

## PROTEIN AND CELL DELIVERY SYSTEMS

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Tissue engineering and the pharmaceutical sciences share a common goal of using therapeutics to reverse disease conditions. Pharmaceutical therapeutics have traditionally been simple synthetic molecules or plant-derived products that are easy to administer to patients. Within the pharmaceutical community there is a trend towards the use of more complex therapeutic agents, e.g. proteins and cells, that regenerate tissue structures. Hence, there is considerable convergence between the scientific developments within these fields.

The challenge is even greater in designing cell delivery systems because the behaviour of the therapeutic cell must be controlled after administration.

At Nottingham, we are developing methods that use the supercritical carbon dioxide to process polymer materials, proteins and cells. In addition, we are interested in the role of self-assembly in the formation of cell aggregates and scaffolds within the body.

A number of major challenges are encountered in the use of proteins and cells as therapeutics:

- They are fragile species that lose activity during conventional manufacturing processes.
- Their functionality is intrinsically linked to their environment within the body.
- Their therapeutic effect is location dependent.
- They may be eliminated rapidly by the body.

As a consequence of these challenges it is essential to design delivery systems that optimize the administration of proteins and cells, alongside the development of the therapeutics themselves.

This talk will review the challenges of protein and cell therapy, the potential clinical benefits of successful use, and a number of delivery systems under development.

The key features of any delivery system for proteins are:

- It should be manufactured within conditions that do not denature the protein.
- The system should release the protein at the desired rate after administration.
- Administration methods should be clinically acceptable.