# Workshop to explore accelerated adoption of automation and digitalisation within Medicines Manufacturing

Innovate UK KTN in collaboration with the Advanced Manufacturing Research Centre

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# Overview

There are a number of reasons why automation and digitalisation are needed within Medicines Manufacturing in the UK.

- To improve efficiency and remove bottlenecks
- To support in process monitoring controls
- To support data analysis
- To combine and use data and metadata
- To gather information from across the supply chain

However, despite these opportunities the UK continues to lag behind other countries in the deployment and utilisation of automation and digitalisation.

To understand why this is the case, and to explore how the sector can take on board ideas and technology from outside of the field, an in-person workshop was held at the AMRC North West on the 30th March, where attendees from 20 organisations involved in Medicines Manufacturing explored robotics and automated systems in the development space, using KTN's Digital Maturity Framework as a benchmark to understand companies' current position, where they would like to progress to, how they can move forward, and where further intervention or investment is needed.

The following report summarises the workshop's content and outcomes. You can also watch a short video from the workshop [here](#).

This was a follow-on workshop from a virtual stakeholder consultation event, held in February, where over 40 individuals participated, from companies from across the industry, representing academia and industrial catapults. This event identified a number of key areas for further attention, including Integration and interoperability; Data and Skills. A summary report of this event can be found [here](#).

# Key considerations

When considering barriers to the adoption of new technologies, the Advanced Manufacturing Research Centre (AMRC) groups these into nine different areas.

1. Legacy infrastructure
2. Departmental silos
3. Lack of internal talent
4. Scale
5. Invisible/unpredictable return on investment
6. Risk aversion
7. Insufficient budget
8. Organisational acceptance

# Legacy infrastructure

The medicines manufacturing sector is a mature sector within the UK and this means many organisations are built on legacy infrastructure, both in actual manufacturing capabilities but also digital infrastructure and interfacing between the two.  In many cases, there is no strong driver within businesses for investment in new manufacturing or for the development of new technology.  As the medicines manufacturing sector is mature, for many businesses processes work (albeit not at peak efficiency) and therefore there is no driver for change.

This legacy infrastructure means adopting new technologies is difficult to implement in a cost-effective manner.  Especially without significant downtime to existing manufacturing schedules.

There needs to be a move away from existing ways of working using legacy infrastructure to embracing and implementing modular systems which enable flexible working approaches as skills change.  There is also an opportunity for the sector to engage with education providers to help shape the skills sector to help embrace and drive this change.

Overarching this, there is a requirement for a workflow schedule which is able to integrate and control with all systems and then a robust data architecture supporting the entire digital frameworks.

## Departmental silos

Within the medicines manufacturing sector, many silos exist both within organisations and between different aspects of the sector.  Research and development and manufacturing for example may exist within the same organisation or may be spread between two organisations which may not be co-located geographically.

These silos pose issues with implementation of digitalisation and automation as the same equipment may not be used between different silos.  These problems exist not just between silos, but also at times exist within the same organisation where systems are unable to be utilised to their full potential between sites of an organisation or even between functions within the same site.

Standardisation and integration flexibility is therefore necessary to enable the transition between R&D and manufacturing to be conducted smoothly. This standardisation/flexibility is also necessary to enable the development of a digital maturity framework, toolboxes and guidance specific to the sector.

## Lack of internal talent

The medicines manufacturing sector is a mature sector within the UK and this means many organisations are built on legacy infrastructure, both in actual manufacturing capabilities but also digital infrastructure and interfacing between the two.  In many cases, there is no strong driver within businesses for investment in new manufacturing or for the development of new technology.  As the medicines manufacturing sector is mature, for many businesses processes work (albeit not at peak efficiency) and therefore there is no driver for change.

### Senior staff sometimes lack digital skills

Throughout many levels of seniority, the sector is lacking in people who understand both the opportunities and skills needed to move forward with the deployment of digital and automation within medicines manufacturing.  This prevents organisations from planning ahead, understanding the direction of travel and adapting to these new challenges and opportunities.

