



Reflecting our values

A closer look at Cook's Ethics & Compliance program

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Building on our culture

Carol Seaman reflects on her journey with Ethics & Compliance



According to **Carol Seaman**, vice president and chief Ethics & Compliance (E&C) officer for Cook Group Incorporated and Cook Medical Holdings, her time with Cook has never been dull.

Carol celebrated her 30th year with Cook in August. However, she did work for Cook for six years before officially joining the company through a law firm where she practiced as a lawyer. During those years with the firm, she was part of many Cook matters, including historic preservation projects like the Grant Street Inn and the West Baden Springs Hotel, which at the time was managed through CFC.

"It was just one interesting thing after another from the beginning," Carol said.

This didn't change once she joined Cook. She began working on general corporate law matters, established the corporate insurance program, and was named a vice president in 2000. Then, things went a different direction at the end of 2001 when she was approached by **Bill Cook** as well as **Phyllis McCullough** and **Kem Hawkins** (former Cook presidents) to create a more formal E&C program. She knew that in creating this program the best thing was to build upon the ideals that Bill Cook had already established.

"I was building on the idea of a culture, which has as much

as anything to do with helping people be consistently ethical and compliant," Carol said. "It is our culture that unites us in our common mission."

The growth of a program

Taking a look back at the culture that Bill Cook had created, it was one of living the golden rule. According to Carol, Bill was a man of his word and expected others to be the same. Having integrity, putting the patient first, treating each other with respect, and making quality products were important to him. Those ideas have carried through to the company's mission and values today.

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"Professional competence is learned through experience but directed by personal integrity."

– Bill Cook

Did you know?

"The & (ampersand) is an important symbol to Ethics & Compliance. The word ampersand literally means, 'this thing by itself and.' This means that the ampersand symbol stresses the unique qualities of two objects that are combined."

– Logan Mumma, Global Ethics & Compliance generalist at Park 48.



ETHICS & COMPLIANCE

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"The name Cook means something to the customers who trust Cook products, to the employees who choose to work for a Cook company, and to the numerous insurers, regulators, and policy makers we have come into contact with in the course of business over the years," Carol said.

Bill Cook wrote the first Code of Conduct himself at his computer," Carol continued. "He had a leadership philosophy that he taught to Cook leaders inside the company and was asked to speak about outside the company. In the early days, he spoke to his employees from the loading dock. He ate lunch with them in the cafeteria. He knew many of their names. There was definitely a tone at the top that set the stage for the success he built."

Carol and the E&C team have taken great care in the creation of their program to help protect that reputation. It was just Carol and Megan in the early days of the program, and they worked on tasks such as creating a map of the countries that the company couldn't trade with and privacy. Today, E&C has grown exponentially and is integrated across different areas within the company and across the globe.

Positioned for success

Over the years, there are several accomplishments that the program has achieved that Carol said puts them in a position to be more successful in the future.

Here are some highlights of those accomplishments:

- ▶ The creation of the [Board Oversight Committee](#), which was named by the Cook Group Board of Directors and charged with overseeing the Cook Group Global E&C program
- ▶ The appointment of E&C employees to the Cook Medical



▲ **Carol Seaman**, second from left, at the 2019 Ethics & Compliance meeting. Also pictured, from left: **Bill Doherty**, executive vice president of Cook Ireland; **Allison Giles**, vice president of Government Affairs; **Steve Ferguson**, executive vice president and chairman of the board; **John Kamstra**, executive vice president and CFO for Cook Group Incorporated (CGI) and Cook Medical Holdings (CMH); **Cynthia Kretz**, vice president, general counsel for CGI and CMH; and **Rob Lyles**, president of Cook Regentec and vice president of Regenerative Medicine.

- ▶ Holdings (CMH) and Cook Medical Executive (CME) teams
- ▶ The development of a program charter
- ▶ The global implementation of an E&C risk assessment process
- ▶ The development of a business policy management system (BPMS)
- ▶ The creation of business planning resources for the divisions
- ▶ A Cook entity leadership visit program, which provides an opportunity to discuss E&C support and resources, interactions between entity management and E&C representatives (ECR), and industry facilitators
- ▶ The professionalizing of ECR and liaisons through official annual appointment, professional development assistance, and guidebook resources developed for support
- ▶ The new Cook Group Values, which were introduced in the modernized version of the Code of Conduct that became effective in January of 2019
- ▶ An increased number of full-time employees in the program, including subject matter experts in global trade compliance and antibribery, due diligence and auditing, and regional data privacy
- ▶ The evolution of the audit and investigation processes
- ▶ An improved use of technology
 - Upgraded restricted party screening provider
 - Third-party due diligence for distributors

- Third-party due diligence for suppliers, including conflict minerals, human rights, and labor standards
- ▶ Provided individualized support for all Cook Group industries by providing E&C facilitators and relevant subject matter meetings
- ▶ Implemented a new global E&C helpline with 24/7 availability through an 800 phone number or by computer, 19 languages, professionally trained operators, and the availability of a PIN for follow up
- ▶ Professional training for helpline investigators
- ▶ Increased trade association and professional association memberships and participation globally
- ▶ Data privacy: created a Cook Group classification system and assisted IT by drafting the Cook Group Security Standards

In the stories that follow in this section, you will meet the E&C team members who helped in achieving these accomplishments and learn more about their E&C programming.

• **Ashley McGuire** (Ashley.McGuire@CookMedical.com) is a Editorial Content specialist for Corporate Marketing and Communications.

For more information regarding Cook's E&C program or for access to resources referenced in this article, visit intranet.cookmedical.com/cbf/ec/Pages/ct.aspx.



▲ **Carol Seaman**, vice president and chief E&C officer, bottom, at the 2018 global E&C functional planning meeting. Also pictured, from left: **Rick Mellinger**, retired; **Drew Northern**, director of Global Anti-corruption; **Angela Moloney**, E&C director for EMEA; **Christina Lam**, E&C director for APAC; **Mark Muller**, director of Finance for APAC; **Megan Charlesworth**, director of Global Privacy; **Lynn Ferguson**, retired; **Heather Hurst**, Global E&C officer; **Neal Daunhauer**, director of Integration for E&C; **Mickey Battista**, E&C regional director for the Americas; and **Lloyd Porter**, director of Global Trade Compliance.

The seven elements of a successful Ethics & Compliance program

The seven elements were created to ensure that corporations are being held to the same standards across the country. They are as follows:

- ▶ Leadership & accountability
- ▶ Written standards
- ▶ Education & training
- ▶ Communication & awareness
- ▶ Monitoring & auditing
- ▶ Investigation & response
- ▶ Continuous improvement

Did you know?

The Ethics & Compliance team is overseen by a Cook Group Board Oversight Committee, which is made up of five people including **Steve Ferguson**, who is chairman of the board. The board created a charter for the E&C program.

Seeing the big picture

Heather Hurst talks Ethics & Compliance at Cook Medical



Heather Hurst has a passion for Ethics & Compliance and for learning policy and structure. She believes this comes from her background as a certified quality engineer in a life before her time at Cook.

This passion is one that makes her well suited for her role in Cook's Ethics & Compliance function.

"The thing that was really appealing to me about Cook is that it is a global company with a lot of variety," Heather said. "There are a lot of different things that you can learn and be involved in. Cook has been and continues to be a tremendous opportunity for me to learn and to develop professionally, which I really appreciate. The Cook tuition reimbursement program was invaluable to continuing my education and earning my Master of Jurisprudence (MJ) degree with a healthcare law focus."

Consistency is key

Heather was named director of Global Ethics & Compliance Operations a few years ago. The focus of her work in this role is to help create uniform implementation of Cook's E&C program across regions.

"Really the purpose of my program is to better help the Cook Medical entities and the functions operationalize E&C," Heather said.

According to Heather, this starts with completing an ethics and compliance risk assessment. On Heather's team, these assessments are being facilitated by **Kristy Spoon**, and their purpose is to help entities and functions understand their business activities and then determine what **external applicable standards (EAS)** apply to those activities. From there, they can work to ensure that the company has proper policies, procedures, training, monitoring, and auditing in place so that Cook can demonstrate compliance with EAS. In addition, Kristy is also responsible for Global Manufacturing E&C, which means that she works with each of Cook's manufacturing entities globally to facilitate implementation of the E&C program.

