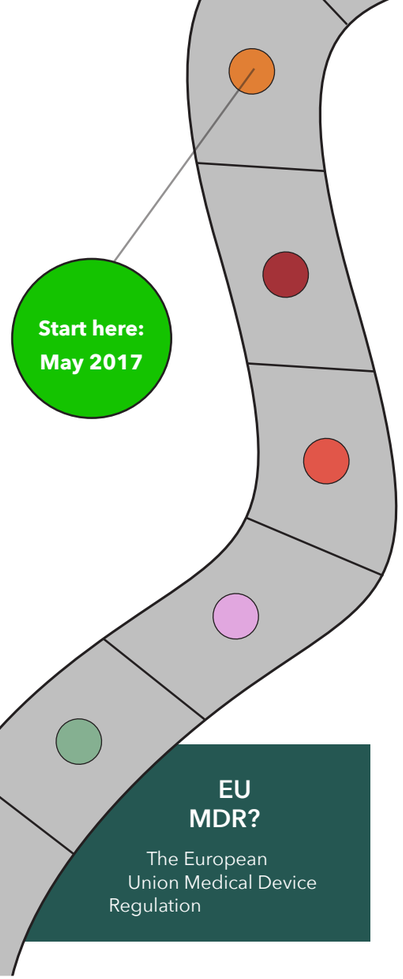
Preparing us for EU MDR

• *All EU MDR stories written by **Jon Hancuff** (Jon.Hancuff@CookMedical.com), the global Editorial Content manager at Park 48.*



It is a Wednesday morning when I email **Sinead Burke**. We have an interview scheduled in her office at Cook Ireland for later that day. Being unfamiliar with the building, I have no idea where her office is located. Her response comes quickly. She is going to meet me at the desk I am using during my visit and then take me back to her office.

The time for the meeting arrives and Sinead appears. After a quick introduction we head off.

It's a long walk.

We push through doors, between the desks of people quietly working, down short flights of stairs, through even more doors, and down a longer flight of stairs, before we finally emerge in Sinead's "home" in Limerick—the Regulatory Affairs (RA) department. As we settle into her office, I realize that we have literally walked from one end of the facility to the other. I also realize that she has just made the trip twice.

She had literally gone the extra mile to help me.

It's a fitting metaphor for the work being done by Sinead and the rest of the employees around the world who are pushing to get Cook in line with the EU MDR regulations that are coming into effect in May 2020.

Getting started

There are several dozen people dedicated to the project—entity leads, team leads, global team members—and all of them are working on EU MDR in addition to doing their regular work at Cook. The group is global and cross functional with employees coming together from all entities and functions such as Clinical, RA, QA, IT, Engineering, Divisions, Medical Affairs, and CSD. Their efforts began with a two-week kick-off meeting in Bloomington in February. They were joined by four project managers from Trinzo, a consulting firm that was hired to help coordinate the effort. The meeting was the first company-wide deep dive into these regulations. Working groups spent entire days dissecting what Cook would need to do to be compliant with EU MDR and then figuring out the processes that will be put in place both to reach that goal and then to stay compliant with EU MDR going forward.

▲ *Pictured is the global team that is working on labeling for EU MDR collaborating during a meeting at Park 48. From left: **Michele Krebbs**, **Karah Hickman**, **Doris Hawks**, **Rohini Patel**, **Russ Clinton**, and **Jacinta Kilmartin**. Not pictured: **Mette Raaschou-Nielsen**, **Pernile Ampling**, and Trinzio Project Manager **Lynn Deyoung**.*

"Everybody was invested in it and everybody was very engaged," said Sinead, who at the time of this interview in May was serving as both the director of Regulatory Affairs at Cook Ireland and the director of Regulatory Affairs at Cook Medical EU (CMEU). "There was a lot of focus and brainpower needed to make sure that we were thinking about all the changes and that everybody was included."

Aligning processes

In her role as director of Regulatory Affairs at CMEU, Sinead will serve as the "authorized representative" for Cook in the EU. She will be the contact for regulatory bodies who have questions about Cook products that are sold in the region, but not manufactured there. Foreseeing some of the challenges that could arise in her new position, she knew it was crucial for all of Cook's manufacturing entities to be in alignment regarding how they implemented the changes brought on by EU MDR.

"We didn't want six entities dong this six different ways," she said. "As the voice for Cook for EU Regulators we must present a consistent approach across all entities. So we wanted to make sure we had a good process for Cook and made the best use of this opportunity to maximize efficiencies".

The meeting ended with a mandate for the 13 established global teams to complete 22 critical work packages addressing requirements in a variety of areas.

Setting goals

Each work package has a set of objectives and a set of deliverables. For example, the global team working on labeling will review the new regulations and figure out what content each set of labeling needs to hold. This can include a variety of information, such as, what do the Instructions for Use (IFU) and the patient card need to say? Once the team has agreed on this, they put together a guidance document that becomes global policy for the six different Cook entities and the labeling teams to follow.

