

EXACT SCIENCES AND PHILLIPS-MEDISIZE COLLABORATE TO FIGHT COLORECTAL CANCER

GROUNDBREAKING PRODUCT, TRANSPARENT TEAMWORK AND WORLD-CLASS MANUFACTURING INCREASE PATIENT SCREENINGS FOR EARLY CANCER DETECTION

CHALLENGES

- Unflinching focus on quality needed to deliver novel cancer-screening product
- Patient-focused design necessitated strong expertise in human factors
- Manufacturing and supply chain agility required for rapid scaling on demand

SOLUTION

- Phillips-Medisize offered one-stop-shop for end-to-end manufacturing
- Product modifications increased usability, ergonomics and manufacturability
- Trusted relationship optimized sourcing, procurement and supply chain management

BENEFITS

- Six million Americans have used Cologuard as a patient-friendly way to screen for colorectal cancer
- Diversified manufacturing footprint now produces 40,000 test kits weekly
- Close collaboration focused on continued product innovations for early cancer detection and next-generation products



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VP of Operations at Exact Sciences

Time is of the essence when it comes to cancer detection and treatment. Fueled by a mission to help people get the information needed to make more informed decisions about their health, Exact Sciences strives to change lives through earlier and smarter answers across the cancer journey.

This overarching mission drove the development of Cologuard®, the first and only FDA-approved noninvasive stool DNA screening test for colorectal cancer. "Cancer is detected too late," explains Tammy Turek-Etienne, VP of Operations at Exact Sciences. "We are committed to using our expertise and determination to help change lives through advancing early detection of cancer."

In 2020, nearly 148,000 Americans received a new diagnosis of colon or rectal cancer. When detected early, about 90% of cases are treatable, yet one in three adults over age 50 are not up-to-date on recommended colorectal cancer screening. The COVID-19 pandemic further complicated this problem as screening rates plummeted amid stay-at-home orders. Concurrently, new cases of colorectal cancer are occurring at a growing rate among young and middle-aged adults, prompting the United States Preventive Services Task Force (USPSTF) to recently recommend screenings starting at age 45.



BLENDING INNOVATIVE SCIENCE AND ADVANCED MANUFACTURING

Scientists from Exact Sciences worked closely with Mayo Clinic to identify signs and signals that are prevalent in colorectal cancer. They then translated their findings into a multitarget stool DNA test using the principles of biology, chemistry and molecular biology. The test looks for DNA changes in a stool sample, which could indicate the presence of colon cancer or precancerous polyps in the colon. The ability to use multiple biomarkers is a clear Cologuard differentiator, along with the simplicity and convenience of at-home testing.

Once prescribed by their doctors, patients receive a Cologuard test kit by mail, which contains everything needed to collect a stool sample, including a bracket and collection bucket with lid, a probe and lab tube set, as well as preservative solution. Clear instructions guide users through each step. "Our focus and our mission is really on the patient experience," adds Turek-Etienne. "So, everything we do at Exact Sciences is around quality and that end-user, so we can ensure they have a really great experience with the products."

Early on, Exact Sciences sought an experienced manufacturer embodying similar principles and philosophies on product quality, patient-centered design and supply chain optimization. "Quality is absolutely paramount," says Turek-Etienne. "So, having a partner that really focuses on quality was critical for us to move forward."

In Phillips-Medisize, a Molex company with decades of manufacturing innovation for healthcare and life sciences companies, Exact Sciences found a collaborator with a like-minded approach and ISO-13485 compliant facilities. Based in Hudson, Wisconsin, in close proximity to Exact Sciences' headquarters in Madison, the Phillips-Medisize team was ideally located for a regular cadence of in-person meetings and conversations.

"We offered Exact Sciences a one-stop shop of advanced manufacturing," recalls Paul Chaffin, President, Molex Medical and Pharmaceutical Solutions, including Phillips-Medisize. "From human factors design, complex molding, reagent handling, volume manufacturing, finished packaging, labeling, serialization—we have everything they needed to bring this innovative product to market."

The fact that Exact Sciences was still awaiting FDA approval didn't dissuade Phillips-Medisize from moving forward. "We didn't see this project as a risk, but rather as an amazing opportunity," Chaffin adds. "We saw a well-established management team committed to an incredibly innovative product. We envisioned our capabilities as key enablers to helping Exact Sciences become a game-changer in the healthcare industry."

**Phillips
Medisize**
a **molex** company

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PATIENT-FOCUSED PRODUCT DESIGN

In preparing Cologuard testing kits for volume manufacturing, teams from Exact Sciences and Phillips-Medisize ensured every aspect of product performance met stringent quality requirements. “The biggest focus with the human-factors effort was understanding which changes or modifications were needed to make the kit successful for the end-user,” says Turek-Etienne.

Human factors specialists conducted extensive market research with the patient in mind, thinking through all the ways the product would be utilized. “Our human factors team starts with the end in mind,” explains Chaffin. “We make sure all the different use cases are built into the front-end product design.”

A top priority was ensuring that patients of all ages and abilities could open and close all the different components that comprise the collection kit. Both hand strength and dexterity were considered for individuals ranging in age from 45-to-90, with special attention on ergonomics. Refinements to the collection bucket’s lid and other components were made to ensure airtight closure.

New tooling was developed for the collection kit’s fit tube and bracket to safeguard against inadvertent leaks. The team also took advantage of something called an energy director to rectify any potential leakage. “Phillips-Medisize helped us understand what the product needed to meet the specifications and tolerances required to produce the highest quality product,” adds Turek-Etienne.



