



Surprising Sustainability Benefits of Electronic Batch Records

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FUJIFILM Diosynth Biotechnologies

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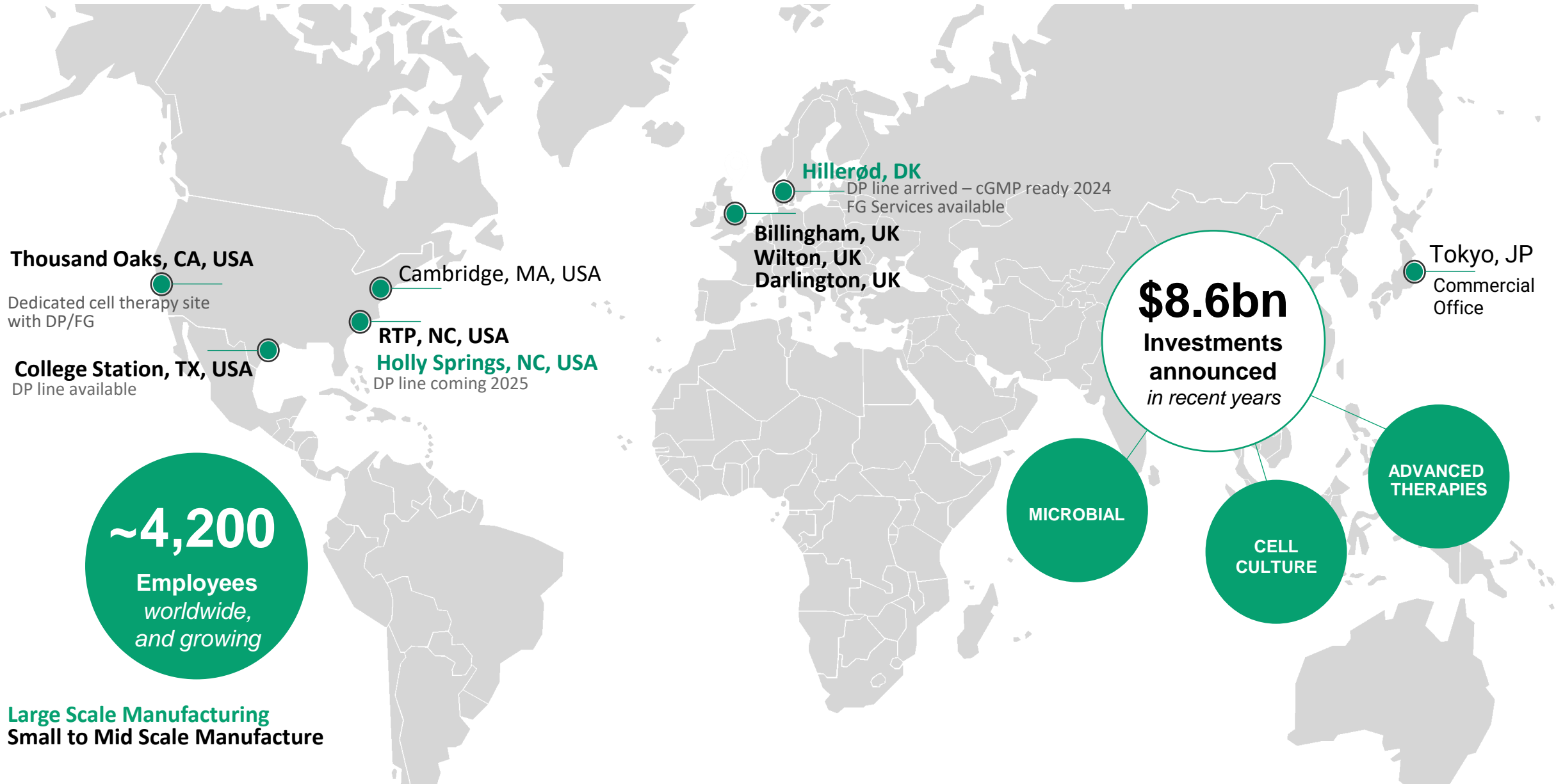


Our Purpose

Partners for *Life* Advancing tomorrow's medicines

FUJIFILM Diosynth Biotechnologies is a CDMO partner for life. Our focus is to combine technical leadership in cell culture, microbial fermentation, and cell and gene therapy with world class cGMP manufacturing facilities to advance tomorrow's medicines.

