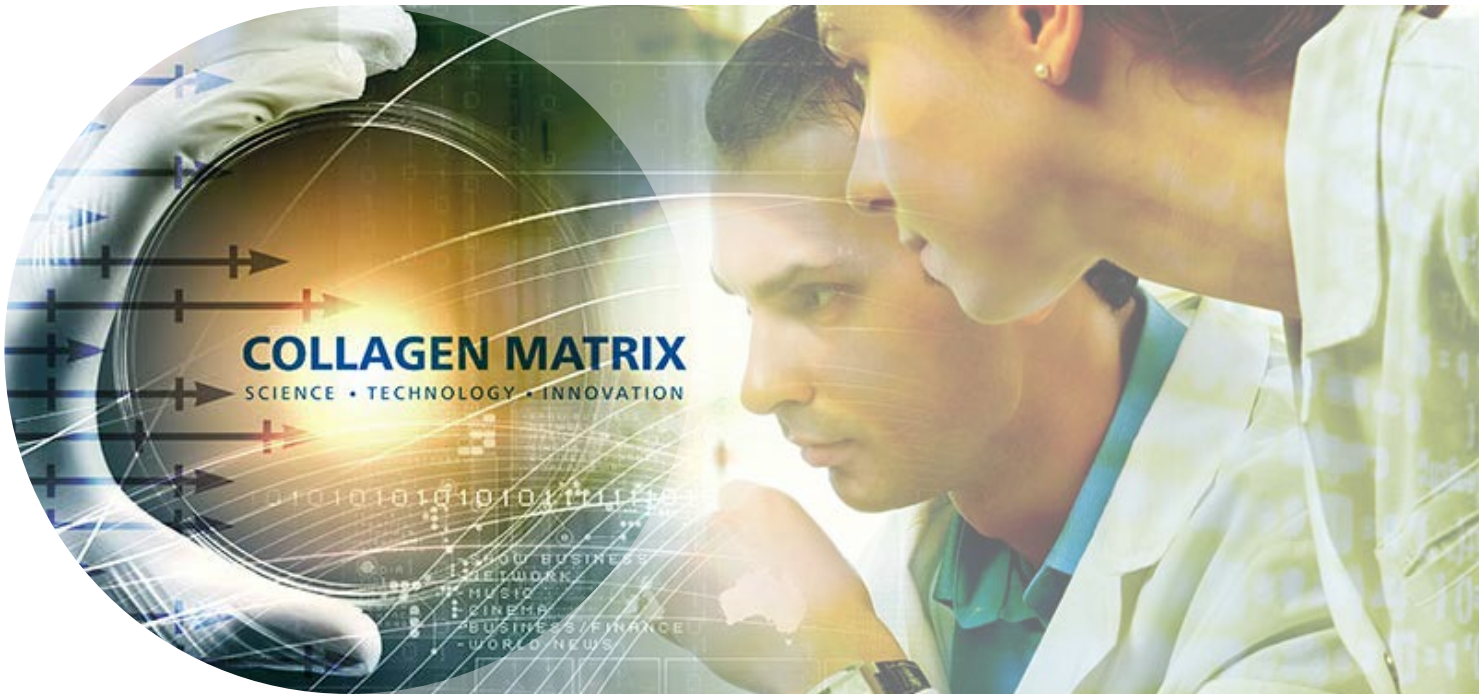
COLLAGEN MATRIX
SCIENCE • TECHNOLOGY • INNOVATION



Overcoming regulatory challenges by embedding excellence in practice

"The BSI project managers have a good understanding of our needs and have been a pleasure to work with."

Gloria Zuclich,
Director of Regulatory Affairs,
Collagen Matrix

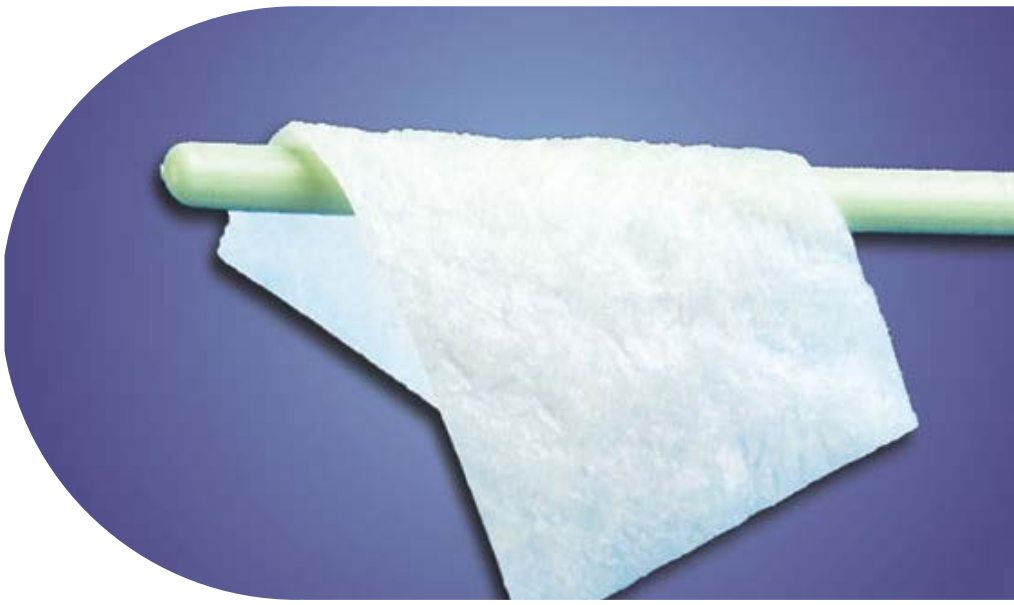
Why choose BSI?