The goal coming out of the meeting was to have those guidance documents in place by early this summer. At that point, the nine teams within each entity would begin working to implement the guidance documents for their areas.

As mentioned earlier, the Cook employees who are working on EU MDR are doing so in addition to their regular responsibilities. That was one of the reasons project managers were brought in from Trinzo. They will help ensure the same deliverables are in place across all entities and they are completed on time.

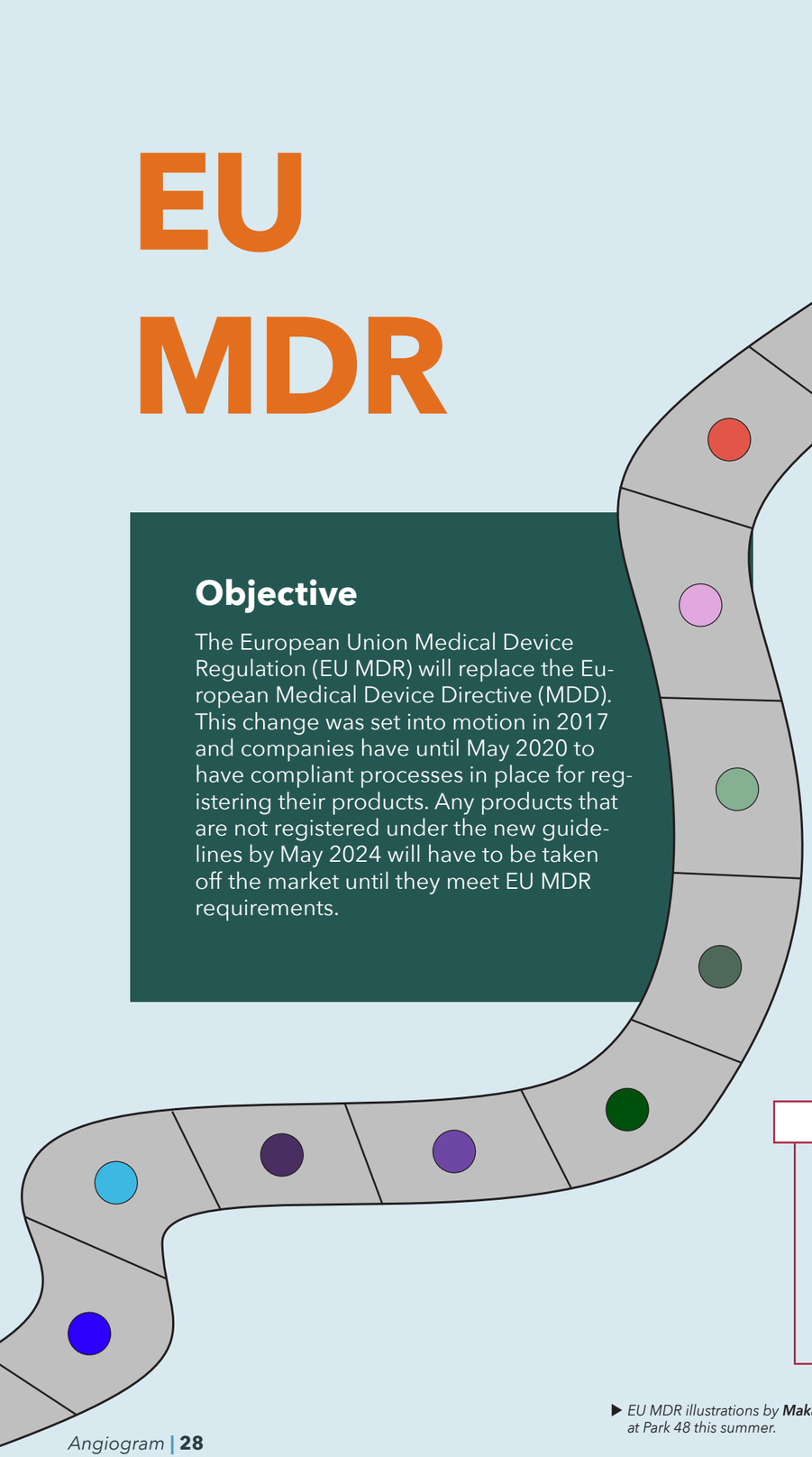
Continued on page 35

"There are several dozen people dedicated to the project—entity leads, team leads, global team members—and all of them are working on EU MDR in addition to doing their regular work at Cook."

EU MDR

Objective

The European Union Medical Device Regulation (EU MDR) will replace the European Medical Device Directive (MDD). This change was set into motion in 2017 and companies have until May 2020 to have compliant processes in place for registering their products. Any products that are not registered under the new guidelines by May 2024 will have to be taken off the market until they meet EU MDR requirements.



Key changes

The changes on the next page need to be made to the current MDD procedures in order to change to the EU MDR model.

