▶ *Employees take a selfie at Cook Thailand's 10th anniversary and new office opening celebration.*

ANGIO GRAM

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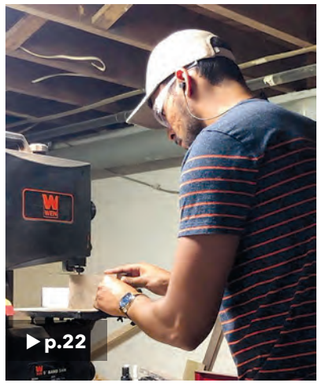
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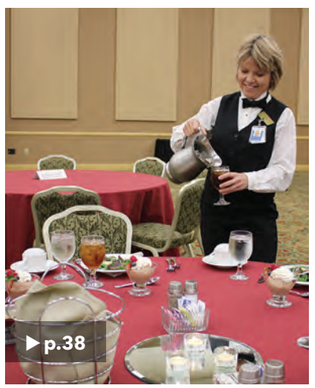
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How are we doing? We want to hear from you!
What are your favorite parts of the Angiogram? What would you like to see more of? Send your comments and suggestions to ***Angiogram@CookMedical.com****.*

A device that supersedes hospital silos

Entuit® Gastrostomy BR Balloon Retention Feeding Tube

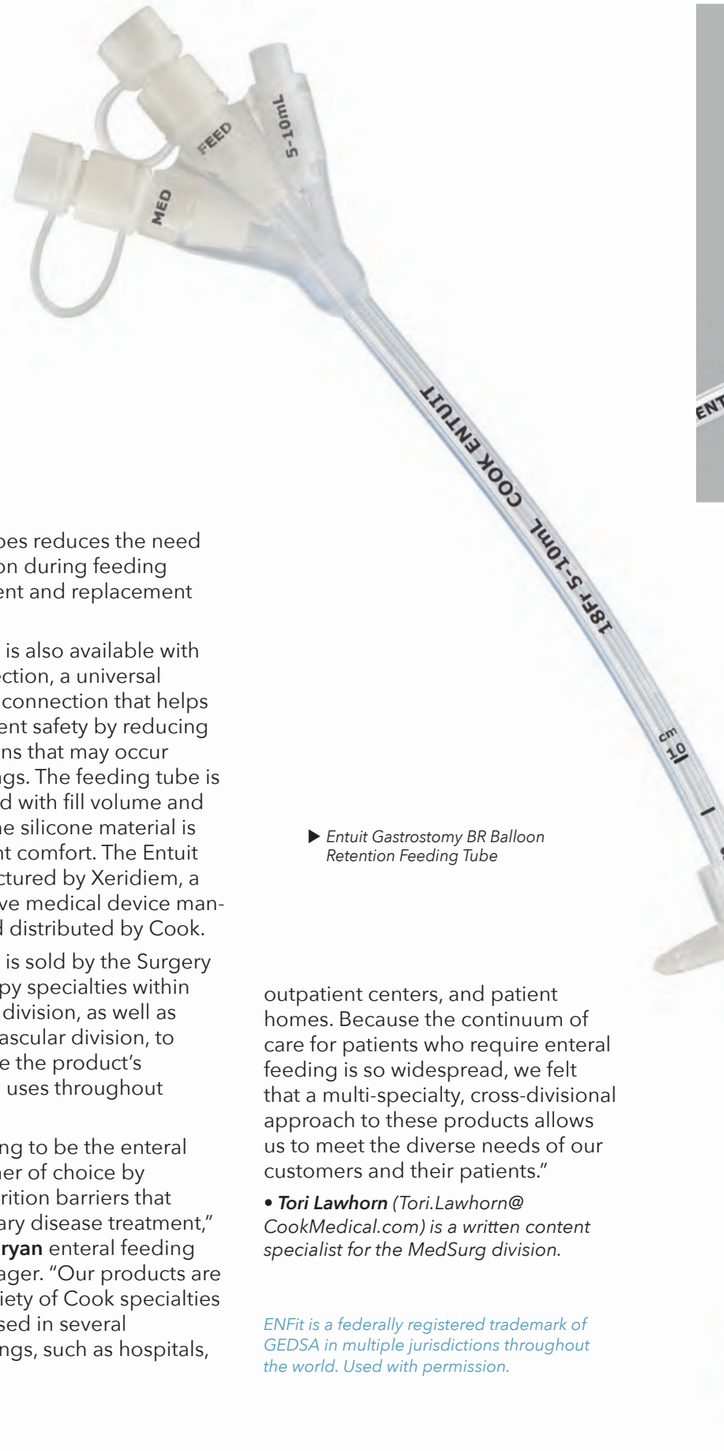
The term "feeding tube" is used to describe any sort of tube that carries nutrition from outside the body to the digestive system where it can be digested. Feeding tubes can be used in all kinds of treatments, such as emergency care, cancer treatment, and long-term care. One type of feeding tube, a gastrostomy feeding tube, is placed through an opening between the stomach and the skin called a stoma. A balloon retention gastrostomy tube is a type of gastrostomy feeding tube with a balloon on the distal end. Once the feeding tube has been placed, the balloon is filled with sterile or distilled water. This filled balloon is designed to prevent the feeding tube from sliding out of place.

Cook's Entuit® Gastrostomy BR Balloon Retention Feeding Tube provides a solution to patients who require enteral nutrition as part of their long-term care needs. This device is intended to provide gastric access for enteral feeding, medication administration, and decompression through an established gastrointestinal stoma tract. The unique, integrated design of the in-line balloon shaft on 12 Fr to 24 Fr tubes reduces the need for overdilation during feeding tube placement and replacement procedures.

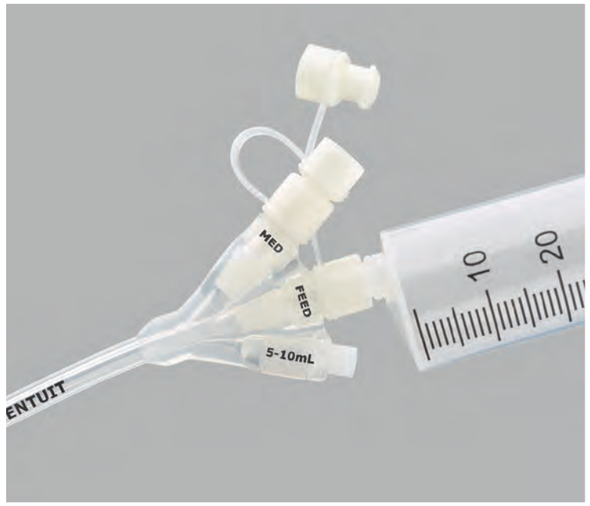
The Entuit BR is also available with ENFit® connection, a universal feeding tube connection that helps enhance patient safety by reducing misconnections that may occur during feedings. The feeding tube is clearly marked with fill volume and Fr size, and the silicone material is soft for patient comfort. The Entuit BR is manufactured by Xeridiem, a comprehensive medical device manufacturer, and distributed by Cook.

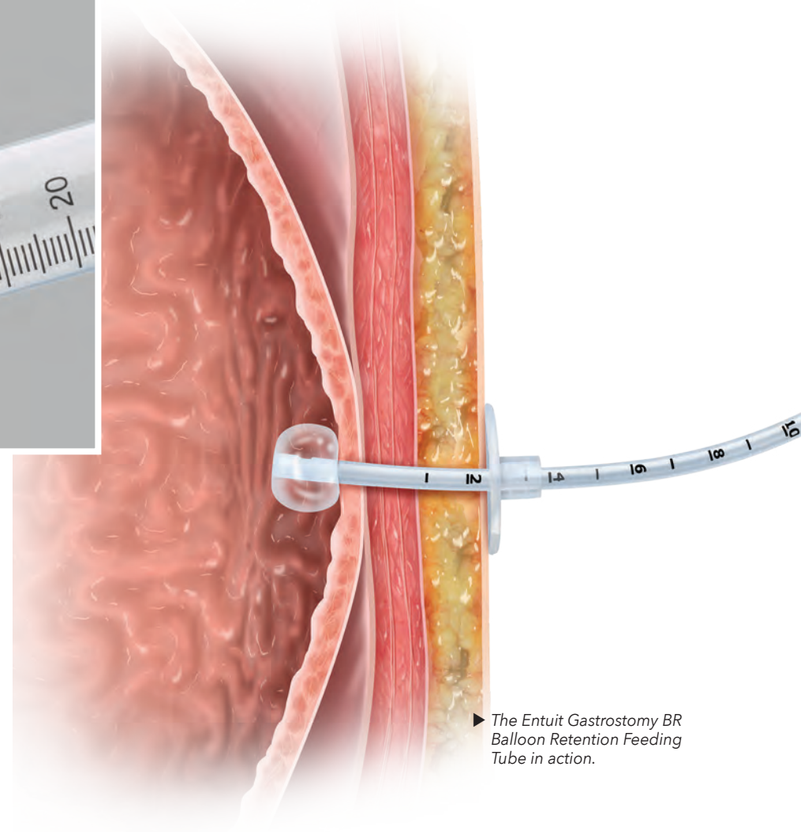
The Entuit BR is sold by the Surgery and Endoscopy specialties within the MedSurg division, as well as parts of the Vascular division, to accommodate the product's multipurpose uses throughout the hospital.

"We are striving to be the enteral feeding partner of choice by removing nutrition barriers that prevent primary disease treatment," said **Mike Maryan** enteral feeding product manager. "Our products are used by a variety of Cook specialties and can be used in several different settings, such as hospitals, outpatient centers, and patient homes. Because the continuum of care for patients who require enteral feeding is so widespread, we felt that a multi-specialty, cross-divisional approach to these products allows us to meet the diverse needs of our customers and their patients."



▶ *Entuit Gastrostomy BR Balloon Retention Feeding Tube*





▶ *The Entuit Gastrostomy BR Balloon Retention Feeding Tube in action.*

• ***Tori Lawhorn*** *(Tori.Lawhorn@CookMedical.com) is a written content specialist for the MedSurg division.*

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Glossary

Enteral nutrition: Food or medication administration that is ingested into the body through the gastrointestinal tract.

Decompression: The removal of stomach contents through a feeding tube.

Distal end: The farthest end from the top of the feeding tube.

Gastrostomy: A minimally invasive procedure performed to make an artificial opening in the stomach called a stoma. This is accomplished by forming a passage, or tract, between the stomach and the skin.

▶ *Pictured is the nursing staff at the Cook Family Health Center, from left:* ***Megan Bruce***, ***Renea Neidigh-Hawkins***, ***Christina Oliphant***, ***Charlene Hardisty***, ***Susan VanDeventer***, ***Angela Harr***, ***Rebekah Wilton-McCloskey***, ***Angela Stoner***, ***Tammy Hawkins***, ***Stephen Enyiaku***, ***Amee Olsson***, ***Miranda Duzan***, *and* ***Sarah True***. *Photos by* ***Doug Wright*** *(Doug.Wright@CookMedical.com), an Archival specialist at Park 48.*

Putting the patient first

A look at the nursing staff at the Cook Family Health Center

• *All Cook Family Health Center nursing staff stories by* ***Jon Hancuff*** *(Jon.Hancuff@CookMedical.com), the global Editorial Content manager at Park 48.*

Being a nurse is no easy job. Often people enter the field because they want to help others and few jobs offer the immediate satisfaction in that regard like nursing does. In many instances, though, once nurses join the workforce, helping people takes a back seat to bureaucracy, paperwork, long hours, and constant stress.

That's not the case for the nursing staff at the Cook Family Health Center (more commonly known as the "Cook Clinic"). Their mantra is one familiar to everyone in Cook—"patients first."