- Vast technical expertise in our products and industry
- Efficient, transparent relationship provides confidence
- Accessibility to the correct technical expert
- Availability and reactivity of the technical experts
- Consistent speed-to-market for high-risk products
- Competitive parity
- Range of additional services that aid the regulatory process

bsi.

...making excellence a habit.™

Specialist in collagen and mineral-based products, Collagen Matrix, is a US-based provider of medical devices designed for tissue repair and regeneration. The company has years of experience in both product development and manufacturing, allowing the development of a product portfolio aimed at oral, neuro and orthopaedic-spine surgery.



Activity in global markets requires Collagen Matrix to comply with numerous regulatory requirements, including those of the European Union (EU) Medical Device Directive (MDD - 93/42/EEC) and the EU Animal Tissue Regulation (722/2012). These requirements are often complex, and require vast amounts of work to ensure demonstration of compliance.

The challenges of compliance

Meeting the necessary regulatory requirements to allow market access can be challenging and time-consuming, even for the most organized and practiced of businesses. A number of technical files must be presented, in the correct format, to regulatory bodies that will scrutinize each detail to confirm they satisfy the necessary requirements. This is necessary for medical devices, due to the nature of the product and the importance of ensuring patient safety. However, for the manufacturer, this requires efficient and precise planning to minimize delays in time-to-market, which requires various teams, including Quality Assurance, Regulatory Affairs, Manufacturing and Research teams.

Planning of regulatory projects is increasingly important with the impending implementation of the Medical Device Regulation in Europe. This change is placing a substantial burden on Notified Bodies – the EU regulatory bodies – to ensure that they are sufficiently capable of reviewing not only new products or renewals, but also existing products on the market. This highlights not only additional requirements for manufacturers in terms of their technical files, but more generally in keeping up-to-date with regulatory affairs and changes to Regulations, Directives and Standards.

> "During complex reviews, BSI project managers have extended themselves to oversee the review process and help clarify or resolve issues in a timely manner."
>
> Gloria Zuclich, Director of Regulatory Affairs at Collagen Matrix.

Overcoming obstacles to allow continual improvement

The most effective way to overcome regulatory challenges in a timely and efficient manner, without compromising the quality of regulatory files and processes, is to use a trusted Notified Body. This would allow robust reviews in a timely manner, conducted by product experts with the relevant, in-depth expertise. Working with regulatory bodies that operate in this way ensures risks associated with the processes out of the manufacturer's control are minimized.

Collagen Matrix recognized the benefits of working with a trusted regulator, and selected BSI as its product and system Certification Body. BSI was chosen as a result of its high quality accelerated review services performed by product experts. This has remained an integral reason in the on-going relationship between Collagen Matrix and BSI. Collagen Matrix has also recognized a number of other benefits of working with a regulator that embeds excellence in its practices.

How does Collagen Matrix overcome the challenges of regulatory reviews?

- **Open communication**
- **Remaining up-to-date with regulatory requirements through BSI e-updates and webinars**
- **Using FastTrack or Dedicated reviews, where possible**

BSI's product experts have significant experience in industry and the regulatory environment; this unique set of skills allows them to provide support throughout the review process. This is important to Collagen Matrix, as explained by Gloria Zuclich, Collagen Matrix's Director of Regulatory Affairs: "During complex reviews, BSI project managers have extended themselves to oversee the review process and help clarify or resolve issues in a timely manner."

