

bsi.

...making excellence a habit.™

SHAPING
~ THE ~
FUTURE
WITH MEDICAL
INNOVATION

Everything
you need to
know about working
with BSI as an
External Medical
Expert

Contents

- 3 What is BSI?
- 3 Why do we work with clinicians?
- 4 Clinical focus
- 5 What are the benefits to you?
- 6 Next steps:
The Process explained

What is BSI?

BSI is a leading Notified Body; we review medical devices to ensure that they conform to the requirements in the European Directives. This ensures that they are safe and perform as intended.

Why do we work with clinicians?

BSI's team of technical experts have a broad range of industry and regulatory experience, allowing them to review most aspects of these devices. However, we sometimes require additional expertise. BSI need your specialist knowledge to help us ensure that patient safety remains the focus of BSI product reviews. Your experience brings a unique view to the products submitted to BSI for conformity assessment in the European Union.

Our mission is to ensure patient safety while supporting timely access to global medical device technology. We strive to set the global standard in thorough, responsive, predictable conformity assessments, evaluations and certifications.

The BSI Medical Device Mission

Clinical focus

Some of the areas we cover include:



Orthopaedic



Dental



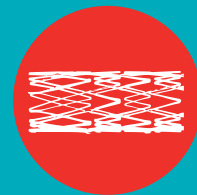
Active Implantable Devices



Active Devices



IVDs



Vascular



General Devices



Biological Substances



Drug-Device Combination

What are the benefits to you?

1 Be involved with innovation

Drive the future of medical devices by working on new product reviews while furthering your own knowledge and awareness of new technology

2 Be involved in product review ensuring patient safety

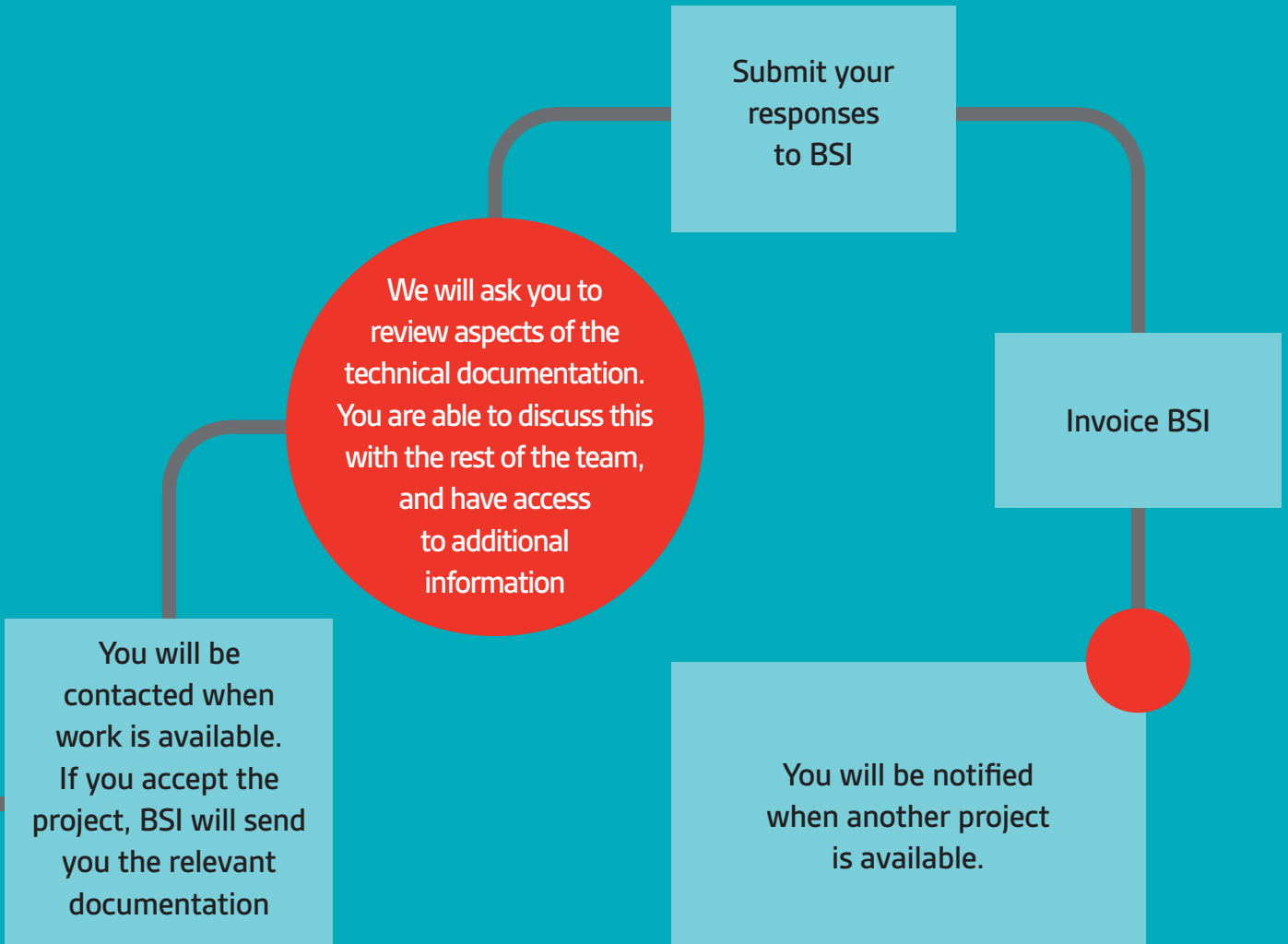
Reviewing clinical evaluations helps us to ensure that devices are safe

3 Be involved with a specialist team

Work alongside our product experts to provide your insight and knowledge

Next steps: The process explained





Toronto Office

6205B Airport Road, Suite 414
Mississauga, ON L4V 1E3
T: 416 620 9991
TF: 1 800 862 6752
F: 416 620 9911

Ottawa Office

515 Legget Drive, Suite 110
Ottawa, ON K2K 3G4
T: 613 271 7007
TF: 1 800 862 6752
F: 613 271 9007

Montréal Office

1, Place Ville Marie, Suite 2901
Montréal, QC H3B 2C4
T: 514 940 1778
TF: 1 800 862 6752
F: 514 866 2115