"Here you get to do the right thing for the patient," said **Susan VanDeventer**, the Cook Clinic's nursing staff manager. "You get to take care of them, you get to listen to what they are saying, you don't have all those hoops to jump through. It's a breath of fresh air, it really is."

Susan heads a team of 14 that includes a variety of qualifications, from certified medical assistants to licensed practical nurses (LPNs). On a typical day, they perform a wide variety of tasks, based on their skillsets. These include placing intravenous (IV) lines, checking basic vital signs, finger sticks, lab draws (for blood tests), lab draws, electrocardiograms (EKGs) (measures electrical activity of the heart), strep throat and mononucleosis testing, stitches, splints, mole and wart removal, allergy injections, testosterone and B12 shots, and answering patient questions and phone calls. They will see patients who scheduled appointments months in advance for a specific reason as well as walk-in patients.

"Here you get to do the right thing for the patient. You get to take care of them, you get to listen to what they are saying, you don't have all those hoops to jump through. It's a breath of fresh air, it really is."

*— **Susan VanDeventer**, the Cook Clinic's nurse manager.*

Each of the Cook Clinic's six providers has a nurse assigned to them. In addition, there is a "float pool" of nurses, including Susan, who assist wherever they are needed and two nursing personnel assigned to the "triage office."

Partnering a nurse with a provider has many benefits for everyone involved. Each of the providers has a different style, personality, and way of practicing medicine. As the nurse learns those tendencies and

Continued on page 8

Gung ho for nursing

Miranda Duzan loves her job.

She didn't utter the phrase "I love my job" during our 20-minute interview at the Cook Clinic, but there is no doubt how Miranda feels about being a nurse.

As she talks, she exudes excitement and positivity, peppering the phrase "gung-ho" throughout our conversation.

She is gung ho about working in a provider's office instead of a hospital or some other healthcare facility. Miranda is also gung ho about learning new nursing skills and techniques.

▲ *Miranda Duzan*

That's not to say, she wasn't a little anxious when she started working at the Cook Clinic, only a couple of months after becoming an LPN. Her only previous professional experience had been a few months at a nursing home.

"At first, I was surprised at how much the clinic offers to the patients," Miranda said. "There were services that I hadn't done yet. I told our manager at the time that I was gung-ho to learn how to do all of these things and broaden my spectrum of things that I can do. My first week on the job I was a little bit nervous, but the training here is awesome."

That training included lots of observation and performance of services under the watchful eye of the more experienced nurses over the course of six weeks. After successfully completing a set number of "check offs" for each procedure, a new nurse is then allowed to do them without supervision.

Now, four years into her career, Miranda is still seeking opportunities to learn more about her craft. It's a mindset she tries to instill in the nurses she now trains.

"I tell nurses to watch as many different procedures as they can," she said. "Get in with a different nurse and see how they check in patients, because everybody does stuff differently. Watch how other nurses do IVs and blood draws. Sometimes I will watch someone and see a technique that I like, so maybe I will try it that way next time to see if it is easier."

Most of Miranda's time at the Cook Clinic has been spent working with Dr. Bob Schimmelpfennig (more commonly known as "Dr. Schim"). She has no doubt that Cook Clinic patients benefit from the rapport a nurse and provider develop by working together.

"All six of our providers do things differently," Miranda said. "When you are with that provider every day, you get a feel for how they do things. I know what Dr. Schim wants for patients. Knowing his preferences means the patient doesn't have to be here as long. They are not waiting around for him to do things that I could have done before he gets into the exam room.

"We are a good team together."

For Miranda, life as a nurse at the Cook Clinic is pretty good.

"I have so many options of different things I can do here," she said. "I like that there are so many nursing skills that I can use here to help our patients. That's my favorite part."

Continued from page 7

preferences, they are able to make sure that each interaction between provider and patient goes smoothly and efficiently, allowing the provider to give the patient the best care possible.

As the name indicates, nurses in the "float pool" will "float" to whatever nursing tasks need to be done. Often this means doing "nurse visits," when patients come in or call to have questions about treatment answered. Being part of the float pool also includes covering for the physician-assigned nurses assigned when they are on break, out of the office, and when the Cook Clinic is at its busiest.

The nurses in the triage office spend most of their day on the phone with patients, either answering incoming calls or contacting patients to let them know the results of any testing they may have had done.

"We are certainly busy, but it is very rare that we are all about to pull our hair out every single day, which is a pretty common occurrence in other facilities," Susan said.

Also, unlike many other facilities in which a nurse may work—like a hospital—the nursing staff at the Cook Clinic know they are only going to be working eight-hour shifts, they won't have to work past 7:00 pm, and they only have to work one weekend shift a month—four hours on a Saturday morning.

The variety of work and the stability of the schedule create an environment in which a nurse can thrive. Instead of constant stress and fear of burn out, they can focus on serving patients.

"When you get to know the patients, it really feels like a partnership," Susan said. "You feel like you are in this together. We will get through this together and we will help guide them to where they need to go."

A passion for helping others

▲ *Sarah True*

When Sarah True was growing up, she would spend a couple of weeks every summer with her grandparents in Plymouth, Indiana, a small town in the north central part of the state. It was during those visits that she decided she wanted to become a nurse.

"My grandfather was a family practitioner," Sarah said. "We'd go on house calls with him where people paid him with eggs or chickens or whatever. I got to see the difference he was able to make in people's lives. My most favorite part about being a nurse are the interactions with patients. Even in tough situations."

Sarah, a registered nurse, has spent the last year at the Cook Clinic as the patient care manager. It is the latest stop in a career that spans 40 years. And during that time, she has not shied away from tough situations. Prior to Cook, she spent 14 years at an oncology (cancer treatment) facility, which followed stints in intensive care, home health, and hospice.

That variety of professional experience was good preparation for her current role.

"Basically, I am a catchall person," Sarah said. "I am here for any question that patients may have. If I can answer it myself, I will. If not, then I make sure I find the answer or refer them to the best person."

When she is not responding to patient questions, Sarah is the one reaching out. She partners with the Cook Clinic physicians to assist patients who are suffering from multiple chronic illnesses, patients who have cancer, and patients who have had outpatient, or emergency room visits.

Often, Sarah is connecting patients with some of the many resources available to them at the clinic including the dietitian, pharmacist, and therapist.

So, the specifics of these calls may vary, but the purpose is the same.

"We want to help them coordinate their care so that hopefully the outcomes will be much healthier," she said. "And we want our patients to know they have an extra support system they can reach out to."

As someone who thrives on helping others, Sarah can't imagine being in a better place.

"It was an eye opener coming to the Cook Clinic, how much patients have at their fingertips, as opposed to what I call the 'real world,'" she said. "Here, people are willing and excited to try to help in any way that they can. It's amazing. Cook is like a huge family. And this is really, truly a terrific model of care to help patients make positive changes."

WCE COS Facilitation team

From strategy to success

▶ *Pictured are the members of the COS Facilitation team, from left:* ***Peter Moerkeberg***, ***Niels Olesen***, *and* ***Camilla Bisgaard****.*

The key focus area in connection with transformation has been to continuously improve the way that we work. A lot of work is done all the time all over the company—in the divisions, in the various functions, and in the departments. Supporting and facilitating these improvement processes requires an overview of projects and monitoring of Key Performance Indicators (KPIs) and targets.

But what do Portfolio Management Office (PMO), Continuous Improvement (CI), and KPI-handling have in common and what is The Cook Operating System (COS)?

These are questions we sometimes hear at William Cook Europe (WCE), where the three functions—PMO, CI, and Manufacturing business support—are joined in one office and generally referred to as the COS Facilitation team.

COS is a way to focus on resources and results, following-up and prioritizing projects as well as programs, KPIs, and continuous improvement initiatives. The COS is focused on:

- ▶ People—Organizational Development
- ▶ Processes—Production Environment
- ▶ Performance—Key Performance Indicators

When reviewing the 2019 WCE Business Plan, we discovered that when we begin working on an initiative in one area, it often collides with another area, when it comes to resources, man hours, etc. Another example is that it is impossible to meet all targets in the Business Plan if they are not prioritized and monitored. The COS Facilitation team is a great help to the WCE Management team in visualizing where one initiative may cause challenges elsewhere in the organization and come up with suggestions as to how to resolve the problem.

We often talk about breaking down silos, and this cross-functional team is a perfect example of how this can be done. Therefore, WCE has joined these functions to ensure that the initiatives in the WCE Business Plan have been initiated and completed by working cross-functionally.

PMO—Camilla Bisgaard:

"I support the process, by following status on top priority projects within the Business Plan, and making sure counter measures are initiated if the projects are off target. I also provide an overview of resource needs within the organization, based on which management can make decisions."

CI—Niels Olesen:

"As the CI lead, I train the company in how to work in a focused and structured way and involve everybody to participate by using tools from the Lean philosophy."

KPI and target-handling (Business Support)—Peter Moerkeberg:

"I support the reporting of KPIs by setting a structure around the reporting process and follow up on KPIs. This is done by providing management with an overview of status, analysis recommended and planned actions, and an outlook on impact to the business for management to make decisions on. To recommend management on changes in focus and development of the KPIs is also part of my role."

• ***Bettina Berend Pedersen*** *was the executive assistant/ coordinator for Administrative Services & Communication at WCE.*

Celebrating 15 years of support

▶ *From left:* ***Malissa Ridge***, ***Lou Ann Fortner***, ***Shawn Taylor***, *and* ***Ella Anderson*** *take part in the festivities at AMER Support Center's 15th anniversary celebration. Photos by* ***Doug Wright*** *(Doug.Wright@CookMedical.com), an Archival specialist at Park 48.*

The AMER Support Center (AMER SC) celebrated a 15-year anniversary in July 2019. This building and the work that has happened within these walls have come a long way since 2004. We've grown significantly in our capabilities, staffing, processes, and so much more. We are proud of what the AMER Support Center has become and the direction it's continuing to go. We had the chance to speak to both **Dave Reed** (vice president (VP) of Healthcare Solutions) and **Ryann Roberts** (AMER Customer Support & Delivery (CSD) director) on some of the history of how this location came to be, and how the idea of one voice, one vision, and one Cook is still the foundation of what this building stands for.

It all started as an idea. **Bill Cook** came to Dave, who at that time was the VP of Operations, and asked him his thoughts on using the Acuff Road building as a Cook shared service center.

At that time, Cook Pharmica (now Catalent) was the only entity using that building, and they were located where Cook Travel resides now (on the top floor of the Acuff Road building). Dave was given the task of creating the shared service center in North America and putting it under one roof. That center would be called CMI up until 2018 when the name was changed to AMER Support Center. Before CMI was created, Cook had customer service and distribution at every manufacturing location.

June 28, 2004, was CMI's very first day of working operation, and it also happened to be Ryann's first day as a Cook employee. She was hired on as Dave's administrative assistant. Employees from Customer Service and IT occupied the first and fourth floors at that time, but the goal was to continue expanding and growing.

From that time until now, we have seen much progress in automating order processing, and hopefully this will continue in the future. We have also witnessed growth that was needed in order to focus on different aspects of our daily business, such as the development of pricing & contracts and inventory. This building has allowed us to spread our wings and forge our own way, putting the patient first with any decisions that are made.

The AMER Support Center has really evolved. Because this building has expanded, technological developments have helped the delivery center continue to flourish as well, which has enabled the two to work more efficiently separately and together.

When Healthcare Business Solutions (HBS) was created, it helped bring the shared service center and the business units together to collaborate more strategically, which was a huge win for our customers and improved the way we worked with them. This also allowed us to become a solution provider in healthcare in a unique way. The concepts that were set in stone during this period have been replicated globally for Cook over the years.

