steps
- Problem-solving routines are embedded in human experience and are often not described, nor recorded
- Hard to extract and encode learning into the PQS
  - Transfer of knowledge?
    - *ICHQ10 (1.6.1 Enablers)*
  - Learning?
  - Continuous Improvement?



Encoded Knowledge ← Embrained Knowledge

(embodied, embedded, embrained, encultured)

(Blackler 1995)

Digitalisation vs Electronification

As an industry we're here

But we think we're here

Electronification – Current State

Data is rendered to an electronic format. e.g.:

- Scanned pdf
- Computer spreadsheet
- Data / words typed into MS Office Document (Word/Excel, etc.)

Human has to read the data or words on-screen to perform actions & transactions (i.e. faux-paper)

- High personal knowledge needed
- Transcription errors
- Inconsistencies
- High repeat transactions
- Data elements not extractable

Electronification - Middle-State

Data is 'pulled' to a system or location from source; or data is extracted digitally e.g.:

- Consolidated report
- 'Bot' extracts from scan
- Data points pulled from source system into / dashboard / field

Human intervention still required for decisions/actions, but simpler, consistent reporting

- Consolidated reporting
- Reduced transcription errors
- Validated outputs
- Reduced transactions

Digitalisation - True State

Data is in a format that 'computer' can analyse and make calculations. e.g.:

- Data automatically pulled into system (e.g. dashboard) in 'Zero-Time' (live feed) from source
- Data-driven calculations against a data-spec

Minimal Human intervention; computer can analyse / report / calculate / recommend

- Just-In-Time
- Zero Human data collection and entry
- AI / Machine Learning opportunities

Digitalisation Phases

- Data is presented in many forms
- We need to digitalise all data so the computer can read & report it.

Structured Digitalised	Un-structured Digitalised	Non Digititalsed	Embrained
• Indexed • Meta data • Reliable • Current • Change-managed • Managed • Ontology	• SharePoint • MS Office doc. e.g. Excel / Word, etc • Email • Phone text	• Paper document • Certificate of conformity • Print-out	• Personal knowledge • Phone-call • Decisions based on complex matters (e.g. Deviations)
Develop Reporting Tool	Use reporting rules to extract & report	Digitalise into systems	Digitalise the outcome Design-out (process)

Mckinsey Report (2023)

“Rewired pharma companies will win in the digital age”

- Every Pharma recognises the importance of digital technology
  - …have only scratched the surface
  - Few have yet succeeded in deeply embedding digital and analytics
  - Silo’d systems not interconnected
  - Data access have been major inhibitors of digital and analytics transformation
  - Resources not trained / knowledgeable / competent in Industry 4.0

1. Rethink operating models and reorient around outcomes
2. Dive into DataOps to drive innovation
3. Industrialise AI
4. Rapidly transform talent strategies
5. Define a digital health strategy

Pharma firms seeking to jump-start their initiatives can begin by aligning stakeholders around [digitalisation] goals and developing a roadmap to guide their efforts

Pharma Industrialisation?

Quality Assurance

We're still here

- "Promise or a guarantee"
- 1971-2022 (51yrs)
- Human checks fallible
- High individualised knowledge and risk

- QA/QP high manual human clerical checking

Today	Tomorrow?
• *Automation (2000)* • Paper on Glass • Complex data sets in many systems • Human manual data checking • Isolated functional systems/docbases	• Industry-standardised data architecture • Data transfer between systems • Data not documents • Data-driven automated assessment • Sensor-driven verification (MES)

