

Chapter 1 : FDA: medical devices still at risk for Y2K -- FCW

On May 26, , medical device manufacturers around the world face a challenging deadline: submit regulatory dossiers to Notified Bodies in compliance with the new medical device regulations (MDR) passed by the European Parliament this past May, or lose the ability to sell these devices in Europe.

IBEC represents the policy interests of 7, Irish companies, including many of the largest multinational medtech firms and many indigenous contract manufacturers. Also in attendance were medical device contract manufacturing companies and pharmaceutical firms. McCoy had been preaching about the dangers of a Brexit vote on complex international supply chains for months ahead of the referendum. Recently, however, the CBI has become more vocal on risks to British businesses if the United Kingdom fails to secure a negotiated settlement with the EU. Of the delegates present, only five people thought Britain might leave, including quite ironically a British futurology expert. Less than 2 percent of the delegates present at the conference correctly predicted the outcome of the vote. Suffice to say, nobody at the conference that day really expected the United Kingdom to break from Europe. All industries seek certainty in their trading environment, but the life sciences sector is especially risk adverse. Medtech companies are built on creating certainty and validated repeatability in their products and processes. How might Britain leaving the European Union impact the certainty of raw material supply and the distribution of finished products? How might complex intra-company transactions be affected by the United Kingdom-Europe breakup? The EU was founded on principles of free movement of goods, capital, and people. Negotiating a trade deal normally takes many years of diplomatic efforts. The EU has trade arrangements with other countries such as Norway, Switzerland, Canada, and Turkey but none of these models are likely to work for the United Kingdom. The United Kingdom will want access to European markets—particularly financial markets—but unlike other countries Norway or Switzerland, it is more than likely unwilling to contribute payments for market access. Medical device companies should stress test their supply chain infrastructure to determine the impact of a hard Brexit by asking themselves some difficult questions: Will sourcing products from the United Kingdom require a calculated tariff rate for those components? Will a tariff rate on U. Does expertise exist within the company to classify goods sourced from the United Kingdom? Does selling to the United Kingdom automatically subject products to tariffs? What impact will customs inspections have on lead times if products are transported through the United Kingdom? Should the United Kingdom be bypassed as a transit point? Will products continue to have U. There are many practical examples of tariffs if the United Kingdom does not secure a trade deal with the EU. A European medical device company, for instance, is currently not charged for sourcing a plastic molded container from a U. An organic chemical like Aminoazobenzene sourced from a U. Reciprocally, the United Kingdom could impose tariffs on EU material imports, making life difficult for medtech manufacturers. Companies that sell products in the U. But manufacturers with U. Though purely hypothetical, these tariff scenarios may impact where medical device companies decide to invest in future manufacturing facilities. Brexit might have its greatest impact on global supply chains in Ireland, a country with a healthy mix of branded medical device developers and contract manufacturers. Irish manufacturing sites access major European markets through U. Raw materials and components sourced in Europe go through the United Kingdom as well, with some likely destined for Ireland. A hard Brexit could have a dramatic impact on Irish-based medical device supply chains. A report from Dr. Ke Han of Imperial College in London estimates that a four-minute delay in paperwork inspection would cause a 40 km tailback of trucks in the U. And while the HMRC is building a new IT system to cope with the expected increase in paperwork, there is little confidence the program will be delivered on time for Brexit. There will undoubtedly be other global impacts to consider besides those affecting the United Kingdom, Ireland, and the EU. These agreements generally take years of preparation and negotiation. Other countries have traditionally treated EU trading block agreements as a priority because of their scale, but a new U. It would be quite ironic, actually, if the United Kingdom missed the opportunity to trade freely with other commonwealth countries because of its decision to leave the EU. Obviously, there is still a lot of uncertainty around the United Kingdom-EU breakup. A hard Brexit might have a significant impact on supply chains, but

a last-minute agreement between the United Kingdom and EU could deliver a much more workable solution. There are an abundance of opinions about the potential impacts: He helps medical device and pharmaceutical firms outsource non-core activities. He has more than 20 years of experience working with companies to create robust supply chains and sales channels across EMEA markets.

Chapter 2 : Y2K Compliance at Duke Outlined as Model Plan - Anesthesia Patient Safety Foundation

Health care providers are accusing medical device makers of possibly leaving them in the lurch by failing to give enough warning that equipment may fail.