▶ *EU MDR illustrations by* ***Makayla Hughes*** *the Editorial Content intern at Park 48 this summer.*

Single-use devices

Reprocessing of single-use devices is only allowed for under strict conditions where permitted by national law.

- Full product liability is placed on the reprocessor, while the original manufacturer will have to identify a thorough set of risks of reprocessing of single-use devices in the IFU and risk documentation.

Clinical requirements

Clinical data or a proven equivalent is required on all devices. The device must also meet the reinforced requirements for clinical evaluation.

- Ongoing post-market surveillance and active post-market clinical follow-up will be required for ongoing conformity assessment of the device.

EUDAMED

The new European Database for Medical Devices (EUDAMED) provides increased transparency.

- EUDAMED will record and exchange info on medical devices' market surveillance, economic operators, unique device identities (UDIs), certificates, clinical investigation information, safety, and clinical performance.
- EUDAMED will be accessible for economic operators, notified bodies, competent authorities, the European Commission, and the general public; different groups will have different levels of access to the information.

Restrictive substances

Substances that are phthalates, carcinogenic, or mutagenic, or that are toxic to reproduction (CMRs) or endocrine disrupting can only be used together with a strictly defined justification.

- Testing will have to be carried out where necessary or new materials will have to be used.
- Additional labeling requirements have been identified for these substances.

Economic operators

The responsibilities of economic operators have been defined in order to regulate the actions of authorized representatives, manufacturers, importers, and distributors.

- Authorized representatives will be jointly and severally liable for the devices they represent.
- Companies need to identify and define who their related economic operators are and carry out a review to ensure that they are all compliant under the new regulation.

Implant cards and labeling

All implant devices will now have to come with an implant card for the patient.

- All labels and IFU will require an update.
- Updates include:
  - UDI
  - Identification of restrictive substances
  - New symbols
  - Addition of warning or precautions for immediate attention
  - Identification of clinical benefits and performance characteristics

Notified bodies

There are more stringent requirements in place for designating notified bodies, particularly the area of clinical competence, with increased control and monitoring by national authorities and the European Commission.

- Not all notified bodies will retain their status, and not all will be designated for the high-class devices.

Unique device identification (UDI)

Under the regulation, each medical device will require unique device identification (UDI).

- The UDI will be composed of two parts:
  - A device identifier specific to the device
  - A production identifier to identify the unit producing the device
- The UDI will include any warnings, precautions, or measures to be taken by the patient or a healthcare professional and a description of potential adverse events.

Person responsible for regulatory compliance

Manufacturers and authorized representatives are required to have a named person(s) responsible for regulatory compliance with expert knowledge in the field of medical devices.

Post-market surveillance & vigilance

EU MDR sets out more vigilant and specific post-market surveillance requirements.

- Legislation also sets out that the post-market surveillance process is an on-going system with outcomes being assessed for impact and driving updates to the technical documentation.
- Vigilance reporting time frame for serious incidents has been reduced from 30 days to 15 days.

The early days of EU MDR

Poly Implant Prothese (PIP) was a French company that was formed in 1991 and started producing silicone breast implants soon after. A little over 20 years later, the company was bankrupt and its founder was fined, sent to prison, and banned for life from working in medical services or running a company. PIP, which produced over two million breast implants during their existence, was found to have been using industrial-grade, instead of medical-grade, silicone in their implants. The implants began rupturing at double the industry rate, causing inflammation and sometimes scarring.[1]

In 2010, DePuy Orthopaedics, part of Johnson & Johnson, issued a recall of their metal on metal hip replacement system after mounting complaints and eventual lawsuits due to device failure, bone fracture, and infection.[2] Both of these cases drew extensive media attention and public ire.

They also happened concurrently with the review of the 1993 European Medical Device Directive (MDD) which was the set of rules and regulations that medical device companies had to comply with to place products on the market in the European Union (EU).

"Under EU policies and procedures, any directive comes up for routine review by a committee of Parliament," said **Emmett Devereux**, Cook's director of Government and Regulatory Affairs for Europe, the Middle East, and Africa (EMEA). "It's a quick check to see if the policy is still fit for purpose."

With constituents demanding to know how the above scandals had been allowed to happen, Parliament determined that the MDD needed to be overhauled. Part of that process would be to do away with the "directive" and replace it with a "regulation"—the EU Medical Device Regulation (EU MDR).

In the EU, member states are allowed to interpret and implement a directive in whatever way makes sense for their country. This is done by the regulator in each member state called the competent authority. This differs from a regulation, which must be implemented into national law exactly as it is written in the regulation.

"The risk of a directive is that you can end up with fragmentation," Emmett said. "Different member states have different interpretations. Hence, a device could be approved differently in country A as opposed to country B. With a regulation, there is no scope for deviation or interpretation."

▲ *Emmett Devereux*

At the core of the debate during the drafting of the regulation was whether or not to continue using third-party notified bodies to approve devices or to shift to one centralized governing body, like the US has done with the Food and Drug Administration (FDA).

Emmett said the Cook stance was to stay with the notified body system, but to hold them to higher standards.