Quality Verification

We need to move to here

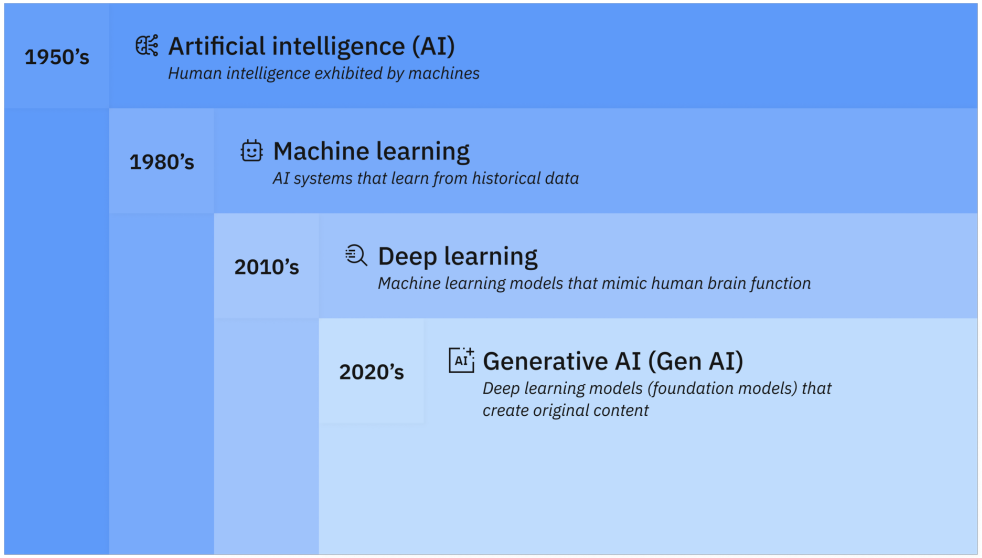
- Verified PQS
- Verified data
- Verified manufacture
- Automated checks
- Reduced waste/reject
- More robust supply

- QP doing what they were designed to do –
  - Walk the PQS
  - Coach / mentor
  - Advise

Artificial Intelligence

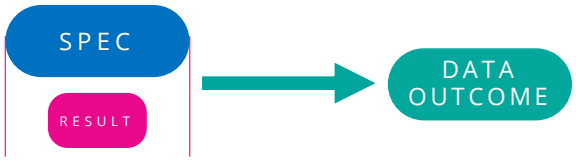
- Data Architecture
- Artificial Intelligence
- Machine Learning
- Deep Learning

Do you as a QP know the difference? (Read these links)



Source ibm.com/topics/artificial-intelligence)

- Key points
  - Data architecture is foundational to AI
    - Without correct data architecture, AI will make it up (Generative)
    - Automation is a simple data calculation task
      - AI not needed



  - AI has many forms – we have low training on this
    - Machine Learning
    - Deep Learning
    - 2025 Generative AI
      - Creates original text, images, video and other content
        - Data Integrity?
        - Validation?
        - Verification?
        - Data

Does your company have a formal digitalisation training plan?
- *ML/AI/*
- *Links to DI?*

AUTOMATED INDUSTRIAL ROBOTICS

PACE - Pharmaceutical Automation for Clinical Efficiency

“The future is now”

PACE Innovation Project case-study

- Enabling Quality Verification
  -through automation and digitalisation

AUTOMATED INDUSTRIAL ROBOTICS

Meet PACE

PACE is an innovative multi-product modular automation line. This disruptive technology has created a more agile and responsible supply chain to quickly bring new medicines to the market.

PACE delivers the production, packaging, and labelling of multiple drugs in a single facility, ensuring full traceability and eliminating cross-contamination risks. Operating on one line in a GMP environment with real-time quality checks, PACE creates a demand-driven supply chain that reduces waste, cuts costs and speeds up drug delivery to patients.

Pharmaceutical Acceleration (through) Clinical Efficiency (PACE)

- Make to order
  - Waste reduction
  - High sustainability
  - Patient-centric supply
- Multiproduct fill
  - Sealed filling heads
  - Active, Placebo, Comparator
  - OSD to start
- Laser etched bottle for tracking
  - Multi-product unlabelled bottle
- Inline labelling
  - Label masking
  - Camera verification
  - In-line label printing

- Automated MES
  - Verified GMP steps
  - Digital QP Batch review Dashboard

Quality Verified!

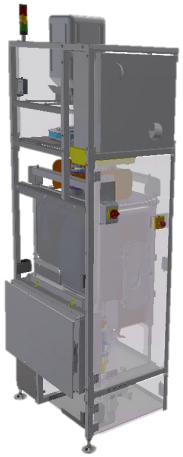
Process Overview OSD multi-product fill

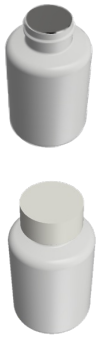
Product Supply
- Tablets
- Capsules*
- Desiccant

Pill Bottle Supply

- Traceable ID code
- Patented cap**

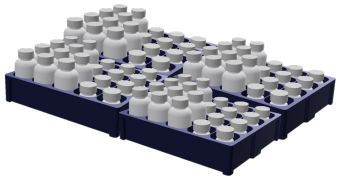
Weigh Stations
- Code check
- Weigh check
- Access-controlled reject chamber

