The ORACLE is a free newsletter of recent medical device regulatory & computer information that may be of interest to designers, and device Manufactures.

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NEWSLETTER FROM **DELPHI CONSULTING GROUP** (**DCG**)

An Internet Based Medical Device Regulatory Service,

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Delphi Consulting Group (DCG), provides medical device regulatory (FDA) release to market via the 510(k) and PMA pathways. DCG is Internet based to boost efficiency and reduce costs

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Changes to the FDA's Electronic Medical Device Reporting (eMDR) and Manufacturer and User Facility Device Experience (MAUDE) Systems

The U.S. Food and Drug Administration (FDA) updated its systems for medical device reporting of adverse events to enhance usability of the Electronic Medical Device Reporting (eMDR) templates and to improve transparency and analysis of the medical device report (MDR) data contained in the public Manufacturer and User Facility Device Experience (MAUDE) database.

Updates to eMDR previously announced in May 2020, as described on the eMDR System Enhancements web page, are complete—including the addition of fields for summary report, number of events, and combination product—and are now available in the eMDR system, eSubmitter, and the MAUDE database.

The FDA has updated the eMDR system, eSubmitter, and the MAUDE database to add a field to help identify the exemption number, where applicable, for the medical device report (MDR). The exemption number may apply to those reports submitted under approved exemptions, variances, or alternative forms of reporting, as described in 21 CFR 803.19. No exemptions change the manufacturer's responsibility to investigate based on available information and to report MDR-reportable events.

With these new fields, the FDA expects submitters to cease reporting exemption numbers in section H10, and instead use this new Exemption Number field, along with the previously announced summary report and number of events fields, on or before February 28, 2021. The new individual field for exemption number helps identify reports associated with approved exemptions, which could previously only be found by searching for text in the narrative field.

The eMDR updates include other minor modifications to the previously announced changes, most notably involving a change to the location of the Combination Product flag. The eMDR Implementation Package file has been updated accordingly.

To align with updates approved by the International Medical Device Regulators Forum (IMDRF) earlier this year, the FDA also updated the list of Device Component codes that eMDR will accept. In addition, the FDA has extended the deadline for use of IMDRF codes in place of retired Patient Problem Codes and Device Component Codes to February 28, 2021.

In addition, the following fields from FDA Form 3500A are now available in public MAUDE:

- Patient problem codes
- Marketing submission number (for submissions such as 510(k) and PMA)

These fields have been added to the public MAUDE database to provide additional information on the nature of adverse events and related devices, when available.

https://www.fda.gov/medical-devices/emdr-electronic-medical-device-reporting/emdr-system-enhancements?utm_medium=email&utm_source=govdelivery

Can you add connectivity to medical devices already in the field?

September 1, 2020 By Nancy Crotti Leave a Comment

You can add internet connectivity to older devices if you identify the right combination of business goals, customer needs and technology solutions.

Piotr Sokolowski, S3 Connected Health

Many medtech companies require their devices to be connected to the internet. Connectivity can be added to the thousands of pre-existing devices in the field. Here are some guidelines to help you succeed.

Identify your business needs

You'll need to identify a genuine business reason to justify the effort required from R&D, regulatory, operations and other functions. For internal stakeholders to back your project, explain how collecting data on the device will benefit the company. Offering tangible gains for particular departments is crucial for success here.

Examples of areas that can achieve tangible improvements from device data include:

- Preventive maintenance.
- Context-based technical support and user training.
- Remote firmware upgrades.
- Device and consumables tracking.

Start with areas that can directly translate into reduced effort for internal support functions, like maintenance and technical support, or lead to improved outcomes and efficiency for device users.

Often, after launching the first connectivity project and showing specific benefits, other stakeholders will see the value information brings and request other types of data to be delivered over your new connectivity mechanisms. This data can be used to direct future enhancements to equipment, improve product differentiation, establish more meaningful customer engagement and service other stakeholders in the device ecosystem. These follow-on features can collectively deliver significant return on investment from the project.

Get clinical customers on board

Hospitals using your equipment may hesitate to allow modifications for fear of taking on additional work and adding to their

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risk of cybersecurity threats. After all, they are operating within the confines of established clinical protocols, strict IT requirements, and overloaded clinical staff.
To succeed and demonstrate the real value of connectivity, show how their real unmet needs can be addressed using data and strive to seamlessly integrate these upgrades into the clinical environment.
The resulting benefits for clinicians and clinical managers can include:

- Reduced device downtime and increased use.
- Improved treatment set-up and patient preparation.
- Improved patient safety.
- Increased clinical performance.
- Reduced consumable usage.

