

## W25: Tissue Engineering Therapy Lower Urinary Tract — the potential and hurdles

Workshop Chair: Karl-Dietrich Sievert, Germany

27 August 2013 14:00 - 17:00

Start	End	Topic	Speakers
14:00	14:25	Introduction and Stem Cell Application	<ul style="list-style-type: none"> <li>• Karl-Dietrich Sievert</li> </ul>
14:25	14:45	Stem cell and tissue engineering research--where are we?	<ul style="list-style-type: none"> <li>• Margot Damaser</li> </ul>
14:45	15:00	How do we organize clinical studies?	<ul style="list-style-type: none"> <li>• Rainer Marksteiner</li> </ul>
15:00	15:15	What is the legal status with EMEA and CAT?	<ul style="list-style-type: none"> <li>• Juergen Bednarz</li> </ul>
15:15	15:30	Why are companies advancing into the biomedical field?	<ul style="list-style-type: none"> <li>• Silke Busch</li> </ul>
15:30	16:00	Break	None
16:00	16:50	round table: ethic and legal aspects	<ul style="list-style-type: none"> <li>• Juergen Bednarz</li> <li>• Silke Busch</li> <li>• Margot Damaser</li> <li>• Rainer Marksteiner</li> <li>• Karl-Dietrich Sievert</li> </ul>
16:50	17:00	Summary and close	<ul style="list-style-type: none"> <li>• Karl-Dietrich Sievert</li> </ul>

### Aims of course/workshop

The aim of this course will be to report on the state of the art knowledge with respect to tissue engineering and stem cells in treating voiding dysfunction and to evaluate the prospective therapy options, which will be discussed with the audience.

Our aim is to bring those interested in progressive translational medicine to enhance their knowledge base of the potential of stem cell therapy.

# TISSUE ENGINEERING THERAPY OF THE LOWER URINARY TRACT— The Potential and Hurdles

## Schedule:

Start	End	Topic	Speakers
09:00	09:25	Introduction and Stem Cell Application	<ul style="list-style-type: none"> <li>Karl-Dietrich Sievert, Germany</li> </ul>
09:25	09:45	Stem cell and tissue engineering research-- where are we?	<ul style="list-style-type: none"> <li>Margot Damaser, United States</li> </ul>
09:45	10:00	How do we organize clinical studies?	<ul style="list-style-type: none"> <li>Rainer Marksteiner, Austria</li> </ul>
10:00	10:15	What are the regulations for tissue and cell use for patient treatment?	<ul style="list-style-type: none"> <li>Jürgen Bednarz, Germany</li> </ul>
10:15	10:30	Why are companies advancing into the biomedical field?	<ul style="list-style-type: none"> <li>Silke Busch, Germany</li> </ul>
10:30	11:00	Break	None
11:00	11:50	Round table: ethic and legal aspects	<ul style="list-style-type: none"> <li>Margot Damaser, United States</li> <li>Rainer Marksteiner, Austria</li> <li>Jürgen Bednarz, Germany</li> <li>Silke Busch, Germany</li> <li>Karl-Dietrich Sievert, Germany</li> </ul>
11:50	12:00	Summary and close	<ul style="list-style-type: none"> <li>Karl-Dietrich Sievert, Germany</li> </ul>

### Aims and Objectives:

The aim of this course will be to report on the state of the art knowledge with respect to tissue engineering and stem cells in treating voiding dysfunction and to evaluate the prospective therapy options, which will be discussed with the audience. Our aim is to bring those interested in progressive translational medicine to enhance their knowledge base of the potential of stem cell therapy.

### Educational Value:

This is a workshop based on latest known technology to address the potential and hurdles of tissue engineering and regenerative medicine and to better understand the legal and ethical concerns.

### Description:

Background Tissue engineering is a promising technique for the development of biological substitutes that can restore, maintain, or improve tissue function. The creation of human tissue-engineered products, generated of autologous somatic cells or adult stem cells with or without seeding of biocompatible matrices is a vision to

resolve the lack of tissues and organs for transplantation and to offer new options for reconstructive surgery. It is a rapidly evolving field in basic research and the transfer into the clinic has yet to be realized. Necessary steps from bench to bed are the proof of principle in animal models and the proof of concept in clinical trials following good manufacturing practice and ethical and legal requirements for human tissue-engineered products. Up to now, obstacles still occur in the neovascularization of implants and ingrowth of nerves in vivo. Moreover the harvesting of mesenchymal stem cells out of bone marrow as well as the explant of urothelial cells yet demands rather invasive surgery to achieve a successful outcome. Thus, other cell sources and harvesting techniques like placenta and adipose tissue for mesenchymal stem cells and bladder irrigation for urothelial cells require closer investigation. Key

