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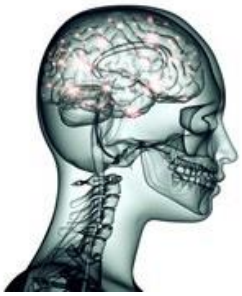
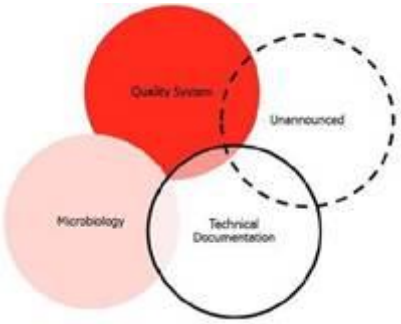


Regulatory review

Your monthly medical devices update

August 2017



Own Brand Labelling - Do you hold sufficient technical documentation?

The EU Commission Recommendation 2013/473/EU requires **all** manufacturers to hold full technical documentation for all devices covered by the scope of their certification. Manufacturers have until **1 September, 2017** to meet the requirement.

This includes OBLs, which will become Virtual Manufacturers, and legal manufacturers whose certificate scope includes devices for which they do not hold full technical documentation.

Visit our website for more information and further guidance, and to read our full statement.

Find out more

"Successful and timely" product launch

A start-up manufacturer, releasing its first device ahead of the biggest regulatory change the industry has seen for over a decade. Despite these challenges, Coala Life experienced a “successful and timely” product launch. Read this case study to find out how.

Download now

New webinar

Usability factors: a new focus

The regulatory expectations for usability - i.e. the ability for a human to interact easily and relatively error-free with a system, product or procedure - are increasing. No matter what stage of development you are in, this webinar will help you to plan and launch your product efficiently according to the necessary requirements. Join Richard Stein on 12 October, 4pm UK BST to find out more.

Register now

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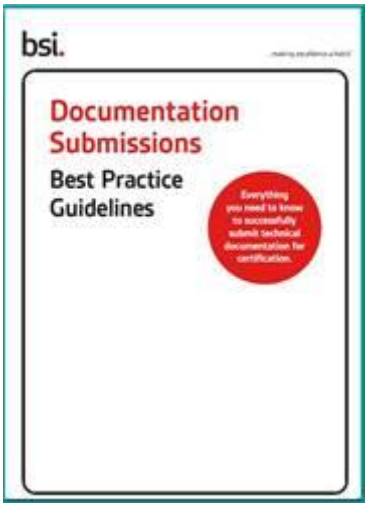
Are you confident with your technical documentation?

Use our guidance to ensure you minimize delays when submitting technical documentation for review. Understand what you need to consider, required formats and find links to useful guidance documents.

IVD guide

Medical Device guide



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