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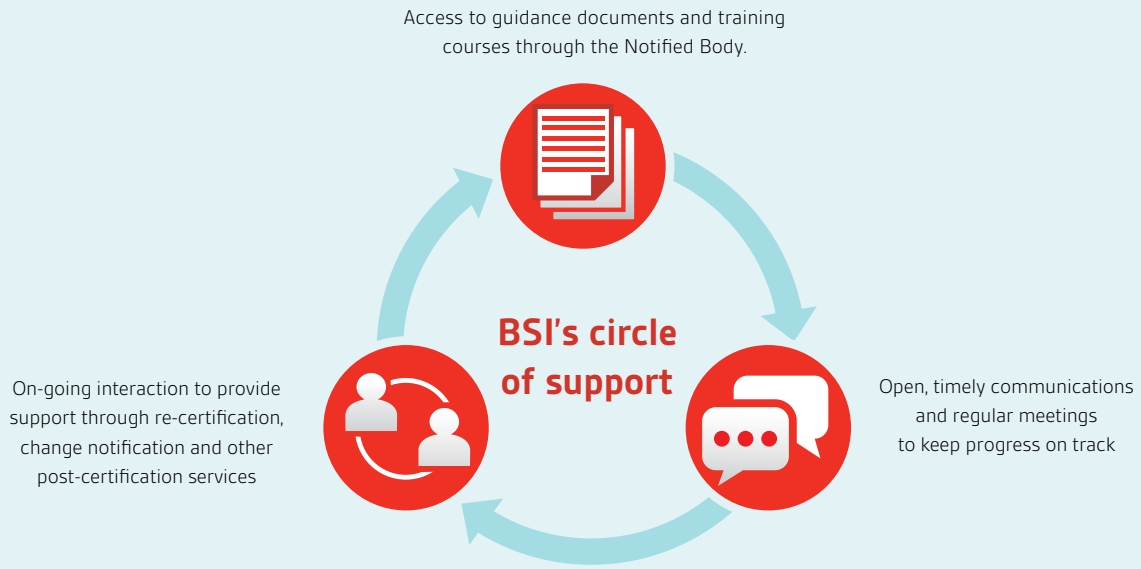
The technical experts' dedication to support their clients has been valuable to Collagen Matrix, particularly due to the use of biological substances in its devices, making the requirements more substantial. Zuclich describes the BSI reviewers as "practical", and cites the way they conduct themselves as an important factor in Collagen Matrix's choice to work with BSI.

A strong working relationship is important to allow effective management of regulatory affairs. There is a lot of work and planning involved in the review process, either for new products, renewals, or change notifications. BSI aims to mitigate the impact of this workload by supporting clients through meetings and regular calls, allowing explanation of its needs and expectations of the client, or simply to allow clarification. Zuclich notes that "these routine meetings ensure appropriate planning and timely review of projects", which not only lessens the burdens of the immediate project, but allows more efficient completion of future projects.

"BSI's FastTrack review services allow us to overcome the challenge of lengthy regulatory processes while maintaining an assurance of quality." *

Gloria Zuclich, Director of Regulatory Affairs at Collagen Matrix.

Why does Collagen Matrix continue to work with BSI?



The wider implications

The effective management of Collagen Matrix's projects by BSI is considered valuable by the manufacturer. This value extends beyond the immediate projects, impacting the wider business by granting faster approvals, which allows quicker market access; particularly important with regard to new products. Collagen Matrix can rely on BSI to provide efficient market access for current and future products, whilst maintaining integrity and quality in the work completed. This ensures compliance continues to be met, and minimizes the risks faced by the business.

The experience that Collagen Matrix has had with BSI through its product and system certification services has encouraged the wider use of BSI offerings. This includes training on regulatory requirements, and also the purchase of standards directly from the BSI Standards team. The continuing strength of knowledge and regulatory experience at Collagen Matrix signifies future success in the maintenance of compliance, allowing on-going returns for the business.

Learn from Collagen Matrix and experience the benefits of BSI's broad range of expertise.

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*BSI's premium review services are subject to availability.

Unrivalled expertise from a leading Notified Body

In addition to providing world-class product and system certification reviews, BSI has a unique range of in-house expertise to support your regulatory needs, including expertise in:

- Materials of animal origin
- Drug-device combinations
- Microbiology

BSI can also offer a comprehensive range of training courses to help you to understand the regulatory requirements, from learning the basics to grasping the requirements for specialist technologies.

BSI technical trainers have over 546 years combined regulatory and industry experience.

For more information contact:
+44 345 086 9000
or visit **bsigroup.com/training**

Talk to BSI

We believe excellence should follow in everything we do, so if you would like to find out more about global market access through BSI, please call or email us for an initial conversation

Call: **+44 345 080 9000**
Email: **eu.medicaldevices@bsigroup.com**
or visit: **bsigroup.com/medical**

Disclaimer
BSI does not guarantee a CE Mark will be issued in a specific amount of working days or calendar days, but is based on completing the review process with either a positive or negative recommendation. This document does not imply that BSI is selling CE Mark certificates.

Our timelines recognize that certain aspects of Design Dossier reviews are outside of BSI's control and that BSI is obligated to utilize clinician guidance to satisfy the Directive(s). Use of external (non-BSI) clinicians may impact timeliness. Some novel devices may not be eligible for CE-45 FastTrack service. The following list provides examples but is not exclusive:

– Medicinal Reviews
– Animal Tissue Products
– Blood Products.

BSI Group America Inc.
12950 Worldgate Drive,
Suite 800,
Herndon,
VA 20170
USA

T: +1 800 862 4977/703 437 9000
F: +1 703 437 9001
E: us.medicaldevices@bsigroup.com

BSI Group - EMEA
Kitemark Court,
Davy Avenue,
Knowlhill,
Milton Keynes MK5 8PP
United Kingdom

T: +44 345 080 9000
F: +44 1908 814920
E: eu.medicaldevices@bsigroup.com

BSI Group Asia Pac
BSI Group - Hong Kong
23rd Floor, Cambridge House
TaiKoo Place,
979 King's Road,
Island East, Hong Kong

T: +852 3149 3320
F: +852 2743 8727
E: hk@bsigroup.com

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Visit us online at: bsigroup.com/medical