**Learning Points Key Points:** 1. Voiding dysfunction is significant quality of life diminishing diseases that progress over time, making timing of therapy important to optimize. 2. Traditional stem cell therapy has focused on differentiation of cells to replace damaged or diseased tissue; however, amounting evidence suggests that bioactive factors secreted by stem cells affect the local and systemic response to injury, providing functional benefit. 3. For tissue engineering applications, stems cells can be seeded onto scaffolds to facilitate the incorporation of the graft by native tissue. 4. While most clinical trials in the field have focused on autologous cell sources, the use of allogeneic stem cells offers the potential for off-the-shelf treatment with disease-free cells and is being used in other fields of medicine. 5. Further basic research to understand the mechanisms of stem cell therapeutic action is warranted to optimize treatment algorithms. 6. Clinical trials are ongoing, yet many hurdles remain.

**Take Home Messages:** *Stem cells have generated a considerable amount of scientific and medical interest. Stem cell research, by increasing our understanding of normal cell development, allows us to understand, and possibly correct, the errors that lead to such medical conditions.*

Category	Reconstructive Surgery: LUT
Length	180
Level	Advanced
Audience	Urologists, gynecologists, neuro-urologists, pediatric urologists, researchers, clinicians interested in learning about regenerative medicine and how it can apply in clinical practice
Keywords	LUT rehabilitation, Tissue Engineering, Translational medicine



### Chair:

Karl-Dietrich Sievert <[kd\\_sievert@hotmail.com](mailto:kd_sievert@hotmail.com)>, Surgeon and Researcher, Germany

*Professor Sievert's clinical, surgical and research interests include oncology (investigation of advanced detection tools and reduced invasiveness and improved functional outcome with anatomical and clinical findings), neuro-urology (diagnosis and treatment of urological nerve disorders), incontinence (pathophysiology), reconstructive surgery (medical devices, tissue engineering and stem cell treatments) and the progressive and innovative treatment of spinal cord injured patients, such as early SNM implantation, which he won a 2010 Klee Innovation Prize award. He has initiated novel clinical trials to investigate the outcome of incremental or combined antimuscarinics dosages to increase effectivity without side effects. In recent years he became one of the few urologic experts in the stem cell and tissue-engineering field who has focused on the real-time processes of bringing research initiatives from the laboratory to clinic.*

- Stem cell therapy for voiding and erectile dysfunction Vaegler M, Lenis AT, Daum L, Amend B, Stenzl A, Damaser MS, Sievert KD. Nat Rev Urol. 2012 Jun 19. doi: 10.1038/nrurol.2012.111.
- The next step in urethral reconstruction. Sievert KD. Lancet. 2011 Apr 2;377(9772):1130-1. Comment on Lancet. 2011 Apr 2;377(9772):1175-82.
- Generation of pluripotent stem cells from adult human testis. Conrad S, Renninger M, Hennenlotter J, Wiesner T, Just L, Bonin M, Aicher W, Bühring HJ, Mattheus U, Mack A, Wagner HJ, Minger S, Matzkies M, Reppel M, Hescheler J, Sievert KD, Stenzl A, Skutell. Nature . 2008 Nov 20;456(7220):344-9. doi: 10.1038/nature07404. Epub 2008 Oct 8.

### Speaker 1:

Margot Damaser <[damaserm@ccf.org](mailto:damaserm@ccf.org)>, Medical Researcher, United States

*She has over 15 years experience utilizing animal models to investigate lower urinary tract pathophysiology in a variety of disorders, including spinal cord injury, diabetes and female pelvic floor dysfunction, including urinary incontinence, fecal incontinence, & pelvic organ prolapse. She is particularly interested in methods to regenerate & repair extracellular matrix and neuromuscular systems. To this end she investigates the mechanism of action of stem cell and cell-based therapy in these animal models. She also conducts preclinical testing of potential therapies in these models, develops diagnostic and assessment techniques for use in animals, and investigates technologies for improved clinical therapies & diagnostics.*