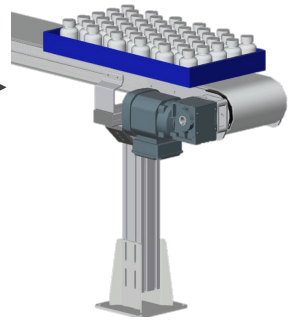
Filling Modules

- Cleanroom grade
- Modular + scalable (multi-product line filling)
- Patented sealed fill mechanism

Bottle Sealing + Capping

- Foil sealing
- Child-proof cap

Label Application

- On-demand Inline printing
- Camera verification
- Data storage + traceability

Storage Solution

- ID tracking

Dispatch Fulfilment

- Assemble dispatch orders
- Manual offload or integration to downstream processes

* Inline capsule-making capabilities available
** Compatible with filling module docking mechanism

Process Overview- direct vial label etching

Product Supply

- Pre-filled Vials

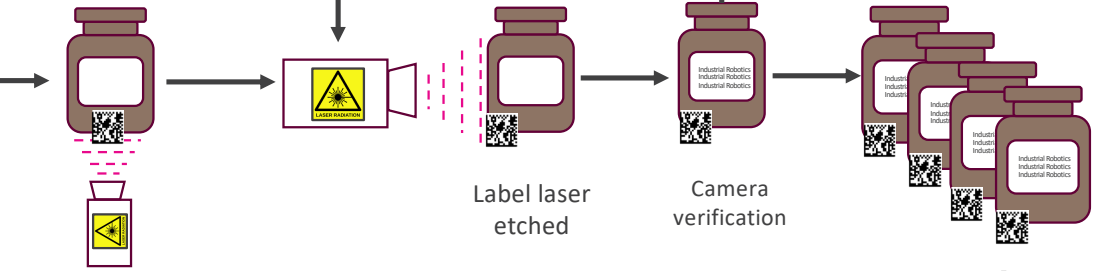
(unlabelled with white pre-painted label patch)

Vial bottle types

Process cell

(Pre-approved label mask & variable data)

Prysm 360



- Laser etched traceable ID code

Label laser etched

Camera verification

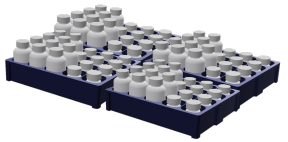
- No paper label needed
- No condensation
- Fully automated

Process Temperatures

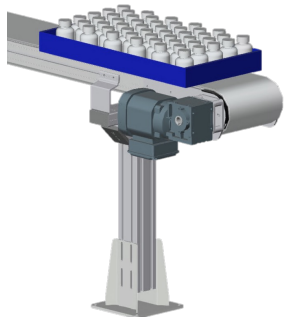
Etching performed inside process cell

- Ambient chain
- Cold chain

Storage temperature controlled



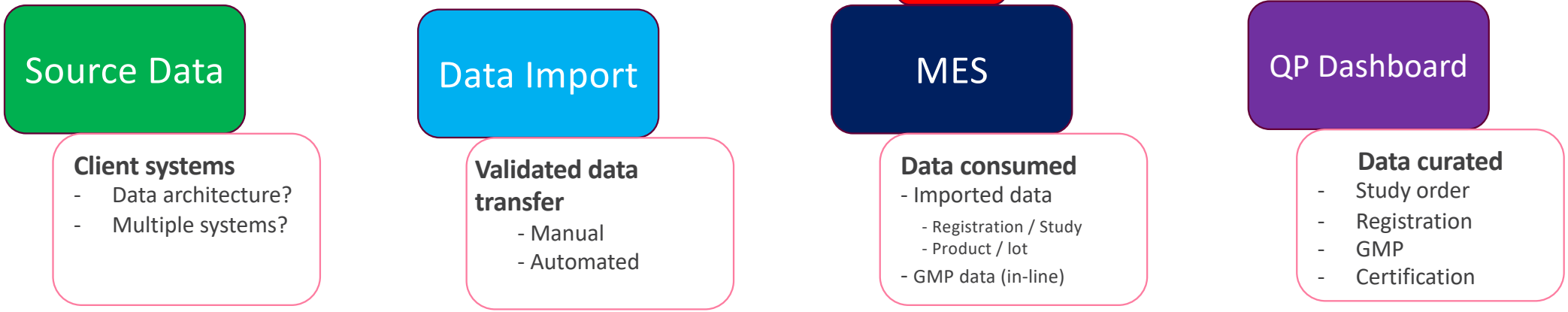
Dispatch Fulfilment



- Assemble dispatch orders
- Manual offload or integration to downstream processes