The lack of internal talent also prevents the formation of digital champions within organisations who horizon scan for new disruptive technologies.  This also prevents the sector from attracting new talent to the sector and being attractive to digitally aware applicants to fill roles.  Providing them with career development opportunities and salaries to reflect the skill set they bring to these roles.

For many organisations, a top-down approach is employed - whereby junior staff are trained or mentored by more senior staff.  Embracing a different bottom-up approach can help disseminate new technologies and digital skills and empower organisations to seriously consider prioritising digital skills and technologies within their workforce.

**Attracting and retaining the right talent**

Organisations therefore are needed to attract and retain people who understand the digital landscape and enable them to be vocal about the opportunities there are out there. These digital champions should have the authority and trust to map and scope out a path for digital development both within the organisation and across the sector as a whole. However, currently, people with the skills and seniority are lacking in many organisations across the sector.

As a sector, there needs to be a real drive to attract the right people. Whether they are from a scientific background with an interest in digital skills, or alternatively from a digital background with an interest in science. The sector has to be attractive to these people to make them want to work in this area but also stay in this area. This attraction has to be not just be financial, but also provide opportunities for growth and development within an organisation.

**Shaping the curriculum to include digital skills**

The skills pipeline also needs addressing. Industry needs to work closely with education providers to explain their requirements and help shape the curriculum to equip young adults with the skills required to enter this sector. This also requires engagement with academics and individuals across the STEM and digital sectors who understand that digital skills are important and use these more widely.

By engaging with people who understand both the science, processes and how digital infrastructure/automation can enhance medicines manufacturing, the sector is able to shape education and highlight the needs and opportunities of the sector more broadly. People such as STEM or digital ambassadors provide an existing network without the need to start from scratch.

# Scale

The medicines manufacturing sector as a whole is broad, and the outputs and products manufactured are increasing in both the number and complexity of products as new innovations come through Research and Development and into the clinic.

Across the sector, many organisations are of the opinion that this scale and diversity of products impacts the ability to deploy automation and digitalisation because products are bespoke either for an individual product or product type. The scale of the market and the fact that product types are evolving means that flexibility in automation and digital opportunities is important to enabling the sector to maintain a competitive advantage internationally. This is where modular approaches and/or platform technologies pose a huge opportunity for the sector to build scalability and future-proofing capabilities. An example of this can be found in the following [video](#).

## Invisible/Unpredictable Return on Investment

For many organisations, the largest barrier to adoption is understanding what opportunities are out there and how these may benefit their organisation both directly and indirectly.

One of the problems with understanding opportunities is confidentiality/Intellectual Property (IP). Many organisations are reluctant to share what they are doing within manufacturing, systems they use which give them a competitive advantage etc. This secrecy surrounding systems and IP mean that suppliers of equipment are unable to share knowledge or case studies meaning people do not know what is out there and what opportunities there are. But what actually constitutes IP is also a grey area - is this a product or is this the manufacturing process to make the product itself?

Due to this reluctance to share and work across the sector, there is limited data to support models or to support change. Communication between businesses is preventing the sector as a whole from moving forward as organisations remain reluctant to share what they have done, share data or process models to highlight where common bottlenecks exist or where efficiency improvements could be realised across similar organisations.

This data also limits the ability to demonstrate what is possible and for other organisations to build a business case for change. As a community a national resource of datasets or case studies demonstrating what is possible in a non-proprietary way would benefit organisations from across the sector.

# Risk aversion

As an industry, there seems to be a high aversion to risk - though the level of risk aversion is not consistent through the supply chain as there are clear differences between organisations in the discovery space compared to those who are within the contract manufacturing space. This most likely stems from the highly regulated environment that organisations find themselves working in. As such, this aversion to risk may be one of the causes hampering the deployment of new technologies. In turn, this prevents the evolution of organisations from having a 'digital champion' within them pushing for automation and digitalisation.