- Stem cell therapy for voiding and erectile dysfunction Vaegler M, Lenis AT, Daum L, Amend B, Stenzl A, Damaser MS, Sievert KD Nat Rev Urol. 2012 Jun 19. doi: 10.1038/nrurol.2012.111.
- Gill, B.C., B.M. Balog, C. Dissaranan, H.H. Jiang, J.B. Steward, D.L. Lin, and M.S. Damaser (2012) Neurotrophin Therapy Improves Recovery of the Neuromuscular Continence Mechanism Following Simulated Birth Injury in Rats. Neurourology and Urodynamics. In

### Speaker 2:

Rainer Marksteiner <[r.marksteiner@innovacell.at](mailto:r.marksteiner@innovacell.at)>, Company Founder, CSO and Medical Researcher, INNOVACELL, Austria

*Chief Science Officer and co-founder of Innovacell. Establishing clinical trials in the field of stem cell and tissue engineering. Innovacell operates one of Europe's largest good manufacturing practice (GMP) certified production facilities, which is fully equipped and established for the proliferation of autologous muscle cells. Innovacell Biotechnologie AG is the first company to have developed a personalized, cell-based therapy for the treatment of stress urinary incontinence (SUI). Innovacell's lead product ICES13, is set out to start submission for regulatory approval by EMA in 2013. Innovacell's other cell-based therapy is for the treatment of fecal incontinence.*

- A comparative study of three different biomaterials in the engineering of skeletal muscle using a rat animal model. Kamelger FS, Marksteiner R, Margreiter E, Klima G, Wechselberger G, Hering S, Piza H. Biomaterials. 2004 Apr;25(9):1649-55
- Combined transplantation of skeletal myoblasts and bone marrow stem cells for myocardial repair in rats. Ott HC, Bonaros N, Marksteiner R, Wolf D, Margreiter E, Schachner T, Laufer G, Hering S. Eur J Cardiothorac Surg. 2004 Apr;25(4):627-34.

**Speaker 3:**

Jürgen Bednarz <[j.bednarz@urotiss.de](mailto:j.bednarz@urotiss.de)>, Director-Regulatory Affairs and Quality Management, UROTISS, Germany

*Jürgen Bednarz is the Director in charge of Regulatory Affairs and Quality Management at UroTiss GmbH. UroTiss GmbH, a pharmaceutical company with headquarters in Dresden, Germany, has developed an innovative and gentle process for the surgical repair of urethral strictures and hypospadias. Using an autologous cell transplant, the patient's own cells are used for treatment of the patient's urological disease. The replacement tissue emerged from the company's own research and development and is the first tissue engineering product in the urology field worldwide that is based on the patient's own cells. He will talk about the legal situation of EMEA and CAT.*

**Speaker 4:**

Silke Busch <[busch@bio.viscofan.com](mailto:busch@bio.viscofan.com)>, Director-Biomedical and Cell Biology, VISCOFAN BIOENGINEERING, Germany

*Silke Busch is the Director of Biomedical and Cell Biology in Viscofan Bioengineering, which is a business unit within the Viscofan Group, a worldwide leader in the manufacturing of collagen, cellulose, fibers and plastic products for the food industry. Their activities are focused on the industrial-scale production of bovine dermal collagen and its further development of products for cell biology and basic research in the medical field. During the last years, collagen based matrix became important for cell seeding. This company specialized in the food sector while developing a new field of interest and invested in basic research. Two new fields of interest opened up during the recent years which became promising to develop TE further: Cardiac and urethral reconstruction. She will discuss why companies are focusing their efforts on the future of tissue engineering.*

# Stem Cell and Tissue Engineering Research

## Where are we?

Margot S. Damaser, Ph.D.

Associate Professor

Dept. of Biomedical Engineering & Glickman Urological & Kidney Institute

Cleveland Clinic Lerner College of Medicine

Cleveland, OH USA

### Take Home Points (1):

- Currently stem cell-based therapies are being tested in animal models and clinical trials for incontinence and voiding dysfunction
- Conventional stem cell therapy has focused on the ability of cells to differentiate and replace damaged or diseased tissue; however, mounting evidence suggests that stem cells also exert functional benefit by secreting bioactive factors that trigger local and systemic responses to injury
- For tissue engineering applications, stem cells can be seeded onto scaffolds to facilitate the incorporation of the graft by native tissue.
- Although most clinical trials in the field have focused on autologous cell sources, the use of allogeneic stem cells offers the potential for 'off-the-shelf' treatment with disease-free cells; this approach is already being used in other fields of medicine
- Further research is needed to better understand the mechanisms of stem cell therapeutic action in order to optimize treatment algorithms