FDB Global Network



Partners for the Planet

We aim to be the leading CDMO setting the standard for sustainable operations



Zero impacts from operations

We will pursue zero environmental impacts in our operations globally*
*Scope 1 & 2



Decarbonize the supply chain

We will reduce GHG emissions across our supply chain**
**Scope 3



Be valued partners for customers

We will partner with our customers to reduce environmental impacts and improve transparency



The Move to Digital Batch Records



Reduce GDP errors



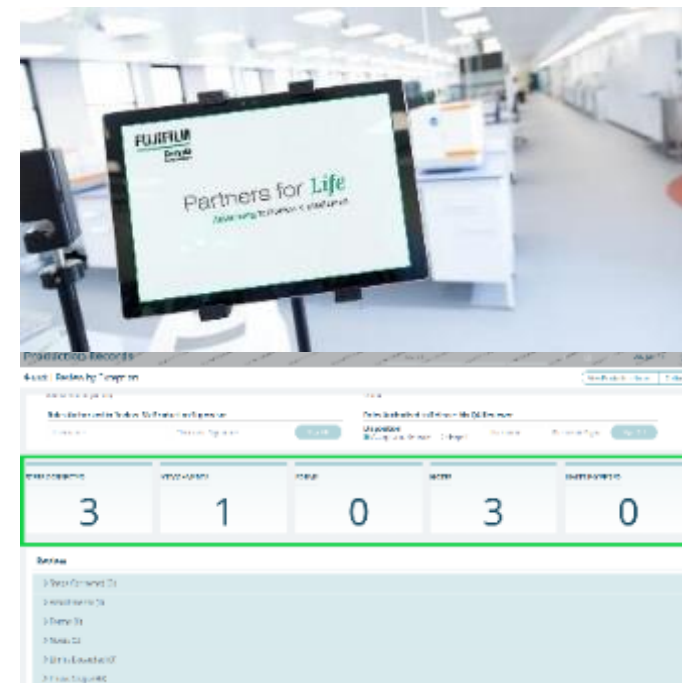
Reduce disposition time of batch records



Globally consistent batch record management



Time to focus on what's important – making life saving medicines



Batch Record Management and Execution

Previously

- Batch records are managed and archived manually requiring dedicated storage facilities
- Average of ~2500 sheets of paper per batch
- Batch record status is not readily available and **requires manual tracking**



- Risk of **loss / damage** (e.g. page rips out, liquid spills)
- Operators have to share batch record and flick pages back and forth
- Open to data integrity **errors** and **mistakes**
- Need to gown / de-gown in /out of facility for batch records increasing the **risk of contamination**

Now

- Batch records all stored in one central place in eBMR system (no physical storage required – **cloud-based system guarantees secure back up**)
- No paper used; **trees saved!** No printing costs, no time used to print, issue or transport
- Digitalization enabling **batch record status readily available** with system dashboards and metrics



- All batch records held electronically in cloud with **back up**
- Multiple tablets in suite, batch records can be **accessed by multiple people** at any given time
- **Error proofing** functionality e.g. automated calculations
- Batch records **readily available** on tablets – no need to leave facility

Benefits = Efficiencies

Improvements and reductions we will see at each of the 4 process stages.

