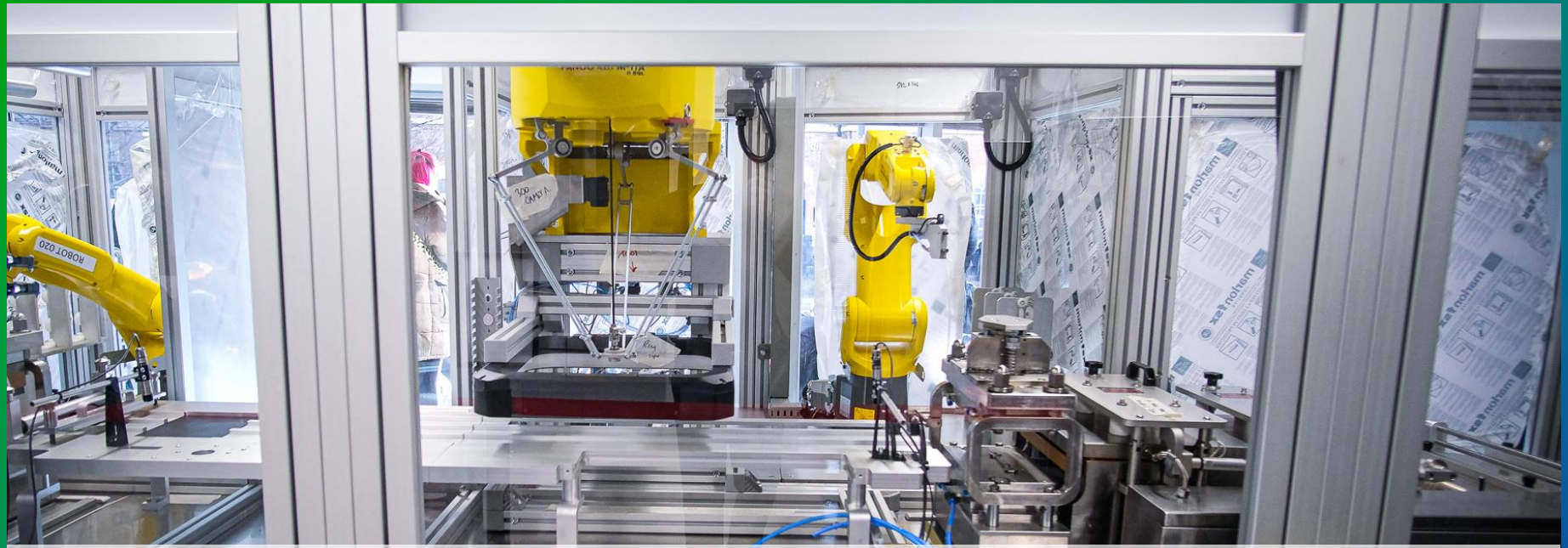
Electronic Work Instructions

A Use Case for Digitalisation Technology

Factorytalk+ BATCHLINE

Dr Tony Margetts
Factorytalk Ltd UK
tma@factory-talk.com
07718801990



Introduction

This presentation talks about a use case for an automated tablet packing line designed by MTC

https://digitalmanufacturingaccelerator.com/

The presentation shows how digitalisation is built in to allow full automation of the operation and collection of data.

Digitalisation

Pharma Industry – Products, Records, Data

Cannot sell the product without the data and records

We need to replace the paper records with electronic records to access the data

Digitalisation

- ***Why should engineers working in the pharma sectors be interested in digitalisation?***
  - Digitalisation is the collection of data about your processes. It enables :-
  - efficient setting up of the process,
  - having a compliant electronic framework for the collection of data in an organised format
  - having a complete visualisation of the data
  - It is an enabler for Industry 4.0 or Pharma 4.0
- ***How does digitalisation improve the operation?***
  - Digitalisation allows complete visualisation of the data which is important for many reasons.
  - To improve processes & to make them more efficient
  - To better understand process variability
  - To improve knowledge management about the process

