Challenges in Translating Tissue Engineering Research into Cell-Based Products for Therapies

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Meanwhile, a limited number of cell-based regenerative therapies has entered clinical studies and the pharmaceutical market. During this process, industry has experienced considerable difficulties in translating laboratory protocols and clinical proof of concept studies into economically viable processes and therapies. It became obvious, that cell-handling and production related research has been neglected and technologies for "living products" are not sufficiently developed. Further, patient specific variations in behaviour and quality of cells, as well as immune responses are challenging to develop standardized cell processes and quality controls in hospitals and industry. These problems are major bottlenecks toward economic success of stem or other cell-based therapies and may still be underestimated in research as a key issue to go beyond clinical research studies and make these innovate therapies widely available as a standardized and controlled treatment. In Europe, new regulation for cell-based advanced therapies will significantly influence practicability and profitability to make stem cell therapies broadly applicable for patients in the future. For commercial translation of cell-based treatments, cost-efficient manufacturing, stability, transport and storage of cell-based products are crucial. Further, specifically autologous cell-based products includes cell-procurement from individual patients which strongly influences the way of marketing and distribution of tissue engineering products.

This presentation will address important pitfalls and missing links to translate basic research to cell products and will include experience from own projects to go from basic research up to market launch.