Heather's team also consists of **Mickey Battista**, **Angela Moloney**, and **Christina Lam**. They are responsible for supporting the divisions in the sales marketing arena within their regions (Mickey is responsible for the AMER, Angela is responsible for EMEA, and Christina is responsible for APAC). Their primary focus is on how the company interacts with healthcare professionals and healthcare organizations.

"As we are developing and implementing the program, we are keeping in mind what governments'

"Data indicates that companies who see ethics and compliance as a strategic business partner are perceived as more ethical by their employees and perform better than their peers. We are proud of the progress we have made towards being a strategic business partner, one that brings value to the conversation."

– Heather Hurst, Global Ethics & Compliance officer



expectations are—and not just the US government, but every government of every country where Cook does business,” Heather said. “Especially where government funds are involved in healthcare. Every government cares about how we interact with our customers.”

Key projects

One of the main tasks that her team is working on is creating a business policy management system (BPMS). Heather explained that at the moment, Cook entities have great quality management systems where all of our quality policies and procedures and work instructions live. However, there is no equivalent for business policies at Cook Group for function-owned policies that apply to everyone.

“It is so important to have policies that impact the way we do our work readily available,” Heather said. “I am a huge proponent that people can’t be expected to be accountable to policies and procedures of which they are not aware. It’s really about fairness. Employees need to know the expectations.”

In addition to the BPMS, the team’s current projects also include creating a conflict of interest disclosure process to allow employees to easily and timely disclose if they have any activities outside of Cook that would conflict with their ability to do their work for the company to the best of their ability. Heather is also beginning to consider the idea of a next generation Code of Conduct that would be even more interactive (exploring digital formats) and engaging for employees.

Our employees value the culture and the reputation of Cook and Heather believes that E&C should be an effective business partner in helping to protect that culture and reputation.

“Data indicates that companies who see ethics and compliance as a strategic business partner are



▲ **Heather Hurst**, Global Ethics & Compliance officer, at the MedSurg division sales meeting at the French Lick Springs Resort.

perceived as more ethical by their employees and perform better than their peers. We are proud of the progress we have made towards being a strategic business partner, one that brings value to the conversation” Heather said.

• **Ashley McGuire** (*Ashley.McGuire@CookMedical.com*) is a Editorial Content specialist for Corporate Marketing and Communications.

What are external applicable standards?

Laws, regulations and regulatory guidance, industry guidance, Cook's policy and ethical principles applicable to Cook's business activities.

A passion for quality

Get to know **Kristy Spoon**, E&C's director of Global Manufacturing

Just based on what gets her "fired up," it would be hard to find someone who was a better fit to work at a medical device company, in one of the most regulated industries in the world, than **Kristy Spoon**.

"What I have realized is that quality is my passion," said Kristy, the director, Ethics & Compliance (E&C), Global Manufacturing. "More so, I enjoy writing procedures, building processes and systems, and even the transition to electronic applications. These efforts support consistent, repeatable, quality results."

Her Cook career started in 2011 in Quality Assurance at Cook Pharmica. Kristy then moved to Park 48 to join the Market Research team (now called Business Insights). During her six-month stint with them, she was immersed in Cook's devices and business structure. This provided her with a solid foundation when she moved to the Cook Inc. Quality Assurance team.

"If not for that experience, I would have gone into Quality with little to no knowledge about our actual device products," Kristy said. "That was very helpful during inspections and audits."

"When I moved to E&C, it just opened up a whole world of other laws and standards on the business side of things that I hadn't had much exposure to," she said.

Her role within E&C is split into three different buckets: Global Manufacturing, records management, and E&C risk management.

Global Manufacturing

This role has evolved over the years to the point where interactions

between Kristy and the E&C representatives (ECR) at Cook's manufacturing and research entities have created a small community.

"We found that because we were in manufacturing facilities or working in the medical device arena in general, like our research companies, that we often come across the same employee concerns and questions," Kristy said. "So, we work together and talk through them."

These discussions can cover topics like prepping for the E&C Manager Toolkits to help ensure that everyone is presenting and responding to that information in a unified way. Sometimes they will bring resources in to provide training or talking points to help facilitate effective discussions.

To those involved in this group, the most important component of these meetings is the experience and the expertise of the individual participants.

"It gives us another group of resources," Kristy said. "It's not just E&C sending out this information; we learn from each other."

E&C risk management

Risk management involves setting up business practices and processes that allow us to function efficiently, effectively, and compliantly while also mitigating the amount of risk to which the company is exposed.

The first step in mitigating risk is to accurately and comprehensively identify the current business activities within our entities, functions, and business operations.

In the second step, they look to see which External Applicable Standards (EAS) or Cook Group Written



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— Kristy Spoon, director, Ethics & Compliance, Global Manufacturing and E&C representative for Cook Inc.



Standards (CWS) apply to each business activities. The third step is to evaluate the potential severity or frequency of possible non-compliance. Finally, they determine what mitigation efforts are needed, such as policies or training.

Risk management has been a collaborative effort with continuous input from both inside and outside E&C. Internally, there is the E&C Risk Steering Committee who works with stakeholders and relevant contacts from all areas of the company.

“We bounce ideas off of folks,” Kristy said. “I send out short surveys and requests for feedback if the committee is stuck on something. We know you can’t make everyone totally happy, but we do want something that will work for everyone.”

Ultimately, all the data collected from all of these interactions will be used to provide Cook with a set of tools that can be used in business planning efforts going forward.

Records management

Thousands of employees operating for close to 60 years in a highly regulated industry are going to create, share, and accumulate innumerable amounts of records of all types: printed pages, emails, voicemails, handwritten notes—likely several copies and/or versions of each of those.



▲ **Kristy Spoon**, director, Ethics & Compliance, Global Manufacturing, at Cook Spencer during E&C Week 2019.

The third area that Kristy covers for E&C is **records management**. It should come as no surprise that her work here is closely intertwined with the work she is doing around risk management.

As with risk management, Cook had already made major progress in developing the records management program. A retention schedule had been established around 10 years ago that identified many of the records that were being produced and set some guidelines for how long they needed to be kept and when they should be discarded.

E&C has taken a very similar approach to records management that was used to address risk management in general—going through the different business groups inside the company to identify the types of records they have and how they should be handled based on the retention schedule and EAS.

“We are going to have something at the Cook Medical Management System (CMMS) level for all of the medical device companies to access their records retention requirements centrally,” Kristy said. “It’s going to take a lot of work. But we need to make sure that we have the right records on the list for the right retention periods.”

Looking to the future

The one thing Kristy is certain about as she looks to the future of the work her area of E&C is doing is that flexibility is going to be key. Regulations, the needs of employees, and the needs of Cook will be constantly evolving—especially when you add in completely unexpected variables like a global pandemic. The goal is to have processes and systems in place that will allow the company to efficiently pivot to meet new needs.

A key to reaching any ideal state will be the continued communication and partnership with the E&C

reps at other Cook entities, as well as with others from throughout the company and the other members of the E&C function.

“I want to continue to build the community we have with the manufacturing and research ECRs,” Kristy said. “I want them also to be confident to talk about the various areas of E&C. They can reach out to our team whenever they have a question—I want them to know that they are surrounded by a team of experts who don’t stay in silos. But I want to instill confidence and understanding for each of them locally.”

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Want more information about Cook’s records management program?

Visit intranet.cookmedical.com/cbf/ec/Pages/RM.aspx.

What is risk management?

The process of risk management involves setting up business practices and processes that allow Cook to function efficiently and effectively while also mitigating the amount of risk to which the company is exposed.

Risk assessments are conducted to identify areas that may potentially expose the company to risk. They allow Cook to:

- ▶ Know their business
- ▶ Reduce or prevent non-compliance with EAS and CWS
- ▶ Design the E&C programs to further unify Cook companies
- ▶ Document their E&C efforts

"Help me understand your business"

Angela Moloney on helping uphold Cook's reputation in EMEA

Angela Moloney is a born extrovert, a sports mom, and a hurling, camogie (sports of Irish origin), and football aficionado—especially when it comes to her kid's teams. She uses her tenacious spirit to lead the Europe, Middle East, and Africa (EMEA) Ethics & Compliance (E&C) group in Cook Medical Europe.