Practical considerations
The final hurdle is introducing connectivity and data collection technology into the device as seamlessly as possible. This means having the least possible impact on the equipment design and associated processes (e.g. manufacturing) and with minimum regulatory burden resulting from the change. The following aspects must be considered:

• Impact on equipment design: The connectivity component (whether internal or external) will need to meet a number of diverse requirements related to aesthetics, mechanical, electromagnetic compatibility, power consumption, heat dissipation, hardware and software integration/separation, bill-of-materials cost, etc. It requires excellent engineering skills and innovative thinking; there is much less design freedom than in new designs.

• Impact on manufacturing and operations: Adding connectivity will mean adding to an established component supply chain, manufacturing line and operations processes; be sure to minimize the impact of this. Re-using existing components and suppliers, complying with their Design for Manufacturability (DFM) and other Design for Excellence (DFX) rules, and, most of all, containing the design change within particular subsystems helps to reduce the impact.

• Selecting the right communication method: There is a wide selection of standards from Zigbee and Bluetooth through WiFi, LoRaWAN, cellular IoT, to WPANs and 5G. However, options will be reduced by the product constraints mentioned above and limited by the environment in which the device resides. Aspects not commonly considered include signal propagation through complex building structures; interoperability with existing protocols, especially WiFi; electromagnetic compatibility with existing medical devices; cellular network coverage or the need to install additional gateway devices; and the total running costs of connectivity, including cellular IoT data plans.

• Cybersecurity framework, for which the connectivity function must meet requirements in three domains:

A Technical, including end-to-end data encryption and other security controls.

B Regulatory, including cybersecurity guidelines and patient data privacy standards.

C Environment, including fitting into customers' cybersecurity frameworks to support ongoing security analysis, software updates, and vulnerability management.

• Integration with internal and external systems: Connected equipment will be integrated with supplementary functions like identity management, secure operations, inventory management, customer care and others that guarantee secure and uninterrupted data acquisition from the entire installed base of devices. Without these processes, the connectivity project is likely to remain a limited pilot installation.
Adding connectivity to existing medical equipment is possible, but it requires combining business, clinical, regulatory and technology perspectives as well as meaningful engagement with all stakeholders.
Piotr Sokolowski is head of services strategy for medtech solutions at S3 Connected Health. He has almost 20 years' experience in designing medical devices and device-based services.
The opinions expressed in this blog post are the author's only and do not necessarily reflect those of Medical Design and Outsourcing or its employees.

On a Budget consider this

Starting up or adding a number of computer seats, and sticker shock from Microsoft hit, take a look at LibreOffice. It is very feature laden, stable, and FREE. Free is good. LibreOffice does lack some of Microsoft Office useless eye candy. However, it does have a learning curve. Go to https://www.libreoffice.org/download/download/ Also of importance it can produce 'real' PDF copies of documents that do not contain restrictive code. Note: This newsletter was produce with LibreOffice. Another good alternative to Microsoft Word, that does have a price; however, it is low is the SoftMaker Office 2021, Go to https://www.softmaker.com/en/. SoftMaker does have a 'free' version. The Office Suite with the most useful 'real' features is WordPerfect Office. However, it's cost is not much less than Microsoft Office. Of note; in the very near future you can buy the complete Microsoft Office and stop the 'rent' forever bit. Okay all of you that believe the only office suite of programs is Microsoft - get over it.

Brexit: UK Guidance on Regulation of Medical Devices from 1 January 2021 Blog Inside EU Life Sciences

Note: Some of the words are very much English – UK English.
The UK Medicines and Healthcare products Regulatory Agency ("MHRA") has published Guidance on the regulation of medical devices from 1 January 2021 (the "Guidance"). It discusses the regulatory requirements that apply to medical devices after the end of the Brexit transitional period under the EU-UK Withdrawal Agreement. In summary:

• From 1 January 2021, different rules will apply to medical devices placed on the market in Great Britain (e., England, Wales and Scotland) and those placed on the market in Northern Ireland and elsewhere in the EEA.

• Manufacturers may continue to use the CE-mark and it will be recognized in Great Britain until 30 June 2023.

• Manufactures may continue to rely on EEA Notified Body certificates until 30 June 2023 for products placed on the market in Great Britain.

• There will be a new route for conformity assessment of medical devices placed on the market in Great Britain from 1 January

2021.

• All medical devices and in vitro diagnostic medical devices ("IVDs") placed on the market in the UK have to be registered with the MHRA. There will be certain grace periods for registering existing devices.

