Helping Start-Ups Avoid Slow-Downs

Paul Brooks

BSI Group America, Inc [1]. identifies the 7 Most Common “Rookie” Mistakes Medical Device Companies Make When Preparing for a European Product Launch

For U.S.-based medical device start-ups, speed to global markets is often the most pressing concern, but trying to move too fast often leads to preventable mistakes that could take the CE Marking process back to the drawing board, according to healthcare experts at BSI Group America, a leading Notified Body that helps companies comply with the essential regulatory requirements of the European Union.

CE Marking on a product ensures the free movement of the product within the European Free Trade Association and European single market that totals 30 countries, giving manufactures a wealth of global opportunities. The best way to avoid snags in the approval process, says Paul Brooks, SVP for BSI Healthcare Solutions, is to learn from the mistakes made by companies who have previously gone through the process.

“Everyone makes mistakes, but in the medical device industry, a mistake can set a manufacturer back months or years and often millions of dollars,” said Brooks. “It’s best to learn from others’ mistakes and get it right the first time.”

To help new medical device companies do just that, Brooks has identified the following seven “rookie mistakes” typically made by medical device start-ups.

1. Assuming regulatory clearance in the U.S. is a gateway to CE Marking in Europe.
   Medical devices in the EU are governed by one of three Medical Device

Directives (MDD, AIMD, IVDD). While going through the FDA's process might help in a manufacturer's ability to present technical data for review, previous FDA regulatory clearance plays no part in the CE Mark certification decision.

2. Your product does not fit the definition of a medical device in the EU.
   European medical device Directives are very specific about what they consider to be "medical devices." As a result, a product that is defined as a medical device in the U.S. might in Europe be considered a cosmetic or drug or personal protective equipment or food or lab equipment (or something else) that would be reviewed using an entirely different set of standards.
3. Your subcontractors do not possess appropriate quality certification.
   When a manufacturer obtains parts or service from a third party, that subcontractor must have the appropriate Quality Management System (QMS) certification, or approval may be declined. Subcontractors must have a QMS certificate issued by an EU/EEA Notified Body that is valid for the indicated product or service and location as specified by the manufacturer.
4. Lack of a risk-appropriate Clinical Evaluation Report (CER).
   Regardless of device classification, all applications must include a risk-appropriate CER conducted by qualified individual(s) evaluating the technology, research methodology, and clinical diagnosis / management of the subject device or equivalent devices. A literature review and predicate device substantial equivalence (similar to what is required in a US 510[k]) may not be sufficient.
5. Not having or executing an appropriate Post Market Surveillance (PMS) Plan.
   To support CE marking of a device, a manufacturer must present a PMS or Post Market Clinical Follow-up Plan to confirm clinical performance and safety throughout the expected lifetime of the specific device or group of devices. Using a generic PMS procedure would not be sufficient.
6. Expecting a fast approval of your device-drug combination product.
   In general, device-drug combination products are ruled class III under the MDD and require both a device review by the Notified Body as well as a medicinal consultation with a Competent Authority — a process that typically takes 210 days to complete. Where claims are made that a drug is present but "not liable to act," the manufacturer will often need to demonstrate this through scientific data (i.e. in vitro or in vivo studies).
7. Submitting a technical file or design dossier that is poorly assembled or incomplete.
   A poorly organized submission wastes time and therefore money while the reviewer struggles to get through it.

Brooks added that there are some mistakes that are less common, but are worthy of an "honorable mention," including:
Not justifying the benefit of a 2003/32/EC device (one using animal tissue) over a lower-risk species or synthetic device.
In Europe (unlike in the U.S.), manufacturers must demonstrate with data that the benefits of using animal tissue outweigh the associated risks relative to lower risk material alternatives.

Paul Brooks qualified as an electro-mechanical technician engineer at BSI Testing

Laboratories. He is a long standing member and Board Member (President 2012) of the Regulatory Affairs Professional Society (RAPS) and a member of American Society for Quality (ASQ) – Biomedical Division, he routinely presents and trains at sessions organized by both of these societies as well as the Association for the Advancement of Medical Instrumentation (AAMI), AdvaMed and other focused meetings. Paul was invited in Spring 2007 to join an International Accreditation Forum (IAF) Working Group to explore the wider acceptance of accredited ISO 13485 certification as a basis for helping to meet regulatory requirements for emerging regulations around the world.

Links:
[1] http://www.bsiamerica.com/Healthcare