Why greener pharmaceutical manufacturing is vital for the industry and our health

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Determined to tackle the carbon footprint of medicine, CPI's Medicines Manufacturing Innovation Centre is addressing key sustainability issues in pharmaceutical manufacturing

Climate change is the most significant health threat to modern society [(1)], and the pharmaceutical industry faces sustainability challenges like every other industry. Even though much of the pharmaceutical industry's output saves and significantly improves the quality of life for billions of people, this cannot come at any cost to the planet. Recently, health agencies, such as the NHS, have set ambitious net zero targets, and as medicine accounts for 25% of NHS carbon emissions, the pharmaceutical industry has a crucial role to play in tackling this threat. [(2)]

CPI's Medicines Manufacturing Innovation Centre has a mission to revolutionise pharmaceutical manufacturing through the development of innovative new technologies. It uses its 'Grand Challenge' model to de-risk pharmaceutical manufacturers' adoption of these technologies. By integrating emergent technologies into production processes, companies can reduce their environmental impact and create more sustainable drugs.

Making Medicine

The most obvious component of medicine's carbon footprint is the energy and materials used in pharmaceutical manufacturing. Pharmaceuticals are highly complex, precise molecules formulated carefully to deliver a safe and effective treatment. Consequently, significant quantities of materials are consumed in the manufacture of medicinal products.

To tackle these issues, drug developers are exploring greener chemistry: Substituting solvents, optimising process conditions to reduce waste and increase yield, using renewable energy sources, and using reagents that are less hazardous to the environment. They are also focusing on digital solutions to transform product development.

In Grand Challenge One, we are transforming how we make oral solid dosage medicines (OSD) by developing a novel digitally twinned continuous direct compression (CDC) platform. OSD products dominate the global market, with a 53% share reported in 2021. [(3)] CDC offers several advantages to tablet manufacture when compared to traditional batch manufacturing techniques:

- 60-70% Reduction in Facility Size [(4)]
- 30-50% Reduction in Manufacturing costs [(5)]

- 69% Reduction in Energy Consumption [6] (environmental benefit)

When Janssen switched an OSD product from batch to continuous manufacturing, [7] they reported a 70% reduction in manufacturing footprint and a two-week production time reduced to one day. [8]

CDC is, therefore, a truly flexible way to manufacture tablets. The ability to adapt the production output to meet the demands of the current market supply, rather than a predicted forecast, eliminates waste and results in a lower environmental footprint.

Grand Challenge Three targets production of oligonucleotides, one of the most exciting emerging patient treatments. With the ability to target previously 'undruggable' diseases, they are moving from limited application in rare diseases to chronic conditions affecting millions. However, the pharmaceutical manufacturing process is complex, challenging and consumes vast quantities of solvent. At the Medicines Manufacturing Innovation Centre, we are working with innovators, academics and industry to develop and industrialise technologies to reduce or, more radically through biocatalytic approaches, eliminate the use of organic solvents in oligonucleotide manufacture.

Developing medicine

The average time for a drug to reach the market from concept is 10-15 years [9] and includes multiple stages from discovery and development, preclinical research, clinical trials, and regulatory approvals. Developing a robust and reliable manufacturing process is critical prior to the launch of a product. However, process development is extremely complex and resource-intensive. The average cost of bringing a typical drug to market is estimated to be £1.15bn, [10] and nine out of every ten drugs that start Phase I clinical trials are never approved for patient use. [11]

Consequently, manufacturers face a continuing dilemma about the amount of resources and effort to put into process optimisation throughout the development of a new medicine. Too much effort too early can be wasted if the drug experiences problems in clinical trials. However, delaying development can lead to the risk of either delaying product launch or launching with a sub-optimal process that can cause reputational damage to the product. Using digital twins to accelerate process development and create a more effectively controlled manufacturing process is one option to shorten process development time and de-risk the development of a robust supply chain. Digital twins can help focus process development on the areas of highest uncertainty and de-risk equipment choices, allowing more timely capital investment decisions. Grand Challenge One has developed a digital twin for continuous tablet manufacture. Studies estimate that an effective digital twin can reduce the process development burden by around 70%, introducing significant resource savings and reducing the carbon footprint of process development.

Medicine supply chain

Medicine supply chains are complex, involve multiple locations, and can be inefficient. Unused medication accounts for significant waste within the NHS, estimated at 300 million annually. [12] The problem of waste is particularly acute in supply chains supporting clinical trials.

By their experimental nature, clinical trials are unpredictable. Many factors influence the course of a clinical trial from rates of patient incorporation at different trial centres to changes to trial design in response to clinical data. The problems that this unpredictability creates are that, unless the pace of the clinical trial is slowed, supply chains cannot respond quickly enough to the changes in demand, meaning significant material is prepared at risk and consequently wasted when not needed for the trials or when it expires. It is estimated that around 50% of the material prepared for clinical trials is wasted. In Grand Challenge Two, we are developing innovative approaches to clinical trial supply, breaking paradigms on how a packing line can be operated and digitising the batch release process to allow very small batches of product to be manufactured without overwhelming the quality system.

Pharmaceuticals have transformed society and will continue to impact human quality of life in the future positively. However, the benefits of drugs must be balanced with their effect on the global environment. There are multiple opportunities for innovation to improve the sustainability of pharmaceutical production and supply, and the work at CPI's Medicines Manufacturing Innovation Centre is turning opportunities into reality.

References

1. https://www.rpharms.com/recognition/all-our-campaigns/policy-a-z/pharmacys-role-in-climate-action-and-sustainable-healthcare
2. https://www.rpharms.com/recognition/all-our-campaigns/policy-a-z/pharmacys-role-in-climate-action-and-sustainable-healthcare
3. https://www.futuremarketinsights.com/reports/oral-solid-dosage-pharmaceutical-formulation-market
4. https://www.businesswire.com/news/home/20151029005733/en/Pfizer-Announces-Collaboration-GSK-Next-Generation-Design-Portable
5. https://www.novartis.com/stories/new-drug-manufacturing-tools-change-pharma-chemistry
6. https://spider.science.strath.ac.uk/cmac_new/Business_Case_Insights_for_CM.pdf
7. https://www.janssen.com/belgium/continuous-manufacturing-improved-production-process
8. https://www.europeanpharmaceuticalreview.com/news/62587/ema-continuous-manufacturing/
9. https://lifesciences.n-side.com/blog/what-is-the-average-time-to-bring-a-drug-to-market-in-2022
10. https://pharmaceutical-journal.com/article/feature/drug-development-the-journey-of-a-medicine-from-lab-to-shelf
11. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9293739/#:~:text=However%2C%20nine%20out%20of%20ten,and%20drug%20approval2%2C3

12. https://www.mysurgerywebsite.co.uk/website/M85097/files/NHS7662_Medicine_Waste_Leaflet_4[1]2013.pdf

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CPI's Medicines Manufacturing Innovation Centre
CPI connects the dots within the innovation ecosystem to make great ideas and inventions a reality. We're a pioneering social enterprise that accelerates the development, scale-up and commercialisation of deep tech and sustainable manufacturing solutions.