



**CMAC**  
FUTURE MANUFACTURING  
RESEARCH HUB

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## Microfactory

Digitally enabled, integrated  
end-to-end processing



**EP SRC**

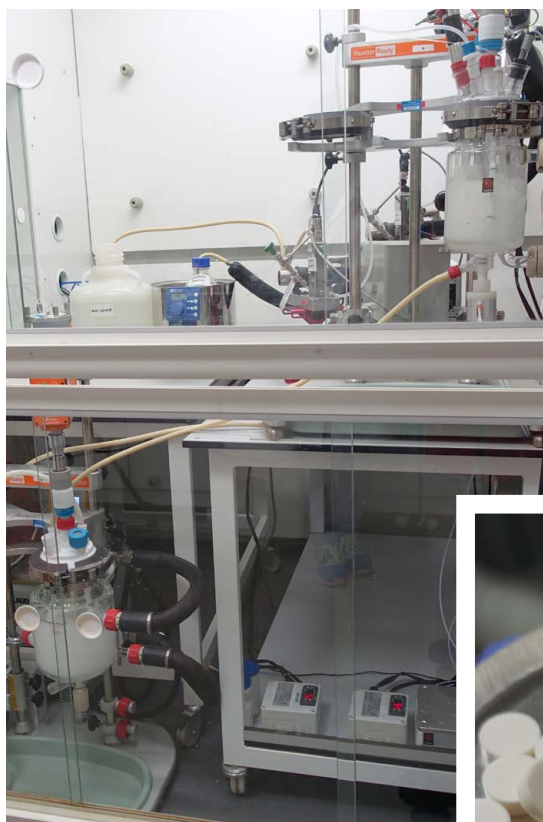
Engineering and Physical Sciences  
Research Council

# Microfactory

CMAC's vision to transform medicines manufacturing requires development of innovative, modular, integrated continuous manufacturing processes for drug substance and drug product. The end-to-end modular lab scale microfactories are being developed within the Hub to provide a rapid prototyping capability to control, measure and optimise critical transformations across multiple length-scales spanning crystal and particle engineering, structured product and dosage form generation; managing variable material properties and increased product complexity.

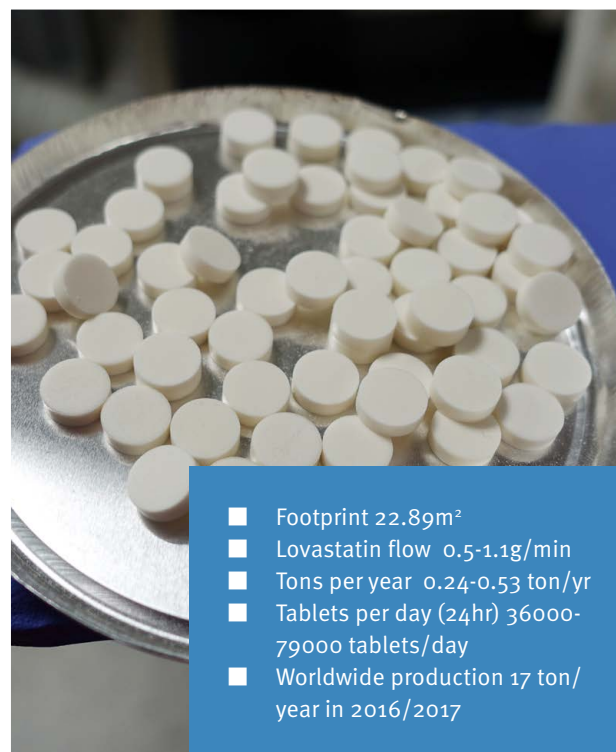
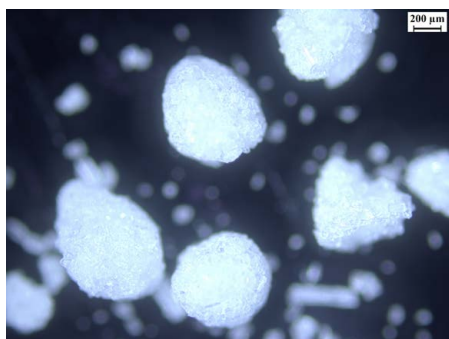
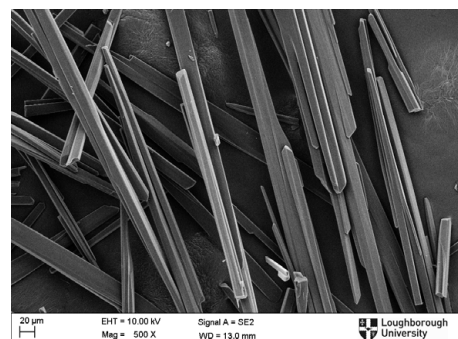
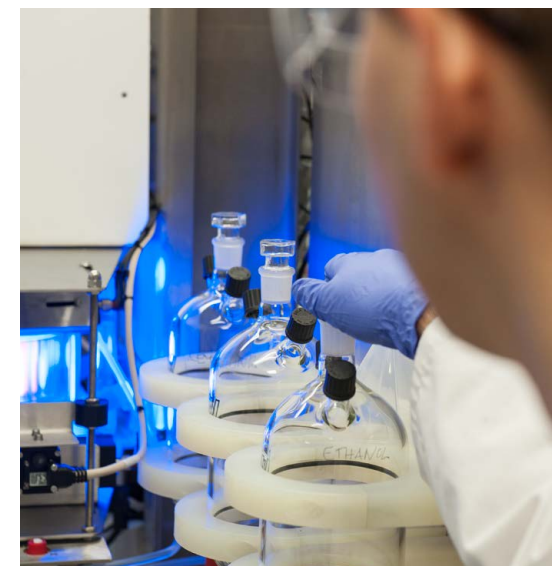
## Future Microfactories for Performance Based Manufacture of Functional Products.

Input from the integrated predictive development pathways, also being developed within the Hub, are used to design, build and operate flexible, integrated continuous manufacturing process chains at scale (kgs/day).



A key deliverable is to enable the simplified process chain targeting the processes and transformations that improve manufacturability of the drug into a dosage form suitable for performance in the patient. By developing integrated continuous direct to dose approaches we avoid multiple unit operations and scale up steps.

One recent example of such a microfactory has been designed to overcome the handling and manufacturability issues for compounds with a needle-like morphology, due to issues such as poor flowability and low bulk density. The exemplar material used in this case is Lovastatin.



- Footprint 22.89m<sup>2</sup>
- Lovastatin flow 0.5-1.1g/min
- Tons per year 0.24-0.53 ton/yr
- Tablets per day (24hr) 36000-79000 tablets/day
- Worldwide production 17 ton/year in 2016/2017

This microfactory has been developed to combine and integrate continuous operations, which have for the first time enabled direct compression of lovastatin. This is in contrast to traditional approaches that would have required an additional wet granulation step prior to compression. The research team addressed challenges presented by needle-like morphology by introducing a spherical agglomeration stage into the process chain.

In fact the process that was demonstrated at the CMAC Open Day 2018 integrates the crystallisation, spherical agglomeration, isolation and drying steps into a single unit operation that can feed into the secondary processing operations. Optimisation of scale, solvent selection and equipment from separate unit operations into an integrated process was important for creating the final microfactory set up.