By 2008, we had continued to grow so quickly that it was necessary to add a new addition to the building. The Cook culture has been a huge part of this building and is the reason many people have stayed with this company for the entire duration of their careers.

"Because this building is so customer-centric, everyone has always understood that the customer's needs come first," said **Lou Ann Fortner** (AMER Support Center Human Resources)**.** "We understand the importance of the product arriving correctly and on time. We know that if we are not responsive to our customers in a timely manner, the patient will ultimately be affected. Because the building where we are located is smaller, it lends itself to a more family-like atmosphere. We have a lot of longevity in this building, so the strong desire to go above and beyond for our customers is truly passed down from one generation to the next."

"Being a part of the Cook company and culture for many years, whether it be on the Curry Pike main floor, or the Curry Pike upstairs (which was added on a few years later), or in the Curry Pike fishbowl, or at Park 48, or at the AMER Support Center, the bonding is still real and unique with all the Cook employees. Patient care still remains number one," said **Alice McMillian** (AMER Support Center Customer Support). "I have worked in all the buildings I've listed and still get gratification when we receive great news of what a difference our products make. The support center building, 15 years later, still has a great group of employees doing the daily tasks to keep the Cook culture going strong."

▲ *The festivities at AMER Support Center's 15th anniversary celebration. Pictured are, from left:* ***Todd Posson***, ***Gard Gardner***, ***Jake Davis***, ***Scott Todd***, *and* ***Kiley Labis****.*

One of the biggest changes over the last 15 years has been in how we use technology. We have shifted from phone or typing in fax machine orders to computer systems and programs. Today, 67% of our orders aren't touched by an actual person, which has given us the chance to focus on other processes and workloads.

What do we see for the next 15 years? To continue being a business partner with the divisions and customers in order to enhance their experience, and to maintain the reputation that we've built and that's apparent to everyone who works with us.

• ***Sydney Spaulding*** *was a written content specialist for Customer Support & Delivery (CSD)*

AMER Support Center fun facts:

- On January 2, 2004, we produced our first invoice: I0000001.
- In 2004, we averaged 2,300 orders a day; today we average 4,300.
- When we started it was customer service, and we called it "Sales Support."
- In about 2005 or 2006, we moved the Sales Support team from Cook Inc. and started handling the sales reps from here. This eventually grew into Sales Operations.
- In February of 2010, we added Cook Canada's customer support services, which included processing Canada's customer orders and inquiries, as well as providing sales support to our reps.
- In the fall of 2016, we combined Sales Operations and Customer Service and named it "Customer Support."

The evolution of Cook Spain

Hola! My name is **Enrique Clua**. I was born in Barcelona in 1948 and I started my relationship with Cook in 1975. In that year, I started working in a company that sold packaging for the food market. One division of this company sold sterilization products for hospitals (plastic bags). This division had a small closet in the office that contained some strange needles, plastic tubes, and wires. This was the stock of a company that I didn't know at that time, called Cook. I had the responsibility of selling the plastic bags and Cook products in Spain. We had a team of sales representatives that occasionally visited the hospitals, but they spent most of the time on the food market.

Around 1976, there was a European Congress of Neuroradiology in Barcelona. In the exhibition hall, I found a small Cook booth. There was a man at the booth, not too tall and quite bald, with a T-shirt with the logo "Cook DK." I communicated with him through one of my friends, because my English was almost zero. I explained that I was selling Cook products in Spain. It seems that he had a good impression of me, because when Cook wanted to set up a company in Spain, he insisted that I should look after the business in this country.

In 1978, the Bartoli family and I founded the company Suministros Clinicos Hispania (Sumiclinic). This company was dedicated solely to the distribution of Cook products in Spain. In 1980, William Cook Europe (WCE) bought 51% of shares belonging to the Bartoli family and took control of the company. In 1982, WCE bought the remaining 49% and the company changed its name to Cook España. At that time, the total sales of Cook España were approximately $100,000. We always ask ourselves why Cook started in Spain with another partner. This has an easy answer: the Spanish law at the time did not allow any foreign company to have more than 50% of shares of Spanish companies. At the same time, the CEO had to be Spanish.

▲ *Pictured are, from left:* ***Montse Pastor****,* ***Cristina Santamaria****,* ***Enrique Clua****, and* ***Carmen Garcia*** *on the terrace at the Cook Spain office.*

The company started with only two employees, one in the office, **Margarita Esteve**, and myself as CEO traveling all over Spain selling Cook products. Both of us continue working for Cook together with 58 other colleagues in Cook Spain. Currently, Cook España is one of the European Cook companies distributing Cook products to the hospitals in the country. It is the oldest subsidiary in Europe. It is based in a business center in the center of Barcelona, near the Mediterranean sea.

• ***Enrique Clua*** *(Enrique.Clua@CookMedical.com) is the managing director for Cook Spain.*

Meeting patient needs

Meet the Customer Service team of South Asia Distribution Centre (SADC). This team of three ladies, based in Singapore, goes above and beyond to serve the customer.

Our attitude defines us

▲ ***Sharon Seah,*** *Customer Service Representative from SADC–Singapore*

I have been with Cook South East Asia since January 2017 and have worked as a Customer Service representative in both domestic and regional sites. Over the past two years, I have seen change occur, generally for the better. I have always believed that with a good attitude for learning and positive energy, I could amplify myself to excel in my current role. It is a great pleasure to work for Cook Medical and I have come across many good souls. I also appreciate the guidance and opportunities that have been given to me. I always remind myself that it is easy to look back and marvel at what has been accomplished, but I also realize that there is still much work to be done going forward. As part of the Customer Service team at the SADC, I always find it fulfilling to resolve a challenging customer request, such as providing a speedy delivery. I always uphold a mission to fulfill customer needs, and it is meaningful to me to help patients overcome their discomfort by using our products. I really hope I can maintain an excellent team with experience, expertise, and passion to achieve high customer satisfaction.

The joy of working in customer service

▲ ***Victoria Quiatchon****, Customer Service Representative from SADC–Singapore*

What we do impacts lives. Our team strongly believes that it is imperative to exemplify our company values on the front lines with our customers. While we uphold these values in our daily work, there are situations when we go above and beyond the call to serve the customer. This involves the emotional aspect of customer service and that is compassion. You become connected to patients you hardly know or have never seen. Your every action revolves around one goal and that is to ensure that the product will reach the patient in the shortest possible time. There is no greater sense of accomplishment than knowing that at one point in time, you became part of someone's journey to recovery.

One-stop solution

▲ ***Namirah Siti****, Customer Service Representative from SADC–Singapore*

We are the one-stop solution for our customers. Customers can approach us and we are the intermediary, who act as a go-between, connecting customers and other departments.

We interact with various departments to serve our main goals, which are fulfilling customers' orders and meeting patient needs.

▶ ***Jean-Marc Creissel*** *(left) and* ***Theo Wong*** *(right) hold a meeting in the collaboration area at Cook Thailand's new office.*

▲ *Cook Thailand's new office.*

Reaching a milestone

Cook Thailand celebrates 10th anniversary and opens new office

Looking back on the past decade, **Ornuma Karo**, office manager for Cook Thailand, feels gratitude.

"On behalf of Cook Thailand, I would like to sincerely thank every co-worker who supported Cook Thailand throughout the past decade," said Ornuma. "This is a significant milestone for us, and also a great motivation to drive the team forward."

This year, the company marked its decade milestone with the opening of a new office. At Cook, celebration is never out of style, especially in a vibrant and bustling country like Thailand.

Cook Thailand's new office

Located on the 19th floor of the Athenee Tower in the central business district of Bangkok, the new Cook Thailand office is a welcoming and human-centric workplace tailored to embrace the Cook wellness concept through the introduction of dynamic features and well-being initiatives. The new office fuses a colorful palette with a large open space. Visitors are greeted by a bright and modern collaboration area, featuring long, shared tables perfect for casual work discussions, lunches, or coffee breaks. The space evokes a relaxing, nature tone with floor-to-ceiling shelves full of greenery and sprawling windows that usher in the bright daylight.

With employees spending 8 hours or more a day in the office, the remaining work spaces are all about comfort and flexibility. Rooms in the Thailand office are thoughtfully designed to accommodate needs of different employees: the two conference rooms are fully equipped with communication devices to facilitate cross-regional collaborations, a multi-purpose room is in place and can be used as a staff-lounge, a nursery room, or a prayer room. To prioritize employees' health and wellbeing, adjustable work stations are available and fresh fruits are provided on a weekly basis.

The celebration

On May 21, Cook Thailand hosted the official opening of the new office and 10th anniversary celebration. **Jean-Marc Creissel**, operation vice president for Greater China & South-East Asia, was invited as the opening guest. A casual discussion was hosted between Jean-Marc and employees at Cook Thailand. They updated each other on latest company plans and goals, raised questions, and shared ways to overcome challenges at work.

The office seamlessly transformed into a delightful celebration setting with vivid colors in the evening. With the theme being colorful night, there was no such thing as too much color when the office itself embodies Thailand's unparalleled vibrancy and diversity. All guests were welcomed with jasmine garlands and the celebration officially began with the sensational Thai dance, Ram Thai, a traditional form of art that has been presented to honorable guests to express blessings and hospitality.

The evening continued with delightful local food and drinks. It also featured a number of mini games, and an intense costume competition. The event provoked excitement for the opening of a new office, and created a unique sense of family within Cook.

• ***Kar See Lock*** *(KarSee.Lock@CookMedical.com) is the written content specialist for Marketing in Asia-Pacific.*

About Cook Thailand

Cook Thailand was established on May 12, 2009, to bring Cook products from both Vascular and MedSurg to the local market. The Thailand team had a total of 14 employees on staff.

▲ *Cook Thailand celebrated its 10th anniversary in May. Above are a few of the photos from the event.*

Supporting wildlife

CRI works to rejuvenate Hawkins Lake

Here at Cook Research Incorporated (CRI) we have continued to support our environmental initiatives inside and outside of the building. Previously, we shared our ongoing efforts to reduce single-use items and plastics in our cafeteria and throughout the building. Now, we would like to share some of our environmental initiatives outside of the building.

While our lawn looks beautiful, the condition of Hawkins Lake has declined over time to adequately sustain the wild life. Lawn fertilizer runoff causes algae blooms; when copper sulfate is applied to control the algae blooms, the dead algae sink to the bottom adding to the sludge (rotting organic material) layer. By maintaining our grounds, we unknowingly caused the health of the lake to change. This sludge layer is full of bacteria that depletes the oxygen levels and increases the hydrogen sulfide levels. After consulting with the Indiana Department of Natural Resources, we determined that the first step to rejuvenating the lake was to add oxygen. Last fall, we added six aerators to the bottom of the lake. These aerators deliver the much-needed oxygen and help stir up the bottom sludge layer. This summer, we began adding beneficial aerobic bacteria. The aeration and beneficial bacteria will work together to decrease the phosphate and nitrite levels in the lake, creating a safer environment for the wildlife that frequent it.

We also needed a way to keep the algae-bloom-feeding fertilizer from reaching the lake, so another improvement to the lake and grounds has begun. A ring of wildflowers, 10-20 feet wide from the edge of the water, has been planted around the its perimeter. The wildflowers act as a biological filter, capturing any fertilizer before it reaches the lake. Another bonus is that the wildflowers require less water and maintenance, no fertilizers, and provide shelter and food to wildlife. We hope that the wildflowers will also attract pollinators, butterflies, and native bird species.

Due to the environmental initiatives outside of the building, CRI has now been certified as a Wildlife Habitat by The National Wildlife Federation.

