



Unlocking potential of beMatrix gelatin and collagen



The first in human clinical study based on iPS cells

The first in human clinical study based on iPS cells was conducted in 2014. beMatrix collagen AT was selected and used for retinal pigment epithelial sheet.

Masayo Takahashi, M.D., Ph.D.
RIKEN Center For Developmental Biology



Gelatin is a material indispensable and promising for drug delivery system

More than 1,000 patients of intractable diseases were efficiently treated to heal with the gelatin DDS technology of growth factor release.

Yasuhiko Tabata, Ph.D., D.Med.Sci., D.Pharm.
Institute for Frontier Life and Medical Sciences, Kyoto University



“Low endotoxin level” of beMatrix gelatin was key!

beMatrix gelatin is used in Solum IV, a resorbable bone void filler, which is an osteoconductive implant serving as a scaffold for the in-growth of new bone. Solum IV forms a cohesive and adhesive consistency upon hydration allowing the shape of the implant to conform to the defect.

Kevin Dunworth, CEO & Founder
Celling Biosciences



EXPANDING THE HORIZONS FOR COLLAGEN-BASED BIOMEDICAL MATERIALS

A conversation with **YOSUKE HIRAOKA**, principal research scientist at Nitta Gelatin Inc, Japan



Nitta Gelatin Inc provides world-class collagen, gelatin and collagen peptide products derived from bovine, porcine and fish sources that are widely used in the pharmaceutical, cosmetics, adhesives and food industries. The company's portfolio began with glues for musical instruments and gelatins for photographic film. It has since evolved to meet changing demands over many decades, today supplying an innovative line-up of materials for biomedical use.

What impact are medical advances having on the development of biomaterials?

During the past decade there have been major advances in stem cell research, regenerative medicine and transplantation. Cell therapy and gene therapy products are evolving at a corresponding pace. New techniques to combine cells with gelatin or collagen are emerging and are already making these new treatment methods more effective.

We recognise that safety is a top priority, particularly at the raw material stage, because it's difficult to remove endotoxins or conduct further purification after the biomaterials have been combined. We developed a unique method to reduce endotoxin levels. Our product called beMatrix™ low endotoxin gelatin is of very high quality and has less than 10 endotoxin units (EU) per gram. The US Food and Drug Administration (FDA) guideline regulates endotoxin levels at no more than 20 EU per medical device, so this is a remarkable achievement.

Can you tell us more about the development of beMatrix™?

beMatrix™ was made possible through Nitta Gelatin's investment in a state-of-the-art cleanroom facility in 2009 and produced this specific product in response to requests from

customers. Planning clinical trials was the next step and therefore reducing endotoxin levels was critical for this type of research because this system is being introduced into the human body in clinical applications.

As we knew that dry heat sterilisation, autoclaving and filtration methods could not be applied to gelatin and collagen, we developed a new method for endotoxin reduction. Since its development, beMatrix™ has been used by researchers and companies around the world.

First, researchers use our materials in animal studies, and get good results. Next they want to use it in clinical studies, and request from us products that are safe for this purpose. We come up with what they need for their clinical study, and after it's done, they produce papers. Other researchers read those papers and also want to directly benefit from our products. This is the story of how we developed and released beMatrix products. Some of the researchers who contact us are with companies who develop medical devices, biologics and regenerative products, all of which utilize our materials.

What are Nitta Gelatin's key areas of business?

Our main products are collagen, gelatin, and hydrolysed gelatin. Our key technologies are endotoxin and virus reduction. Collagens are a large family of proteins

found within the extracellular matrix (ECM), an important constituent of many of the tissues in the human body and in other vertebrates. Gelatin is a heat-denatured product of collagen, and hydrolysed gelatin (also known as collagen peptide) can be made via enzymatic hydrolysis.

Collagens, gelatins and collagen peptides have distinctive characteristics. For example, collagen has a triple helix structure and is an excellent biocompatible material. We supply medical device manufacturers, universities and research institutes with a wide range of collagen products for artificial skin and bone, as well as other regenerative medicine applications. Gelatin is known for its water-binding, film-forming and adhesive properties, and is used in many applications ranging from food and pharmaceuticals to photosensitised materials. Collagen peptides are increasingly being used in dietary supplements and health foods, as they can help regulate bodily functions and improve skin, bone and joint health.

What sets Nitta Gelatin apart from other collagen and gelatin makers?

Recently there has been a surge in demand for the biomaterials for medical use and we are well positioned to respond to this demand. We provide collagen

and gelatin biomaterials that are not only of exceptionally high quality but also control the level of endotoxins, viruses and bacteria.

In addition, our collagen and gelatin products are valuable for many other healthcare applications due to their absorbent, protective and conformable properties. They are also suitable for sol-gel transition, meaning that they can be made into either a liquid or gel by adjusting the temperature and pH. We offer a unique range of products such as beMatrix™, sterilised gelatin solution and collagen solution for three-dimensional culture, to name a few.

What other innovations are in the pipeline?

Innovations arise as a consequence of combining our products with the user's ideas. Our goal is to contribute to global health by combining our materials with various technologies and needs of companies and researchers. We have recently developed new types of gelatin that have a gelling temperature that is significantly higher than that of conventional gelatin.

In 1918, Nitta Gelatin began producing gelatin and animal glues. In 2018, as the company celebrates its centenary, we intend to keep evolving as we believe the potential of collagen and gelatin is infinite.

 **Nitta Gelatin Inc.**