Standards to accelerate innovation in biological manufacturing

Dr Ben Sheridan, Market Development Manager – High Value Manufacturing, December 2013
Why does successful commercialisation matter?
Contribution of manufacturing to wealth creation

Government support for manufacturing.

- Identified 3 advanced manufacturing sectors where the UK Government could add value:
  - Aerospace;
  - Automotive;
  - *Life Sciences.*
Lessons learned from semiconductors*.  

- Number of transistors per unit area doubles every 18 months – Moore’s Law.  
- Semiconductor industry continues to be very innovative, deriving from very strong R&D productivity.  

Biological manufacturing and medicines – the problem.

- Number of new drugs per billion US$ spent is falling.
- Medicines industry has very low R&D productivity.
- This has led to a situation governed by ‘Eroom’s Law’.*

Manufacturing innovation and standards.

• Manufacturing pioneers continued to innovate:
  • Lean production;
  • Time-based manufacturing;
  • Mass customisation;
  • Agile manufacturing.

• Each of these innovations had a critical dependence on standards*:
  • Interoperability of parts and information.
  • CAD, CAM, CAV.
  • Process design.

* Manufacturing paradigms: the role of standards in the past, the present and the future paradigm of sustainable manufacturing, Brian Griffiths, Proc IMechE Part B: J Engineering Manufacture 0(0).

What do we infer from this?

• Mechanical and electrical manufacturing (MEM) disciplines have high R&D productivity rates.

• MEM disciplines have a high level of innovation that have a critical dependence on standards.

• This enables engineers to contribute to wealth creation by designing high quality and productivity manufacturing processes.

Conclusion:
• To reverse Eroom’s Law towards higher R&D productivity, we need to enable biological engineers to design better manufacturing processes with a higher rate of commercial success.

• To do this successfully will require an element of standardisation to drive innovation.
Case study – synthetic biology.

• Application of engineering principles to biological systems develop new digital biomanufacturing capabilities.

• BSI working with major UK stakeholders (including IKC) to develop UK strategy for standards to drive innovation (draft available early 2014).
Draft strategy – sneak preview.

A) Codified basis on which the synthetic biology community agrees to act
- Open innovation
- Responsible innovation
- Open access
- SBOL
- DICOM-SB (Seamless link between CAM, CAD, and CAV)

B) Consensus on the meaning and consistency of measurements
- Best practice in characterisation strategy selection
- Reference data
- Characterised biological parts

C) Selection of productive manufacturing route
- Best practice in material selection
- Best practice in process design
In conclusion.

- UK has a great opportunity to develop significant wealth from Life Sciences (includes industrial biotech biopharma, cell therapies etc.) – but this requires significant manufacturing innovation to happen.

- This manufacturing innovation requires engineers to have available better tools for manufacturing process design, and standards are a prerequisite for this.

- The UK needs a strategic programme of standards to accelerate biological manufacturing innovation – this is already happening in synthetic biology.

If you are interested – get in touch!

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