"We argued that there should be greater oversight of the notified bodies, greater transparency, and greater visibility into what they do," he said. "Basically, what we were advocating was that a notified body operating in Ireland needs to operate to the exact same standards as a notified body in Germany. Oversight of the notified bodies would remain with the competent authority in each country."

When the EU MDR text was released in 2017, Emmett and the Cook Medical Government Affairs team were relieved that this was the approach the commission had adopted.

> ***"This is a once-in-a-lifetime, once-in-a-career sort of legislation. This is not something that is going to happen in five years' time. This is massive."***
>
> *– **Emmett Devereux**, Cook's director of Government and Regulatory Affairs for EMEA*

Implementation issues

The clock started ticking as soon as EU MDR was unveiled. From that moment, companies had three years, until May 2020, to have compliant processes in place for registering products. Any products that are not registered under the new guidelines by May 2024 will have to be taken off the market until they meet the EU MDR requirements.

The time frame has done no favors for the industry, because it requires companies to have begun EU MDR work before the European Commission and the member states had their own EU MDR systems in place.

"What we would have argued at the time was, do all the work, implement all of the systems correctly," Emmett said. "Once they are fit for purpose and ready to go, then start the clock ticking on the transition period. What you are seeing at the moment is that the European Commission is trying to put everything in place while the clock is running down."

One of the biggest areas of concern has been the inability of the governing entities to approve the notified bodies. Of the 49 notified bodies that have applied, only four have been designated at the time this was written, and one of those is based in the United Kingdom, which is set to leave the EU in October (Brexit), which means that notified body will no longer fall under EU jurisdiction.

So, to sell products, companies need to approve them with notified bodies. But they can't do that until the notified bodies are designated by the government agencies. So, while the companies are waiting for that to happen, they are stockpiling product submissions. This means that once the notified bodies, who work with many different device manufacturers, can proceed with registration, they are going to be overwhelmed with submissions.

It's a situation that Emmett believes will sort itself out and ultimately, be a benefit for patients around the world.

"Overall, I think EU MDR is a positive change," he said. "We work in a global environment,
so we would like to get to the point where if you get a device approved in Europe, it should happen in the US and Japan at the same time. The only way that can happen is if you have proper standards in each of those jurisdictions."

"This is a once-in-a-lifetime, once-in-a-career sort of legislation," he continued. "This is not something that is going to happen in five years' time. This is massive. Why there is such an effort required in this one is because they are going to do this, we are going to live with the outcome of this for 25 years. Hence, the major investments in time, money, and resources that is going to be required. It's definitely a once-in-a-generation change."

Sources:
1. Hegyi T. PIP breast implant scandal: a story that triggered change. IMARC Web site. https://www.imarcresearch.com/blog/pip-breast-implant-scandal. Published on November 7, 2017. Accessed on July 31, 2019.
2. Kennerly MS. DePuy hip replacement recall lawyers. Litigation & Trial Web site. https://www.litigationandtrial.com/depuy-hip-replacement-recall-lawsuit/. Accessed on July 31, 2019.

Working together

EU MDR pushes William Cook Europe and Cook Ireland to forefront of Cook world

▶ ***Mette Nielsen*** *(left) and* ***Henriette Christiansen*** *(right).*

William Cook Europe (WCE) is located in Bjaeverskov, Denmark, a town surrounded by farm fields, with a population of just under 3,000. It is located a little over 30 miles from Copenhagen, the nation's capital and home to over a million people.

It's safe to say that Bjaeverskov is a quiet town and not used to attracting much attention.

But at WCE, the town's biggest employer by far, it is a whole different and vibrant ball game. In 2017, when an implementation date of May 2020 was set for EU MDR, WCE and Cook Ireland, based in the city of Limerick (a sprawling metropolis compared to WCE's home base, with around 85,000 people), were joined at the hips and leading the charge with Sinead Burke, director of Regulatory Affairs at Cook Ireland and the director of Regulatory Affairs at Cook Medical EU (CMEU) at the forefront.

"It just makes sense, since this is a European regulation, that the drivers should be out of Europe," said **Henriette Christiansen**, the director of Regulatory Affairs (RA) at WCE.

Emmett Devereux, Cook's director of Government and Regulatory Affairs for EMEA, made sure that no one inside the company was caught unaware by the 2017 announcement. He had been giving updates to the RA teams as the regulations moved through the legislative process. In 2016, he started working with the European teams to start formulating how WCE and Cook Ireland would address EU MDR on a global scale.

Even before the date was set in 2017, it was clear to everyone in Europe that the regulation was not just going to require some extra work by the RA team. Once Henriette and **Mette Nielsen**, RA project manager at WCE, together with the rest of the European and the global teams began digging into the breadth and complexity of EU MDR, they knew it was going to take a lot of work by a lot of different functions within Cook to become compliant.

One of the driving parts of the legislation is that the facility where a device is manufactured is now responsible for providing and updating information about the device.