• ***Scott Hooten*** *(Scott.Hooten@CookMedical.com) is a senior histologist at CRI.* ***Kalub Hahne*** *(Kalub.Hahne@CookMedical.com) is a regulatory scientist at CRI.*

From discovery to sustaining

A look at the life cycle of a Cook product

While Cook's product innovation remains very similar to the way Bill Cook connected with physicians and initiated product development in our early history, the life cycle of a medical device has changed significantly.

A different focus

The warning letter Cook received in 2014 from the US Food and Drug Administration (FDA) has played a transformative role in Engineering.

"The warning letter was a reminder to us and led us to dedicate engineering resources to all phases of a product's life cycle," explained **Tom Roberts**, vice president, Quality Assurance for Cook Group.

As an immediate response to the warning letter, Cook directed resources that would have ordinarily been dedicated to product development and used those resources for remediation efforts. Remediation efforts included upgrading our current products and improving them. Another result of the warning letter was a restructuring initiative for all facets of Cook's engineering systems.

A new structure

Global Research & Development (R&D) became a new function for the company to focus on new products, and plans were announced to create a separate combined Manufacturing and Post-Market Engineering function to support existing products. However, according to Tom, after much discussion and exploration, they decided to take an additional step to split Manufacturing and Post-Market work, resulting in three separate engineering functions.

Before restructuring, the engineering process was two-fold: development and manufacturing. R&D generated the product design, and Manufacturing created the process to build the product. But there was a problem with this approach. Any time Manufacturing had to change the product's design, the product had to backtrack to R&D to be redesigned.

"Now, we develop the product and hand it off to the Post-Market Engineering team, and they manage the product design," said Tom. "Once the product is available on the market, Post-Market Engineering changes the design as needed. We are now targeting engineering resources to all phases of the product's life cycle."

Propelled into change

Today, in the wake of the warning letter, restructuring efforts continue. R&D, the first step in the product life cycle, has been propelled into change. Under the leadership of **Dan Kaiser**, vice president of Research & Development, a new journey in product development has begun at Cook.

Dan described product development as a wheel where all functions contribute to the effort.

"When I came on board, I noticed we needed a more cohesive plan at the beginning of product development from a team effort," added Dan. "We put together a strategy with the divisions to allow us to do more up-front planning. We asked ourselves, 'Are we planning effectively and doing what we planned?'"

Identifying priorities

Dan began his career at Cook in January 2017. He spent his first six months visiting manufacturing locations in Ireland, Denmark, Australia, Winston Salem, Vandergrift, and Cook Inc. He hosted town hall meetings and listened to employees' feedback. Through that communication he discovered a pivotal revelation.

"We didn't have accurate or clear priorities, and we didn't know what tradeoffs to make when there were competing resources. We were doing good work, but it was difficult moving products forward," he said.

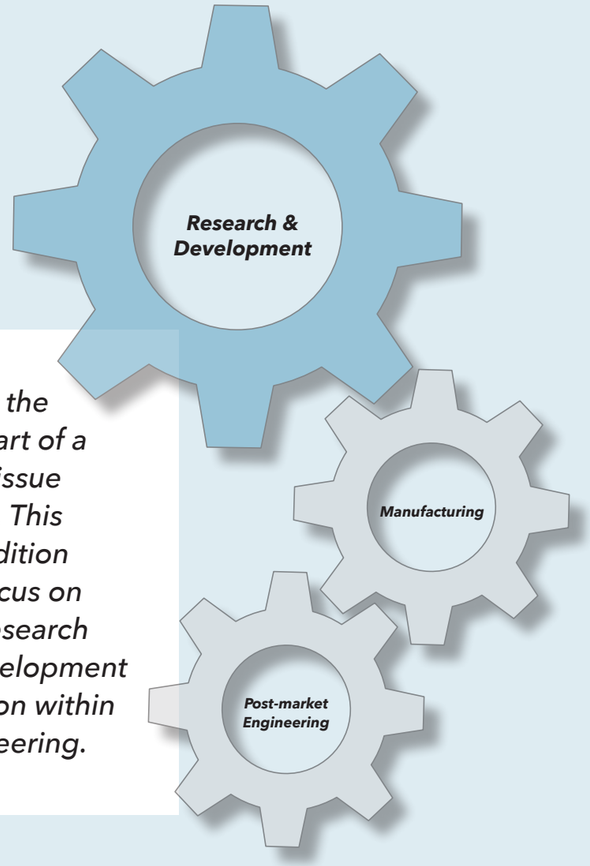
The solution was to build a team to develop an improved vetting process and establish an infrastructure for prioritizing our product development projects.

Continued on page 21

▶ ***Triona Campbell**, senior manager Post Market & Manufacturing Engineering, and **Donagh O'Sullivan**, engineering laboratory manager, perform device testing in the Innovation Centre's lab.*

▲ ***Dan Kaiser***

▲ ***Tom Roberts***



This is the first part of a multi-issue series. This first edition will focus on the Research & Development function within Engineering.

What does R&D do?

R&D is the team responsible for documenting the testing and design requirements. It is the central hub where product information resides and is coordinated. For example, R&D gathers product information from multiple areas like sales, product testing, and clinical trials, and R&D supports what is needed for regulatory approval and regulatory submission.

▶ *Illustrations by **Ashley McGuire** (Ashley.McGuire@CookMedical.com), an Editorial Content generalist at Park 48.*

What's R&D like now?

Several R&D employees shared their stories of how transformation efforts have changed and rejuvenated their careers.

Blayne Roeder

Director, Global R&D–**New Ventures**

Connecting product development more closely with our customers' needs has been a consistent theme in Cook's product development transformation. The New Ventures team prioritizes and manages the process for developing new technology that falls outside the divisions. Blayne is leading the effort to manage these opportunities, including technology scouting, evaluation, and bringing new technologies into Cook.

"When Cook Incorporated received the warning letter, our global bandwidth for product development was cut in half almost immediately," said Blayne. "As we worked through transformation, we knew we couldn't leave product development on the back burner. We had to innovate and bring new products to patients. We also had to innovate the way that we bring new products to patients "

New Ventures was a key part of the R&D strategy, not just to rebuild our internal, existing products but to focus on bringing new technology from the outside into Cook Medical. Prior to the warning letter and transformation, Cook's R&D team was almost completely focused on internal product development efforts. "Bringing in new technologies and products from outside Cook allows us to bring additional products to market that are complementary to our current and future product pipeline," explained Blayne. "Moreover, we're starting to put a focus on later-stage technologies that we can take directly to market and more immediately impact patients and sales."

The New Ventures team serves as a resource to support divisions and currently has ongoing projects with both divisions. The team identifies what new products are needed and closely aligns with the leadership of both divisions.

Michael Clancy

Program Manager, Global R&D–Endoscopy (Cook Ireland)

Since transformation and the formation of the Vascular and MedSurg divisions, Michael has become the program manager for Medsurg R&D Endoscopy.

"My role is to help get R&D projects into the pipeline and finish products out at the end" explained Michael.

"Prior to transformation we had too few engineers working on too many projects," he said. Post transformation, R&D has a stage gate process. During feasibility, projects are vetted for all aspects, like regulatory, market impact, reimbursement, intellectual property, finance, and market projections. The projects are evaluated through these department lenses; everyone comes together to vet the potential projects. This review stage is completed earlier in the process and the entire review goes to the executives of MedSurg for vetting and approval. "Traditionally this was not done before transformation and this level of project scrutiny did not take place. We have transformed how we do things for the better," stated Michael. "Once projects go into development, they continue to be scrutinized and project milestones are monitored."

"We have transformed so much around R&D, but our patient focus, a key philosophy at Cook, remains fundamental to what we do," he added.

Continued from page 19

A global focus

When R&D was separated as an independent function, a global leadership team was formed. The team's formation was a necessity to ensure global connectivity and leverage the skills and abilities of employees across sites.

"We took six independent teams around the world and globalized them," explained Tom.

In order to globalize, the Engineering teams had to standardize processes, defining new processes and standards for design control and risk management.

An emphasis on product development that required team participation was key to manufacturing products anywhere, globally.

"With a global perspective on development, the decision can be made to manufacture more effectively and transfer products from one site to another," explained Dan. "This created opportunities for engineers to work at other sites for one- to two-year terms and broadened hiring options. We can hire engineers not limited to specific regions. The more limited you are on hiring talent, the more limited you are in success."

Innovative product development shines again

As Dan and his team worked with product management creating prioritization methods, the Engineering teams started to get back in the swing of new product development, bringing new product ideas to the market.

"It's important for our business to revive the spirit of innovation to remain competitive in the field," said Tom.

It's a team effort to create products, according to Dan. "I refer to product development generally and mean a team that involves R&D, Product Management, Regulatory, Quality, Operations, and the many functions that contribute," he added.

"We continue the culture of being an innovative company, we want to retain that culture and perspective. Our quality is superior, and the products are invaluable. We all have a responsibility to provide products that impact the lives of as many patients as possible," said Dan.

• ***Teresa Nicodemus*** *(Teresa.Nicodemus@CookMedical.com) is a written content specialist for Corporate Marketing & Communications Park 48.*

Making woodworking a fine art

One hundred pounds of German Shepherd could be akin to a bull in a china shop when it comes to your living room. And so it was with **Donny** and **Heather Graham**'s German Shepard **Ozzy**, whose exuberance and immense bulk knocked down and broke the Grahams' TV stand.

▶ ***Donny Graham*** *(Park 48 Regulatory Reporting) works with a bandsaw.*

▲ *Some of Donny's works.*

▶ *Donny is pictured with his wife* ***Heather*** *and their German Shepherd,* ***Ozzy****.*

Self-taught woodworker

On that fateful day two years ago when the TV stand met its demise, Ozzy's mistake became a springboard for Donny, a Regulatory Reporting specialist at Park 48, to take a creative leap into woodworking. "I decided to make my own wall-mounted platform to hang the TV. I had never created anything from wood before," explained Donny. "It was amazing to see the project develop from a pile of wood to a unique piece of wall art." He also put up a pair of floating shelves to complement his new TV platform.

For Donny, learning woodworking was a matter of trial and error. He sought the assistance of a friend, and together they reviewed how-to online videos for ideas and techniques. You could say Donny had the knack for woodworking. He picked up the skill quickly and was soon building more furniture pieces for his home, remodeling his laundry room, and accepting project requests from friends and family.

"Since my first wall-mounted TV platform, my skills have improved so much," said Donny. One of his favorite projects he did upon request was to take the idea of the wall-mounted TV platform and expand it to an entertainment space in a home. "I transformed the space, framing it out using shiplap paneling painted in white tones," he said. "It was a good mix of combining woodworking and connecting it to the house by creating a permanent space that is unique to the home."

The basement workshop

Donny finds working with wood rewarding, and he considers it a problem-solving process. Taking a piece of wood and making it useful furniture or decor takes consideration, time, and creativity, like solving a problem. In fact, Donny has his own problem-solving space at home, which is his basement workshop.

Donny's shop is filled with the tools of the trade, from multiple saws (circular, miter, and table) to jointers, wood stains, and finishes. "I like the idea of working with my hands and creating something unique," he added. "The things in my workshop have an order to them; it just makes sense. It's a place where I can get away from stress."

The artistry of wood

"Different woods are good for different types of projects," Donny stated. For example, rustic pine, with the wood's knots and grain visible, makes a great table top for a patio farmhouse table. Denser, exotic woods make decorative projects look richer. Donny has made ornaments, coaster sets, and cutting boards using a variety of woods, such as Dark American Walnut, Mahogany, Purple Heart, Zebra, Padauk, and even plywood.

