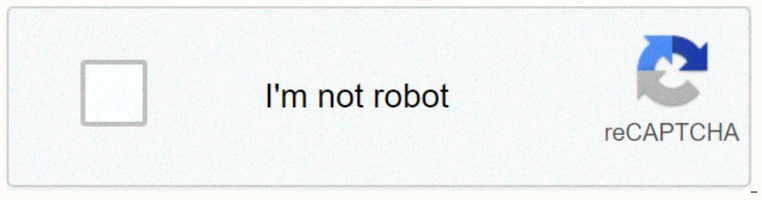

Continue

Anvisa medical device adverse event reporting

24 July 2019 The Brazilian medical device market regulator ANVISA has started requiring manufacturers and sponsors to provide information on safety corrective actions through an electronic petitions system. According to an anvisa announcement, companies whose medical devices or IVDs are involved in adverse events or other incidents must now submit FSCS through the agency's online system, Sistema Solicita (links in Portuguese). ANVISA no longer accepts hard copies or email. Additional Brazilian Medical Devices and IVD Regulatory Resources: Author Connected It's 3:00 p.m. on Friday and you're ready for the weekend after a busy week. Suddenly, you go back to reality with an email about a serious incident at a French hospital involving your company's monitor. The details are sketches and somewhat lost in translation. Now it's 9:00 p.m. in your office in Europe. They are closed for the weekend and you can't get any more details. Can it wait till Monday? If you've been in the role for a while, you already know that incidents like these happen... and you have no control over time. In the event of very serious incidents, your response time is limited, sometimes only 48 hours. In some markets such as Australia, Brazil and Europe, regulators want to know about very serious incidents, even before you have had time to investigate them. Since you may not have much time to look at the incident – not to mention explore reporting requirements – you need to be aware of what can be reported in any major market and when. What should be reported? Each country has different rules about what should be reported and how quickly. But in general, you need to file a report with a medical device regulatory authority when: There is death or serious deterioration in health. There has been a serious threat to public health. A sustained negative trend has developed. A safety corrective action (FSCA) was issued. Usually, if your label is sufficient, no reporting is required when: There is a very low probability of death or serious injury. The incident was caused by a patient/user error. The service life or shelf life of the device has been exceeded. Side effects are predictable and disclosed. A problem with the device was detected before using. The device shutdown or failure mechanism is working as intended. Don't delay – The clock is ticking for events that are reported, The moment you realize about an incident that you think is reportable, the clock starts. It is vital that you quickly establish how long you have to report the incident, which will depend on its seriousness. If death or serious injury has occurred, you have between 2 and 10 days to report as shown in the table below. Less serious events/incidents can be reported in 15 to 30 days. Keep in mind that these are calendar days, not working days. For example, if you learn of a death involving your device on Friday at 11:00 a.m. you will need to report on the incident by Sunday, if this happens in Australia. You can change your preliminary report with additional information later. Also, if you've heard of an incident but aren't sure if it's reportable, send a report anyway. It's important to remember that submitting an incident/event report is neither an admission of liability nor that your device caused or contributed to the event. When in doubt, report it. Quick reference to timelines for reporting medical devices When accidents occur, you should be ready to investigate them quickly. This is important because you obviously want to ensure that no further harm will be done to patients or consumers, but also because regulators have commissioned a quick response. The following are the basics of the events that can be reported and how soon they should be reported. Keep in mind that this is not a complete list, and each party has exceptions and details that can change your reporting responsibilities. * The European requirements are for the Medical Devices Regulation (2017/745). ** Japan has specific reporting times for incidents involving device failures, breakage and failure that can lead to serious events. It is only required if you sell the same device on this market. The types of events reported vary by country. The U.S. FDA requires the reporting of all former U.S. events, but in Brazil, for example, this only applies to death, serious deterioration of health, and counterfeit devices. As they say, the devil is in the details. You don't want to miss the deadline because you thought something wasn't reportable or because you thought it was less serious than the regulator had picked up. It's better to be on the safe side and report too early than too late. It's also easy to forget that an event that can be reported in Europe, for example, can also trigger reporting requirements in Brazil or the U.S. if you sell the device there. Never assume that an ANVISA regulator would not have been aware of your incident in France. Also, once the Eudamed database starts living in Europe in the early 2020s, incident data will be publicly visible, as will today through the U.S. FDA database. Learn more about medical device reporting We hope you enjoyed this high-level quick review on incident reporting deadlines. If you want to learn a lot more about incident reporting and complaint handling, check out our series of four blog posts on the topic. You can also dive even deeper into this topic in our intensive ad complaint reporting training class, which takes place in different U.S. cities. Us.