Email If you have a medical problem, or care for someone who does, all the talk about possible Year computer failures may sound a little scary. Doctors have operated right through hurricanes, using battery-operated lights if they have to. They know how to treat people without the help of computer-operated gadgets. Aside from FDA-monitored medical machines, remember hospitals are prepared for the unexpected every day, says Rick Wade of the American Hospital Association. There are plenty of prescription drugs, so consumers should not hoard. Here, in question and answer form, is a look at some common Y2K health questions: Will my pacemaker stop working on Jan. Pacemakers and anesthesia machines "could care less about what day it is," said Dr. David Feigal of the Food and Drug Administration. They measure time second-to-second or hour-to-hour and will keep right on ticking as the century turns. Some other medical machines do have computer chips that use a date, but a recent FDA audit concluded those that pose risks to patients have been fixed. Patients can ask their radiation technician if that was done. Will home medical equipment, like glucose monitors, stop working on Jan. Some sophisticated home medical machines keep dated records of readings. The date is only a recording mechanism - your glucose monitor will still read blood sugar, even if the date is wrong, Feigal explained. He calls this just a nuisance, but says consumers can call the manufacturer the name and number should be on the machine to ask what to expect. What if I need an ambulance? If you dial , "someone will answer," pledged Mark Adams of the National Emergency Number Association, which next week will release a study of readiness. Anyone concerned could keep the local police number by the phone too. What about my medical records? The vast majority of doctors still use paper medical records. If yours uses computerized records, there probably is a paper copy too, but ask your doctor if he or she is Y2K compliant, Palmisano said. This material may not be published, broadcast, rewritten, or redistributed.

Chapter 3 : Y2K Medical Concerns - CBS News

Y2K Update. FDA releases Y2K list of critical medical devices. Pay special attention to these items before Jan. 1. The Food and Drug Administration (FDA) recently published a list of computer-controlled medical devices that have the potential for the most serious consequences for patients should they fail because of year (Y2K) date-related problems.

Ruskin, MD With the year less than days away, individuals as well as large corporations are concerned about how computers and computer-driven devices will be affected after December 31, Fortunately, however, many life-sustaining biomedical devices do not use date calculations to perform their tasks, and will continue to function after or can be easily updated. Briefly described here are the Y2K bug and how it affects anesthesia and monitoring devices. What, exactly, is the Y2K problem? Until recently, computers had only limited amounts of storage space for programs and data. To conserve this valuable resource, computer programmers used only the last two digits of the year when performing date calculations. Although this seems like only a small difference in size, this technique resulted in a significant reduction in storage space as databases grew to include millions of records. The problem with this approach is that it works only as long as both years occur in the same century. If for example, a patient was born in 1962, his age would be determined by subtracting 62 from 98, leaving 36. On January 1, 2000, however, a program that uses only the last two digits of the year would subtract 62 from 00, leaving 38. This is not the only problem related to the year 2000. Leap years occur every four years, except on century years. The exception to this exception rule is that a leap year does occur on a century year evenly divisible by 4. So January 1, 2000, is not the only date to worry about – some programs may also behave unpredictably on February 29 and March 1, 2000. A third problem will occur somewhat later, when the calendar of computers that use the Unix operating system, which counts milliseconds since midnight, January 1, 1970, rolls over. Old Programs Still in Use The developers of programs now facing the Y2K bug largely assumed that their programs would be updated and replaced long before the end of this century. Contrary to their expectations, however, this did not occur. The result is millions of lines of program code that must be read, understood, and modified, and also database structures that must be updated, so that date calculations can be performed correctly after the year 2000. Unfortunately, the consequences of the Y2K problem are not limited to inaccurate date calculations. Since most programs never anticipate a date result less than zero, calculations of all types might become unpredictable, leading programs or entire systems to malfunction. Many older mainframe, desktop, and laptop computers will malfunction or become unpredictable after the Year 2000. The problem is not limited to desktop and mainframe computers. Importantly, many electronic medical devices employ microcomputers and embedded software, possibly even in such a way that their presence would be unknown to the user. Some of these devices may stop working or produce unpredictable results. Some manufacturers of affected medical equipment offer solutions to the problem with existing equipment, while others require that a solution be purchased or even that a new device be bought. To begin to solve the Y2K problem, the first step is to recognize that it exists, and also to convince administrators of the involved medical facility hospital, surgery center, clinic, office, etc. It is important for anesthesiologists either to be sure that someone is being responsible for this or to take responsibility for their own equipment. The second step is to understand that is too close to implement a definitive solution to the problem for all affected devices. Instead, it is important to triage equipment and computers into three categories. Life sustaining equipment that is susceptible to the Y2K bug must be fixed or replaced prior to the year 2000. Equipment which is not life sustaining should be fixed, although not necessarily prior to the year 2000. Some equipment may not be able to be updated, and should be replaced or discarded. Physicians and administrators should contact the manufacturer of each medical device and work with them to determine which items will be affected by the Y2K bug and what action should be taken. Some life sustaining devices used daily by anesthesiologists e. While a comprehensive list of which pieces of relevant equipment are compliant and which are not is far beyond the scope of this article, such resources do exist. The Food and Drug Administration has set up a World Wide Web resource with their statement regarding Year 2000 compliance, a letter to equipment manufacturers, and the status of many brands of medical equipment. Y2K will have a substantial impact on nearly all sectors of the economy, from air travel to

