Sustainable Manufacturing: Are re-shoring, redistributed manufacture, *Industrie 4.0* and the circular economy important in the health industry?

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Materials conversion processes from extraction through to the final product in the consumer's hands are the basis for manufacturing industries. Essentially these make up manufacturing systems with nested and linked loops of materials chains. Often, waste materials from one process (e.g. Pt group metals, Te, Se and Co from the primary production of Cu) become the primary materials in other chains. This is one aspect of Industrial Symbiosis but it can be difficult to take advantage of this in lower value streams such as low-grade heat and waste products for a variety of reasons such as geographical proximity or material contamination levels.

Since the industrial revolution, materials conversion processes have tended to increase in size to take advantage of what has been called "economies of scale". The philosophy being the bigger the "process" the more cost effective and thus the cheaper the product is to make. However, most economists have worked in a linear form of production without consideration for the non-market costs of using the planets resources or of the effect of waste products on society and natural eco systems, or the limitations that resource availability sets on economies. Most models have focussed solely on product cost. With the move towards a more sustainable systems approach to materials and the circular economy business model aimed at sustainable processes the argument for "economies of scale" is not so clear and the potential of an approach along the lines of "small is beautiful" and localised production becomes more attractive (i.e. economies of scope).

All sectors in manufacturing are investigating the possibilities of sustainable closed loop manufacturing with a circular economy, and revisiting the way it views its manufacturing strategy and footprint decisions. Historic off-shoring decisions were driven primarily by a desire to reduce manufacturing costs. There are three key drivers to re-shoring and localisation of manufacturing: first; where taking a total landed cost perspective, costs are comparable and supply chain risk is reduced, second; by increasing responsiveness for more unpredictable demand, particularly for customised products, third; the development of a localised supply chain to support the development and production of innovative new products. The recent review of German manufacturing strategy, Industrie 4.0, calls for the ICT enablers' convergence of business and technological processes to herald the next generation of manufacturing. This calls for industry and academia to work in close collaboration to identify the next generation of business models that can make this a reality.

Recent developments and sustainable thinking encouraged by increasing material/energy costs and security of supply are forcing companies to re-think their strategies for materials conversions. Disruptive technologies such as Metal Injection Moulding (MIM), Additive (Layer) Manufacturing (AM/ALM) and Constrained Rapid Induction Melting Single Shot Net Shape Up-Casting (CRIMSON) are maturing rapidly and becoming realistic alternative processes that challenge the larger scale processes by offering materials and design flexibility unachievable within large-scale processes.

The pharmaceuticals industry is itself facing a patent cliff and challenges from generic medicines to the tune of \$150 B p.a. The methods being used to address this situation include reduction of inventory, improving right-first-time (from 3σ to 5σ) and reducing development costs. Pharma companies are increasingly being driven down the route of personalised medicines and thus have a requirement for highly flexible single patient batch sizes which cannot be retro fitted to existing plants. In the consumer goods manufacturing sector companies such as Amazon

Discussions with a major orthopaedic implant manufacturing company have led to a vision in which products such as knees and hips are no longer made en-mass in large plants but would be embedded within a hospital campus and with a direct link to the theatre list for procedures. Research in additive layer manufacturing and metal injection moulding has indicated that the technology challenges are being overcome. However, as well as the technical challenges there are massive changes in culture required to be able to operate like this, but there are also benefits. Business models would be affected – would the manufacturer be a major or a franchisee within the hospital using a licenced process? How would FDA approval be ensured at so many sites? There are other issues around regulation and trust form the consumer/patient perspective. If we are talking about orthopaedic implants (say) then there's a question about how patients/consumers will evaluate the likely quality of the implant. With mass production there are routine methods for quality assurance and so on – how will these issues of trust in the technology be handled in distributed systems.

Big data and machine learning based info-analytics has enabled far better use of patient data. Disruptive technologies, such as MIM, CRIMSON and ALM, could enable the supplies of medical components to be manufactured on an as required basis - similar to the concept of tailor-made and just-in-time (JIT) manufacturing. Furthermore, the latest research under manufacturing informatics could offer the possibility of bridging gaps among different user groups, such as patients, medical professionals and hardware manufacturers and leave several critical questions to be further explored. How would the patient's walking pattern affect the model building intended for ALM? Are we able to incorporate medical professionals' empirical knowledge to fine-tune the process parameters of MIM for a better finish of metallic part? This WP will primarily focus on a methodological study using an info-analytic approach that by exploiting the large amount of patient data, from physical conditions, medical history to patient's individual geometric data, the intrinsic relations between patient profiles and manufacturing process characteristics can be identified so that it enables an on-site fabrication of patient-specific single medical part at an optimal process condition which collectively yields a higher accuracy and agility.