The role of standards

The speed at which new products of the cell therapy and biopharmaceutical industry arrive on the market could be increased by wider adoption of DFM principles. The challenge now is to establish how standards development organizations, such as BSI, can be instrumental in enabling the industry to improve its DFM practices. BSI has already published a number of standards to enable DFM in the mechanical and electrical sectors, which provide the designer with a framework for the selection, preparation and presentation of documentation to transfer the design concept into the manufacturing environment, which in turn has enabled major leaps forwards in the industry in terms of more efficient processes and reduced waste. A natural step is to apply this philosophy to the design of high quality, repeatable cell therapy manufacturing processes.

The framework for standards for cell therapy manufacturing would intend to:

- Improve the probability of success by enabling product developers to design higher quality and more repeatable manufacturing processes;
- Increase the number of cell therapy products available on the market, and decrease the time taken to get there;
- Reduce the investment costs required to successfully launch a product to market.

The first standard to arise from this framework will be PAS 157, which guides users in making better choices when selecting raw materials, thus resulting in more repeatable cell therapy manufacturing processes. The types of topics that could be considered for standards development to further enable better process design include:

- Best practice to underpin QbD principles
- Targeted analytical standards that address the safety and efficacy attributes of the specific cell under development
- Standards that enable the physical process elements to be more flexible and redeployable, perhaps through the development of 'plug-and-play' capabilities.

A framework for standards to support innovation in cell therapy manufacturing

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Timely, consensus-based use of standards plays a vital role in ensuring that the knowledge created in the UK's research base is commercialized and brought to market as well as playing an important role in driving innovation. Innovate UK is working with BSI, Research Councils and Catapults to establish new standards earlier in the development of new technologies and services.

We are collaborating in four emerging areas to define standards that will accelerate the development of those technologies and services; and provide UK businesses with a competitive "first mover advantage":

- Synthetic biology
- Cell therapies
- Assisted living
- Offshore renewable energy

The four technologies are at different stages of development and face different challenges in their commercialization. All four technologies are internationally competitive areas, and it is important that the UK creates successful capabilities quickly.

BSI is the UK National Standards Body, and is responsible for developing British Standards and related publications that serve the interest of a wide range of stakeholders, including Government, business and society. BSI represents the UK view on standards in Europe, and internationally (ISO and IEC), and has a globally recognized reputation for independence, integrity and innovation, ensuring standards are useful, relevant and authoritative.

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Introduction

The medicines industry has seen a decline in the output of new drugs emerging from its R&D programmes over the last few decades. This decline is in direct contrast to the rise in R&D productivity experienced by the semiconductor industry through following Moore's Law, which has led to the coining of the phrase 'Eroom's Law' ('Moore' spelt backwards) to describe what is occurring in the medicines industry.

The development of standards in the semiconductor industry has been a critical factor in this rise in productivity, particularly those under the industry trade association, SEMI, which developed a wide range of standards, particularly with regards to silicon wafers, automation and computing. In the 1970s, standardization of silicon production led to higher productivity due to increased specialization from the development of specialist silicon suppliers and a longer supply chain. Since then, further specialization through the development of standards has enabled significant productivity growth, a trend the medicines industry could follow.

A paper by Griffiths demonstrates how these innovations critically depended on the implementation of the right standards

Innovation

Innovation in manufacturing systems, such as lean production and time-based manufacturing, has contributed to improving productivity since the industrial revolution through increased efficiencies in terms of cost or material, or responding more rapidly to changing demands. A paper by Griffiths demonstrates how these innovations critically depended on the implementation of the right standards. At the core of these innovative systems is the concept of Design for Manufacture (DFM), which is the design of the manufacture of a product to reduce costs and improve productivity. An example of best practice in this area is PD 6470, a document published in 1981 by BSI, which details how best to organize the processes involved in mechanical and electrical manufacturing to boost productivity and efficiency.

In the biopharmaceuticals industry, a major manufacturer, Lonza Biologics, highlighted in their published papers the lack of good practice in manufacturing design and how this could be improved. A key concept of theirs is 'developability', which is a risk assessment at the early stages of development that could improve the probability of success by designing products and processes with the right characteristics. Another concept that applies more broadly to the medicines industry is 'Quality by Design' (QbD), which is the idea that good quality processes are designed and planned for, a principle consistent with the values of DFM.