### What are stem cells?

Stem cells by definition can self-perpetuate indefinitely and can differentiate a variety of types of cells, depending on the local cellular environment. Embryonic stem cells are derived from an early stage embryo. They are pluripotent or totipotent and can differentiate into all adult cell types. In contrast, adult stem cells are multipotent and classically are thought to be able to differentiate only into a limited number of types of cells. Adult stem cells make up a distinct minority of cells in a given tissue and are generally slow cycling, multipotent and are referred to by their tissue of origin. The use of human embryonic stem cells has been limited in the United States and in most European countries because of their tumorigenic potential and due to ethical concerns with harvesting of embryonic cells, resulting in government regulations limiting their use (2;3). This talk will focus on characterization and use of adult SC since they are the ones most utilized to develop therapies for incontinence and voiding dysfunction.

### Where do stem cells come from?

Although bone marrow is the classic site for extraction of adult stem cells, they can be obtained from almost any tissue or even body fluids, including but not limited to muscle, fat, hair, and urine (4). Stem cells are not identical in each tissue and therefore the source of therapeutic SC may impact efficacy. Adult SCs from all these sites have been utilized as therapeutic agents in preclinical animal studies or clinical trials and their use to treat incontinence and voiding dysfunction will be discussed in this talk.

### How are stem cells thought to work therapeutically?

Stem cell therapy in urology has, for the most part, presumed that stem cells have their therapeutic effect by differentiating into muscle tissue, for example to increase muscle mass and strength of urethral sphincter muscle (5). Similarly, tissue engineering for reconstruction has been developed via ex vivo differentiation of stem cells. Stem cells can also act via paracrine and autocrine mechanisms (4). In some studies, therapeutic effects resulting from stem cell therapy appear disproportionate to the number of cells that engraft to injured organs, supporting this mechanism of action. The profound possibilities of this mechanism of stem cell therapeutic effect are best illustrated by a study in which stem cells were injected into the hamstring muscle of hamsters with heart failure. Although cells were unable to migrate out of the muscle, they generated significant cardiac improvement (6).

### Current research on stem cells to treat stress urinary incontinence

Clinical trials have shown that autologous muscle derived stem cells are safe and have promise as a therapy for stress urinary incontinence symptoms (5). However, clinical studies cannot determine the mechanism of action of stem cells, partly because, in humans, the cells cannot be tracked in vivo. Therefore, although therapy has entered the clinical trial stage of testing, determination of mechanism of action in animal models remains necessary. This talk will summarize the results of research in animals and humans testing stem cells as potential therapy for stress urinary incontinence.

### Current research on stem cells to treat voiding dysfunction

One study has demonstrated that stem cells injected into the bladder walls of rats with bladder outlet obstruction can restore contractility (7). Several similar studies in animals have demonstrated the ability of stem cells to initiate bladder remodeling after prolonged obstruction—even in cases where only a few stem cells homed, survived, and differentiated into smooth muscle tissue—suggesting the importance of a paracrine mechanism of action (8;9).



## Conclusions

The studies conducted to date demonstrate that stem cells hold great therapeutic potential for treatment of urological disorders. However, much research is yet to be done, particularly into mechanism of action of the cells, ideal cell population to utilize for therapy, and optimal delivery method. Because of the hype and great potential for stem cells there is also the potential for misuse of the term as well as unethical research to advance a specific agenda. These have occurred in the Urological field and researchers ought to be vigilant to guard against them.

## References

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- (2) Goldman HB, Sievert KD, Damaser MS. Will we ever use stem cells for the treatment of SUI? *Neurourology and Urodynamics* 2012;31(3):386-9.
- (3) Choumerianou DM, Dimitriou H, Kalmanti M. Stem cells: promises versus limitations. *Tissue Engineering Part B Rev* 2008;14:53-60.
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# Advanced medicinal products (ATMPs\_ requirements for clinical studies: how do we organize clinical studies?

Rainer Marksteiner  
Chief Science Officer  
Innovacell Biotechnologie AG  
Innsbruck, Austria

Regenerative medicine in an increasingly expanding area with hopes of providing therapeutic treatments for diseases/injuries that conventional medicine cannot effectively treat. This presentation will address a few key requirements that cell-based approaches will become clinical routine.