Industry 4.0 (Pharma 4) a Five Step Process

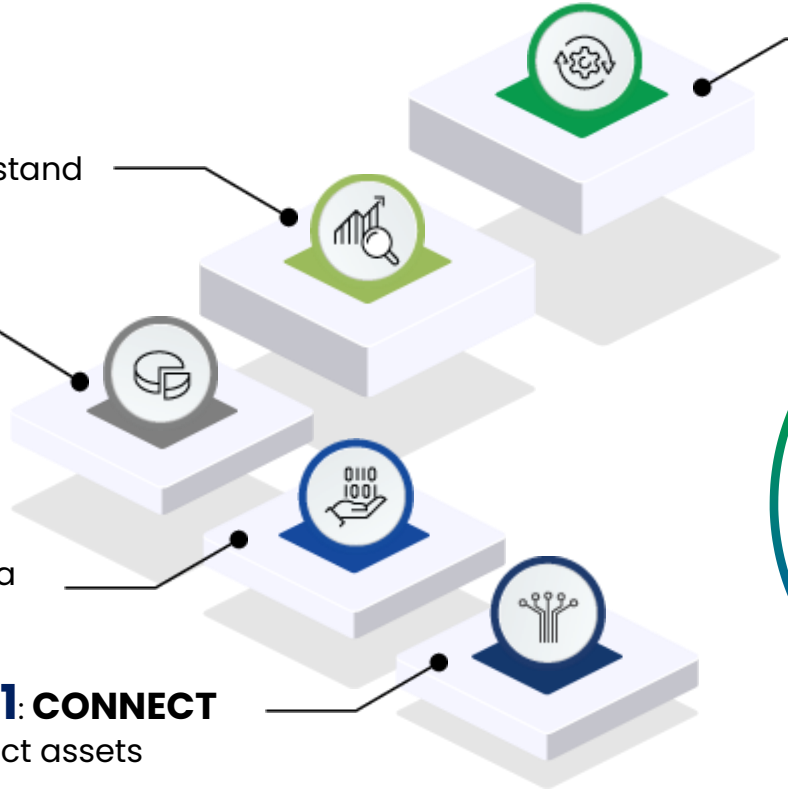
STEP 5: AUTOMATE
- Operators are like aircraft pilots