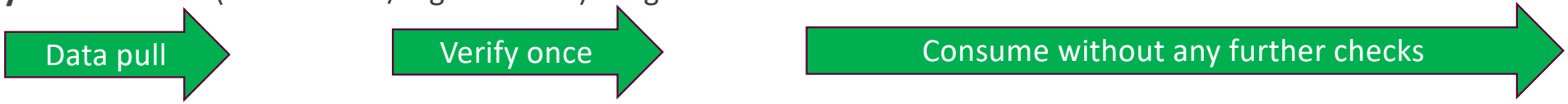
Qualified Person Dashboard

PACE Data Flow



Quality Assurance (Human)

Quality Verification (Automation/Digitalisation): single source of truth



PACE Digital PQS Dashboard

PQS State of Control — Verified

- ICHQ10
  - 1.5.2 State of control
    "To develop and use effective monitoring and control systems for process performance and product quality…."

- GMP Part 1 — Verified
  - Training — Verified
  - Validation — Verified
  - Env. Monitoring — Verified
  - Cleaning — Verified
  - Procedures — Verified

- QP Annex 16
  - 1.7.1 Batch GMP — Verified
  - 1.7.2 — Verified
  - 1.7.3 — Verified
  - 1.7.4…1.7.21 — Verified

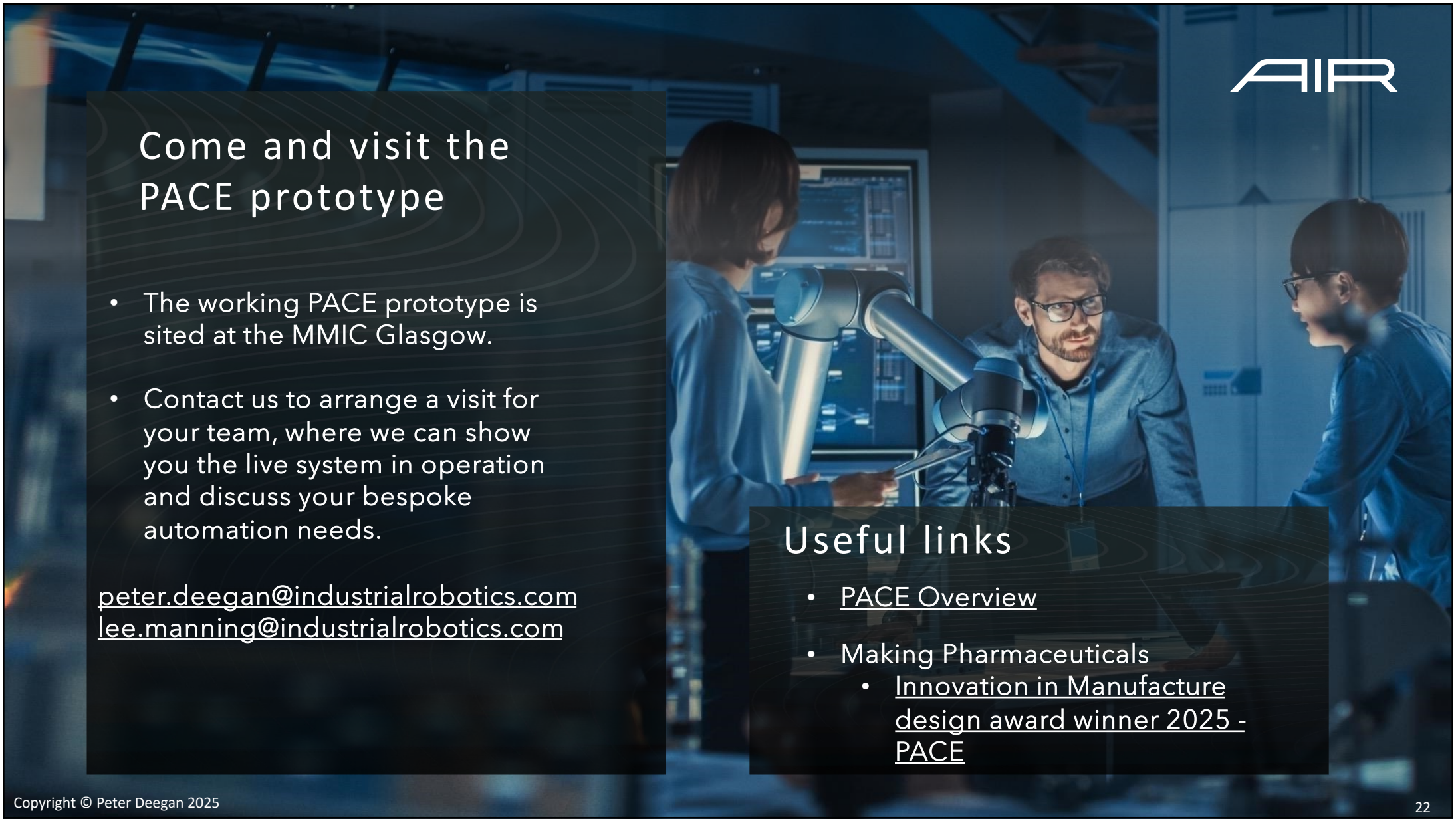
Certified

Registration Status — Verified

- Pre-flight
  - MA (Country) — Verified
  - Study — Verified
  - Shelf life — Verified

GMP Lot status — Verified

- MES — Verified
- EBR — Verified
- Deviations/remarks — Verified



Come and visit the PACE prototype

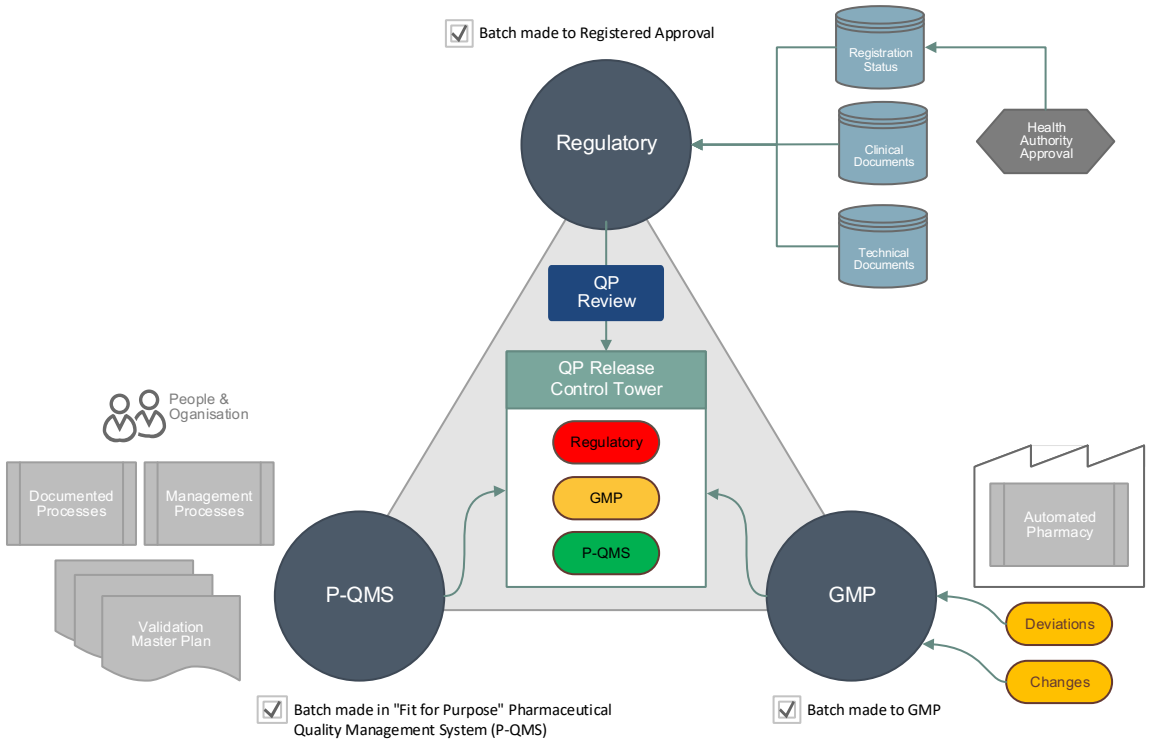
- The working PACE prototype is sited at the MMIC Glasgow.
- Contact us to arrange a visit for your team, where we can show you the live system in operation and discuss your bespoke automation needs.

peter.deegan@industrialrobotics.com
lee.manning@industrialrobotics.com

Useful links

- PACE Overview
- Making Pharmaceuticals
  - Innovation in Manufacture design award winner 2025 - PACE

Digital PQS – Future Concept



Automated PQS

Data-driven

- Digitally verified pre-flight
- Materials auto-hold if not verified
- Personnel hold if not trained
- Batch run hold if:
  - Not validated
  - Not calibrated
  - SOPs/process expired

Quality Verified PRE-FLIGHT, IN-FLIGHT, POST FLIGHT

QP Delegation

*Annex 16 - 1.7 "It is recognised that the QP will need to **rely** on the Pharmaceutical Quality System and the QP should have **on-going assurance*** that this reliance is **well founded**".*

1.7.2

Entire Supply Chain

Documented and available

1.7.3 / 1.7.19

All audits carried out / self inspection programme is current

Available to the QP

1.7.4

Supplier QMS in place

Supply of materials of right quality

1.7.11

Records complete

Endorsed by appropriate personnel

1.7.16

All investigations (inc. TRENDS)

Have been completed

This is driving absolute reliance on human-checking.