## Regulatory and medical aspects

Historical cell-based treatments were subdivided into somatic cell therapy, gene therapy and tissue engineering. Regulatory it was placed somewhere between medicinal products and medical devices. This unclear definition lead to an unsettled situation in Europe. Some countries like Germany used requirements for medical products, other countries like Great Britain the regulation for medicinal devices. This insufficient situation lasted until the year 2008. In this year the European Union set in force a new regulation for all kind of cell based products. The main aspects of these new ATMP regulation is a centralized approval process similar to medical products.

## Cell quality aspects

GMP (Good Manufacturing Practice) is a key requirement for the isolation and expansion of cells for human use. Beside the clean room facility the quality control of cell-based products are an important issue. It is generally known that the cell populations are described by their cell marker expression. But it is often unnoticed that residuals of cell culture components (e.g. fetal calf serum, antibiotics,..) has to be measurement in the final product as well. A particular challenge is the potency testing. A necessary prerequisite for clinical trials and marketing approval.

## Clinical study aspects

Taking a tissue biopsy is usually the first step in a clinical trial application. The unique situation in cell therapy is that taking a biopsy is part of the manufacturing process and therefore requires a special approval from the local competent authorities according the tissue procurement regulation. In addition the logistic of the transport of tissue samples and final cell products should not be underestimated. It should be stressed in conclusion that cell therapy products takes as long as standard medicinal products until approval.

## Hospital Exemption

The question rises whether the “Hospital Exemption” is an alternative pathway to this long lasting and expensive centralized EMA approval procedure. For single case treatments this exceptional regulation is a real option for physicians and patients. But one should consider that the quality aspects for cell product are identical with standard ATMP products.

## What are the regulations for tissue and cell use for patient treatment in Europe?

Dr. Jürgen Bednarz

Director-Regulatory Affairs and Quality Management

Urotiss GmbH

Dresden, Germany

Cellular and molecular technologies offer new promising treatment approaches. To ensure high quality standards and free movement of the related products within the European Community, the European Parliament and the Council of the European Union have issued a specific regulation for the so called advanced therapy medicinal products: ATMP (ATMP Regulation).

ATMP represent a heterogeneous group of medicinal product. This group comprises:

- Gene therapy medicinal products (products aimed at the transfer of a prophylactic, diagnostic or therapeutic gene to human/animal cells and its subsequent expression in vivo)
- Somatic cell therapy medicinal products (somatic living cells, the biological characteristics of which have been substantially altered as a result of their manipulation to obtain a therapeutic, diagnostic or preventive effect through metabolic, pharmacological and immunological means)
- Tissue engineered products (containing engineered cells or tissue and is aimed to regenerate, repair or replace a human tissue.

The product is regarded as a combined product if it contains a medical device as an integral part.

Products that are not Advanced Therapy Medicinal Products:

- Organs (e.g. kidney or heart)
- Tissues that have not been manipulated and are used to fulfill in the recipient the same function as in the donor (e.g. cornea or heart valve)
- Tissues that are procured and re-transplanted within the same operation (e.g. vessels for bypass operations)

The use of these tissues and organs is regulated on a national level just as the procurement of the tissue that is required for ATMP manufacturing. Although European Directives have been implemented to ensure quality standards for tissue procurement, the statutory regulations had to be transposed to national legislation and relevant differences now apply in the Member States.

To clarify whether a product is an ATMP and if so what kind of ATMP it is, the European Medicines Agency (EMA) has introduced a Classification Procedure that is directed by the Committee for Advances Therapies (CAT). After submission of required information on the product a decision by the CAT will be received within about 2 months.

If a product is an ATMP, it may only be used in humans if a centralized marketing authorization has been granted by the EMA or in approved clinical trials. There is only one exception. Centralized marketing authorization is not required for a product “which is prepared on a non-routine basis according to specific quality standards, and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient” (hospital exemption). There is no legal definition for the expression “non-routine basis”. Therefore the national competent authority has to be contacted to clarify whether the hospital exemptions applies to a specific product.

In summary the implementation of the ATMP Regulation has given some legal security and harmonization in the Member States concerning the use of new developed products that are based on molecular and cellular technology. However aspects on tissue procurement are still regulated on a national level and therefore exhibit relevant differences between member states. More importantly such differences also exist with regard to the question, whether the hospital exemption applies. This is of particular interest because receiving a centralized marketing authorization is a long-term process that requires important personal and capital resources even if orphan drug status has been received. Orphan drug status can be applied for the development of a product intended for the treatment of a rare disease or if administration of only a limited number of products is expected.