"EU MDR is pushing things that we as a company could use more of," Henriette said. "It's very data driven, and that's very, very good. What do we have in clinical data and what does that tell us? It puts people in place to draw conclusions and make decisions based on evidence. In the long run, this will make life easier for all of us."

To meet these requirements is a cross-functional effort. It necessitates input not only from RA, but from the Vascular and MedSurg divisions and from the Supply Chain, Clinical, and Engineering functions at each of Cook's manufacturing entities.

The regulation is also pushing a more global approach within Cook Medical to meet the requirements efficiently.

"This is a really good opportunity, actually, to have all of the Cook companies work together, which also, in my mind, makes so much sense; specialists from each entity working together on this," Mette said.

"To have the work organized in a global Cook project also makes sense from an efficiency point of view, rather than having all manufacturing sites doing the same things but in their own way," Henriette added. "But it is a steep learning curve for all of us because it is a different way of thinking, measuring and following up than we have been used to in the past. It is going to change that part of our culture."

That cooperation among global entities as well as all the requirement for increased data collection are two initiatives that will help drive Cook toward one of its transformation goals—becoming a truly modern company.

For the time being, the teams at WCE are focused on getting their processes in place so that they can start registration work on around 800 products that they manufacture. Many of which are high-risk implantable products (Class III products), which means that there is a lot of scientific documentation required, especially on clinical evidence, but also due to more complexity of the product design.

The work that lies ahead will definitely challenge everyone involved, but both Henriette and Mette have faith in the Cook teams' ability to hit their EU MDR deadlines.

"We just need to focus and allocate resources on the right things," Mette said.

"We have planned accordingly—we can do it," Henriette added.

Continued from page 27

Preparing us for EUMDR

"The deliverables at William Cook Europe will be exactly the same as the deliverables at William Cook Australia," Sinead said. "We are all speaking exactly the same language from an entity perspective."

The plan was to have all of the deliverables rolled out by early summer.

An allotment of 30 new hires, divided as needed between the entities, has also been approved for EU MDR work.

Smaller, bi-weekly call-in sessions are being held, and larger quarterly sessions are being planned between the global and entity teams to ensure everyone is on pace to hit their milestones.

The major deadlines are the end of 2019 (when certain global teams need to have their deliverables completed), May 2020 (when EU MDR comes into effect, validated processes must be in place at Cook), and May 2024 (when all products not re-registered under the new guidelines have to be pulled from the market).

"I think people are engaged," Sinead said. "I think people are doing as much as they possibly can, with all of the other work that is going on. But when people are asked to get involved, they do get involved and continue to support these efforts. The project has excellent guidance and support from the steering team which is made up of CME members and the EU RA, Government Affairs leadership team."

Patient first

The workload is definitely daunting, but still doable.

"Everyone is doing an incredible job and we are confident we have a great plan in place," she said. And the end result is very much in line with Cook's primary objective.

"Ultimately, EU MDR is a benefit for the patients," Sinead said. "I would whole-heartedly agree to that. The emphasis on gathering and sharing clinical data will also have a positive impact on our business. We have always wanted to be transparent with our customers and the patients. We feel that this will only benefit Cook."

We can do this

Five minutes into an interview about EU MDR **April Lavender**, Cook's senior vice president for global Regulatory Affairs, gets up from her desk and moves to the corner of her office. She knows exactly what she is looking for—a large rolled up piece of paper wrapped in a rubber band and stashed next to a bookshelf. She unfurls it to reveal an Excel printout that is three or four feet wide and probably just as tall. Only her head is visible over the top of it as she explains to me the significance of the document.

"When I first heard about EU MDR, my first thought was that we had been through this before. We can do this," she said. "We had already developed a workstream when MDD went into effect."

The "MDD" (Medical Device Directive) was initially implemented in the EU in 1993 and then overhauled in 2007. April is showing me the chart that outlines the framework of Cook's efforts around compliance with the 2007 MDD update. While there are some significant differences between that version of the MDD and EU MDR (the latter includes 35 more regulations and 100 more pages), she is undaunted. Cook's work in 2007 helped prepare for the more elaborate demands of EU MDR.

"There are new requirements with EU MDR that will be in addition to what we have previously done," April said. "For example, the requirement for us to update a EUDAMED database for all of Europe has not previously existed. We will also be required to perform more proactive post-market surveillance for our devices."

But from her perspective, the timing seems to be in Cook's favor regarding the work needed to become compliant with EU MDR. Cook is already deep into legacy remediations (re-registering older products to meet current regulatory standards) in both the United States and Asia-Pacific (APAC). That task has required the creation and collection of much more detailed technical product information.

It is the same type of work that is needed to keep Cook devices on the market under EU MDR, which is our main goal to achieve regulatory compliance.

With a perspective shaped by 40 years of experience in the medical device industry, April is confident that Cook has the resources, the skill, and the people, to ensure patients continue to have access to our products once EU MDR comes into effect.