Improvements	Process Step	Reductions
<ul style="list-style-type: none">↑ Sustainability↑ Templating	eBMR Creation	<ul style="list-style-type: none">↓ Paper & plastic use↓ BMR variance↓ Tech Transfer time
<ul style="list-style-type: none">↑ Efficient manufacturing↑ Simplified data input↑ Accessibility/Availability↑ Automated inputs	eBMR Execution	<ul style="list-style-type: none">↓ Repetitive manual tasks↓ GDP/DI errors↓ Risk of BMR loss/damage
<ul style="list-style-type: none">↑ Compliance↑ BMR Readability↑ Reporting/Analytics↑ Review by Exception↑ Visibility of disposition status	eBMR Review	<ul style="list-style-type: none">↓ Observations from FDA/MHRA↓ Disposition time↓ Events/Deviations↓ Searching times
<ul style="list-style-type: none">↑ Customer experience↑ Customer confidence↑ Customer satisfaction	Customer	<ul style="list-style-type: none">↓ Time to receive data↓ Time to review data

Improvements

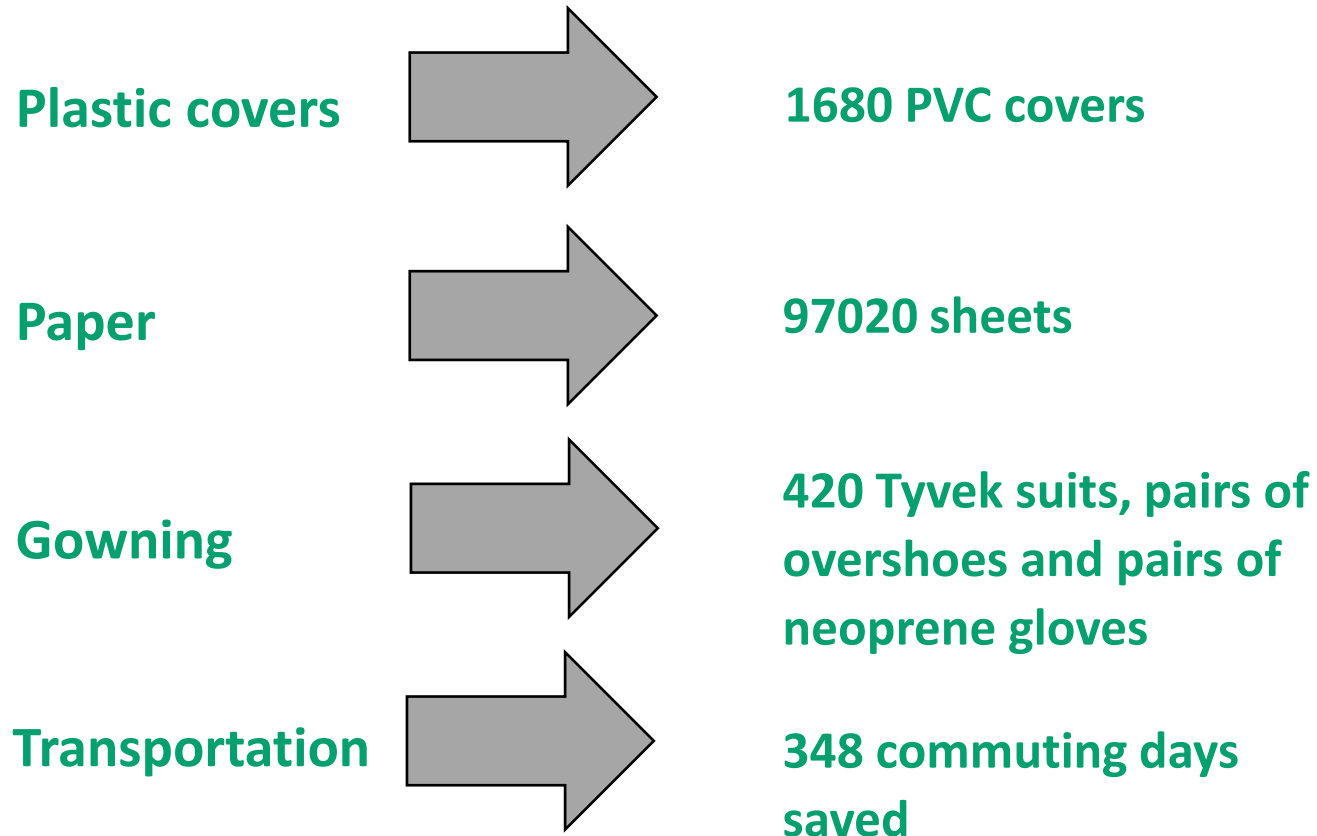
Reductions

Globally Consistent Ways of Working

- One FDB – allowing customer programmes, templates & learning to be shared globally