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credit card transactions. Our patients, however, will not be adversely affected under our care if appropriate steps are taken in a timely fashion. Contains a letter to manufacturers, and a database of equipment. Has a link to a free PC test program.

Chapter 4 : "Y2K Bug" Equipment Concerns Intensify - Anesthesia Patient Safety Foundation

*Y2K and medical devices: Testing for the Y2K bug: joint hearing before the Subcommittee on Health and Environment and the Subcommittee on Oversight Congress, first session, October 21, [United States] on racedaydvl.com *FREE* shipping on qualifying offers.*

These tests consist of simultaneously moving as many systems and components as possible forward or backward to various critical dates. These tests require an extraordinary level of preparation and coordination to ensure the safety of all systems and that the impact to the electric system would be minimal should a unit trip during the test. Of all the integrated unit tests reported to date, not one test of a fully remediated unit has resulted in a Y2k failure that caused the unit to trip. In some cases, units that were moved forward to a post January 1, date have been left to continue running with clocks set ahead with no negative consequences. Others report setting units back as a mitigation strategy. A typical setback is 28 years to more closely align the calendar dates. The NERC reports smash that myth. In fact, the nuclear power industry is more tightly regulated than the rest of the electrical industry and began Y2K remediation a year before the rest of the industry. All of the nuclear generating facilities completed the initial inventory by May, and most were scheduled to have completed their assessments by the end December, Thus, Y2k problems in nuclear facilities do not represent a public health and safety issue. However, a number of systems synchronize their central clock function to a signal provided by a Global Positioning Satellite, which would automatically correct time and date anomalies. Many Internet sites express a concern that since electrical distribution is tied into a grid by computerized distribution, that a failure in part of the grid will bring down the entire electrical grid. Although this is possible, it is not uncorrectable. In addition, utilities have the ability to cut off parts of the grid that are negatively impacting their own ability to supply power. There was also a question of power plants being unable to restart after a power outage. I came across an article that discusses the ability of power plants to "black start". To do that, the plant needs what we call black-start capability. It has to be able to first generate a small amount of power to energize the motors and the controls in the plant to start the plant itself. All nuclear plants and many fossil plants have diesel generators whose purpose is to supply the internal power needs in case of emergency. During the summer, when everyone is running air conditioners, it is true that there is very little spare capacity. It is very fortunate that there will be an entire weekend to work out bugs and get power supply problems fixed before the business crunch of the workweek. In conclusion, it seems reasonable that there will no electrical industry Y2K failures on or after January 1, From my perspective, I think it would be very improbable that entire electrical grids will fail. The spare electrical capacity should be sufficient to more than make up for any failures. Y2K and the embedded chip problem The problem with embedded microchips is probably the most serious because of the difficulty in identifying and replacing the problem chips. However, as noted above, and in other studies, the problem with embedded chips appears to be less than originally thought. Those that do fail will fail at the millennium, and the majority of these will only fail once. Early this year, Ann K. Coffou of the Giga Information Group, a consulting firm, was among the many experts who were warning that most businesses and government agencies were too far behind in making the needed fixes. However, the finding that embedded chips are causing very few, if any, problems in nearly all systems tested has changed her mind. Other cities and agencies are finding that this is an easy, economical way to solve certain Y2K problems. This solution has been recently used to "repair" an old legacy system. California Casualty Management Company , a San Mateo-based insurance company, has found a unique way to buy more time. All dates that are input into the system are changed to 28 years in the past. The legacy computer system operates on these dates as it usually does and will not encounter the year for another 28 years. All dates that are output from the system are incremented by 28 years, so that all policies, etc. Nearly all of the failing institutions are small banks and credit unions. When the date was set to January 3, the first trading date of all trades were completely successfully. According to Director of Information Clearing Systems, George Thomas, "I think this will go a long way to show the world that the world payment system is intact and ready to go for As with any business, there are potential Y2K problems in accounting systems, computers and computer