She views this as an opportunity. And, despite everything Cook has gone through since the FDA warning letter was issued in 2014, April is pumped up about EU MDR.

"The last five years have seen us make significant changes in our processes by working on all of these projects," April said. "It's just so great to be able to implement the work that leads to what you know is going to be the successful outcome for patients."

"But the awesome part of this is that it has required so many people to do this," she continued. "And that makes it embraceable by the whole organization. I never, ever, ever doubt that we can do projects like this. The power of our teamwork is incredible when it is aligned in the same direction."

▶ *April Lavender*

"I never, ever ever doubt that we can do projects like this. The power of our teamwork is incredible when it is aligned in the same direction."

*— **April Lavender**, Cook's senior vice president for global Regulatory Affairs*

EU MDR site leads

Jacinta Kilmartin (Cook Ireland)

Cook Ireland started EU MDR site-specific research in 2017 and began planning in 2018. In 2019, they are now in the execution phase. It will be complete by May 2024.

Most of Cook Ireland's departments are involved—Regulatory Affairs, Engineering, Quality, Clinical Communications, Operations, the divisions, and Medical Affairs. Our team leads are **Tracy O'Sullivan**, **Heather Ryan**, **Connor Heffernan**, **Koran Carr**, **Ciaran Toomey**, **Annemarie Beglin**, **Sinead Burke**, and myself. Some employees are part of global teams while some of the team leads are leading global teams or taking part. Those involved on the global side include **Sinead O'Leary**, **Siobhan Casey**, **Jane Kennedy**, and **Charlene Ryan**.

The number of people involved is evolving, and we foresee a sharp rise in the number of resources being impacted across the site over the implementation period.

The interdependencies are higher than anticipated between teams, and tracking these will be vital to implementation. This will ensure consistent information across the quality system documents.

It has been great to get an opportunity to work across sites and different functions—especially the workshop in Bloomington in February. It was great to work together to break this large project down into bite-size pieces.

Aaron Santner (Cook Inc.)

Cook Inc. started site-specific research and planning activities in the second quarter of 2018. Detailed planning efforts at Cook Inc. ramped up in February 2019. We moved from the planning to execution phase in July 2019. Our MDR transition plan will roll out starting in May 2020 and be complete by May 2024.

This program is massive and will involve many departments and functions including: Quality, Regulatory, Engineering, Clinical, Medical Affairs, Operations, and the clinical divisions. The work is currently planned under nine teams. The team leads are myself, **Laura VanVleet**, **Lauren Kucera**, **Nick Kappas**, **Karah Hickman**, **Naomi Funkhouser**, **Amy Ham**, **Kevin Delaney**, **Lisa Webb**, **Ryan Opheim**, **Michelle Shafer**, **Tanya Crawford**, and **Jennifer Canada.**

I knew that there would be a significant amount of work to do to meet the new requirements of EU MDR. I wasn't aware of how many new deliverables were needed until we got into the detailed planning phase.

Tom Kardos (Cook Vandergrift)

Cook Vandergrift (CVI) started planning for EU MDR in 2018 and attended the Global EU MDR Workshop in Bloomington in February and March 2019. CVI entered the project execution phase in July 2019 and will complete the project in 2023.

The departments involved at CVI are Regulatory Affairs, Engineering, Quality Assurance and Operations-IT. The team leads are myself, **Brian Johnston**, **Rich Horn**, and **Elaine Ruminski**. There are nine teams; several employees lead two or three teams, and most of the team leads participate on multiple teams.

The are two Class I nonsterile devices that will need to be in compliance with EU MDR by May 2020. The class III devices will transition in September 2022, and the remaining devices will transition in May 2023.

It has been great to see Cook come together to work through all the obstacles to ensure compliance to the new EU MDR. A lot of work has gone into the project already, and there is a long way to go. This project has had outstanding leadership, and the approach Cook has taken with the establishment of global teams creating policy statements for the interpretation of EU MDR and local entity teams for the implementation of these policies at each site will lead to the success of the project.

Steve Stackpoole (Cook Medical Europe, CMEU)

CMEU began scoping out the changes required to comply with EU MDR in 2018, and detailed planning commenced in early 2019. By the second quarter of this year we initiated the execution phase.

We have identified eight work packages, with key areas of focus including the review and identification of distributors elsewhere in our supply chain, identifying new obligations we will have as a medical device importer and distributor, as well as making required changes to our Field Action and Product Complaint processes.

The project requires close work with colleagues from across the organization, including Legal, Finance, Quality Assurance, Customer Support & Delivery, Regulatory Affairs and IT.

At the moment, regular meetings are taking place to ensure all work packages have detailed actions identified and milestone dates agreed. The aim is to have the majority of CMEU related tasks completed by the end of this year with a final date for completion of April 2020.

This project can be quite challenging due to the complexities of the tasks at hand. Close collaboration with the other EU MDR project teams globally is vital to ensure we understand what is happening in other locations, and to avoid the possible duplication of tasks. This project has given us a great opportunity to review impacted processes with our colleagues locally and globally, to share ideas, and to collaborate with others to improve and align.