Donny's inspiration for his woodworking can come from anywhere: videos, online furniture galleries, magazines, etc. He can build just about anything, and his woodworking hobby continues to flourish. As he says on his website, "It's never a bad time for a new build and a new challenge."

• ***Teresa Nicodemus*** *(Teresa.Nicodemus@CookMedical.com) is a written content specialist for Corporate Marketing & Communications Park 48.*

Fighting fires

Tatsuro Hirayama dedicates his time to local volunteer fire corps

Japan has fallen victim to numerous natural disasters throughout the decades. Recently, Japanese TV programs have begun to feature volunteers who actively engage in relief work during serious accidents and natural disasters.

When he isn't working as an operator for Supply Chain Distribution at Cook Japan, **Tatsuro Hirayama** dedicates his time to helping out in these situations as part of the volunteer fire corps for the Chiba prefecture. The word prefecture is used to describe 47 different regions within Japan.

These groups are part of a nationwide network set up as part of Japan's Fire Service Act, which was created in an effort to protect the countries citizens from fires and the damage caused by natural disasters.

While these volunteer networks are not regularly in-service, they jumped to action as soon as they are needed. In case of fire, national emergency, or natural disasters, fire corp volunteers immediately head to the local fire station, where a fire engine is waiting to rush them to the emergency site. Once there, they take an active role in emergency services, such as fire extinguishing, rescue work, evacuation guidance, and safety confirmation for the citizens of the surrounding community.

Tatsuro has been in the volunteer fire corps for about 10 years.

"In the beginning, I joined the fire company following the advice of a senior in my community," said Tatsuro, "I was not so active in volunteering, and was rather reluctant to spend my holidays taking part in the trainings and events because I felt it was a waste of my private time."

▶ ***Tatsuro Hirayama*** *(Cook Japan) takes part in a drill for the volunteer fire corps he is involved with outside of Cook.*

> ***"The volunteering activities remind me of long-forgotten excitement and thrills from my boyhood."***
>
> *– **Tatsuro Hirayama**, Cook Japan SCM*

However, Tatsuro reached a turning point that changed his attitude towards volunteering. He had the opportunity to participate in a firefighting operations competition, which demonstrated the skills he had developed through his daily trainings with the fire corps.

The competition was not designed to score individual skills, but was a team competition designed to evaluate their overall operation speed, accuracy, and their ability to communicate and cooperate as a team of four fighters.

"We practiced for the competition for about six months every day after regular work hours until midnight on weekdays and all day long on holidays,"said Tatsuro.

Tatsuro's team received support and from devoted fire officers and was selected to participate in the national firefighting competition in 2010. The event is held every four years and only 23 teams from Japan were selected to participate.

"The volunteering activities remind me of a long-forgotten excitement and the thrills from my boyhood," said Tatsuro. "I truly thank my friend for leading me to the fire corps and I will continue firefighting activities in hopes of being some help to the community,"

• ***Fumie Momose*** *(Fumie.Momose@CookMedical.com) is a meeting and events coordinator for Marketing at Cook Japan.*

▶ *Tatsuro (second from left) is pictured with his fellow firefighters. Pictured to the left, Tatsuro participates in a rope training on a helicopter.*

What's your story?

What are your hobbies? Are you involved in a cool group? Do you do volunteer work or donate your time to helping your community? Or maybe somebody in your department, clinical division, or company does?

We are always looking for stories like these.

Send your story ideas to **Angiogram@CookMedical.com.**

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.

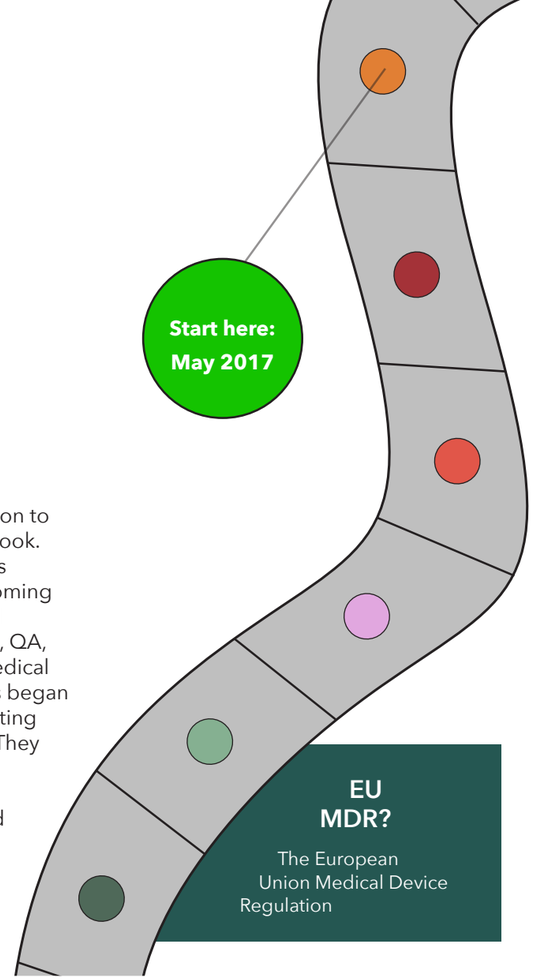
We push through doors, between the desks of people quietly working, down short flights of stairs, through even more doors, and down a longer flight of stairs, before we finally emerge in Sinead's "home" in Limerick—the Regulatory Affairs (RA) department. As we settle into her office, I realize that we 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**.*

"Everyone 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.

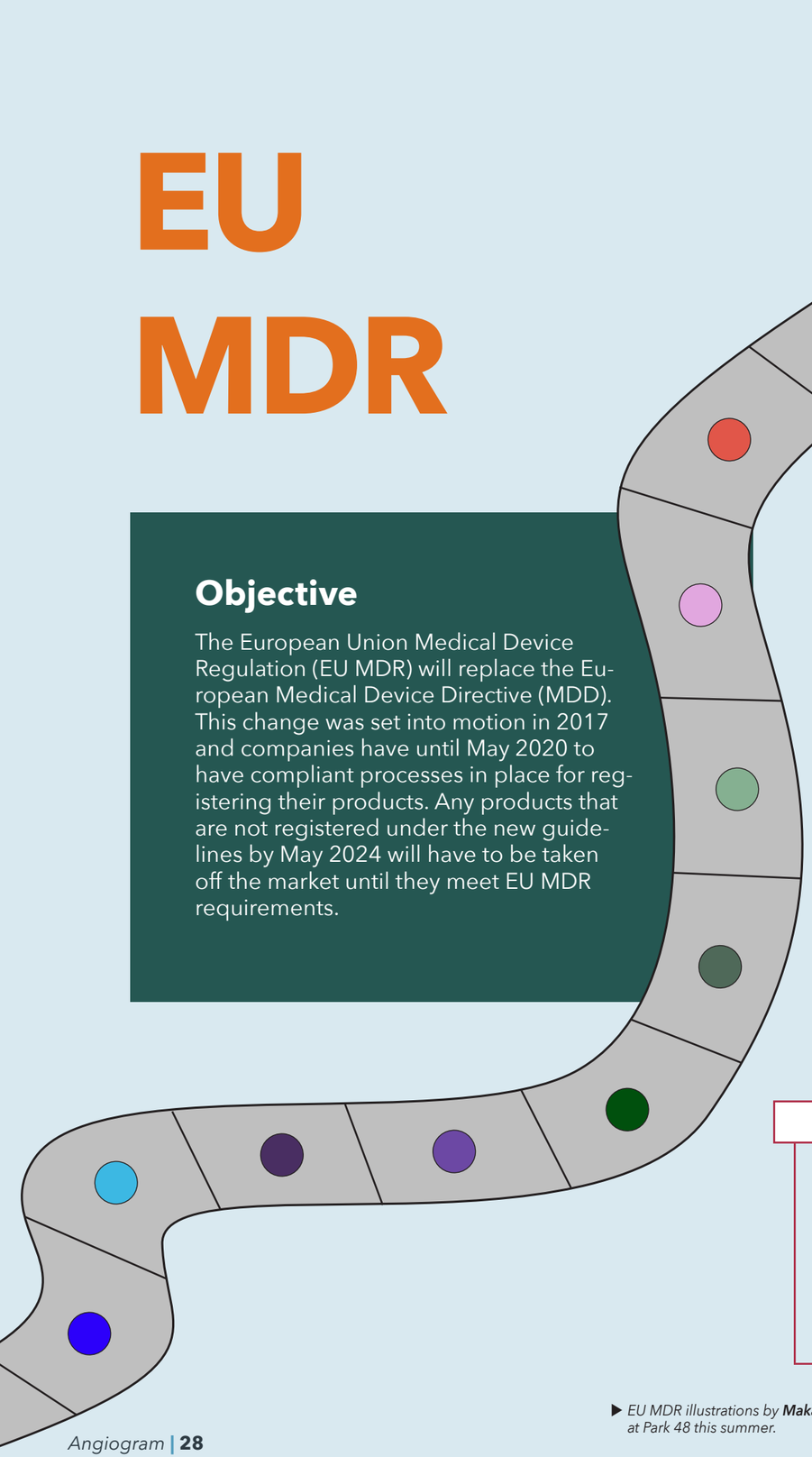
Continued on page 35

"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.

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.

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

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."

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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."

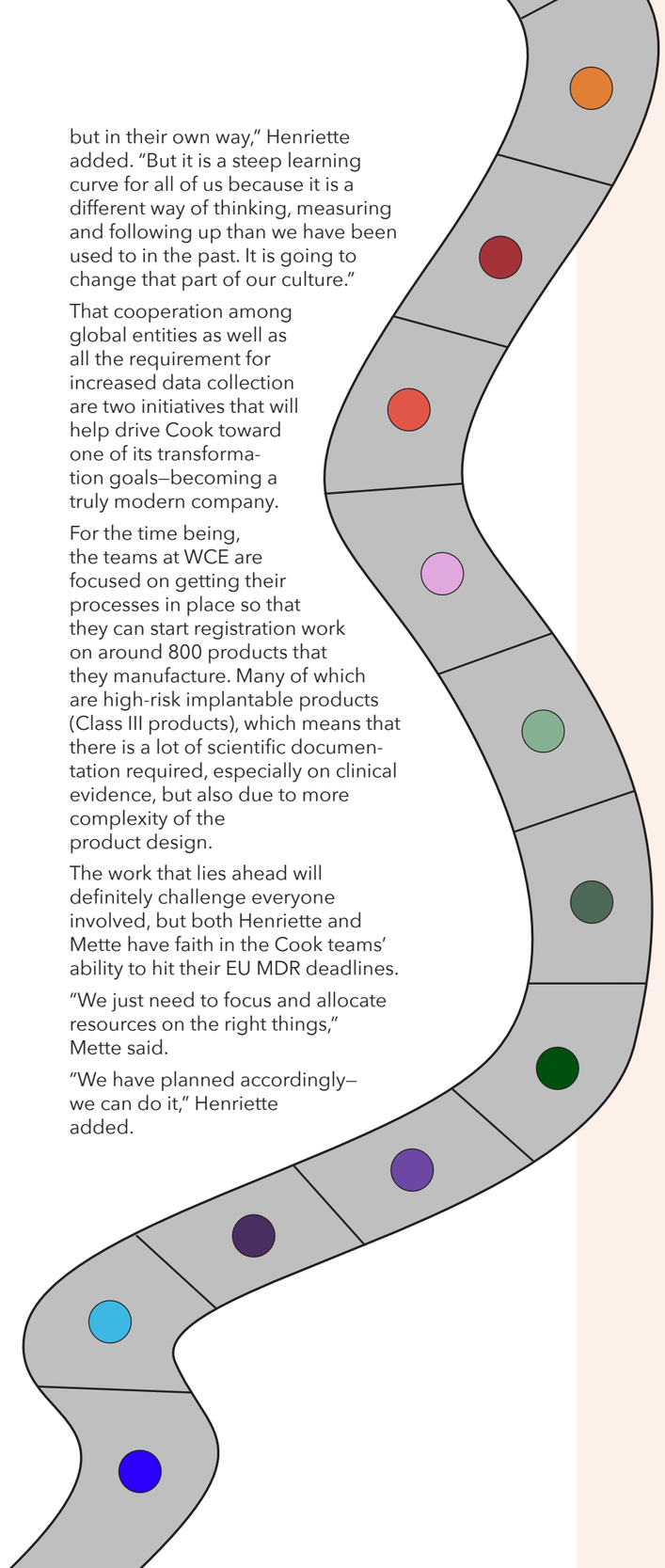
That cooperation among global entities as well as all the requirement for increased data collection are two initiatives that will help drive Cook toward one of its transformation goals—becoming a truly modern company.