The competitive nature of the industry also means that there is a real lack of sharing successes and highlighting failures individual organisations have faced on their own journey. This in turn fuels a lack of understanding of the priorities across the sector and also means many organisations lack the tools and knowledge required to perform proper gap/risk analysis when looking at new technologies to deploy.

The lack of drive to harness new technological developments also feeds into the regulatory space and so becomes a chicken and egg situation. Regulators scrutinise the processes presented to them by organisations, however organisations therefore feel they are unable to work outside of the normal toolkit. The Medicines and Healthcare products Regulatory Agency Innovation Office and the FDA are keen to engage with parties at an early stage and be part of the 'innovation journey', therefore the sector as a whole should work together to drive this change.

For companies to change the regulatory environment to enable digital infrastructure to play a larger role they need to champion this change rather than waiting for it to happen. A bolder approach is therefore needed which engages both industry and regulators to forge a path ahead to investigate, analyse and deploy new technologies. For digital innovations to be properly realised, engagement with these organisations requires a culture shift in how the industry works.

# Insufficient budget

Compared to other countries, the UK fiscal, tax and planning legislation may play a role in the reason why organisations are slow to implement digitalisation. For many organisations there is a need for investment both in terms of the cost of capital to deploy physical hardware/infrastructure and also in terms of training new employees to utilise new technology.

Investment in both is key for the industry to evolve and utilise automation and digital technologies more widely. Organisations should commit sufficient time for a whole process/business cost/gap analysis. By modelling processes in depth with enough detail, they are then able to truly understand where digital needs can best support change within the organisation. The UK should therefore not be complacent in the need for both to help capitalise on the world leading research and skills the UK has to offer. Organisations which invest early in both digital technologies, automation and training/upskilling would reap the benefits sooner rather than waiting for government support.

An example of this is Moderna which employs a digital first approach to the deployment of technology of this type. The success of the organisation has been linked to the ability to build a company from the ground up which has digital technology at the heart of the operations. Further examples within the biotechnology/medicines manufacturing sector demonstrate the benefits that technology can have for an organisation.

# Organisational acceptance

For many organisations, there is a real drive to embrace new technologies, but there is also at the same time a lack of understanding as to what priorities are. Organisations can see the direction of travel and believe they have an understanding of what they want to achieve but lack an understanding of the priorities, gaps and risks.

This may be institutional - with individuals within an organisation lacking the understanding of what digitalisation could do for their business.  Alternatively, it may be sectorial - with many organisations concerned about things such as job losses or lack of flexibility/agility.

More transparency therefore is needed to share ideas, what has worked and what has not when implementing a digital implementation strategy and why decisions were made and the impact these had on the business.  It is also important to engage with others across the sector such as supply chains to ensure that changes made benefit the entire supply chain as well as the individual organisation deploying it.

Organisational acceptance is changing and this across the sector may be accelerated further by external factors such as the drive for environmental sustainability or external geopolitical headwinds that the world faces.

## Take home messages

Organisations across the medicines manufacturing sector need to start working on digital transformation now as the UK is lagging behind other countries and could slip further behind if action is not taken soon.

Initial steps which should be undertaken begin with an in-depth gap analysis within an organisation which feeds into formulating a digital transformation roadmap.  Identifying individuals within an organisation to champion digital transformations.  Properly understanding the long-term cost/benefit analysis as well as reaching out for partnerships and learning from other sectors.

Across the sector having open dialogue will foster better understanding of capabilities and gaps as well as share ideas without compromising intellectual property.  Organisations should be open to sharing and demonstrating use cases of deployed automation and robotics in an industrial environment.

Research technology organisations such as the Medicines Manufacturing Innovation Centre, Cell and Gene Therapy Catapult, and AMRC play an important role in

helping the sector understand the potential benefits and applications new technologies using automation and robotics can have.