Mette Nielsen (William Cook Europe)

WCE initiated a local EU MDR project in 2017 and, after a long analysis and planning phase, began the execution phase in July 2019. The WCE project plans extend to the end of 2023.

The WCE departments involved are mainly Regulatory Affairs, Engineering (Biosafety, Post-Market Engineering, Labeling), and Quality. There are 9 WCE team leads, 12 team sponsors (manager level), and several additional people for project teams in the execution phase. Our team leads are **Janne Vejlby**, **Tooba Noorzae**, **Mette Schæffer**, **Mette Raaschou-Nielsen**, **Helene Jackson**, **Lars Christensen**, **Marianne Høy**, **Catharina Engelhart**, and myself. We are currently estimating the resource needs for 2019 through December 2023. It's going to be huge!

Furthermore, WCE participates as part of the EU MDR global team—either as global team leads, work package leads, or team members (seven in addition to the people already listed).

The project complexity is getting bigger and bigger as we learn more about the EU MDR requirements and how these require cross-functional solutions which, again, require strict control of interdependencies of the project tasks among teams. We have also found that high project management skills and resources are critical for success.

Being part of this project is being part of yet another transformation process within Cook, and that is an interesting journey.

Joanne Daniels (William Cook Australia)

William Cook Australia (WCA) has been planning for EU MDR since the regulations were published officially in 2017. The initial phase was mapping what we learned and in the past year we've ramped up with implementation plans.

The key departments involved in EU MDR are Regulatory Affairs, Post-Market Engineering (PME), Quality Assurance (QA), and Manufacturing Engineering (Mfg Eng). We have nine teams set up to implement our plan for compliance to the EU MDR regulations, and these teams are led by seven people: **Ming Lim**, **Hemangi Malde**, **Miriam McMahon**, **Nicole Burke**, **Mohammed Ahsan**, **Jillianne Keller**, and **Nannette Lewis**.

The lack of guidance and information from the European Commission has meant that Cook will be relying on our own interpretation of the regulations. The global teams working on these interpretations will be a valuable source of information for each of the sites.

I've been pleasantly surprised by how well Cook pulls together globally. We're working on projects where we're separated by major time zones, and we're all doing this work on top of our day job. Yet, the level of engagement is high, and people are producing quality outputs.

Paula Joyce (Winston-Salem)

Cook Winston-Salem (CWS) started planning in 2018-2019 and is in the execution phase as of May 2019. It will be complete by our MDD certificate expiry date, which we are working to extend until 2023-2024.

At CWS, most departments are involved, including Regulatory Affairs, Engineering, Quality, Clinical, Marketing and Communications, and Medical Affairs. The team leads are **Julie Tuttle**, **Scottie Fariole**, **Doris Hawks**, **Bruce Green**, **Alicia Altizer**, **Brian Rucker**, and **Theresa Forshey**.

The CWS product portfolio includes many Class I non-sterile devices, which will require compliance by May 2020. There are also cases where we are waiting for the output from global teams to move ahead and there are areas where the European Commission still needs to issue additional guidance in order to pursue (i.e., EUDAMED, UDI, common specifications).

The level of tracking and formal oversight by outside project management contractor resources is very different from other projects, but based on the very large scope this is required. We also agree that it has been great to get an opportunity to work across sites and different functions.

Brian Rucker (Winston-Salem)

Cook Winston-Salem (CWS) began working on the EU MDR project about a year ago, and my guess is that we'll wrap up the final loose ends in 2023.

At CWS about 10-15 people are involved so far, but that number will increase and almost every department will be involved as we near May 2020. Our team leads are myself, **Julie Tuttle**, **Scottie Fariole**, **Doris Hawks**, **Bruce Green**, **Alicia Altizer**, and **Theresa Forshey**.

There are many new requirements across many systems, and each one is reasonable by itself, but smaller, incremental changes would help us support our customers better than saving up 20 plus years' worth of improvements in a single revision.

One of the biggest surprises as part of this project was that at one point there were a lot of "expert" opinion articles predicting EU MDR would go away because it was too complicated.

The EU MDR SharePoint site is now live!

This site is ideal to access information, get an understanding of the EU MDR, share documents and see the progress of this very important project across all our entities and global working groups.

You can access the site by visiting https://intranet.cookmedical.com/eumdr/Pages/EUMDRComHompage.aspx or by selecting "EU MDR" on the "Teams" tab on the Cook SharePoint site.

A ground-breaking regulation

Bill Doherty discusses the impact of EUMDR

EU MDR coming into effect will have a significant impact across many different areas of our business. EU MDR is in many ways a ground-breaking regulation; it seeks to fundamentally change the landscape for medical devices.