The QP has to rely on people doing their job right – but has to rely on human checks (where we have seen unforced errors – e.g. recent labelling recalls post QP certification)

QP Verification – Future Concept

*Annex 16 - 1.7 "It is recognised that the QP will need to **verify** the Pharmaceutical Quality System and the QP should have **on-going verification** that this reliance is **accurate**".*

1.7.2

Entire Supply Chain

Documented and available

Digitally Mapped Contemporaneous Change-flags

1.7.3 / 1.7.19

All audits carried out / self inspection programme is current

Available to the QP

Live status Corrective Actions

1.7.4

Supplier QMS in place

Supply of materials of right quality

Digitally Mapped Contemporaneous Change-flags

1.7.11

Records complete

Endorsed by appropriate personnel

GMP Automation Digital Verification

1.7.16

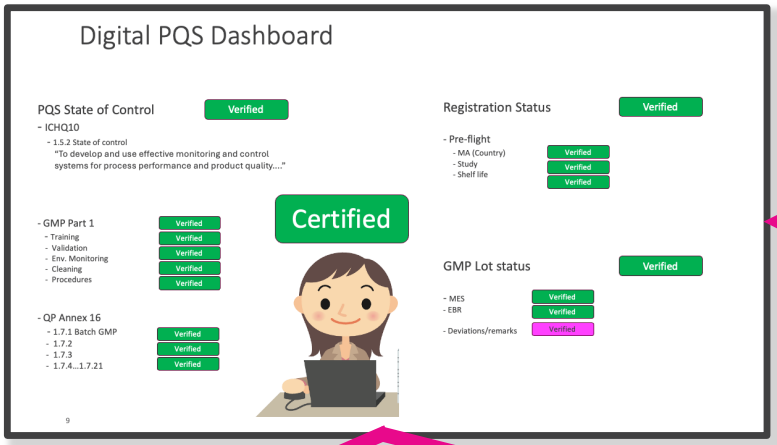
All investigations (inc. TRENDS)

Have been completed

AI trending - Better than human!

Real-time PQS – Future Concept

Should the live PQS dashboard be visible to the Health Authority so it verifies your license to operate contemporaneously?