The first item on Angela's agenda when she accepted her new role in 2018 as director of E&C was to meet with the people on her team and listen to them. Much of her first year as director was spent traveling from meeting to meeting to reach out to her colleagues. She wanted to absorb what her team and EMEA colleagues were working to achieve, especially the divisions, and make sure everyone was working compliantly. She would say at every meeting, "Help me understand your business." She finished her first year as director with a well-rounded knowledge of her team's successes and challenges.

Early career successes

An inquisitive nature and a can-do attitude have followed Angela throughout her career. She graduated from the University of Limerick with a business studies degree in 1992 and followed this with an accountancy professional qualification two years later. Her expertise in finance led her to a position at AIB Bank in Dublin, which was a mecca for any college grad in their early career. However, she

was no city slicker. She was born in Kilmallock, County Limerick, and now resides in Adare. She could not deny her preference for the rural life. Fifteen months after accepting the AIB position, she accepted a role with a French manufacturing company, GMX Krups Moulinex, in Thurles, County Tipperary, Ireland. She described the two and a half years she worked for the company as a fabulous learning experience in the manufacturing industry.

In 1998, opportunity came knocking for her to expand her career horizons and bring her back to her home city of Limerick. She accepted a position as Finance manager, heading the accounting division and setting up the Finance function for Cook Medical's new office in Limerick. Angela loved working in Finance, but as she approached her 20th anniversary with Cook, she began to wonder what the next years would bring.

"I was thinking about my next career challenge. When the E&C director position opened in EMEA, it was a light-bulb moment for me. My philosophy in life has always been, 'What's for you won't go by you.' I took the position, and I've been grateful for the new opportunity to learn ever since," she said.

A connected purpose

Angela likens E&C to a moral compass for Cook. Taking the role of advisors, her team works to interpret industry guidelines in the ways Cook does business,



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— Angela Moloney, Ethics & Compliance director for EMEA



including transparency requirements, reporting methods for our business interactions with healthcare professionals (HCPs), meal limits, etc. Every country has guidelines, said Angela, and it is her team's responsibility to understand those rules and decipher them. In the EU, the guiding beam for industry ethical codes is MedTech Europe, a trade association for the medical technology industry.

E&C risk assessment is another program of E&C, and, according to Angela, the importance of documentation and managing risk elements is a huge part of running our business. Who we are selling to and how we are selling needs to be transparent to healthcare organizations. Essentially, E&C is continually checking procedures to make sure all contracts and interactions with HCPs are ethical and compliant.

"Basing Cook's culture on ethics and compliance is a choice. Ethics protects our culture and reputation, and compliance enables us to stay in business. It's also living our values, and it's part of our global Code of Conduct," explained Angela.

Globally, Angela works with multiple groups within Cook to bring E&C to the heart of Cook's business interactions. On a weekly basis, she connects with a diverse group, including the divisions, Legal, Data Privacy, Medical Education, the Grants & Donations board, Event Management, IT, Travel, and HR. Every day she interacts with global E&C colleagues as well. She described the great respect she has for her colleagues and their willingness to guide and support. Her own small but mighty team in EMEA has a global representation that includes employees from Peru, Portugal, and Denmark.

"We needed language support on the team (French, Spanish, and Danish), coupled with a legal and compliance background," said Angela.

Just to name a few responsibilities, this team is responsible for all aspects of the Global E&C program



▲ **Angela Moloney**, Ethics & Compliance director for EMEA, and **Mickey Battista**, Ethics & Compliance regional director for the Americas, in Lisbon in 2019.

in EMEA, such as managing the grants and donations program, HCP agreements, travel requests, and E&C training and education, and the team also keeps up-to-date about national and European compliance rules, transparency reporting, labor standards, and auditing and monitoring.

What's new

During the COVID-19 pandemic, the biggest discussion point within E&C has become virtual engagement with customers.

"Our HCP and third-party interactions and company events are changing massively in the digital arena. Legal, compliance, and data privacy conversations at the start will help," Angela said. "To quote **Mark Breedlove** (vice president, Vascular division), 'We need to be nimble and flexible in this new world.' E&C will continue collaboration with all divisions and functions within Cook, making sure we are visible and supportive at all times."

As Cook engages with customers, training and awareness through E&C and communication and collaboration remain key strategies. The E&C team is being brought into business discussions earlier, she added, and is now being viewed as a partner in business, helping business be

successful through the E&C lens.

Additionally, the recent French anti-gift decree will significantly impact how Cook interacts with French HCPs. The team is currently initiating a work group to interpret the new legislation and introduce new policies and procedures to accommodate Cook's business needs.

"We want to take a collaborative approach to understanding this legislation and interpreting its impact," said Angela.

Educators and business enablers

Every employee is responsible for E&C. This has led to a rollout of education and training programs, including the Quarterly Manager Toolkit. Through awareness and education, E&C hopes to continue to contribute to Cook's business success.

"We all help maintain the stalwart reputation that Cook has for ethical business practices," said Angela. "Ethical companies by their nature are more successful."

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Providing an E&C perspective in APAC

Christina Lam on aligning local APAC E&C programs with global initiatives



As Cook employees, we all take pride in working for an organization with strong values. The Ethics & Compliance (E&C) function is there to support the business in reflecting these values in our day-to-day work. We also guide each other to align our business decisions with external applicable standards (EAS) and Cook written standards (CWS). All of this helps to safeguard our long-standing reputation.

The E&C program is supported by Cook at all levels, including the Board Oversight Committee, entities, divisions and functions, and E&C representatives. In **Christina Lam's** view, the program's purposes are to create a culture of compliance and accountability, provide applicable CWS in accordance with the EAS, provide guidance on following these standards, ensure Cook's business activities reflect our values, and stay informed of regulatory and industry trends in areas where Cook operates.

Christina, the E&C director of the Asia-Pacific (APAC) region, is the person that the APAC divisions and functions count on to provide perspectives from an E&C angle.

On top of that, Cook has dedicated E&C representatives in all APAC operations who serve as the trusted primary contacts, interpreters, and experts for each local entity, and who provide advice on local regulations and nuances.

"I work closely with the APAC E&C team and our APAC leadership on a day-to-day basis," Christina said. "This is important to make sure everyone is receiving the same messages from E&C teams across APAC, but it is also an opportunity to discuss improvement areas and feed that back to our head office. My manager **Heather Hurst** and I also have regular catch-ups so that she is informed and can advise on how we are aligning the local programs with global E&C objectives."

Because of the global pandemic, the way in which many healthcare companies interact with healthcare professionals (HCPs) has drastically changed, and Cook in APAC is no different. There are definitely questions that employees interacting with HCPs want answers to.

"Virtual interactions with HCPs is a heated topic of discussion in the industry, and our team has been answering a lot of queries related to the fair-market value on fee-for-service and virtual-conference sponsorships," said Christina. "APACMed is having discussions about guidelines covering this topic, and our team will continue to provide guidance to the divisions and the Medical Education team in the meantime."

So what happens in this period of time when companies are still adjusting to the new normal and navigating their way out of the pandemic?

"I've been advising our business partners that compliance doesn't stop because of COVID-19. Our EAS and CWS still apply, and we continue to work with each other on reflecting Cook values."

– Christina Lam, Ethics & Compliance director for APAC





▲ **Christina Lam** (third from left), E&C director for APAC, at the Aortic Asia 2019 conference in Bangkok, Thailand. She had the opportunity to attend and learn about Cook's educational events held during third party conferences. Pictured, from left: **Jariya Thirat**, **Daroonwan Jantasarn**, **Christina**, **Pimnuttha Sitthiphon**, **Suchada Mentaphao** (red shirt), and **Natalie Liang**.

"I've been advising our business partners that compliance doesn't stop because of COVID-19," Christina said. "Our EAS and CWS still apply, and we continue to work with each other on reflecting Cook values."

