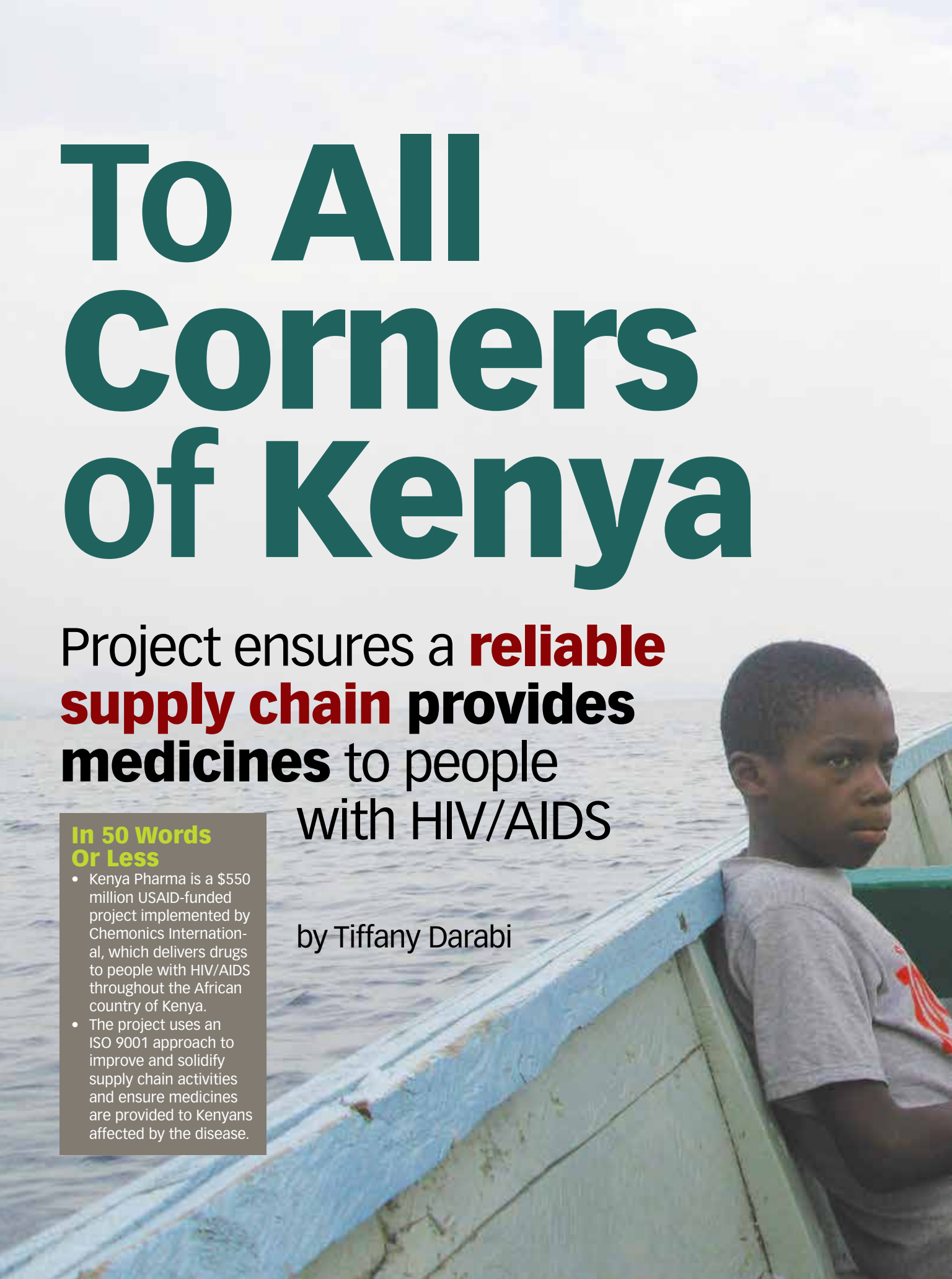
To All Corners of Kenya

Project ensures a **reliable supply chain** provides **medicines** to people with HIV/AIDS