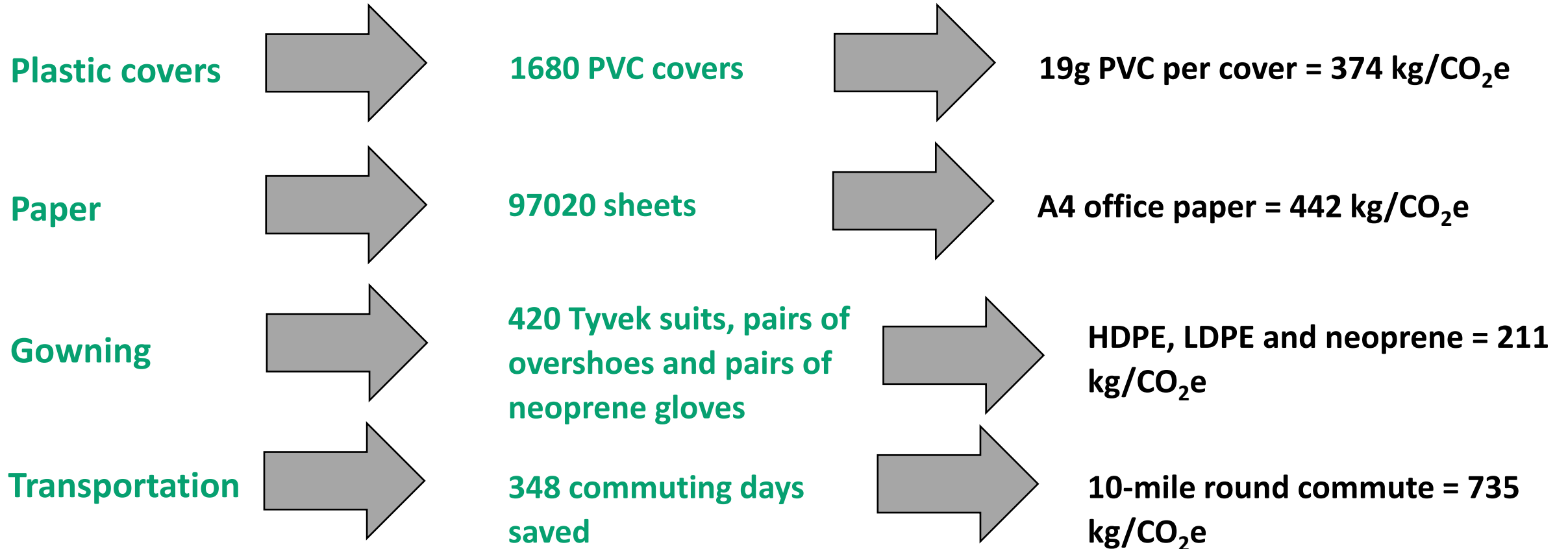
Sustainability benefits

Below are demonstrated benefits from eBMRs in FDBK MCC only, based on **1 year's manufacturing**