## Why are companies advancing into the biomedical field?

Silke Busch

Director-Biomedical and Cell Biology

Viscofan BioEngineering, Division of Naturin Viscofan GmbH

Weinheim, Germany

The Viscofan Group is known as the world leader in the field of sausage casings (food industry, full range company). The head quarter of the group is located in Pamplona, Spain, subsidiaries exist in Germany, Serbia, Czech Republic, USA, Brazil and China. Today the Viscofan group is split into different business units such as:

- Sausage casings
- Canned vegetables & convenient food (IAN)
- Electricity supplier for the northern Spanish market
- BioEngineering

Naturin, the home of BioEngineering, is located in Weinheim, Germany, as the center of excellence for collagen casing for the whole Viscofan group. In Weinheim we can look back on 80 years of experience in industrial production of collagen casings that are edible and non-edible. In the beginning of 2000 there were considerations about other possible collagen products next to sausage casings. The goal was always the development of new products for a new market.

After intense R & D work on the collagen membrane itself and variations in the composition of the collagen mass, the first proved principal studies with collagen films for cell cultivation was performed. All the data looked very promising and resulted in the funding of Viscofan BioEngineering, a new business unit for Naturin. Consequently a new production of collagen films was build up in 2008 and new laboratories were established in the second half of 2008. It was absolutely obvious and considered that the regulatory requirements for biomedical products are different and much higher compared to the core business, the manufacturing of products for the food industry. So, if comparing the history/development of Viscofan BioEngineering with other start-up companies in the biomedical field, one can find differences in strategies. One of the main reasons is the very special situation of Viscofan BioEngineering. On one hand we are a small start-up enterprise, but on the other hand, we have the structures (and of course the financial background) to form a large global operating company. This allows us to follow a long-term goal, like the development of a biomedical product.

From the very beginning, the focus was on products for biomedical applications. Thus we invested energy in both by building up the laboratories and R&D, but at the same time, we established a certified quality management system. This milestone was achieved in October 2011 with the certification according to ISO 9001:2008 for Viscofan BioEngineering.

In 2010 Viscofan BioEngineering stepped into the "Life Science" market with the first collagen product, the CCC (Collagen Cell Carrier) for use in research and development. It was well-known that the business development into a highly

competitive market is quite hard for a newcomer. The other hurdle is that a lot of possible customers assume that collagen type I is a well-known product for cell cultivation. That is true! But the way how these CCC membranes are produced and subsequently the characteristics of this biomaterial is very unique!

During the evaluation period Viscofan BioEngineering began to establish a network with external cooperation partners for intensive research in the field of biomedical applications. All these investigations were proof of principle studies to demonstrate the applicability of the CCC membranes for implantation. These in vivo data were strongly supported by the in vitro analytical data of the material. These investigations--together--paved the way for the decision to fund our own BioEngineering Department.

In parallel market analyses showed a strong market potential for biomedical products for Regenerative Medicine and/or Tissue Engineering. The re-evaluation of the market potential, together with the status of Viscofan BioEngineering resulted in a strong commitment of the Management together with the Board and the shareholders to further investments into the development of biomedical products.

Even if we have established several processes, e.g. the raw material purchasing chain, a quality control and quality management system, a packaging and a sterilization process that fulfill a lot of regulatory requirements, we would have to make bigger investments to reach the next milestone. This new milestone is the establishment of a GMP-approved production facility. Today we are in the middle of this highly complex and challenging process. So far-to our knowledge-no comparable facility exists in Europe.

So why is a world leading company in the food market advancing into the biomedical field?

The thoughts in the early 2000 were:

We are able to produce high amounts of collagen products with an industrialized process in a standardized quality – so which other market potential exists besides the food industry? After examining, analyzing and evaluating different opportunities, there were still some open questions:

Is it possible to translate the unique features of our edible collagen casings and films, such as:

- no chemical cross-linking
- preservation of long fibers
- ultra thin structure
- high stability and elasticity
- high purity

...into novel products for Cell Biology, Regenerative Medicine and/or Tissue Engineering?

The answer is YES! We strongly believe in the potential of the market, the potential of our products and our capabilities! We have built-up a team of experts that consists of chemists, engineers, biologists and clinicians who bring together their knowledge in the fields of biomaterials, production technology, cell biology, biomedical research and clinics.