PREPARING FOR UNPREDICTABLE GROWTH

The organizations addressed the typical uncertainty associated with bringing a new product to market. “We felt Cologuard was a solution for an unmet need, but we couldn’t predict how fast it would take off,” says Mindy Bennett, Senior Director, Supply Chain & Logistics for Exact Sciences. “We needed to be prepared for unplanned ups and downs in demand.” This required unprecedented levels of supply chain flexibility and the ability to ramp manufacturing with speed and agility.

According to Kim Eckmayer, Associate Director, Sourcing & Procurement for Exact Sciences, Phillips-Medisize played a major role in streamlining the acquisition of all parts, products and raw materials needed to scale kit production. “Phillips-Medisize is adept at building relationships with other suppliers and vendors,” she says. “This really helped us get the production line up and running fast while making sure all of us were in lockstep.”

Phillips-Medisize was flexible and nimble in starting manufacturing on a manual production line, before scaling to semi-automated and then fully automated lines as volumes increased. “One of our comparative advantages is starting small before ending big,” adds Chaffin. “The knowledge that’s developed throughout each one of those steps is easily transferred to the next line or the next facility, which is what having a global footprint and world-class team enables us to do.”

By 2014, Exact Sciences received FDA approval for Cologuard, which led to inclusion on nationwide lists of recommended screening options for colorectal cancer. Demand for the noninvasive home screening kit skyrocketed. “When we launched in Q4 of 2014, we delivered 4,000 collection kits to patients,” recalls Turek-Etienne. “In 2021, we now deliver 40,000 patient tests a week! And that’s a huge growth that all of us had to work through with quality and the end-patient always at the forefront.”

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CASE STUDY



REDUCING SUPPLY CHAIN RISK

Countless collaborations accelerated successful scaling while reducing supply chain risk. To that end, Phillips-Medisize located and validated alternate supply sources for certain items that weren't highly defined by specifications put forth for the FDA submission. The supply chain was further optimized through in-depth risk assessments and forecasting, as well as sourcing and procurement plans to protect against unplanned disruptions.

"Having a great working relationship from the beginning has gone a long way to reduce supply chain risk," Bennett says. "Phillips-Medisize was willing to invest with us and increase safety stock, hold spare parts and work through all the details to ensure we could keep pace with customer demand." Exact Sciences also took advantage of Phillips-Medisize's buying power for certain raw materials, like resin.

Moreover, Phillips-Medisize orchestrated a global supply chain to alleviate constraints. "When there's a global shortage of certain materials, we feel confident that Phillips-Medisize has taken the steps necessary to secure the materials, so that our patients can always be tested," Bennett adds. Overall, Phillips-Medisize has helped Exact Sciences better grasp the nuances of tooling, molding, manufacturing, assembly and quality testing.

Transparent teamwork is the key to quick and effective solutions to unforeseen challenges, such as the sudden impact of COVID-19. Exact Sciences alerted Phillips-Medisize as clinics were shutting down

and physicians were focused on ramping test efforts for the coronavirus. "We were able to formulate a plan that was really in everyone's best interest while minimizing disruption for our patients and both organizations," says Bennett.

Supply chain issues regarding raw materials were examined, resources were re-deployed and production schedules were adjusted to accommodate volume changes and avoid overstocking. Additionally, labor uncertainties were addressed as stay-at-home orders and factory closures were announced. "Together we weathered the storm," recalls Turek-Etienne. "We worked closely to balance the demand placed on Phillips-Medisize, and they worked closely with us to ensure they had all the raw materials and safety stock available to continue to produce Cologuard."



INVESTING IN A HIGHLY SUCCESSFUL COLLABORATION

Thanks to the highly successful collaboration between Exact Sciences and Phillips-Medisize, Cologuard is poised to help transform how Americans think about colorectal cancer screening. According to a recent study by researchers at Mayo Clinic, most individuals at average risk of colorectal cancer said they would prefer a stool-based screening over a colonoscopy. To date, Cologuard has been used to screen more than six million Americans.

To prepare for sustained growth while mitigating risk, Phillips-Medisize diversified its manufacturing footprint by adding a manufacturing site in Little Rock, Ark., which previously served as a Molex facility. Converting this site from traditional

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manufacturing into medical manufacturing required modifications and updates to meet stringent regulatory requirements.

"Given the incredible power that Cologuard has to make a difference in people's lives, and the demand for it, we are doing everything we can to meet that demand," says Chaffin. "We're now using two facilities with three production lines, combining manual, semi-manual and highly automated manufacturing. We really look forward to working with Exact Sciences on their next-generation products and helping them fulfill their vision."

For Exact Sciences and Phillips-Medisize, their strong bonds are rooted in trust, innovation, open communication and commitment. "Exact Sciences is going to continue innovating solutions for patients along the cancer journey, from early detection to late-stage treatment decisions," concludes Bennett. "Phillips-Medisize's focus on innovation and quality, along with the great relationship that we've developed over time, is key to our success in building out those solutions."

ABOUT EXACT SCIENCE

A leading provider of cancer screening and diagnostic tests, Exact Sciences relentlessly pursues smarter solutions providing the clarity to take life-changing action, earlier. Building on the success of Cologuard and Oncotype DX®, Exact Sciences is investing in its product pipeline to take on some of the deadliest cancers and improve patient care. Exact Sciences unites visionary collaborators to help advance the fight against cancer. For more information, visit [exactsciences.com](https://www.exactsciences.com).

ABOUT PHILLIPS-MEDISIZE

Phillips-Medisize, a Molex company, brings decades of innovation to leading healthcare and life science companies to develop groundbreaking solutions that help people live healthier, more productive lives. On average, the company commercializes 50 new products a year for customers, including the first-to-market FDA-registered drug-delivery device utilizing a connected health system. In addition, Molex brings decades of experience in advanced electronics, connectivity, and sensor technologies to help transform medical and pharmaceutical solutions. For more information, visit [phillipsmedisize.com](https://www.phillipsmedisize.com).

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