networks. In addition, there are a number of medical devices that use embedded chips to perform some of their functions. However, the number of Y2K-sensitive medical devices is small. For example, Dakota Heartland Health Systems inventoried 2, pieces of equipment, of which, only 20 were not year compliant. Only 10 of those 20 directly impacted patient care. I got to talk to him for a few minutes about what the hospital will be doing to be Y2K compliant. Cedars-Sinai has adopted the policy of "its cheaper to replace than be sued" and so are replacing all their EKG and other medical equipment that is not Y2K compliant. They are also replacing all of their accounting software that is not Y2K compliant. This will actually be a good thing, since it will unite the now separate accounting systems found in the hospital. Other large telecommunications companies plan to have their systems ready before mid-year. Y2K and businesses The Y2K outlook for businesses is quite variable and very dependent upon the individual situation. Most large and medium-sized companies are well on their way to Y2K compliance. Some of the automated manufacturing plants may have Y2K problems caused by the changing of the century. Businesses may experience Y2K problems in their accounting, computer, and networking systems if they are not Y2K compliant. The simple solution for most businesses will be to replace the non-compliant systems with ones that are compliant. As I surf the Internet, I have noticed that virtually every software manufacturer has a statement about Y2K compliance on their web site. Those databases that use two digit dates will also have to be converted to handle four digit dates. In most instances, the task is relatively trivial. Many businesses use customized applications as part of their normal business operations. Many of these custom applications will have to be rewritten or replaced. In addition to fixing the code, there are programs that reside between the application non-Y2K compliant and the operating system. Phaseshift produces one such language-independent run-time utility that intercepts dates and automatically corrects them, insulating both the non-compliant program and data sources from improper date reporting. There are numerous programs, many of which are available free on the Internet, that test and fix BIOS problems, Windows problems, and software problems. For instance, a number of Federal Programs are dependent upon the cooperation of state and local agencies. The Department of Agriculture is dependent upon the states for food stamps, WIC, child nutrition programs and food safety inspections. A few states are not yet Y2K compliant, so those services could be interrupted if there are computer failures. Other departments at risk due to unprepared program partners include Education student aid requires functioning of state, granting agencies, and school administration , Health and Human Services child care, child welfare, child support enforcement, Medicaid, Medicare, and other assistance programs dependent upon state and local agencies , HUD public housing agency dependence , Labor unemployment insurance dependent upon state compliance , and Transportation air traffic control is dependent upon airline carrier compliance. I have bad news for those of you who thought you might not have to pay your taxes because the IRS would be unable to process them. IRS officials announced in early January that they will finish work and testing on 70, computer programs by the end of the month, a process that has taken 1, people two years to complete. IRS workers have rewritten some 40 million lines of computer code. According to the project director, John Yost, "By the end of January, every computer program we have will be Y2K-compliant. Claims were properly and timely processed by all 50 states, Washington, D. Claims processing was vulnerable to Y2K problems beginning Jan. Y2K and the Post Office According to postal authorities, the mail will be delivered after January 1, The postal service recently completed tests of mail processing equipment that were successful. Coughlin, "These tests were able to verify the ability of our equipment to accurately sort mail in the year environment. Most of the actual vehicles used for transportation are completely unaffected by year issues. However, all industries are dependent upon computers for scheduling, billing, etc. All critical BNSF equipment containing embedded devices was remediated and tested by December []. Crossing signals and switches are free of Y2K problems because they are "event-driven," activated when a train drives over certain portion of track, rather than time- or date-driven. The new "intelligent" grade crossing signals installed in Connecticut and Michigan are Y2K compliant. General Motors and General Electric, two principal manufacturers of trains with onboard microprocessors, have been testing for Y2K compliance. So far, the only problems found do not affect operations. Some trains are equipped with electronically controlled air brakes and integrated cab systems with computerized flat-panel display screens. These suppliers have certified their equipment as Y2K compliant. He

said only 8 to 10 percent of all failures related to Y2K will occur within two weeks of Jan. If companies believed they were going to fail because of Y2K problems, one would think they would put more resources into the solutions. As mentioned previously, the conversion of code to Y2K compliance can be handled by ordinary staff as demonstrated by a bureau of the federal government. Two-thirds of the respondents said that their companies would spend less than 10 percent of their budgets on the Year problem for the coming fiscal year. Only 13 percent plan to give it more than a third of their budgets - a lower percentage than in Peritus Software Services Inc. Computers are running at capacity - Many individuals also claim that computers are running near capacity, and so are unable to run Y2K testing. For most companies and agencies, computer systems may run near capacity during the day, but usually perform maintenance and backup functions at night. The information systems department of my company does their maintenance and testing during "off" hours.