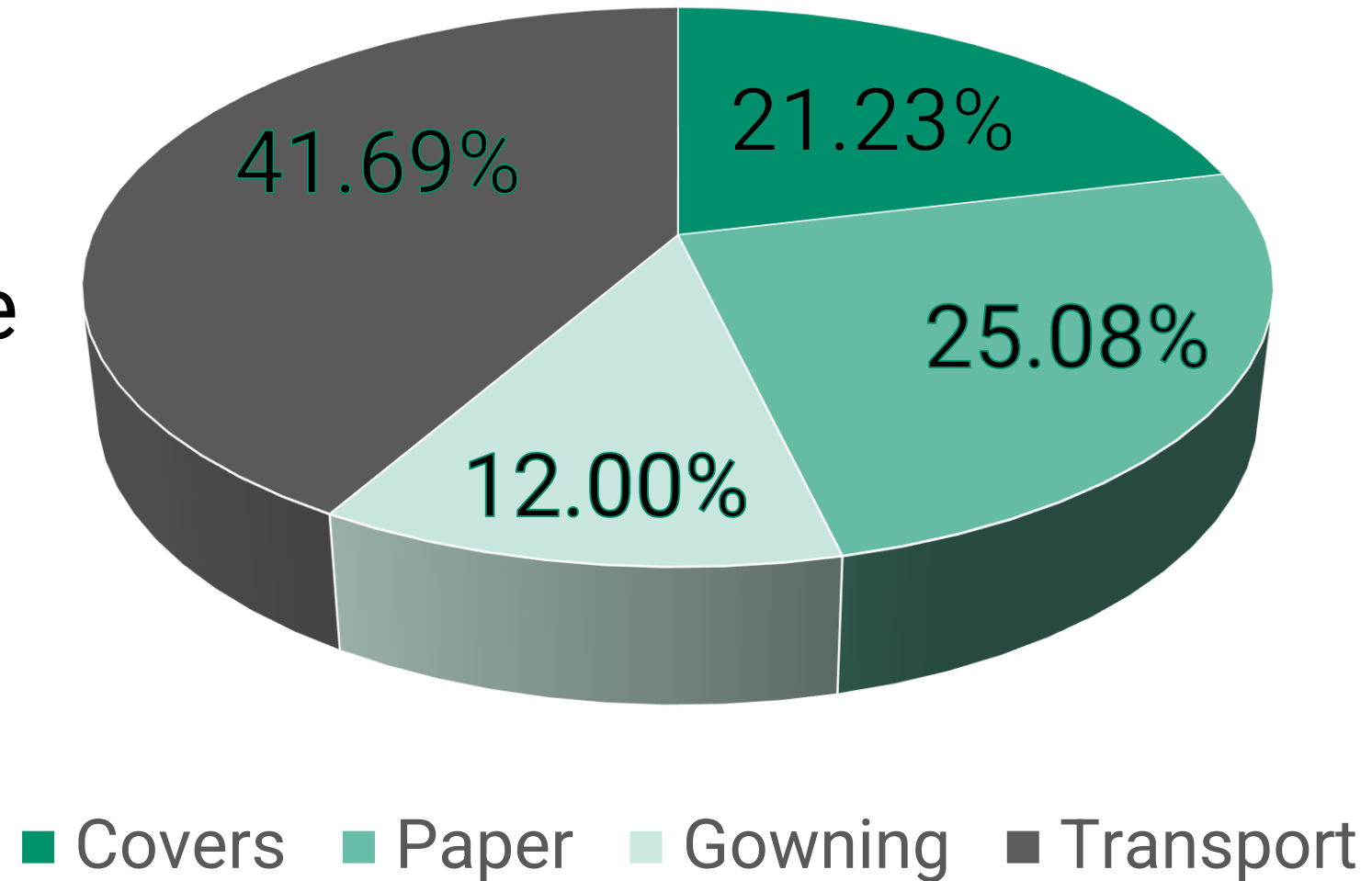
Sustainability benefits in CO₂e savings

Below are demonstrated benefits from eBMRs in FDBK MCC only, based on **1 year's manufacturing**



Annual Emissions Savings for MCC

1.76 tonnes CO₂e
per year saved



An aerial photograph of an industrial and commercial district. In the upper left, a large green field is visible. Below it, a large white industrial building with blue accents is under construction or recently completed. To the right of this building is a large parking lot filled with cars. Further right, there are several other industrial buildings of varying sizes, some with flat roofs and others with more complex structures. A road with a roundabout is visible in the lower left. The overall scene depicts a busy industrial area with a mix of developed and undeveloped land.