MHRA
Data Strategy

Health Authority

Marketing Authorisation

Direct access to MAH contemporaneous PQS

You should be here

Not here

PQS Pre-analysis

Tollgate Make/ No-make

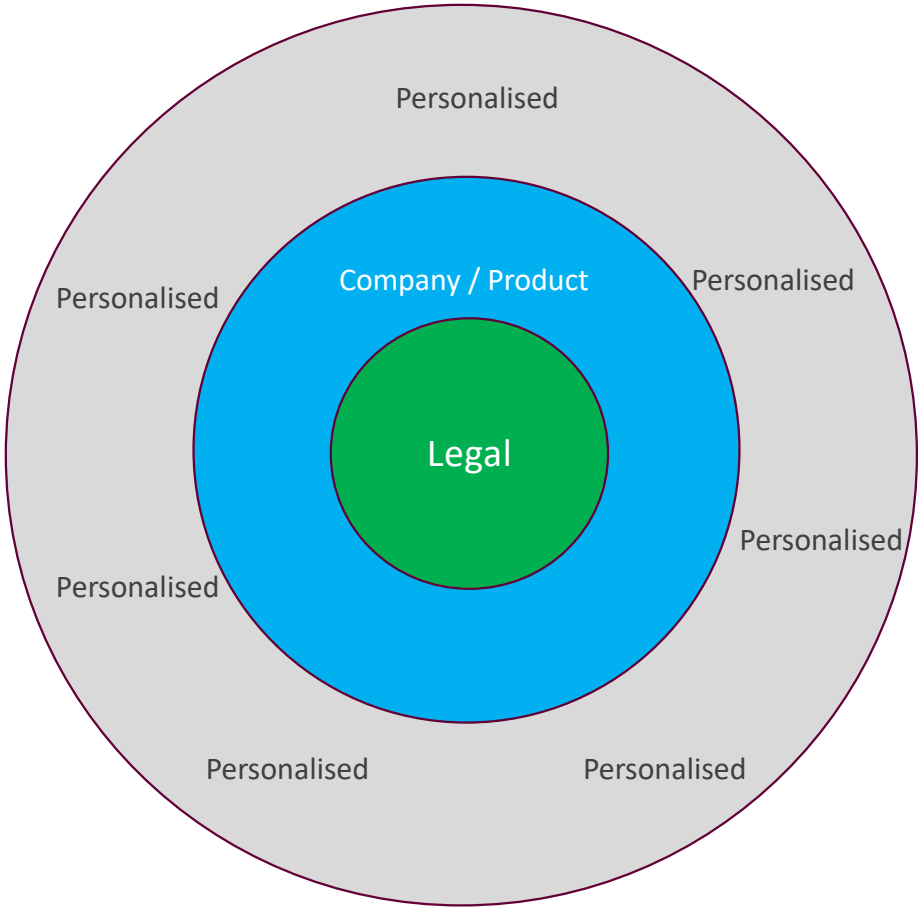
Batch Manufacture

Distribution

How Digital-ready are you?

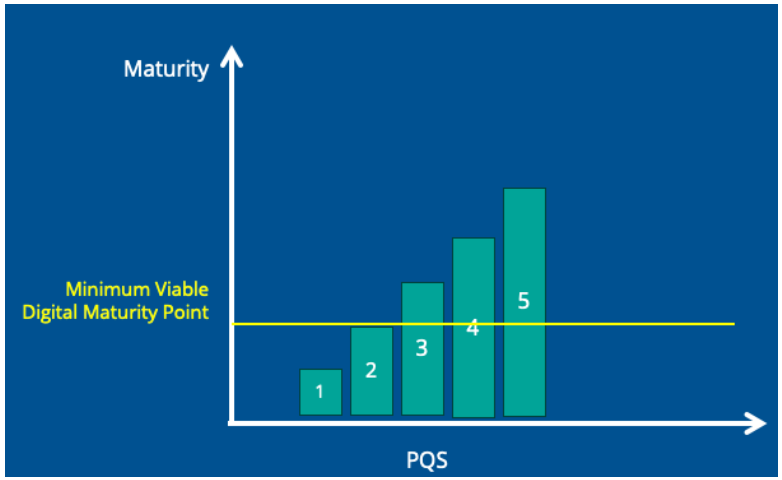
QP Data review – how ready is your data architecture?

- Does my company have a defined data listing of what should be checked?
  - Regulatory
  - GMP (Batch manufacture)
  - PQS
- How much is ‘personal preference’?
  - Are QPs consistent?
- How much is data vs documents?
  - Human-eye readable only?
  - Human-checking process capability and error-rates?
- How easy can the data be extracted and put through e.g. Tableau/Spotfire?
  - Transaction-cost-analysis?



Digital Quality Maturity Readiness

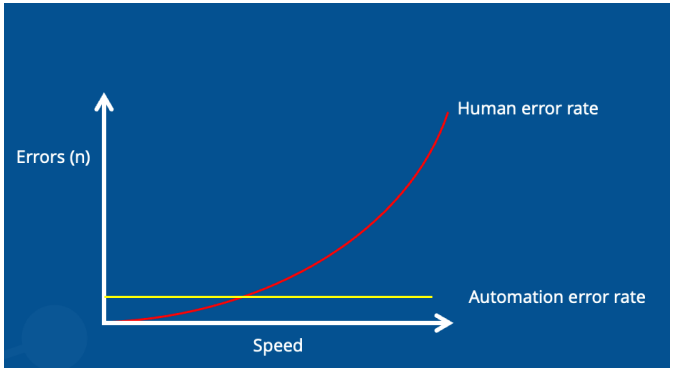
- Digital maturity audit
  - Good way of assessing your digitalisation road-map needs
    - Data architecture
      - Future systems change strategy?
    - Data extraction
    - Data Integrity
      - Human processes today
    - Electronic batch Sheet
      - Paper-on-glass or digital capable?
- Process Improvement
  - Human checking process capability vs automation
    - Quantifiable
  - Just-in-Time capable?