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.

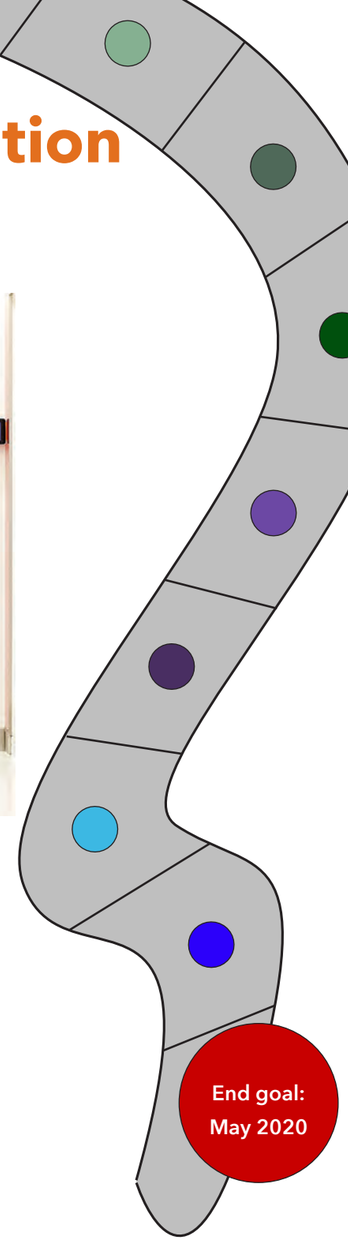
Perhaps the greatest change from a business perspective is the role and responsibilities of the authorized representative (AR). For Cook, that person will be **Sinead Burke** and her new team in the Cook Medical EU office. We are familiar with the concept of an AR, however this role will assume more 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.

▲ *Bill Doherty*



▶ 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."

Jeni Wright, *Cook Australia Logistics*

Hired in: 1989

Jeni was born and bred in Pittsworth, a small country town near Toowoomba, Australia. She completed 10th grade at Pittsworth State High School. She then left school to work at a local upholstery shop. For the last 30 years, Jeni has lived in Brisbane. She previously lived in Victoria, where she had her three children. Before coming to Cook, she worked at two companies making wiring harnesses for the Escort cars and washing machines. She then moved back to Queensland and was employed at Cook.

During her time at Cook, she has worked in Catheters, Catheters/Drainage, Production R&D, Vet, Stent Soldering, Label Bay, and now Logistics. She has been with Logistics for 14 years and has been a leader for at least 10 of those years. She has had perfect attendance during most of her 30 years with the company.

Outside of work, Jeni donates plasma. She has performed 50 donations, but aims to get to 100. When she can, she also takes part in local park runs on Saturdays and visits the local pool to swim laps and do aqua aerobics.

"I have enjoyed the opportunity to work my way around the company in different departments and end up where I would like to see my time out. I have also enjoyed watching the company grow from a handful of people to where it is now. Cook values their employees and it shows with the people they choose for certain roles, the great end-of-year celebrations, and Company Day."

Steve Spykes, *K-Tube Welding*

Hired in: 1988

Steve was born in Dallas and moved to Chula Vista, California, in 1963. He attended Hilltop High School. He currently resides in El Cajon, California, where he has lived since 2002. He has only worked at K-Tube and has worked in several departments at K-Tube, but has spent the most time in Welding.

Away from work, he enjoys playing bass guitar. He also likes to go camping, shooting, and fishing.

"I enjoy the people that work here and the operators on the floor."

Alex Le, *K-Tube OC Operator*

Hired in: 1989

Alex was born in Vietnam and came to the US in 1986. He has lived in San Diego since coming to the states. He attended San Diego City College, and Cook has been his only job.

In his years at K-Tube, Alex has worked in all departments except Welding. He has two brothers that also work for Cook. In his free time, Alex enjoys spending time with his three daughters.

"What I have enjoyed most about my time at Cook is the people I work with."

Danny Tran, *K-Tube Straightening*

Hired in: 1983

Danny was born and raised in Vietnam and came to the US in 1982. He went to school in Vietnam and worked small jobs here and there before hiring in at K-Tube. He currently resides in Lemon Grove, California, where he has lived for about 10 years.

During his time at Cook, Danny has worked in several departments, including E-Cut, QA, and Straightening. Away from work, his small children keep him busy.

"I love the people that work here."

Kyle Le, *K-Tube OC Operator*

Hired in: 1988

Kyle was born and raised in Vietnam. He came to the US in 1988 and K-Tube was the first company that he worked for. He has lived in Oak Park since 1988.

Kyle has worked in many departments during his time with the company, including Straightening, Sink, Lumen, and OC. He currently has two years perfect attendance. His brothers **Aaron** and **Alex** also work at K-Tube.

In his free time, Kyle's hobbies include mountain biking.

"Cook is just a great company to work for!"

Thomas Campbell McIntyre, *Vascular Division SEA & Pacific*

Hired in: 1996

Thomas was born in Glasgow, Scotland. He has also lived in Melbourne and London. For the last 30 years, he has lived in Beaumaris, Melbourne. He attended Bellahouston Academy in Glasgow and Royal Melbourne Institute of Technology. Before coming to Cook, he worked as a radiographer at Royal Southern Memorial Hospital in Melbourne; a superintendent radiographer at St. Mary's Hospital in London; an applications specialist at Philips/Siemens; and a territory manager for Toshiba Medical.

Thomas started his Cook career in Radiology/Cardiology. He later added IVF and Endovascular. He has worked exclusively with Endovascular and Aortic for the last 21 years. He is currently the Vascular clinical training manager for Aortic and Lead Management Therapies.

Away from work, Thomas's wife **Debra** and 3 adult children, **Cameron**, **Lucinda** and **Robert** keep him busy. He also enjoys attending concerts, theatre, and movies. His hobbies include travel, tennis, golf, skiing, cycling, and adding to his CD and vinyl collection.

"During my time at Cook, I have enjoyed the satisfaction of knowing that everything that everyone does as their job in the company, contributes in some way to delivering a better outcome for a patient somewhere, anywhere on the planet. Although we might never know who they are, we will know that we have made a difference. That's what gets me to work every day, that's what I enjoy most about being part of Cook."

Del Sullivan, *Cook Australia Stents*

Hired in: 1991

Del was born in Laidley, Australia, and grew up in the Lockyer Valley. She attended Gatton High School and then the University at Darling Downs in Toowoomba, where she studied Biological Techniques. Del has called Shailer Park home for the last 35 years. She worked as a plant physiology technician at the Agricultural College at Gatton for 10 years before coming to Cook.

During her time at Cook, Del has worked in Balloons, Pipettes IVF, Stents, and has helped out in various other departments.

Outside of work, Del's grandchildren, all five years old and under, keep her busy. She also enjoys following the Broncos and collecting coins. She camps and caravans around from time to time. She played squash for 30 years.

"I have met some incredibly nice friends (for life) and share some spare time with them. I also love the work and it makes me proud to say we are saving lives every day. Minor changes in my day may make major changes for some of our patients. It has been a fulfilling job in all ways."

Gary Piazza, *K-Tube Sales*

Hired in: 1989

Gary was born and raised in Vancouver, Washington, and graduated from Mountain View High School in 1984. Soon after, he joined the Navy and was stationed at Miramar, California, and was an aircraft armament technician for six years. After the Navy, he went to the Hollywood Script Writing Institute and graduated with honors. At the same time, he had an opportunity arise and was offered a position at K-Tube. He resides in Washington State, but is on the road quite a bit.

He began his Cook career in the Quality department at K-Tube and then he moved to the R&D department two years later. After that, he was the first shift production supervisor. In 1998, he moved into sales and has been there ever since.

"My time at Cook has allowed me to become close enough to my coworkers to call them family. So much, in fact, that I have written and published a story based on some of their life experiences.

Gary's hobbies include traveling with his family, writing, photography, videography, and filmmaking. He also enjoys off-road riding, motocross, and adventure dirt-biking.

"You can feel the strong family vibe throughout the company, and I believe that it is passed down from the top. Also, the manner in which employees are treated overall is a step above from what other companies can offer. My position in the company and in the medtech arena is unique and provides some great challenges."

Linda Shields, *Park 48 Catheters*

Hired in: 1995

Linda was born and raised in Bloomington. She attended Bloomington High School South. She has lived in Solsberry, Indiana for 15 years. Before coming to Cook, she worked at Indiana Home Health Care.

Linda has spent her entire Cook career in Catheters. She has 13 years of perfect attendance. Several of Linda's family members have worked at Cook over the years. Her daughter **Krystal Lloyd** has been at Cook Polymer Technology (CPT) for 27 years. Her husband **Tim Shields** retired from CPT in 2018. Her grandson worked at CPT for seven years. She also has a niece and a great niece who also work at Park 48.

Outside of work, Linda loves to camp. She also enjoys spending time with her first great grandson, who turned 1 year old in May.

"I have enjoyed the people I have met during my time here and knowing that we make products that help others and some times save lives."

My Cook Pathway

▶ ***Amy Orr*** *spends time on her Friday nights and weekends and holidays as a server at French Lick Resort.*

Well worth the journey

▶ *Amy has been a teacher at Springs Valley Elementary School in French Lick for 25 years. She was named the new principal a few months ago.*

Catch Amy Orr if you can.

She's taught for 25 years at Springs Valley Elementary School in French Lick. When she has time on Friday nights, weekends, and holidays, she's pouring iced tea and serving entrees at banquets held at French Lick Resort. And for a span of about two years, Amy was pulling triple duty, taking 18 credit hours toward earning an administrator's certification.

She's also a wife and a mother of two daughters. Actually, that number needs an update.

"Now I have 367 children," Amy says with a laugh in the new office she's settling into at school.

A few months ago, Amy was named the new principal at Springs Valley Elementary. She had always planned on pursuing a position in administration, but it became a little easier thanks to the My Cook Pathway employee development program offered at Cook-owned French Lick Resort.

When Amy first started at the resort four years ago to pick up some additional income, she could hardly believe all the perks associated with the education assistance program that different people kept telling her about. And she isn't the only member of the family to take advantage of these benefits. Both of Amy's college-age daughters have worked at the resort and drawn from the education assistance—and her oldest just graduated from IUPUI with a financial headstart.

"Basically, she has graduated debt-free," Amy says. "That is a blessing."

Of course, Amy made plenty of sacrifices. She spent Thanksgiving Day last year working at the hotel's holiday dinner. With school out, she spent one of her first Saturdays of the summer putting in a 12-hour shift at the resort.

Amy jokes that her house got a little messier during this gauntlet of teaching, banquet serving, and juggling online classes through Indiana Wesleyan. But, when she's sitting behind the principal's desk? The journey's been well worth it.