In the future, the E&C team will be rolling out more initiatives around risk assessment and E&C auditing and monitoring.

"We continue to tailor our compliance trainings using real case studies within Cook and in the industry, and we are preparing a set of global E&C FAQs," Christina said. "Global E&C policies, which include conflicts of interest and interactions with HCPs, will also be coming. You'll be hearing more from us."

In addition, Christina has recently taken up another role as an APAC representative on the Equity Task Force, along with **Jean-Marc Creissel** and **Barbara Yeung**. This has been another source of inspiration for her at Cook.

"Being part of the task force allows me to work with and e-meet colleagues whom I have not collaborated with before," Christina said. "It's a wonderful opportunity to see colleagues with varying perspectives and experiences come together to tackle issues of racism and discrimination."

E&C might be a serious topic by nature, but Christina and her team always put in the extra effort to make it more engaging. She is very

personable. It is always fascinating to see her reel off multiple tasks under a tight schedule, and at the same time manage to build professional and personal connections with people in the office. Outside of work, Christina enjoys doing yoga, high-intensity interval training (HIIT), and boxing. She also enjoys making drink coasters.

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Setting up guardrails

A look at how **Mickey Battista** and his team identify the out-of-bounds lines for Cook

In a broad sense, the role of the Ethics & Compliance function at Cook is pretty simple, according to **Mickey Battista**—it's making sure that the way we do business aligns with the way that we want to do business—with integrity.

"I look at our values—act with integrity, transparency—you name it," he said. "Our values are what defines E&C's job."

Mickey, the E&C regional director for the Americas, joined the function five years ago, after spending his first 10 years at Cook in Finance and Peripheral Intervention. He now oversees a team that is focused on four main areas: E&C Commercial Interactions, E&C Operations in the clinical divisions and Customer Support and Delivery (CSD), Charitable Donations and Grants, and Transparency Reporting.

Commercial interactions

Mickey and his team focus on Commercial Interactions, which is led by **Neal Bridgett**, director of E&C Commercial Interactions. Neal recently moved to E&C after having spent almost 30 years working in Cook's MedSurg clinical division.

His new role is one that is still being defined. But part of the plan is for him to regularly interact with the divisions, Medical Education, Legal, and other functions so that E&C can better understand their policies and help mitigate any potential compliance risks.

"We really want to use Neal's role to give us better visibility in to what the business is doing, especially with annual planning, so that we can help them in advance. It is definitely

something that is evolving," he explained.

Mickey is excited to have someone with Neal's deep well of experience join their team.

"Neal brings a different aspect to the team with his time spent in marketing," he said. "He has a diverse background within the company. He brings that to the team to help us see things from a different perspective."

E&C Operations

Mickey also serves as an advisor for the MedSurg and Vascular clinical divisions and CSD as part of E&C Operations. Essentially, this means he regularly attends their meetings to provide feedback on any situations that might be approaching E&C gray areas—or are new endeavors for which no policy exists in the employee Code of Conduct.

A recent example of the latter, brought about the COVID-19 pandemic, has been requests to hold virtual meetings, trainings, and meals with HCPs. Presented with these potential new ways of doing business, the first thing that all members of the E&C team have to do is ask, "What risks does this present for the business and the company's reputation?"

"And it's not easy, because it's not like one virtual event will be the same as another virtual event," Mickey said. "So, with something new, we put many teams together, and we start answering questions. Then we get with the leadership and communicate where we are and what our position is."

Once a decision is made, E&C



"We are not here to run the business. We are here to set up the guiderails for the business. In football, you know where the out-of-bounds lines are—in E&C, we assist in identifying those lines."

— Mickey Battista, Ethics & Compliance regional director for the Americas



will work with Marketing Communications make sure it is shared throughout Cook.

"We want everyone to be aware of the risk, and then we want to be consistent in how we mitigate these risks and are talking about it to everyone within the company," Mickey said.

It's this sort of partnership that Mickey feels best exemplifies E&C's place inside of Cook. The drive behind their actions is to offer advice and educate. Their ultimate goal is to protect Cook and the reputation for integrity that was established in 1963 by **Bill** and **Gayle Cook**.

"We are not here to run the business," Mickey said. "We are here to set up the guiderails for the business. In football, you know where the out-of-bounds lines are—in E&C, we assist in identifying those lines."

Charitable Donations and Grants

Teresa Collins, E&C regional administrator lead, has facilitated this program for over 10 years.

The Charitable Donations and Grants program provides educational grants and product donations for training to healthcare professionals (HCPs). These grants

are separate from community donations for things like B-Town Boom and the Limerick Women's Mini Marathon.

"**Carol Seaman** and I oversee the global program, but Teresa and the regional administrators take care of the day-to-day operations," Mickey said.

As part of that daily work, Teresa leads a group of administrators in the Americas, Europe, the Middle East, and Africa (EMEA), and the Asia-Pacific (APAC) regions to prepare the grant and donation requests they receive for review. The requests are then sent to the Charitable Donations and Grants Review Board (CDGRB) in each region. If a grant or donation is approved, the appropriate regional administrators process the grants.

"These regional administrators are subject-matter experts," Mickey said.

Transparency reporting

Many countries around the world, including the United States, require medical device companies to provide a detailed list of all "transfers of value" between themselves

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▲ **Raquel Boularot** (Global Transparency Reporting Manager, E&C) at an E&C Week event in 2019.



▲ **Neal Bridgett**, director, E&C Commercial Interactions



▲ **Mickey Battista** (center) and **Heather Hurst** (right) provide information to **Gretchen Gutman**, vice president of Public Policy for Government Affairs, an attendee of the 2019 E&C meeting at French Lick Springs Resort.

Acting with integrity

Drew Northern on the Global Anti-Corruption program's role in protecting Cook's reputation



One of Drew Northern's favorite parts of his job as the director of Cook's Global Anti-Corruption Program is that he and those he works with in Ethics & Compliance, get to defend the company's good name and reputation.

"We get to act as advisors to people in how we can conduct business that is consistent with our core values," Drew said.

Drew has been with Cook and in his current position for just over three years. He retired from the Federal Bureau of Investigation (FBI) in 2017. During his time with the FBI, he worked as a supervisory special agent, chief division counsel, and division compliance officer for the FBI in Indiana. His focus was on international corruption and transnational crimes issues. This part of his background made him a good fit for his current role, which he credits to divine intervention and meeting **Carol Seaman**.

"I ran into Carol at a Monroe County Historical Society event, and I was telling her what my background was," said Drew. "She said, 'We are getting ready to post for a position exactly like that, and I can't even believe that we've met.'"

Reflecting Cook's values

According to Drew, Cook's anti-corruption program grows out of a desire to reflect the company's core values in everything we do.

"The reason I am here is that there

are certain Cook core values which require someone with professional expertise to ensure that we understand what those requirements mean for us and the way we do business. So we want to reflect our core values, specifically acting with integrity," Drew said.

In addition, the need for Drew's position also comes from the company's necessity to comply with external applicable standards (EAS), which include the Foreign Corrupt Practices Act (FCPA), the UK Bribery Act, and several other laws across the globe that aim to prevent bribery.

Anti-bribery

Anti-bribery is one of the three main focuses of Drew's program. The Cook Group Global Code of Conduct states that Cook actively opposes fraud, bribery, and corruption and emphasizes that bribery is illegal everywhere. According to Drew, bribery can take many forms and is generally defined as offering or giving anything of value to win or retain business or improperly gain a business advantage.

"We want people to purchase Cook products and services because it is the best for them and it provides the best outcomes for patients and customers," Drew said. "We don't want to improperly influence their decisions because we have improperly given them something of value."

"We want people to purchase Cook products and services because it is the best for them and it provides the best outcomes for patients and customers. We don't want to improperly influence their decisions because we have given them something of value."

– Drew Northern, director of Global Anti-Corruption



Knowing our customers

The anti-corruption program also focuses on preventing money laundering in order to safeguard the integrity of financial transactions. According to Drew, Cook wants to ensure that all of these transactions properly reflect the business that the company is actually doing and that they don't, either intentionally or unintentionally, help a criminal group or a terrorist group launder money.