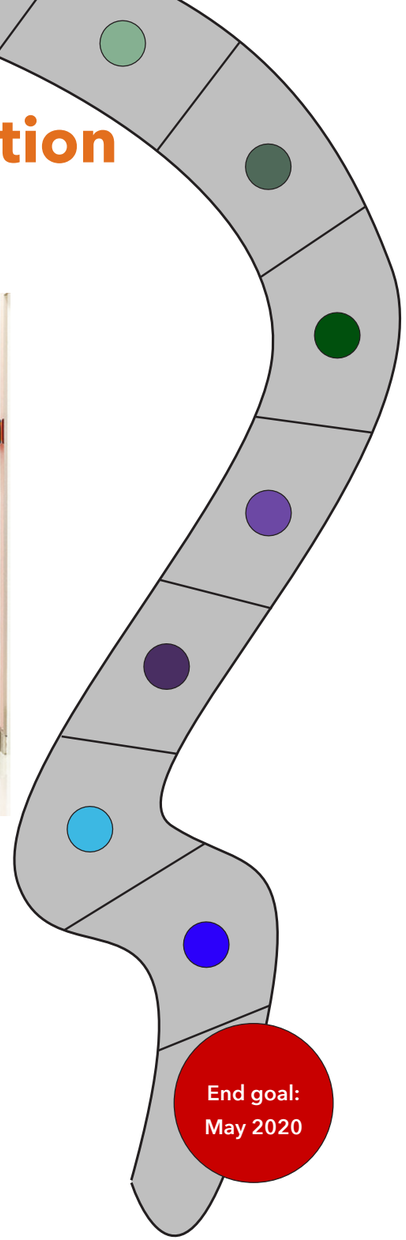
▲ *Bill Doherty*

Perhaps the greatest change from a business perspective is the role and responsibilities of the authorized representative (AR). For Cook, that person will be **Sinead Burke** and her new team in the Cook Medical EU office. We are familiar with the concept of an AR, however this role will assume more risk and liability under EU MDR and will, for the first time, share legal liability with the manufacturer. Under MDR, the AR, and not the manufacturer, will have the final determination on whether or not a product meets the requirements and can be placed on the European market.

Another significant change under EU MDR is the emphasis on clinical evidence, both prior to CE marking (the certification mark used to indicate that a device is approved for sale in Europe) and throughout the life of the device. This applies to all products with a higher threshold for Class III products (higher risk devices used to treat more serious illnesses) and products that enter the body permanently or for a period of time. Unlike most regulatory regimes in other parts of the world there is no exemption for products that are already on the market, and therefore, manufacturers are faced with the task of compiling clinical evidence for products that were first placed on the market many years ago. In addition, EU MDR requires that clinical evidence reports must be updated annually or periodically, depending on the risk profile of the device, and EU MDR sets out specific requirements for post-market clinical follow-up.

The MDR also places a strong emphasis on the provision and transparency of data. For the first time we will have a European database (EUDAMED) which will hold data on all elements of the device and will make certain information available to the public. Every device will have a unique device identification (UDI) to ensure traceability and to facilitate EUDAMED searches and all implantable devices will need to carry an implant card for the patient. Labeling will need to identify any restrictive substances as well as identifying clinical benefits and any warnings or precautions.

These changes along with definitions and requirements for economic operators and more stringent oversight of notified bodies make MDR one of the most significant, if not the most significant, recalibration of medical device regulations anywhere in the world. It remains to be seen what effect these regulations will have on innovation in Europe and, indeed, what other unintended consequences may unfold, but they certainly reflect the public mood and demand for increased oversight and transparency.



▶ For more information on EU MDR, make sure to watch the mid-year company update webcast available on the transformation site or check out the *Life@Cook* blog.

Honoring our people

Preben Funder Pedersen,
William Cook Europe Production Support

Hired in: 1978

Preben was born in Frederiksberg, Denmark and grew up in Rødovre. He began in a public school and moved to a private school in Frederiksberg when he was in sixth grade, where he continued until he had finished lower secondary school. He and his wife Marianna have lived in a house in Køge, approximately 11 kilometers (7 miles) from Cook, for 21 years. Preben started working for a company manufacturing and developing B&O record players, before moving to Køge where he had a job at Hellesens, a manufacturer of batteries. Since then, he has been working for Cook.

While William Cook Europe was still located in Søborg, Preben was hired in to establish six new coiling machines, which were moved to Bjaeverskov in 1978. He was responsible for the toolshop and a few operators at that time. Subsequently, he has held positions as a technician and a manager. His assignments gradually grew as Cook Bjaeverskov developed, and he became a member of the Top Management team. His children have worked at Cook as interns during the summer holidays.

Away from work, Preben enjoys working on his house and garden. He has a lot of projects and also helps his children with their projects. He also likes to help his neighbors with various repair projects. His hobbies include shooting a bow and arrow, hiking, and biking, preferably long distance. He also repairs bikes.

"I have enjoyed the responsibility that comes with leadership, the technological development, the challenges, and the cooperation with colleagues in the broad sense of the word, including colleagues from other Cook Group companies as well."