"It's almost surreal, because it's been like a whirlwind. It's kind of crazy to think, 'Wow, just a few months ago I was cranking out papers and submitting tests and talking to professors (for my online classes), and now here I am in charge."

And while she's at it, she's talking up the education assistance program to the next generation nearing the workforce.

"I'm always advertising that, with my daughters' friends and the high school helpers we have coming up here to the elementary school," Amy says. "I'm like mom hen, dropping hints: Hey, you could go over to the resort and pick up some hours."

True to form of someone who stays perpetually busy, Amy says she can see herself working at the resort full-time after she retires from education.

"It's a blessing for this community and it's a blessing for the employees at the resort. I think it's pretty amazing what Cook puts into their company and their employees," Amy says. "I'm just grateful. I think, 'Wow, this little community, look what we can provide.'"

• ***Brendan Perkins*** *(bperkins@frenchlick.com) is a copy writer at French Lick Resort.*

Fueled by a promise

Jim Miller's journey to receive his diploma through the HSE program saved his life

Note: This article includes mention of suicidal thoughts.

In 2016, **Jim Miller**'s only son, **Jay**, died in a car accident.

Their relationship wasn't just parent and child—Jim considered Jay his best friend. So, for months after losing him, Jim battled with thoughts of ending his life.

But a promise kept him going.

Earlier that year at the unemployment office, Jim picked up a pamphlet about Cook's high school equivalency (HSE) program, which had just been launched. He mentioned it to Jay during a phone call and Jay immediately started encouraging his dad to give it a try.

"He said, 'Dad, that is something you need to do. You need to get your diploma so you can go to work there and I can come and watch you graduate,'" Jim recalled.

Jay passed away before his father started the HSE program. He left behind not only his parents, but his wife of two weeks and an eight-month-old baby.

Jim spent the next couple of months, including his first three weeks as a student and part-time Cook employee, in a fog. He couldn't sleep. He couldn't eat. But he still forced himself to go to work and to go to class.

"I was very suicidal. I didn't care any more about anybody or anything," Jim said. "This job and school helped me think about something other than what I had been concentrating on.

▶ *Jim Miller (right) is pictured with his wife Darlene and daughter Brylee.*

> ***"This job and school helped me think about something other than what I had been concentrating on. Cook literally saved my life."***
>
> *— **Jim Miller,** an assembler for WireGuides at Park 48*

"Cook literally saved my life."

Slowly the routine of regular life pulled him out of the haze of mourning. Despite having been out of school for longer than most of his classmates had been alive, Jim had little trouble with his studies—with one exception.

"The part that I had the hardest time with was algebra and the math," he said. "When I took the math test the first time, I missed it by one question, so I had to take it over again. But then I nailed it; I was bound and determined to get this."

He was at work in the Wire Guides department at Park 48 when he found out he had passed the final test.

"I lost it emotionally in front of everybody," Jim said. "Everybody knew what I was working toward."

Three years later, and Jim is still going strong. After having spent 30 years working outdoors as a tree trimmer, he is now content to spend his days indoors as a welder in Wire Guides. Jim and his wife, **Darlene**, have adopted and are raising their daughter **Brylee**, who is almost eight. Much of his time outside of work revolves around spoiling her.

Their relationship is anything but one-sided, though.

"The best part of my schooling was after I graduated and Brylee said, 'Congratulations, daddy, I'm so proud of you,'" Jim said.

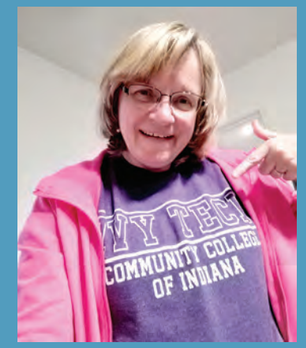
• ***Jon Hancuff*** *(Jon.Hancuff@CookMedical.com) is the global Editorial Content manager at Park 48.*

Want to learn more about the My Cook Pathway program?

Contact your local HR department for more information.

Learning a new culture

This past year Sharon Moore, a member of the Environmental Health and Safety team at Park 48, studied sign language for two semesters at Ivy Tech through the My Cook Pathway program. Knowing sign language can come in handy as part of Sharon's job, especially during emergency situations.



▲ *Sharon Moore*

Sharon set out to take the class in order to learn important signs that deal with safety concerns, but ended up coming away with much more.

"The deaf community has a culture that is very rich and is looked upon with pride. By getting a peek inside, we too become richer for the experience."

Sharon's team leader, Shawn Adams, took sign language in college and has some familiarity with the language.

"We have signed to each other confirmation of where a medical emergency is located," Sharon said. "I also use this skill to relay information to a deaf employee. For example, for a fire drill, I would sign the words fire and practice. Plus, to be able to converse even basic greetings is something that I think he truly appreciates.

"It is truly an amazing program that I was allowed to take free of cost due to the My Cook Pathway program here at Cook," Sharon said. "Not only did it help me to get a grasp on this new communication skill, but it also opened my eyes to the deaf culture."

Ivy Tech offers sign language classes for all levels. For more information, contact Amanda J. Sparks by email at Amanda.J.Sparks@CookMedical.com or by phone at extension 10-2576.

• **Ashley McGuire** *(Ashley.McGuire@CookMedical.com) is an Editorial Content generalist at Park 48.*

Handle personal data at Cook?

Here is what you need to know

As a Cook employee, you may be required to handle different types of data, including information about individuals from anywhere in the world. Some of this data requires a high level of security.

Cook has developed a framework, called the Cook Group Security Standards, to protect its global resources, such as data, people, and property. Guidance and awareness materials for employees are an important part of this framework. One of these documents is the "**Guidelines for Handling Personal Data at Cook**," which is designed to raise awareness of different data types and provide guidance on the practices for handling this information.

Your responsibility

As a Cook employee, these are your responsibilities:

1. Review the guidelines thoroughly.
2. Determine how you may handle personal data in your job.
3. Ensure that you are handling and protecting this information in a way that is consistent with these guidelines.
4. Ask questions and report any concerns you have about the protection of personal data to the appropriate representatives.

Steps to secure and protect personal data

When dealing with personal data, Cook employees should take the following steps:

Identify the personal data that you may handle.

It is important to know the types of personal information that you handle and understand whether it is considered sensitive or nonsensitive. The "**Cook Data Classification Chart**" provides definitions, data types, and examples. If you are unsure about the data you handle, speak to your supervisor or manager.

New projects or initiatives that involve the collection or processing of personal data at Cook require, by law, a data protection impact assessment (DPIA). To determine whether a new project requires a DPIA, the project lead should complete the "Personal Data Protection Impact Screening & Assessment" form. Your regional Data Security representative can provide the form and additional guidance through the process.

Minimize the collection and use of personal data.

The personal data that is collected should be limited to what is necessary. Before using any of this information, make sure that the use is based on the original purpose for which the data was collected, unless you obtain additional consent from the subject, in accordance with your department's policy.

Restrict the sharing and access to personal data.

Before sharing information, you must be sure that they have the right to know. Personal data can only be accessed by authorized people. You should never handle, view, or discuss personal data in areas where it will be seen or overheard by unauthorized people.

Transmit personal data securely.

Never use end-user messaging technologies, such as email, SMS (text messages), instant message, or chat, to electronically transmit sensitive personal data. When emailing a large group of individuals, use the "blind carbon copy" (bcc) function so that the email addresses of all recipients are not shared with the group. Please contact IT Support if you need a solution to securely transmit personal data or if you have questions about using the bcc function.

Store, retain, and destroy personal data securely.

Do not store personal data in a personal device or any unencrypted portable equipment such as USB, CD, or mobile phone. Never use a public hosting website to host, store, or transfer personal data because these sites are not secure. Contact IT Support Services for assistance if you need a solution to host, store, or transfer data in a secure way.

All personal data at Cook should be deleted or destroyed when it has served its original purpose. Be sure to follow the Cook management program policy and procedures for retaining and disposing of personal data. For detailed information, contact your manager, supervisor, or the Cook Records Management team.

If you have any question about the "**Guidelines for Handling Personal Data at Cook**," contact your global Data Privacy office at **Privacy@CookGroup.com**.

If you are concerned about the handling of personal data or you suspect that a data privacy and security incident has occurred, you must immediately contact your regional Data Security representative at **CookStandards@CookMedical.com**.

• ***Alexandra Hernly*** *(Alexandra.Hernly@CookGroup.com) is a Data Privacy specialist at Park 48.*

E&C trainings

What has happened in 2019, and what to expect for the rest of the year

The Ethics & Compliance team recognizes there are an increased number of trainings assigned from multiple functions and that it can be difficult to find time in your work schedule to complete the assignments. We thank each of you for your effort and dedication to complete your assigned courses, as well as your patience as Cook continues to grow and transform as a company. We appreciate your commitment to reflecting Cook values in your daily work.

This is a quick overview of the courses that have been launched in 2019, and a list of some of the additional E&C trainings employees can expect this year.

Cook Learn e-learning courses:

- Code of Conduct (released and enrolling)
- Data Privacy (released and enrolling)
- Additional courses planned for this year:
  - Records Management Program Awareness
  - Anti-Corruption
  - Non-Retaliation
  - Conflict of Interest

If you haven't been enrolled in the Code of Conduct or Data Privacy courses yet, no worries, your enrollment will occur before the end of 2019. Many employees have already completed one or both of these trainings through Cook Learn; if needed, you may be provided with an iPad or with access to a computer in order to log in to your Cook Learn account and complete these required courses. However, others may receive these trainings in an Instructor-led setting with your manager or supervisor and/or a Cook Learn site lead.

• ***Neal Daunhauer*** *(Neal.Daunhauer@CookGroup.com) is the director for Global Ethics & Compliance Integration.*

PEOPLE NEWS

Corporate Marketing & Communications

Cecily Donnelly has been named Regional Events manager for EMEA. She joined the team in 2004.

Anette Jul has been named Marketing Materials Processing manager for EMEA. She has been with the company for more than 25 years.

Jesper Frimann has been named Corporate Creative manager for EMEA. He joined Cook in 2011.

Clare Ellis has been named Corporate Brand and Communications senior manager for EMEA. She has been with the company since 2010.

Ainara Borda has been named the Global Marketing Materials Management manager. She joined Cook in 2004.

Emily Williams has been named Communications manager for William Cook Australia. She has been with Cook for three years.

Beverley Drysdale has been named Events and Marketing Materials specialist for APAC. She has been a part of Marketing at Cook for more than 22 years.

Ian Baxter has been named Graphic Design specialist for APAC. He has been with Cook for 11 years.

Vascular

Pauli Escobedo has been named Global Communications manager for the Vascular division. She most recently served as manager for Global Content Marketing for the division.

Brandon Jones has been named manager for Commercial Business for Vascular in the Americas.

John Lauffer has been named area program manager for Venous Therapies. He joined Cook in 2011.

John Burke has been named area program manager for Interventional and Embolic Therapies. He has been with Cook since 1992.

Customer Support & Delivery (CSD)

Emily Redden hired into Cook as the director of Global Quality Assurance for CSD. She has 11 years experience in Regulatory Affairs and Quality Assurance.

Liz Cook has been named manager for Global Supplier Accounts for CSD. She has been with Cook for over 12 years.

Cook Inc. Manufacturing

Kenny Byrge has been named senior Manufacturing Operations manager for Cook Inc. He has been with Cook since 2007.

Mark Lamb has been named Manufacturing Operations manager for Cook Inc. Spencer. He joined Cook in 2011.

Silas Morris has been named supervisor for the Post-Sterilization Services second shift at Cook Ellettsville. He joined Cook in 2015.

James Kelley has been named a group leader for Implants. He joined Cook in July 2015.