In his work with the anti-corruption program, Drew collaborates closely with the Indirect Market Management (IMM) function's Governance, Contracts and Audits (GCA) team to do due diligence, contract, and conduct audits on Cook's distributors.

"This allows us to know who our distributors are and what their capabilities are, to enter into proper agreements with them, and then to follow up and audit and understand that they are doing business on behalf of Cook in a way that reflects our core values and is in compliance with external applicable standards," Drew said.

In addition, he also works closely with the Legal and Finance teams, as well as the divisions, Medical Education, Manufacturing, and Supply Chain Procurement.

Drew said that the program is focusing on three important current projects. One of these is to create increased red flag resolution and monitoring of Cook's third-party distributors. Another is working with the Procurement and Supply Chain teams to develop human rights and labor standard assurance certifications.

"The biggest focus in the year to come is building a more robust investigation and internal audit capability for business interactions across Cook," Drew said.

Human rights

The second area of focus within Drew's program is human rights. According to the Code of Conduct, Cook promotes dignity and basic individual rights and aims to be a positive social role model and promote basic human rights by following applicable labor, wage, and hour laws.

This portion of Drew's program deals with fair labor standards, modern slavery, conflict minerals, etc. The program helps ensure that everyone Cook does business with and anyone who is doing business on Cook's behalf (distributors, for example) are working in a way that is consistent with global human rights standards.

• **Ashley McGuire** (*Ashley.McGuire@CookMedical.com*) is an Editorial Content specialist for Corporate Marketing and Communications.

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Setting up guardrails

and any HCP. In February 2019, Cook established a Global HCP/HCO Payment Transparency Council. The council consists of regional, functional, and program representatives who oversee Cook's global transparency reporting obligations and program documents.

The idea behind the concept of transparency reporting, commonly referred to as the "Sunshine Act" and "Open Payments" in the US, is that patients have the right to know what sort of financial relationships exist between companies and HCPs and whether those relationships are impacting the treatment choices HCPs are making.

"Being transparent is one of our core values," Mickey said. "With these country's laws, you can see who your doctor is working with and if that doctor is prescribing something, because there may be a financial tie back to that company that produces it."

For example, every June since 2014, all companies have to report these transfers of value—royalties, consulting agreements, meals, hotel costs, etc.—that they've had with any doctor who is licensed to practice medicine in the US. For Cook, that list of transactions can reach into the thousands. Those lists are then posted on **CMS.gov** and are accessible to anyone.

The cross-functional Transparency Council meets quarterly to review, monitor, and oversee the effectiveness of transparency reporting.

"Transparency reporting is growing globally—and the requirements for medical device and pharmaceutical companies are growing as well," Mickey said. "We also have certain states in the US that require reporting, as well as some of the countries in Europe and APAC."

• **Jon Hancuff** (*Jon.Hancuff@CookMedical.com*) is the manager of Global Editorial Content for Corporate Marketing and Communications.

Supporting our product marketing compliantly



Rick Mellinger reflects on the evolution of complexities relating to advertising and promotion prior to his retirement

After several years of working in the field as a sales representative for Cook, **Rick Mellinger** (now retired) moved to Bloomington in 1985 to take an in-house position in marketing. At that point, 22 years after its founding, the company had run exactly two paid ads—one for Peel-Away® sheaths and another touting the use of Micropuncture® technology in central venous catheters.

There were a few significant reasons for this, one of them coming straight from the top of the company.

“Bill Cook didn’t believe in advertising,” Rick said.

Cook was exceptional at that time for a couple of reasons, Rick explained. For starters, there was less competition in the areas of medicine in which the company was doing business. Additionally, Cook was set apart due to its emphasis on working with customers, in a way that was much more than simply exchanging cash for goods.

“We were listening, we were understanding, we were developing products, and we were developing products for individual physicians to take care of individual patients,” Rick said. “Nobody was doing that stuff.”

The respect clinicians had for Cook was also evident in how often our products were mentioned in medical journal articles. At that time, these mentions did more to attract new customers than almost every other channel.

“These journals would come out, and my phone would start to ring,” Rick said. “I would start getting messages from physicians asking me to come talk to them about those products. It was all you could do to keep up with making sure you touched base with people who were so interested that they were calling you to come talk to them. And then they would go ahead and place an order.

“Product information sheets used by the sales team were fairly simple, with a photograph of the product, line art, part numbers, and feature and benefits described. Things like product positioning and claims language were quite minimal. It was just such a different world.”

A logical move

Rick’s career is a perfect example of this difference. After spending many years in Marketing, including a long stint as the global vice president of the function, he moved

“It’s really about the voice of the organization— who we are, the way that we present ourselves, the way we present our products, the way we represent our organization, the way we present Cook to the world. And we are trying to help everyone navigate that.”

— Rick Mellinger, retired, prior vice president of Global Advertising and Promotion Compliance



to Ethics & Compliance (E&C) in late 2017 as the vice president of Global Advertising and Promotion Compliance.

His move to E&C from Marketing was a logical one. In Marketing, one of Rick's responsibilities was to provide final sign-off for many of Cook's marketing materials. Over the last decade, he began to see increasing regulations and other issues around compliance for advertising and promotion—with variances depending on the country and the channel. But there are some [universal standards](#).

Beyond these standards, though, things start to move from “black and white” to gray. Examples of this include: What we can say about our competitors? How we can present clinical data? How do we substantiate claims we make about our products? Again, the answers to these questions will likely be different if you are in, say, France versus Australia, and also on what channel your message is going to go out through. The regulations around promotion and advertising on social media can be very different from those for a medical journal.

“Global regulation has become complex and increasingly difficult to navigate, requiring specific knowledge and expertise to help Cook effectively and efficiently support our marketing and sales teams regardless of region or jurisdiction,” Rick said.

To help answer questions and to stay abreast of what has become a very fluid regulatory environment, Rick and Cook's Regulatory Affairs manager for Advertising and Promotion Compliance, **Danny Pettingill**, work with Cook people, including other E&C folks, “on the ground” in the countries where we do business, as well as with representatives from other Cook functions and entities like Legal, Regulatory

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Congratulations to Rick on his retirement after 40 years! Best wishes!



▲ **Rick Mellinger**, vice president of Global Advertising and Promotion Compliance, at a 2019 E&C Week event at Park 48.

Universal standards for advertising and promotion

- ▶ Any communications that we put forward into the marketplace cannot be false or misleading.
- ▶ Fair balance must be considered as we discuss the positive attributes and effects of our technology. Present benefits as well as risks.
- ▶ We cannot promote off-label use of our products.
- ▶ Transparency of our clinical data and relationships with physicians that we work closely with must be appropriately described and disclaimed.
- ▶ All claims must be substantiated.

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Affairs, Indirect Market Management, Cook Research Inc. (CRI), Engineering, the clinical divisions, and Business Care Integration (BCI). Additionally, they consult with outside legal resources and attend external meetings held by groups like AdvaMed.

"These touchpoints are necessary to determine risk and to understand, assess, and make the most appropriate decisions," Rick said. "Simply put, it takes a 'village.'"

What is considered promotion?

One of the most seismic shifts to take place over the last 10 years regarding how advertising and promotion are regulated is the ever-expanding idea of what is included under that umbrella. It's no longer just pieces that end up in medical journals.

"We tell our sales reps that anything that they say is promotion," Rick explained. "Anything that they put in an email really is promotion. It's really about the voice of the organization—who we are, the way that we present ourselves, the way we present our products, the way we represent our organization, the way we present Cook to the world. And we are trying to help everyone navigate that."

This also extends to people from outside of Cook, who are speaking on behalf of the company, like paid consultants or physicians who are paid to present on Cook products or clinical studies at medical meetings or webinars. They are held to the same guidelines relating to advertising and promotion as Cook employees. Careful coordination is required to ensure that information is appropriately presented.

A lot of that work will involve ensuring that there is complete transparency regarding Cook's financial relationship with the

"It behooves us to really create a system that is efficient, and a lot of that means that we need to be doing a better job at the front end of these projects before placing them into our review process for final sign-off."