Digitalisation – Ethical Considerations for the QP

- *Batch size 1,000 – 1 Certification vs Batch size 1 – 1,000 certifications*
  - *Multiple certifications all at once*
- *PQS State of Control window*
  - *Batch packed in minutes*
  - *PQS feedback loop?*
  - *Previous 7 days state of control (Tollgate)?*
- *Patient administration in days/hours*
- *Rapid distribution*
  - *Drone/Courier/Ward dispensing robot*
    - *100% verifiable (non-human) due to error-prone Machine-Human interface*
      - *Human error risk of attaching wrong product to the distribution device*
        - *Checks prior to (rapid) administration?*
        - *Patient? HCP? (e.g. paramedic)*

- *Speed vs quality*
  - *Human – Machine interface*



JIT requires automation

- *Non-human QP batch certification?*
  - *Feasibility?*
  - *Regulator view?*

- *Role and professional duties of QP*
  - Unchanged
  - Knowledge of system verification / validation
  - Greater reliance on trends / state of continuous control
  - QP Training Curriculum? Digitalisation?
  - QP CPD in Digitalisation?

Digitalisation Change Map

Type 1

Full digital verification - likely to be greenfield design plant

- Greenfield applications
- Nothing in place, plug and play full system
- Cost benefit for automation / reduction in waste / transaction costs

Type 2

Digital retrofit – likely to be modern plant that has some level of automation and databases

- Would require new data architecture and digital transfer/extraction processes

Type 3

Digital start again – likely to be aged plant / paper-driven systems

- The value proposition would in fairness have a high entry barrier due to cost; but opportunity for systems that have highest manual and thus highest human error potential/record
- Late-adopter?
- Incremental build

Digital Competence

New knowledge, new skills, new language

IT Systems
ML/DL/AI
Data Architecture
Cybersecurity

Validation
Agile
Automation

Quality Verification
Process re-design
Mapping technologies e.g. BPMN

Leadership
Active digital champion
ICHQ10 1.5.3
Business acumen

PQS Guardian
Vs just bx sheet

Futurist
Horizon-planning
Disruptor
Business acumen

Analytics
Methodologies
Interpretation

Failure Tolerance
Repeat human-error high frequencies
Business acumen

Does this make a bit more sense now?

Summary – The journey to Quality Verification

Digital Competence

- New knowledge and skills
- New language
- New technology now available (e.g. PACE)

Are you digital-competent?

Digital Roadmap

- Digital maturity
- Digital appetite
- Digital process improvement

Can you digitally change?

Digital QP

- Digital disruptor
- Digital champion
- Digital enabler (Tollgate)

Are you digital-enabled?

Overview: The document discusses the evolving role of Qualified Persons (QPs) in the digital age of the pharmaceutical industry.

Digital Learning – Unique Perspective

- Emphasizes the need for new knowledge, skills, and language in digital quality assurance.
- Highlights the importance of digital competence in IT systems, machine learning, and data architecture.

Automation/Digitalisation Drivers in Pharma

- Discusses the shift from manual processes to automation and digitalisation in pharmaceutical manufacturing.
- Highlights the ability to release products "just in time" through automated verification systems.

Data Standardisation

- Identifies the lack of standardized data architecture across different Marketing Authorization Holders (MAHs).
- Initiatives are underway to create an industry-standard data architecture for QPs.

Digitalisation vs Electronification

- Differentiates between electronification (current state) and true digitalisation (future state).
- True digitalisation involves data being automatically pulled and analyzed, reducing human error.

Digitalisation Phases

- Outlines the need to digitalize all data for better reporting and analysis.
- Emphasizes the importance of structured and unstructured data management.

McKinsey Report 2023

- Highlights the need for pharmaceutical companies to deeply embed digital analytics.
- Suggests rethinking operating models and driving innovation through data operations.

Pharmaceutical Acceleration through Clinical Efficiency (PACE)

- Describes the PACE project as a modular automation line that enhances supply chain efficiency.
- Focuses on patient-centric supply and waste reduction through advanced manufacturing automation processes.
- PACE prototype is available for view at the MMIC Glasgow.

Digital Quality Maturity Readiness

- Proposes a digital maturity audit to assess readiness for digital transformation.
- Emphasizes the importance of data integrity and process improvement in quality assurance.

Digitalisation – Ethical Considerations for QP

- Discusses the implications of rapid distribution and automation on quality assurance.
- Raises questions about the feasibility of non-human QP batch certification.

Digital Competence

- Stresses the need for QPs to acquire new skills and knowledge in digital technologies.
- Encourages QPs to become digital champions and enablers within their organizations