WORKSHOP SUMMARY COMMENTS (February 1-2, 2007)

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1. Definition

    - Regenerative medicine: restore, maintain, enhance tissue and organ function

    - Tissue engineering: replacement, not repair and regeneration

2. Strategies

    - Delivery of cells alone, cells in scaffold, or simply a "smart" scaffold

    - Whether it is replacement or repair and regeneration depends on the tissue or organ

    - Bottom line: the delivery of signals and cues

3. Cell Source

    - Cells that "smile" and don't "frown"

    - Autologous vs. allogeneic cells

    - Differentiated vs. stem/progenitor cells

    - Define a stem cell

    - Stem cell function, fate

      orchestrated by a symphony of signals
      stem cells make a "ton" of molecules, they are a literal "drug store"

4. Issues for Stem Cells

    - Procurement and isolation

    - How does one differentiate a stem cell to a particular, specific cell type, e.g. a valvular endothelial cell as compared to a large vessel endothelial cell, what are the signals that direct this?

    - Gender, age of donor of cells

- Dosing
- Delivery methods/vehicles

5. Engineering Technologies
    - Scaffolds

        biological vs. synthetic materials

        Need “smart” materials

    - Bioreactors

        expansion of cells

        growth of tissues

        model systems

        bioreactors will need to be more sophisticated for stem cells, microenvironment will need to be optimized

    - Imaging

        non-invasive functional, molecular imaging

6. Basic Biology
    - The key is to deliver the right signals at the right place at the right time
    - Cell function, cell fate is orchestrated by a symphony of signals; what are the components of the symphony?

        soluble molecules, substrate, physical forces

        need systematic studies of the synergy between the various signals

    - Immunology
    - Systems biology, computational biology will be invaluable to tissue engineering and regenerative medicine

7. Commercialization
    - Commercial success can be very different from scientific success, a

technology is not a product

- The golden rule is the KISS principle: Keep it simple stupid
- Need to focus on functional outcomes
- Some key issues

    cell source

    optimization of delivery

    scalability

    shipping/logistics/shelf life

    quality control

    safety

- Regulatory issues and reimbursement
- Safety

    dosing/delivery vehicle

    effect of delivery vehicle on biologic activity

    toxicology

    tumorigenesis

    immunogenicity

- Tissue engineering is a disruptive technology
- There will be a range of uses of cell-based therapies

    single use, autologous approaches to allo approaches
    for thousands of patients

    these will require a different logic for product development and
    regulatory approval

8. Applications

    - Long term the goal is to harness the intrinsic repair/regeneration potential of the body so as to develop new clinical therapies and treatments

    - Short term an impact can be made developing in vitro models for the study of basic biology and for drug development

9. Multidisciplinary Teams

    - Will need biologists, engineers, clinicians

    - This includes developmental biologists

    - The biology research and the engineering can proceed in parallel as they “feed” off of one another

    - Clinicians need to be part of the teams, not just clinical researchers, but the clinical users who make the broad healthcare system