• Manufacturers based outside the UK will need to appoint a UK Responsible Person.

Future Regulation of Medical Devices and IVDs in the UK

In the EU, Regulation 2017/745 on medical devices ("MDR") will enter into force on 26 May 2021 and Regulation 2017/746 on in vitro diagnostic medical devices ("IVDR") on 26 May 2022. Since both Regulations will enter into force after the end of the Brexit transitional period, they will not be automatically transposed into UK domestic law through the EU Withdrawal Agreement Act. Thus, the UK Government intends to hold a formal consultation process with stakeholders in autumn 2020 with the aim of delivering an attractive world-class regulatory system. The Medicines and Medical Devices Bill, which seeks to increase oversight over medical devices and improve patient safety, is also currently pending before Parliament.

1. Great Britain

The Guidance explains the different rules that will apply to medical devices placed on the market in Great Britain (i.e., England, Wales and Scotland) from 1 January 2021. We summarize certain of the key changes below.

a. Registration Requirements

Manufacturers who intend to place medical devices on the market in the UK have to register with the MHRA. Manufacturers based outside the UK will need to appoint a UK Responsible Person, established in the UK, to register on its behalf.

From 1 January 2021, any medical device, IVD or custom-made device must be registered with the MHRA before being placed on the UK market. There will be certain grace periods for manufacturers to complete the registration process. The length of the grace period depends on the category of device:

- Registration by 30 April 2021:
  - Active implantable medical devices
  - Class III medical devices
  - Class IIb implantable medical devices
  - IVD List A
- Registration by 31 August 2021:
  - Class IIb non-implantable medical devices
  - Class IIa medical devices
  - IVD List B
  - Self-test IVDs
- Registration by 31 December 2021:
  - Class I medical devices
  - General IVDs

The MHRA has published separate registration guidance to assist manufacturers with the process.

b. UK Conformity Assessment and UKCA Mark

Until 30 June 2023, manufacturers may rely on conformity certificates issued by EEA Notified Bodies for Class II and Class III devices. Moreover, until that date, the CE mark will be recognized on the Great Britain market. CE-marked devices that have been assessed by an EEA Notified Body will be deemed to meet the requirements of the new (UK conformity assessed) UKCA mark. From 1 July 2023, all devices placed on the Great Britain market, will have to bear the UKCA mark.

The UK intends to roll over the designation of any existing UK Notified Bodies, which are currently designated under the Medical Devices Directive 93/42/EEC, the in vitro Diagnostics Medical Devices Directive 98/79/EC and the Active Implantable Medical Devices Directive 90/385/EEC. From 1 January 2021, these bodies will be called "Approved Bodies". These Approved Bodies will be able to carry out certain conformity assessments under the UK Medical Devices Regulations 2002, as amended.

For self-certification devices (Class I medical devices and general IVDs), the manufacturer will be able to complete the UK conformity assessment procedure and affix the UKCA mark to their devices. Manufacturers of these devices may also continue to rely on the EU CE-mark until 30 June 2023 for products placed on the Great Britain market.

c. Labeling

From 1 January 2021, devices placed on the market in Great Britain will need to bear either the UKCA mark or the CE mark, as well as the number of the EEA Notified Body or UK Approved Body.

Products that bear the CE mark and the EEA Notified Body number do not have to be relabeled until 1 July 2023.

1. Northern Ireland

Special rules will apply to devices placed on the market in Northern Ireland.

1. Placing Devices on the EU Market

Any device placed on the EU market from 1 January 2021 must comply with the applicable EU legislation and the CE mark must be affixed to the device. The UKCA mark will not be recognized in the EU (including Northern Ireland), unless the device is also accompanied by the CE mark.

Manufacturers that are currently relying on a UK Notified Body need to bear in mind:

• Any devices placed on the EU market before 1 January 2021 in accordance with the EU-UK Withdrawal Agreement, may remain on the EU market.

• For any devices placed on the market after 1 January 2021, the manufacturer can no longer rely on the conformity assessment of a UK Notified Body. A conformity assessment by an EEA Notified Body will be required.

For self-certification devices, Great Britain-based manufacturers may continue to self-certify compliance with EU requirements. All Great Britain-based manufacturers intending to place CE-marked devices on the EU market will also need to appoint an Authorized Representative in the EEA.

Manufacturers based outside the EU may no longer rely on Great Britain-based Authorized Representatives for devices placed on the EU market. They will need to appoint an Authorized Representative in the EEA.