– Rick Mellinger

presenter and that the appropriate disclaimers are included. Additionally, that vetting and approval process will need to be standardized so that it is conducted in a consistent way throughout Cook.

"It behooves us to really create a system that is efficient, and a lot of that means that we need to be doing a better job at the front end of these projects before placing them into our review process for final sign-off," Rick said.

The new normal

An already ever-shifting area of regulations has had a new variable thrust upon it by a global pandemic that is forcing everyone to figure out the "new normal." For Cook, the push to hold more virtual meetings with customers has been the most prominent twist to how we present ourselves to the world.

An extreme example of this was September's Cardiovascular and Interventional Radiological Society of Europe (CIRSE) meeting, which typically draws thousands of attendees from around the world. This year, the event was held online, and Cook participated with a virtual booth and a full agenda, which included several symposiums, training sessions, and round-table discussions with physicians. Much of this was recorded.

"A tremendous amount of content was captured," Rick said. "Now the divisions are saying that they want to use it. We are going to have to think about that. We captured it during a meeting in Europe for European physicians—but now, if we want to push it globally—what do we need to be thinking about relative to how we present that information to the world?"

It's those sorts of questions, the people who are helping find the answers, and the opportunity to move Cook toward becoming a truly modern company, that keeps Rick motivated.

"A lot of what happens is that people have good ideas, but maybe the way they are describing them isn't going to be possible," he said. "Often there is a way for us to get to the same goal, but we are going to have to do a few things differently to allow them to do so in a compliant way."

"At the end of the day, we believe in our products and want to give them every opportunity in the markets that we serve around the world so clinicians can enhance patient care by using them," Rick continued. "We just have to be able to do that in a compliant way by working together navigating an evolving and complex environment."

• **Jon Hancuff** (*Jon.Hancuff@CookMedical.com*) is the manager of Global Editorial Content for Corporate Marketing and Communications.

Moving Cook products

Lloyd Porter on the work that goes into shipping our products globally



Never before in human history have we had more access to goods from around the world. A smartphone is essentially a catalog of unlimited pages. If you want to buy something—no matter what it is or where it is manufactured—it can be yours in a matter of days, if not hours.

On the buyer's end, it seems easy enough—you click a button on a website and then you wait for your package to be delivered.

Behind the scenes, though, things can be much more complicated, depending on where the product is made and where it needs to go.

That behind-the-scenes world is where **Lloyd Porter**, Cook's Ethics & Compliance (E&C) director of Global Trade Compliance, spends most of his days.

And it turns out that if you want to ship medical devices and raw materials around the world, you can't just put them in a box, slap some postage on them, and drop them off at the post office. Every country has a myriad of constantly shifting regulations and restrictions that must be abided by if you are looking at moving goods across borders.

Lloyd joined Cook and the E&C function in October of 2015 after having spent years working in import and export trade controls for companies in North Carolina and northern Indiana. His current role

includes those areas and dips into several others as well.

Government filings

Every time Cook ships products from one country to another (exports) or receives a shipment from another country (imports), there are declarations, filings, or reports that we are obligated to complete. These filings involve a listing and description of everything included in the shipment. Sometimes Cook makes the filing or declaration. At other times, depending on the country, Cook engages customs brokers or outside logistics providers to assist us.

Accurately completing and filing these documents in a timely manner is one of the many factors that will allow Cook to remain compliant and continue to provide products to patients in those countries in which we do business.

Most of the global movement of Cook products flows through our three main delivery centers, which are located in Bloomington (AMER DC), Baesweiler, Germany (EMEA DC), and Singapore (SADC), and our smaller sub-delivery centers, which are located in major markets such as India, Korea, Japan, and China. When you add in shipments that go to our distributors in the countries

"It's like a physical internet of products that is moving through all of these different channels and delivery centers and ultimately through air shipments, primarily, to their ultimate country destinations."

– Lloyd Porter, director of Global Trade Compliance



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ETHICS & COMPLIANCE

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where we don't sell directly to customers, there are over 100 global destinations for Cook devices.

"It's like a physical internet of products moving through many different channels and delivery centers—primarily by way of air shipment—to their ultimate country destinations," Lloyd said.

Sanctions and embargoes

There are some countries in the world where Cook is not allowed to freely do business. This is because an entity like the United States government or the United Nations has placed sanctions or embargoes on those countries. Currently this includes places like North Korea, Syria, and Iran.

"Those are destinations where either we are not allowed to do

any business at all, or our ability to transact sales of medical devices is highly restricted and tightly controlled," Lloyd said. "That's an important aspect of trade compliance—making sure we provide clear information to those in distribution and sales about where we can and can't do business and what the rules of engagement are for such destinations."

Export controls

It's not just physical items that have to be accounted for as they move from country to country. Export controls cover not just devices for Cook but also certain technologies and information that are used to create or operate those devices.

"There could be restrictions on the transfer of that information because it is a sensitive manufacturing technique," Lloyd explained. "It could also be used to manufacture

some type of weapon. Cook doesn't have a lot of that type of controlled technology, but we do have bits and pieces here or there that we need to monitor to ensure appropriate controls on access and transfer."

Supporting export controls on technology is our "deemed export program," which, in the US, refers to the transfer of a controlled technology to a non-US person while in the United States.

"The concept is, if you share information with a non-US person—who is in the US at the time of transfer—it's presumed by export control authorities that it is the same as sending that information to their home country," Lloyd said.

There are multiple ways in which Cook seeks to keep track of these kinds of technological exchanges, including the annual deemed export review and export license determination processes.



▲ From left: **Alex Hernly**, Data Privacy specialist; **Lloyd Porter**, director of Global Trade Compliance; **Greg Smith**, director of Global Human Resources; and **Rex Hinkle**, president of Cook Aviation, collaborate at an Ethics & Compliance meeting at French Lick Springs resort.

“One of the strategic things that we are working on is becoming more organized with trade data. That is going to lead us into global trade management solutions from an IT and a business process perspective that are going to help us to know ourselves better.”

– Lloyd Porter

During Cook’s annual deemed export review, E&C will partner with Engineering to inventory and identify any of the company’s controlled technology.

In the instances in which we have a controlled technology or commodity that we need to share, it would go through an export license determination process. This process will establish what rules apply to its transmission and whether or not an export license is required, or whether a license exception is available.

“That would be a key way that I would intersect with and support the business to make sure they are abiding by the rules,” Lloyd said. “And if they need to get an authorization, such as a license, to complete that activity, I can help make sure that we have that in place.”

Restricted party screening program

Similar to the sanctions and embargoes effort detailed above, there are also lists of individual people and organizations with which Cook is unable to conduct business.

“There are listings of people and

organizations that are sanctioned or restricted due to a criminal activity, because they violated a federal acquisition rule, or they are debarred from receiving exports from the US—whatever the reasons might be,” Lloyd said.

Restricted Party Screening helps support the company in ensuring that we are adhering to those lists, using a screening system that regularly reviews over 100 different restriction lists.

Team and partnerships

Recently, the formation of a new Global Supply Chain function was announced, which combines the Customer Support and Delivery (CSD) function with global Procurement & Supply Chain under **Ross Harvey’s** leadership. As part of this realignment, **Stephanie Letman**, Import/Export manager for Procurement and Supply Chain, has moved in to a new role as manager of Trade Compliance reporting to Lloyd. Stephanie will continue to manage critical trade administrative functions for Cook’s US entities, but will add participation in key strategic projects with a global scope.

“She’s been supporting a more frontline tactical role helping Cook Medical, Cook Incorporated, and Cook Winston-Salem,” Lloyd said. “Those are our largest and most busy importers and exporters in the US operations. They are literally doing hundreds of millions of dollars’ worth of import and export transactions on an annual basis.” Maintaining effective trade compliance in these areas is vital for Cook’s product and material flows and involves both Customs and other government agencies, such as the US FDA.

Stephanie works directly with customs brokers and within different functions at Cook to help with problem solving, record keeping, and overseeing the customs brokers who do all types of those filings for us.

