## ‘remedi’: Meeting the measurement needs of regenerative medicine

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The next health care revolution will apply regenerative medicines using human cells and tissues (Langer *et al.*, 1999). Significant progress has been made towards the realisation of this, in particular, through the development of regenerative therapies for the treatment of diabetes, cartilage defects, wounds and bone defects (Griffith *et al.*, 2002). Whilst from a biological point of view, the therapeutic strategies of regenerative medicines are well defined there is a lack of commercial success (Mason, 2007; Lysaght *et al.* 2001). In addition to biological considerations, the production of regenerative therapies also requires consistent manufacturing and appropriate business and cost structures (Archer *et al.*, 2005). Remedi is a multidisciplinary consortium of UK-based universities and biotech companies which is addressing key challenges in regenerative medicine. These challenges are being met by combining the skills of a multidisciplinary team with the implementation of effective engineering strategies, both of which are integral to the establishment of regenerative medicine as a commercially viable, competitive industry.

The remedi consortium have expertise in: tissue engineering, economic modeling, policy and regulation relating to medical devices; machine platforms and sensor technology as well as production engineering that is necessary for the scale up of laboratory processes. Further, to ensure the commercial relevance of the program key inputs are received from industrial partners and a clinical advisory panel.

Central to the work of remedi is the application of effective engineering and manufacturing strategies for the scale up of regenerative medicines. This requires the economic production of functional therapies within a specification that satisfies both the regulator and clinical customer. In practice engineers and life scientists in the consortium are working together to analyse existing manufacturing systems utilising emerging measurement, sensing and control techniques to re-engineer and scale-up current laboratory bench-based processes. This requires each stage in the process to be sufficiently robust and reproducible. Further, each stage must be well characterised and its impact on the resulting product well understood.

This paper reports the role measurement and sensing systems are playing to expedite the scale-up of regenerative therapies. This work describes three case studies, tissue scaffold fabrication, cell culture and tissue engineering, in which greater process understanding can be obtained through the application of measurement and engineering principles. Specifically, time-lapsed imaging and acoustic impedance monitoring are applied to in-process monitoring of tissue scaffold fabrication. Scanning electron microscopy, micro x-ray computed tomography, magnetic resonance imaging and terahertz pulsed imaging are utilised to characterise scaffolds post-fabrication. An automated cell culture platform is used to facilitate identification of key environmental factors affecting cell culture. Further, the measurement challenges associated with non-destructive characterisation of engineered tissue are demonstrated through characterisation of a dermal skin substitute with optical spectroscopy.

This work concludes that there is a need for a greater emphasis on the engineering and manufacturing issues related to regenerative therapies if commercial viability is to be realised. In particular, attention needs to be paid to: improving process and system design in tissue production; implementing process monitoring in all stages of the therapy production; and improving strategies for preservation of final products and product release. This work demonstrates that the principles of design, measurement and process monitoring from the physical sciences will be integral to the translation of regenerative therapies into the clinic and that much of the technology needed to realise this is already available.

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