STEP 4: ANALYSE
- Improve and understand

STEP 3: VISUALISE
- Use dashboards

STEP 2: COLLECT
- Production & quality data

STEP 1: CONNECT
- Connect assets

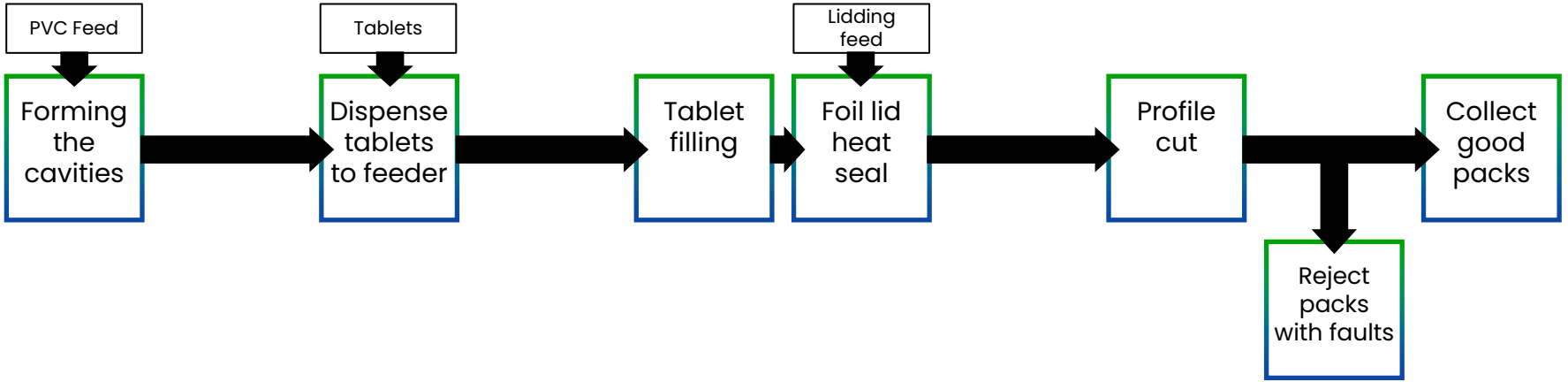


Many companies have only just started to connect assets

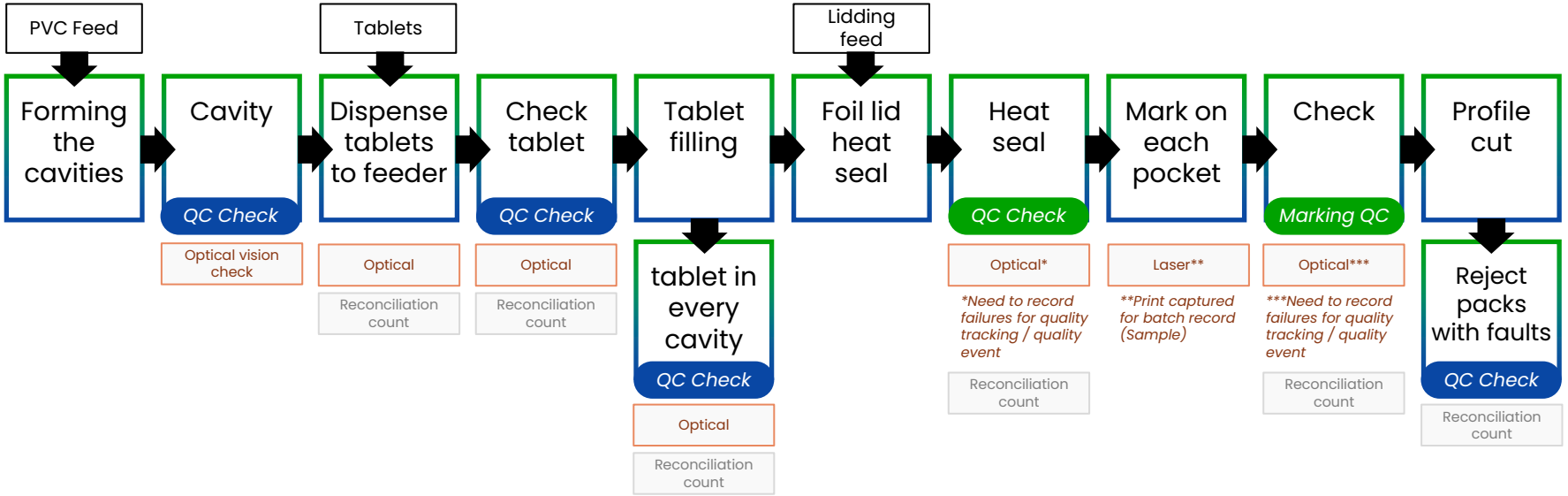
Use Case Example

This use case is an automated tablet packing line with robotic filling of tablets into pre formed pockets with heat sealing , on line printing and automatic checking of all operations. Digitalisation is built in to collect and visualise all the critical data