Don Capouch has been named production manager for Cook Inc. Spencer. His Cook career began in 2015.

Facilities Maintenance and Housekeeping

Branden Mobley has been named a custodian supervisor for Cook Ellettsville. He joined Cook in 2006.

MedSurg

Keroleen Chen has been named global Brand Marketing manager for the Surgery specialty and will directly support the biliary disease program. Her Cook career began in 2011.

Lauren Manges will continue her role as global Brand Marketing manager for the Surgery specialty, but will now directly support the diseases of colon and rectum program.

Mike Maryan has been named global product manager for all of enteral feeding. Mike began his career with Cook in 2010.

Procurement & Supply Chain

Rose Kelly-Falls hired into Cook as director for Global Procurement & Supply Chain Management.

Continuous Improvement (CI)

Lee Coppin hired into Cook as the director for global Continuous Improvement (CI).


▲ *Cecily Donnelly*


▲ *Anette Jul*


▲ *Jesper Frimann*


▲ *Clare Ellis*


▲ *Ainara Borda*

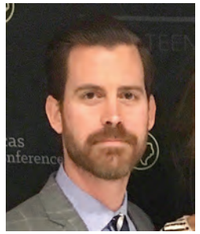

▲ *Emily Williams*


▲ *Beverley Drysdale*


▲ *Ian Baxter*


▲ *Pauli Escobedo*


▲ *Brandon Jones*

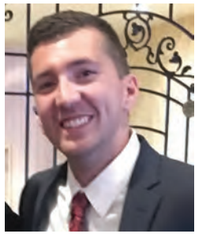

▲ *John Lauffer*


▲ *John Burke*


▲ *Emily Redden*


▲ *Liz Cook*


▲ *Kenny Byrge*


▲ *Mark Lamb*


▲ *Silas Morris*


▲ *James Kelley*


▲ *Don Capouch*


▲ *Branden Mobley*


▲ *Keroleen Chen*


▲ *Lauren Manges*


▲ *Mike Maryan*


▲ *Rose Kelly-Falls*


▲ *Lee Coppin*

"We are truly blessed"

Renee Cruciani on how a wildfire changed her family's perspective

▶ *The view from Renee's home during the California wildfire in November 2018. Renee and her family are pictured to the right.*

It was a Thursday night in November 2018. I was putting my daughter, **London,** to bed (my husband was traveling). I turned off the lights and my eyes were pulled to our windows in the back of the house. Something was bright, glowing even though it was 8:00 pm—dancing colors of yellow, orange, and red. It felt like time stood still. I was holding my daughter and getting ready to brush her teeth. I just stood there—looking at the flames in the distance. They were moving quickly. The fire line changed so frequently. I broke into action mode. We were lucky—I had time to think and do things that some didn't get a chance to do.

Considerations

1. **Call spouse.** We agreed I'd pack up the car with irreplaceables. I turned the car around in the driveway so I could pull out immediately when I needed to.
2. **Turn on the news and sign up for local automatic alerts.**
3. **Talk to our daughter.** London saw the fire out our back window. She was scared, crying, and didn't want to let go of me. Once she calmed down, we talked about people versus things and as long as our family was ok, the other things didn't matter and could be replaced. We talked about why we needed to leave. I kept repeating, "Things don't matter, people do."
4. **Notify our family and post to social media.** I wanted our family to hear it from me instead of from the news. I quickly sent a group text and posted to Facebook.
5. **Make a plan.** Where will we go? Start lining up multiple options on where to evacuate to. My Facebook post helped line up options while I packed and calmed London.
6. **Create a packing list.** It needed to fit in the car and needed to be enough to last us for one week. It also included items that were irreplaceable in the event that we lost our home.
   - Memorabilia: Photo albums.
   - Personal documents and fire box: Passports, social security cards, copies of drivers licenses, and external hard drives. I remembered our fire box but forgot the key.
   - Comfort Items for daughter: favorite blanket, favorite stuffed animal, unicorn slippers, fluffy robe,etc.
   - Clothes: Enough for 10 days for the whole family.
   - Consumables: Gallons of water and enough non-perishable food to last our family 4-5 days.
   - Items I already had in my car: Flashlights, blankets, etc. I also have a light and a whistle on my keychain which I always have with me.
7. **Video of home.** The last thing I did before I walked out the door was take a video of the entire interior of our home, just in case of a loss. It was an odd feeling.
8. **Gas.** The first thing to do is to fill up your car's gas tank. If electricity is turned off, you can't pump gas. Luckily I had filled up.
9. **Check routes.** What roads are closed? The freeway and nearby roads were closed so we couldn't go west or north.

There were still things we needed to do to be better prepared.

- We needed to decide on meeting places or where to leave messages in advance.
- Communication. If cell service and wifi are down, how could we get in touch with family from out of state or even each other?

I went to bed that night (eventually) and got up every hour to look outside and check the news. It was the absolute worst night of sleep. Packing that night and physically doing something was helpful. We left that next morning following a fire briefing. We drove to a friend's house, but were overwhelmed with all the offers of places to stay thanks to social media (and many offers from Cook colleagues).

We left before the official mandatory evacuations. I wasn't waiting for someone to tell us to leave. Pulling away from our house that morning was eerie, however, as I saw the huge smoke plume looming over us, I knew we made the right decision—we had everything we needed with us.

"Pulling away from our house that morning was eerie, however, as I saw the huge smoke plume looming over us, I knew we made the right decision—we had everything we needed with us."

*— **Renee Cruciani**, Strategic Account Executive for Business Care Integration*

This experience has impacted us in many different ways. It has helped our daughter in order to go through her toys each season to decide which ones to donate. She better understands how a few toys she plays with all the time are her special toys.

It has caused us to re-evaluate purchases and how we make decisions. It has given us pause, and we have decided not to buy quite a few things we were considering.

We are prioritizing more on vacations and experiences as a family, rather than things for birthdays or holidays. We also focus on quality time together. We are actively reducing our stuff. We are also taking advantage of being outside and breathing fresh air. We didn't think about the air quality issues upon returning home. London usually plays outside at school every day for two hours or more. We don't appreciate how lucky we are. Her daycare was closed for multiple days, and when they re-opened the air quality was so poor, children were not allowed outside. It has also caused us to reflect on how much we have to be thankful for.

We weren't prepared, and I'm sure there are many other lists and tips out there that are more comprehensive. I'd suggest talking to your family, putting a plan in place, buying supplies, having a list of things that can fit in your car if you need to leave quickly. This experience has still left us feeling incredibly lucky. We had so many amazing friends and coworkers who offered their homes. London is a trooper as always—she never ceases to amaze us. Out of the blue she frequently says, "Our family is what is important, mommy," and it makes us so proud.

This has helped to remind us to take advantage of every moment, every day, and focus on experiences, as well as friends and family, instead of things or stuff.

We hadn't experienced a natural disaster before, and while this one came close, it didn't touch us or our home. The experience, while frightening (and we were lucky), did impact our outlook on life in a positive way and we wanted to share our experience with others. Thank you for the outpouring of love from our friends and family. We are truly blessed.

• ***Renee Cruciani*** *(Renee.Cruciani@CookMedical.com) is a Strategic Account Executive for Business Care Integration.*

The EU MDR

EU MDR Communications

OBJECTIVE

Develop and execute an internal and external communications plan to educate relevant audiences on the importance and impact of EU MDR and our progress to becoming EU MDR compliant.

Product Certification and Transition

OBJECTIVE

This group will review the General Safety and Performance Requirements (GSPR's) under the new regulation to define the Cook interpretations and to ensure the evidence required for CE marking under EU MDR is clear. They will also define a global location for housing and management of technical documentation.

EU Authorized Rep Office

OBJECTIVE

This office will be legally responsible for Cook's EU MDR compliance going forward. This is a key change to the way we do business in Europe.

Notified Bodies

OBJECTIVE

Initially, this group is driving the implementation of EU MDR globally within Cook with a longer-term objective of setting up the EU authorized rep office.

OBJECTIVE

To assess the suitability of existing and new notified bodies for EU MDR going forward and assist those global Cook entities who want to move to a new notified body.

Clinical Guidance Implementation

OBJECTIVE

Bringing together the estimated costs of remediation of all tech files for EU MDR compliance for submission to the divisions for review and identification of the tech files and corresponding products that can be optimized.

EUDAMED Transition: Economic Operators and UDI

OBJECTIVE

EU MDR as a new legislation is not tried and tested, therefore we are reliant on guidance from Notified Bodies, Medtech Europe, and other sources to determine what our Cook interpretation of what the final implementation should be.

This group is responsible for making sure that Cook has a standard and defendable approach for clinical compliance ready in advance of the May 2020 date.

OBJECTIVE

Setting up processes and systems for entities to prepare their data for EUDAMED upload and transition the use of unique device identifiers (UDI).

Define and identify who all our economic operators are (mostly distributors) and review to ensure they are set up to comply to EU MDR.

Product Portfolio Review

Restrictive Substances

OBJECTIVE

This group is working on 18 projects to put the necessary Information Technology (IT) systems in place to support EU MDR compliance.

Specifically focusing on managing internal data or setting up data to be ready to share externally.

IMDRF Coding/Vigilance and Recall

OBJECTIVE

Implementing a system to access all raw materials used in Cook products and to either justify their inclusion or create plans to remove and/or redesign.

OBJECTIVE

IMDRF is an Integrated system of regulators who came together to create a body with the aim of standardizing codes used to record compliant data on medical devices. These are being incorporated into EU MDR.

Under EU MDR, Cook is bringing these codes into our compliant process to standardize our coding. This work group also considers new timelines for vigilance, new ways of reporting (through the EUDAMED database) and increases in the requirements regarding the amount of info we report. This group is working to automate our systems and processes to accommodate all these changes.

IT Systems and Databases

Labeling

OBJECTIVE

This group is providing the frame work through the CMMS to ensure any global policies and standards required for EU MDR can be created.

This will ensure a consistent approach to the implementation of the changes necessary to ensure Cook is EU MDR compliant.

Post Market/Sustaining Clinical Data Collection

OBJECTIVE

New requirements mean that more info, as well as more languages, need to be included on product labels, Instructions For Use (IFU's) and patient cards.

This group is managing the introduction of this new info in addition to considering marketing material that will need to change as a result of changes to our ability to make product claims. They are also working to define a system to control all of these pieces going forward.

CMH

OBJECTIVE

To set up a system to determine gaps in clinical data at each entity and to agree to a Cook-wide process to obtain post-market clinical data on all products.


Post Market/Sustaining Clinical Data Collection
Team Lead: Henk Snyman
The EU MDR
IMDRF Coding/ Vigilance and Recall
Team Lead: Heather Ryan
The EU MDR
EUDAMED Transition Economic Operators and UDI
Team Lead: Dong Min
The EU MDR
Notified Bodies
Team Lead: Tracy O'Sullivan
The EU MDR
Product Certification and Transition
Team Lead: Mie Dyrholm
The EU MDR
Labeling
Team Leads: Malissa Ridge, Dave Blick, Josh Haines
The EU MDR
Restrictive Substances
Team Lead: Erin Kunkel
The EU MDR
Clinical Guidance Implementation
Team Lead: Maja Skytte
The EU MDR
EU Authorized Rep Office
Team Lead: Sinead Burke
The EU MDR
EU MDR Communications
Team Lead: Clare Ellis
The EU MDR
CMH
Team Lead: Shawna Hayden
The EU MDR
IT Systems and Databases
Team Lead: Dheepa Lekshmanan
The EU MDR
Product Portfolio Review
Team Leads: Ryan Opheim, Sinead Burke
The EU MDR
The EU MDR