A Notified Body for medical devices with ancillary medicinal substances

Updated February 2016

BSI specializes in medical devices with ancillary medicinal substances

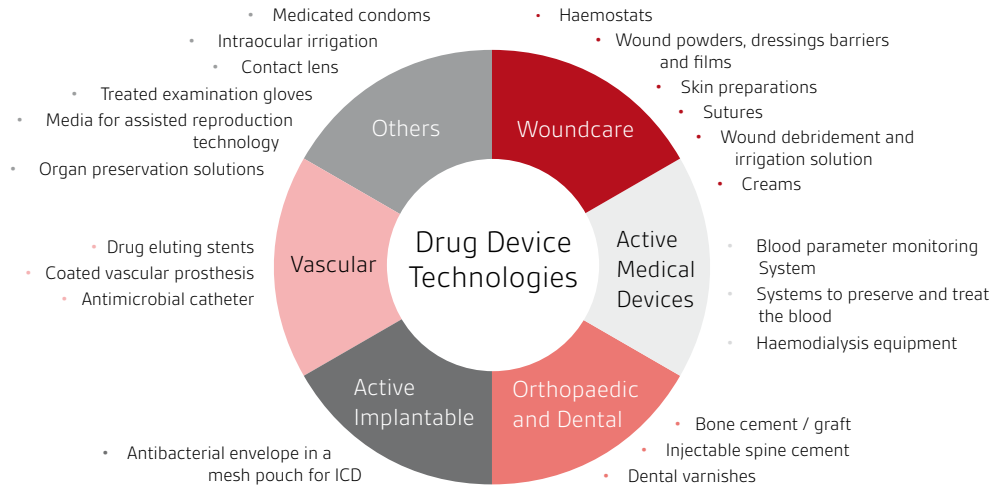
Experience and expertise

BSI recognises that regulatory requirements for manufacturers of medical devices incorporating medicinal substances can be challenging. With a long history in this field and a vast range of certified devices, BSI has the expertise and knowledge to guide you through this specialized process.

BSI understands that the addition of an ancillary medicinal substance to your device will bring added benefits but that the regulatory process will be more demanding.

BSI is proud to offer a full Notified Body service in this area. Our dedicated in-house team of experts are here to guide you efficiently through this intricate regulatory process.

Experience in Device Drug Consultations



Examples of Ancillary Medicinal Substances

Gentamycin	Heparin	Allopurinol, Mannitol, Adenosine
Human Serum Albumin	Silver, Triclosan, Polyhexanide, Idoine	Herbal medicines
Chlorhexidine	Nicotinamide, Hydrogen peroxide	Dexamethasone
Fluoride	Paclitaxel, Sirolimus, Novolimus	
Lidocaine	Benzocaine,	
Thrombin, Growth Factors, recombinant peptides	Erythromycin, Vancomycin, Doxycycline	
	Rapamycin	

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Classification

Early classification of medical products containing or delivering drug substances is essential in order that the appropriate regulatory path is determined:

- Medical products designed to deliver drugs, supplied without the drug itself are regulated as medical devices, e.g. infusion pump.
- Medical products designed to deliver drugs, supplied with the drug combined, are regulated as medicinal products, e.g. sub-dermal contraceptive implants and insulin-filled syringes.
- Medical products which incorporate as an integral part a substance which, if used separately, can be considered to be a medicinal product and which is liable to act on the human body are regulated as Medical Devices, e.g. catheters coated with heparin.

To ensure an accurate classification you must consider the following questions:

- Whether any constituents, if used separately, may be considered to be a medicinal product, for example silver, some herbal ingredients, analgesics, etc.
- What claims are made for the product – what is the intended purpose?
- The method by which the principal intended action is achieved – mode of action?
- Liability of the medicinal substance to act on the human body.

Medicinal Consultations

During the certification process for devices with an ancillary medicinal substance, the Notified Body must review device aspects and seek the opinion of a European Competent Authority in relation to the ancillary medicinal substance incorporated in the device.

Prior to seeking the opinion of the Competent Authority, BSI must verify the usefulness of the medicinal substance incorporated in the device.

The Competent Authority will provide the Notified Body with a scientific opinion on the quality and safety of the substance taking in to account the clinical benefit/risk profile of the incorporation of the medicinal substance into the device.

The review of the medicinal substance by the Competent Authority may take up to 210 days and usually runs in parallel with the review of the device by the Notified Body.

Here for you

BSI is very proud of our unrivalled history in certifying medical devices incorporating medicinal substances. With our extensive knowledge and experience in this area, BSI will provide you with timely, responsive and informed support at every stage of the certification process. Every case is different so feel free to contact us and we will be happy to discuss your individual circumstances.

Your partner in worldwide compliance: Call BSI today on 1300 730 134 or visit bsigroup.com/en-au – to start your partnership

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