Tablet Packing Process



Tablet Packing Process & Critical Checks



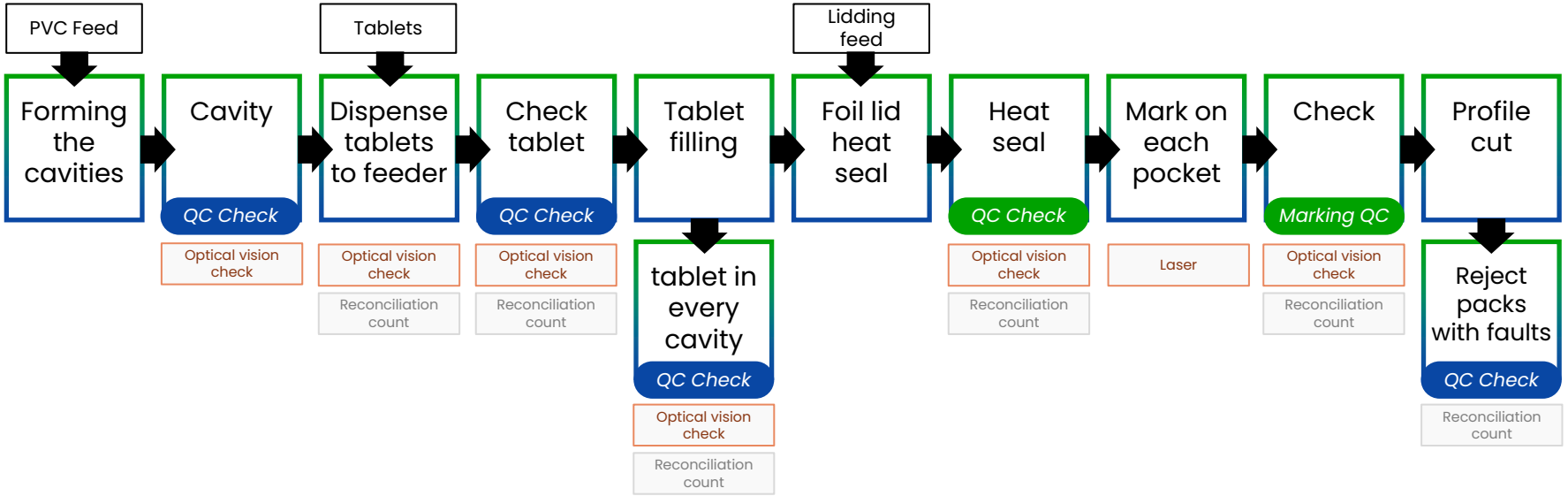
QC Check

- The Validation checks ensure that the QC checks are working and that any faults are rejected at the reject station. The batch record does not need to know about these faults.
- Efficiency / predictive maintenance does need to know about these faults.

QC Check

- QC checks are quality events and do need to be recorded in the batch record

Tablet Packing Process & Tech Solutions



Raw material management

Work instructions for line clearance

Work instructions for raw materials

Collection of data from the optical checks including reconciliation count

Work instructions for line problem or stoppage

Continuous display of production & reconciliation count

Work instructions for line clearance

TULIP No code Applications

Batchline Electronic Batch Record

Tulip ‘No Code’ Manufacturing Solution

- No code manufacturing applications (Apps) are now available which provide a configurable manufacturing platform that connects people, sensors and machines
- Engineers can create Apps to guide operators and record the data from the process in real time.
- Apps can easily connect to sensors on the line to collect data.
- The data can be displayed and/ or transferred to other systems.
- In this use case data can be transferred to the electronic batch record

Batchline Electronic Batch Record

BatchLine entirely digitises production including creating processes, recipes, master batch records (MBR's), and product specifications. The system guides operators through the process with digital work instructions. There are device integrations via IoT. The system provides quality review and approval of the batch electronically (review by exception), and batch record reporting and retention.

The GMP record includes:

- Issue of batch number & expiry date
- Raw material identification and status
- Change parts identification & status
- Line clearance
- Set up tests which check the QC checks and line speed
- Reconciliation, number started, rejects, number completed
- Printed information
- Any major failures eg heat seal or printing recorded as quality events
- Final approval by QA

Summary

We have talked about a use case for an automated tablet packing line designed by the Manufacturing Technology Centre (MTC)
https://www.the-mtc.org
This is part of the Digital Manufacturing Accelerator (DMA) project.
This shows how digitalisation is built in to allow full automation of the operation and collection of data.

The DMA is an initial 10-year partnership between the Liverpool City Region Combined Authority and the MTC to invest in and develop UK manufacturers and their workforce to successfully build global competitiveness.

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