In working with the new Global Supply Chain function, Lloyd and Stephanie stay closely connected with the Customer Support and Delivery teams, including by having regular interactions with the US and global delivery centers, and their logistics providers.

“Those are the teams and places where so much of the activities give rise to these import and export transactions,” Lloyd said.

Looking ahead

Having gone through a major organizational transformation, Cook is now moving toward establishing itself as a truly modern company. With that goal in mind, Lloyd is working to identify systems and processes in his area that will increase the efficiency and effectiveness with which the company does business.

“One of the strategic things that we are working on is becoming more organized with trade data,” he said. “That is going to lead us into global trade management solutions from an IT and a business process perspective that are going to help us to know ourselves better. Implementing systems that help us manage specific information about import and export and our products—that’s the future for us. I am very excited to be working with the IT teams and with Ross and others and looking at solutions that are available to us to help us very effectively manage that data and basically leverage that information to be even more successful.”

• **Jon Hancuff** (Jon.Hancuff@CookMedical.com) is the manager of Global Editorial Content for Corporate Marketing and Communications.

Cook's Data Privacy by design

How **Megan Charlesworth** and the Data Privacy team are working to protect personal data



When Megan Charlesworth, director of Global Data Privacy, reflects on her time with Cook, she notes that the company has made significant strides towards integrating and aligning with external applicable standards (EAS). Megan's path to Cook started in 1993 when she moved to Bloomington and began working for Ferguson & Ferguson law firm. **Steve Ferguson** brought Megan on board at Cook Group in 1999 to work in the new Patent Office as a patent researcher and technical writer.

The beginning of Cook's Global Data Privacy program

When **Carol Seaman** started Cook's Ethics & Compliance program in 2000, she asked Megan to come work with her. Together, they built the program and created Cook's first Code of Conduct. Very soon after, the Health Insurance Portability and Accountability Act (HIPAA) went into effect, which had numerous implications and obligations for Cook and our US customers.

"It presented a significant challenge for Cook, because we suddenly had to review hundreds of HIPAA agreements being requested from almost every US customer's hospital or clinic," said Megan.

The need to have someone focus on data privacy issues became apparent and was made a priority by E&C. Megan developed Cook's first on-line training program with

the help of an external supplier to push required HIPAA training to US sales representatives and applicable employees. In addition, the Cook Family Health Center required HIPAA policies, forms, and authorizations, as well as a risk assessment and review of processes and procedures and the development and delivery of annual training for physicians and staff. Megan partnered with the clinic leadership to develop protocols to minimize risks of patient information being overheard or viewed by other patients during their visit to the clinic.

Once the dust had settled on the initial efforts to comply with HIPAA, Megan conducted a risk assessment to identify and build a strategy to comply with global data privacy requirements. The EU Data Directive necessitated a review of how Cook was handling clinical trial data and moving protected data around the world for necessary business activities. Megan partnered with Cook's clinical trial group to conduct a self-assessment and enroll in the Safe Harbor Program (now the Privacy Shield Framework) with the US Department of Commerce to receive clinical trial data from the EU.

In early 2015, French Lick Resort suffered a cyberattack that demanded full focus and remediation. This experience allowed Megan to mature Cook's Global Data Privacy framework and formalize policies, processes, and the overall structure. It also

"Data privacy is the responsibility of everyone, so we work to help employees understand the different types of data that must be protected."

– Megan Charlesworth, director of Global Privacy



gave her a first-hand look at what enforcement agencies and regulators expect from a sophisticated data privacy program.

What had been a single-person team at the end of 2015 became a global team of six. **Kristin Stone** (global data privacy manager) is based in Bloomington. **Aoife O'Rourke** is an attorney and the EMEA data protection officer based in Ireland. **Noel Fitzgerald** joined the EMEA data privacy team as a specialist and is based in Ireland. **Agnes Li** joined the team in December as data privacy manager in APAC based in Hong Kong. Aoife is a lawyer with knowledge and experience of EMEA requirements. Kristin, Noel, and Agnes have years of experience in compliance, information security, and applicable ISO standards. (The US data privacy specialist position is currently under recruitment.)

The team was instrumental in developing the **Cook Group Security Standards**, which serve as the roadmap for data privacy and security to align with EAS. Cook's Global Data Privacy framework has been constructed to include "privacy by design" program elements which ensures that new initiatives involving personal data consider the risk and security of the data at the outset of the project.

"I am proud of the effort and hard work of our Global Data Privacy team and our continued collaboration with **Dave Breedlove** (VP & CIO) and **Melinda VanderBok** (manager, digital product) with Cook IT," Megan said.

The development of the Cook Group Security Standards was a significant undertaking and serves as the single-source for Cook's data controls.

Data privacy is everyone's responsibility

The Global Data Privacy team acts as an internal resource and provides advice, guidance, and recommenda-

tions regarding best practices. The team has worked to create a culture at Cook that values data privacy. This message is delivered through employee trainings, newsletter articles, employee resources, and various outreach activities.

"Data privacy is the responsibility of everyone, so it's important that we work to help employees understand the different types of data that must be protected," Megan said.

The team created the **Cook Data Classification Chart** as a resource for employees to understand how Cook classifies data and the corresponding security requirements. There are numerous reasons that the protection of personal data at Cook is important. For instance, failure to properly protect personal data can have far-reaching negative effects for employees, customers, and patients. It could result in significant penalties or fines for the company.

"One important point is that protecting our customers and patients means being committed to protecting their data," Megan said. "When we talk about patient safety or protecting our customers, that conversation needs to include safely maintaining the data Cook is entrusted with. This commitment protects the trust we have built with our customers and the reputation of our brand."

In a constant state of change

The ever-changing nature of the data privacy regulatory landscape keeps the team busy. The laws governing how personal data is processed and controlled around the globe are being proposed and passed at an unprecedented rate.

"New requirements have historically popped up every 12-18 months. Every time a new requirement issues, we have to review all of our documentation, policies, website statements, and trainings and communicate the new changes to those affected. In 2020, our team

has had to navigate nine different regulatory changes (new laws or requirements). I've never seen so much change in a single year, and I've been a privacy professional for 20 years," Megan said.

For the last few years there has been a big push in the US to pass a Federal privacy bill that would protect consumer data much like the General Data Protection Regulation (GDPR) in the EU. Each state has enacted its own privacy laws with data breach notification requirements. Nearly 200 countries have data privacy legislation, and many states and jurisdictions have additional requirements. At the moment, the most comprehensive data protection law is GDPR. Much of what the team does is geared towards aligning with GDPR requirements.

Monitoring new and emerging legislation has become an increasingly large part of Megan's focus. As the US considers a Federal

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Visit the Data Privacy site on the Cook Intranet to view the **Cook Data Classification Chart**.

intranet.cookmedical.com/cbf/priv

The **Cook Group Security Standards** are available on the Cook Intranet at intranet.cookmedical.com/ops/cgss/Pages/default.aspx#

Integrating Ethics & Compliance

A look at how **Neal Daunhauer** and his team promote E&C at Cook



When Neal Daunhauer was initially told that Cook was looking for someone to help consolidate what at the time was multiple companies under one brand umbrella, which would eventually become Cook Medical, he turned down the offer. At that point, he was working for a multinational start-up company in Bloomington and was content with where he was.

“Then I kept bumping into people from Cook at the YMCA, at the farmer’s market, and at church, and I thought, ‘I need to pay attention. There may be something to this,’” Neal said.

And that must have been the case, because he celebrated his 16th anniversary with Cook last July. Before coming to Cook in 2004, Neal had spent his entire career working for marketing and advertising agencies and had held positions such as art director, creative director, and brand strategist. This experience made him a great fit when he was brought on as Cook’s director of Global Brand Management. He has since held various roles with the company, and his achievements include building the brand of Cook Medical and building the company’s global marketing department. He switched gears a couple of years ago when

Carol Seaman, vice president and chief Ethics & Compliance officer for Cook Group Incorporated and Cook Medical Holdings, asked him to help brand the company’s Ethics & Compliance (E&C) program. He now serves as the director of Integration for E&C.

Why integration?

