The risk-managed approach in the race to market launch

Clearing the final hurdle

bsi.

...making excellence a habit.™

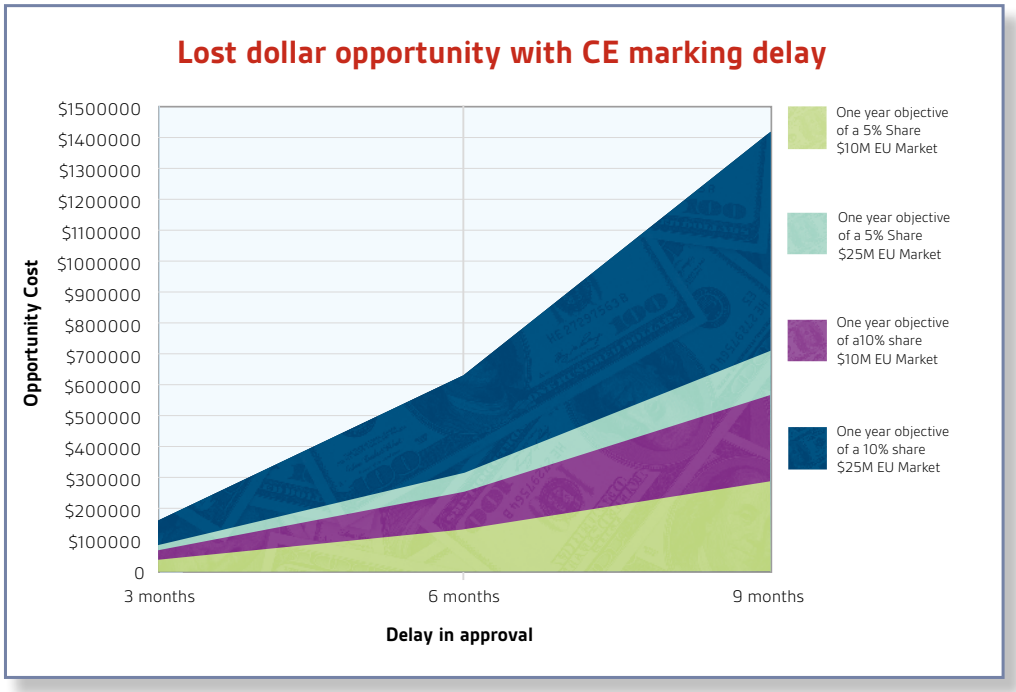


Counting the cost of a delayed product launch

With a new product launch in sight, it is important that when it comes to CE marking the product for the European Union market, the process doesn't get stalled at this final hurdle causing a failure to launch on time. Such a delay even of a few months, can have far reaching effects for the company.

A late to market launch means:

- Market expectation is missed
- Shareholder expectation is missed
- The market opportunity is missed
- The market share is missed
- First to market advantage is missed
- Missed or declining revenues
- Plans and forecasts are missed
- Boardroom dissatisfaction



Assumptions: Market share Growth linear from Launch, Graph Represents Cumulative sales to Date expected if Launch date Hit. Therefore any given point of the line reflects the cumulative lost sales opportunity at that delayed launch point. e.g. 6 months Delay in $25M market and a 10% objective year end equates to a 5% share at six months in the half year market of $12.5M or Lost sales of $600K

As a Notified Body, BSI can help you manage product launch risk

Experience and expertise:
You can be rest assured by increased patient safety, thereby reducing your corporate risk.

Tailored Service:
BSI offers a premium customized service, giving you a greater level of flexibility as well as predictability.

Market Access:
Our speed-to-market service means your product reviews won't slow down your launch plans, helping you to stay ahead of the competition.



The fast and experienced route to global markets

BSI has a strong commitment to providing the most experienced and efficient routes to global markets. This delivers the speed-to-market you need if you want to stay competitive, or more importantly, move ahead of the competition.

CE-Onsite FastTrack

BSI's CE-Onsite FastTrack Review Service is aimed at medical device manufacturers needing to get their products to European markets quickly and safely. The review service is conducted at the customer's premises,
in which BSI Product Experts visit the facility for a dedicated period of time.

This premium service works toward a CE marking target of 45 working days from submission. CE-Onsite Reviews usually allow for a much faster timeline with dynamic communications and opportunities for immediate response to questions.
Real time for real results.

CE-Dedicated FastTrack

BSI CE-Dedicated FastTrack Programme is designed for Medical Device Manufacturers needing to get their products to European markets quickly and safely. This premium CE marking Programme is for high risk medical devices requiring design dossier reviews. We provide you the same high quality reviews just at an accelerated rate, usually within 45 working days or less.

CE-Dedicated is conducted via telecommunications, as a result it does not require Product Experts to travel to
the customer's site. This means scheduling times can be more flexible and adjusted if needed.

CE-45 FastTrack

We make getting your product to global markets as important to us as it is to you. BSI knows every day can have an impact on the bottom line, so we created the
CE-45 FastTrack Programme.

The CE-45 is an expedited Design Dossier service where most reviews are completed within 45 working days from submission. Our goal is to assist you in getting your products to market faster, realizing a faster return on
your investment.

Note: *Note: Programmes do not guarantee a CE marking certificate in a certain amount of working days but commits to completing the review process with either a positive or negative recommendation. Programmes exclude reviews outside BSI's control (e.g., products containing medicines, animal or blood derivatives).*

Global expertise

Certification services

ISO 13485 QMS Auditing

CE marking

Health Canada CMDCAS

Japan PAL

FDA 510k Third-Party Review Programme

FDA Accredited Persons Inspections

Australia EU CAB

Hong Kong CAB

Russian Registration Certification

Taiwan TCP

Training courses

CE marking for AIMD, MDD and IVD

ISO 13485 QMS

Medical Devices Risk Management ISO 14971

CE marking Medical Devices with Software

Compiling and Maintaining Technical Files and Design Dossiers

Clinical Evaluation for Medical Devices

Device - Drug Combinations: Practical Guidance on Borderline Issues and the Consultation Process

Process Validation for the Medical Device industry

Post Market Surveillance and Vigilance

Medical Devices Utilizing Material of Animal Origin.

Your partner in worldwide compliance: Call BSI today on 1 800 862 6752 or visit bsigroup.ca/medical – to start your partnership

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

Visit us online at: bsigroup.ca/medical

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