Rollout across other assets

2025 - further 6.6 tonnes CO₂e per year saving realised when rolled out to all Microbial assets

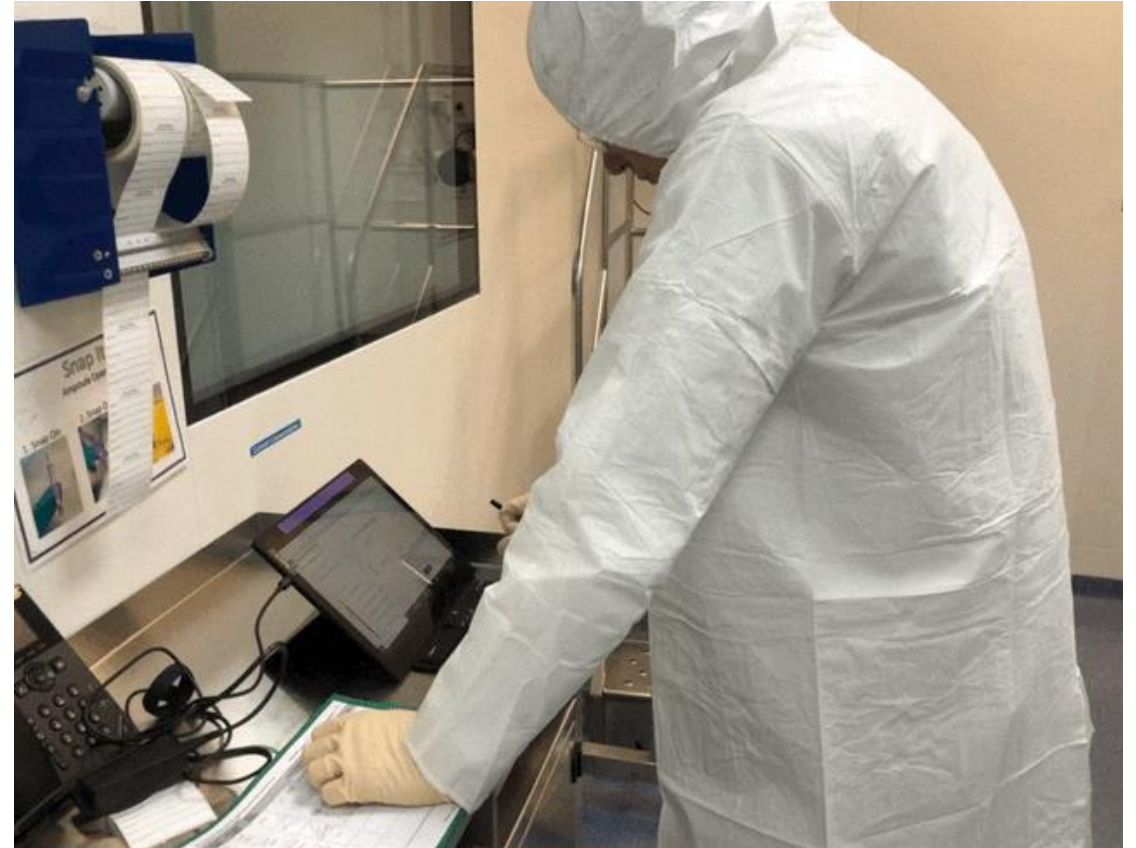
Impact of electronic tablets

MCC:

Lenovo Thinkpad X1 =
462kg CO₂e per tablet

Microbial assets:

Microsoft Surface Pro =
196kg CO₂e per tablet





Conclusions

- ① Sustainability impact of batch record digitalisation project (and potential future gains) have only now begun to be realised/fully understood
- ② Single decisions such as model of tablet, can have a huge impact on a project when viewed through carbon footprint lens
- ③ Many assumptions are required to estimate CO₂e but suppliers are beginning to provide useful data to help with decision making
- ④ 'Hidden' factors such as commuting miles saved can have a large impact