Integration is the goal of the E&C program. When an E&C program and all that entails becomes part of everyday business activities, including ongoing business strategies and planning, the program becomes second nature and a part of the DNA of company culture.

Full integration of the company’s values and the elements of the E&C program are a measure of the maturity and effectiveness of the program based on industry standards and government expectations.

Integration efforts

When it comes to company interactions, it is the Integration team’s responsibility to coordinate programs that involve all Cook entities. These interactions can take several forms and include training and education initiatives like e-learning courses. According to Neal, E&C Week, which takes place

“Manager Toolkits help managers to have a conversation that they may not otherwise have and help employees feel comfortable asking questions about topics they may not otherwise ask.”

– Neal Daunhauer, director of Integration for Ethics & Compliance



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▲ *The Manager Toolkits are just one example of a communication initiative that Neal and the Integration team coordinate for Ethics & Compliance.*

every November in all Cook Group companies, would also fall under this category.

Neal's team is also tasked with developing communication strategies for the E&C function working with the other E&C directors. The integration team identifies the key message each sub function wants to communicate during the year and the optimal communication pathway.

Manager Toolkits

The Manager Toolkits are just one example of a communication pathway. These toolkits promote a culture of transparent communication by equipping leaders at Cook to fulfill an expectation that ethics and compliance is discussed regularly by leadership.

"Manager Toolkits help managers to have a conversation that they may not otherwise have and help employees feel comfortable asking questions about topics they may not otherwise ask," Neal said.

Another benefit of the Manager Toolkits is that they give leaders an opportunity to show their teams how ethics and compliance applies to them in their specific business activities.

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Cook's Data Privacy by Design

consumer protection law and continues to pass increasingly strict State data laws, Megan works with key industry groups to help educate policymakers on the ways in which medical device companies need data for legitimate reasons, such as patient safety and clinical research.

"Lawmakers are rightly wanting to protect citizens' personal data, our social security numbers, and our birth dates," Megan said.

"It's important that new laws find a balance between protecting data from misuse by social media companies and retailers while allowing companies, like Cook, to have authorized access to certain types of personal data that are needed to innovate, conduct clinical trials, and protect the safety of our customers' patients."

Looking ahead

As Cook moves towards being a data-driven company the Global Data Privacy Team is prepared to keep pace. With change being the only constant employees can be sure the Global Data Privacy team will continue to provide updates and work to keep them informed. The team appreciates the continued support.

As always, questions are welcome at **Privacy@CookGroup.com**.

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Solving problems together

E&C and HR work together to find a new helpline system



Greg Smith, director of Global Human Resources, along with **Heather Hurst**, director of Global Ethics & Compliance (E&C) Operations, have been the key players in implementing the current E&C helpline at Cook. The switch to this new system has helped Cook make strides towards becoming a more modern company.

One hallmark of successful companies and effective E&C programs alike is a willingness to actively listen to employees who want to express a concern or ask a question.

The original helpline was a much more manual and cumbersome process. At the time, it was just one toll-free number that an employee could call and leave a voice message at if they had a concern. Only one E&C team member was assigned to check the line once daily and physically transcribe any received messages. That person would then determine the appropriate person to handle the concern.

There were several issues with this system. The person leaving the message might fear a lack of anonymity due to the fact that the person transcribing the message might recognize their voice or be able to identify them based on their phone number. The caller had no way of knowing the protocols put in place to protect their anonymity. The transcriber removed any potential

identifying information, such as the caller's gender.

Another issue was that the person calling was unable to speak to a live person, thus eliminating the possibility for clarifying questions to be asked. In addition, there was the potential for a language barrier if the person calling did not speak English.

Over the course of a number of meetings, E&C (**Heather and Carol Seaman**) and HR (**Greg and Ron Mobley**) discussed the future of the helpline and eventually landed on using an outside vendor, NAVEX. According to Heather, this process involved a lot of collaboration between the two functions.

"HR brings one perspective and E&C brings another perspective," said Heather. "We worked together to choose the vendor and then we worked together during the implementation process to create a communications plan and communication resources."

"I've actually used NAVEX at a previous job and have found it to be a very robust system, very protective for our employees, and very user friendly for the folks on this side of it that are actually using it to track cases," Greg said. "I think there was a definite comfort level in going with NAVEX and knowing that it was very secure and then also that it had a lot of protections for anonymity."

The new NAVEX system is an

"It has been great collaborating and partnering with E&C on this. It takes both functions to really make this operate well. I feel like we really do interact very well."

– Greg Smith, director of Global Human Resources



improvement over the old system in several ways. Now, employees can report a concern electronically or by phone, 24 hours a day and 7 days a week. The helpline is also available in 14 different languages. Where allowed by law, an employee is also able to make an anonymous report, but receive a personal identification number (PIN) that allows them to follow up on their concern. The system also allows E&C and HR to generate reports based on the information they receive, which allows them to determine whether there are trends that indicate a systemic issue.

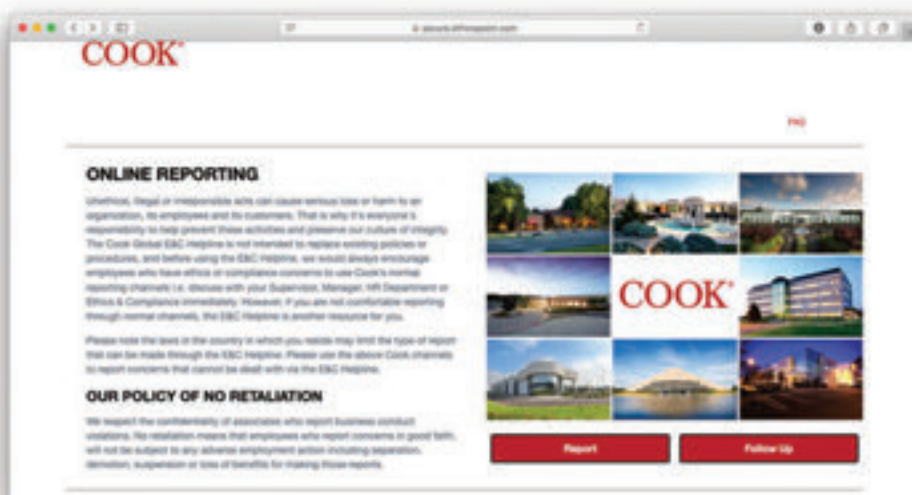
“By looking at these trends, we can say, ‘You know what? We probably need to be doing some additional refresher training in X or we need to do some additional coaching with leadership on Y,’” Greg said. “There are all these opportunities that come out of this because people are open with us, and we do try to truly be responsive.”

Greg acts as the gate keeper for the helpline in that he assesses the incoming concerns that are submitted via NAVEX and then assigns them out to the appropriate people to conduct the investigations. Additionally, he meets on a monthly basis with Heather to review all the cases that have been submitted.

“We look at any reports that are concerning, we look at how long it is taking to conduct the investigations, whether we are getting good documentation of the investigations, and making sure that the reports are being properly resolved,” Greg said.

“While some of these issues that are brought forward are challenging and concerning and sometimes disheartening, this system helps us to track those things and make sure that we work to resolutions,” he continued.

While E&C and HR had been collaborating on the helpline long before the switch to NAVEX, they were able to work together and come up



▲ Employees have the option to submit concerns to the E&C helpline via an online portal. Above is a look at the home page of this site.

with a solution to better benefit the company and its employees.

“It has been great collaborating and partnering with E&C on this,” Greg said. “It takes both functions to really make this operate well. I feel like we really do interact very well.”

“This is an ongoing collaboration and an ongoing, solve problems together, kind of thing,” Heather said.

• **Ashley McGuire** (*Ashley.McGuire@CookMedical.com*) is an Editorial Content specialist for Corporate Marketing and Communications.

“This is an ongoing collaboration and an ongoing, solve problems together, kind of thing.”

– *Heather Hurst, director of Global Ethics & Compliance Operations*

Did you know?

Employees in the US and Canada can reach the Ethics & Compliance Helpline at **877.353.8442**.

A list of international toll-free numbers can also be found at **Cook.EthicsPoint.com**.

Employees can also visit this site to submit a report online.