Medical implants - There are a number of sites that claim that medical implants will malfunction in the year. The notion that pacemakers will stop working next year "is an urban legend," says Thomas B. Shope, who is working on year issues at the Food and Drug Administration. Boeing Company has found embedded Y2K problems in three different on-board systems affecting roughly of the 12, commercial planes it has manufactured over the years. In of the non-compliant aircraft, the embedded bug would merely cause the year to be displayed incorrectly on a control panel. In the other 50, though, the bug would keep the plane from ever leaving the gate.

Chapter 5 : Y2k Medical Pa - Lake Jackson, TX - Family Medicine

FDA releases list of high-risk medical devices. Inclusion depends on assessment of patient risk. To more sharply focus its efforts on the possible impact of the year (Y2K) date problem on medical devices, the federal Food and Drug Administration (FDA) in Rockville, MD, has developed a list of types of computer-controlled, potentially high-risk medical devices that have the potential for.

Although an estimated 80%, personal computers will not properly handle the date change from December 31, , to January 1, , the Y2K problems facing the health care industry involve much more than just mainframe and desktop computer failures. The problems potentially involve life-and-death situations because many medical devices use embedded microprocessors or "chips. Medical records, including payment and billing records, could also be adversely affected for the same reasons. The Y2K problems developed years ago, when it was common for computer programmers to conserve computer memory by using a shortcut in which only two digits, rather than four, were used to represent each calendar year. Y2K problems can occur whenever date-sensitivity is involved. Other dates which programmers used for "testing" computers may likewise trigger Y2K problems. A commonly-cited example is the date of September 9, . Computers, software programs and embedded microprocessors are the essential components of many medical devices and pieces of business equipment, and many medical devices use multiple embedded chips from multiple manufacturers. Unfortunately, if any one of these embedded chips is Y2K sensitive, the device may not operate normally or may not function at all. Unlike desktop or mainframe computers, embedded systems are not always easy to recognize, check, or fix. Even when these chips are located, another problem in determining if they and the device are Y2K compliant arises because many manufacturers have apparently used different embedded chips for the same model of devices. It is for these and other reasons that most experts now think that the embedded chips are the larger Y2K problem. The Institution of Electrical Engineers provides very helpful information about embedded chips and the related Y2K problems at <http://> As a result of the Y2K problem, equipment may operate abnormally or may quit functioning altogether. Even when the computer chip identified in a device is found to be compliant, dangerous problems could result if the device communicates with a non-compliant computer through telemetry to provide mathematical calculations. The Food and Drug Administration FDA has been calling upon Medical Device Manufacturers to voluntarily identify those devices which they have determined to be compliant, those that have been determined to be non-compliant, and those that have yet to be fully tested. This report and other reports focusing upon Y2K issues involving the health care industry are found at <http://> While several Y2K-related, health care class action lawsuits have now been filed, they have only focused upon the damages incurred in remediating upgrading or replacing purportedly non-compliant medical software that was sold to doctors and hospitals as being Y2K compliant. The more frightening suits for the health care industry, however, will involve patient injury and wrongful death suits. Their claims will be that many of these defendants breached their fiduciary duties owed to patients to use reasonable care in locating and correcting dangers associated with Y2K problems. Such patient dangers are not imaginary. Even with the limited responses provided to the FDA by the medical device manufacturing industry, among the already identified, non-compliant devices are:

Chapter 6 : Y2K Issues Facing the Health Care Industry

The FDA has found no device implanted into people that causes any Y2K concern. Some other medical machines do have computer chips that use a date, but a recent FDA audit concluded those that pose.

Chapter 7 : Y2K - How Serious Will It Be?

Y2K and Medical Devices: Screening for the Y2K Bug: Joint Hearing Before the Subcommittees on Health and Environment and Oversight and Investigations of the Committee on Commerce, House of Representatives, One

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Hundred Sixth Congress, First Session, May 25,

Chapter 8 : DOD resold non-Y2K compliant computers, medical devices -- FCW

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Chapter 9 : Brexit: D-Day Or The Y2K For Global Supply Chains? - Medical Product Outsourcing

From Medical Correspondent Eileen O'Connor (CNN) -- With many concerned about the potential effects of the Y2K bug, experts say there is no need to worry about pacemakers and defibrillators.