by Tiffany Darabi



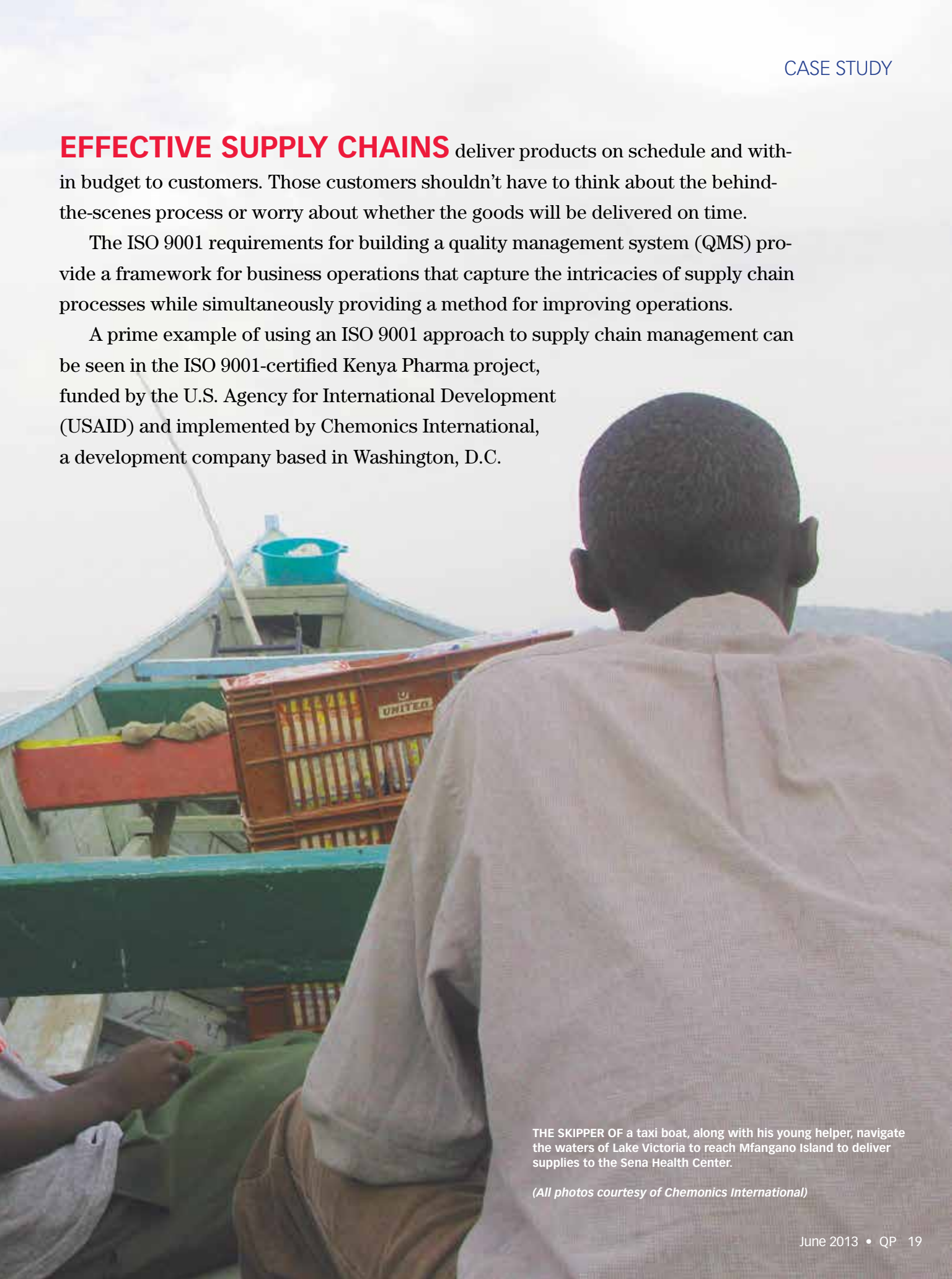
In 50 Words Or Less

- Kenya Pharma is a $550 million USAID-funded project implemented by Chemonics International, which delivers drugs to people with HIV/AIDS throughout the African country of Kenya.
- The project uses an ISO 9001 approach to improve and solidify supply chain activities and ensure medicines are provided to Kenyans affected by the disease.

EFFECTIVE SUPPLY CHAINS deliver products on schedule and within budget to customers. Those customers shouldn't have to think about the behind-the-scenes process or worry about whether the goods will be delivered on time.

The ISO 9001 requirements for building a quality management system (QMS) provide a framework for business operations that capture the intricacies of supply chain processes while simultaneously providing a method for improving operations.

A prime example of using an ISO 9001 approach to supply chain management can be seen in the ISO 9001-certified Kenya Pharma project, funded by the U.S. Agency for International Development (USAID) and implemented by Chemonics International, a development company based in Washington, D.C.



THE SKIPPER OF a taxi boat, along with his young helper, navigate the waters of Lake Victoria to reach Mfangano Island to deliver supplies to the Sena Health Center.

(All photos courtesy of Chemonics International)

Kenya Pharma ensures a reliable supply of high-quality, low-priced pharmaceutical commodities for people with HIV/AIDS in Kenya. The project's customers are children and adults, including pregnant women, from some of the poorest and most remote regions in the country. The ability of the project to operate a successful supply chain is fundamentally about serving people—much more than just being a business proposition—because it is quite literally a matter of life or death.

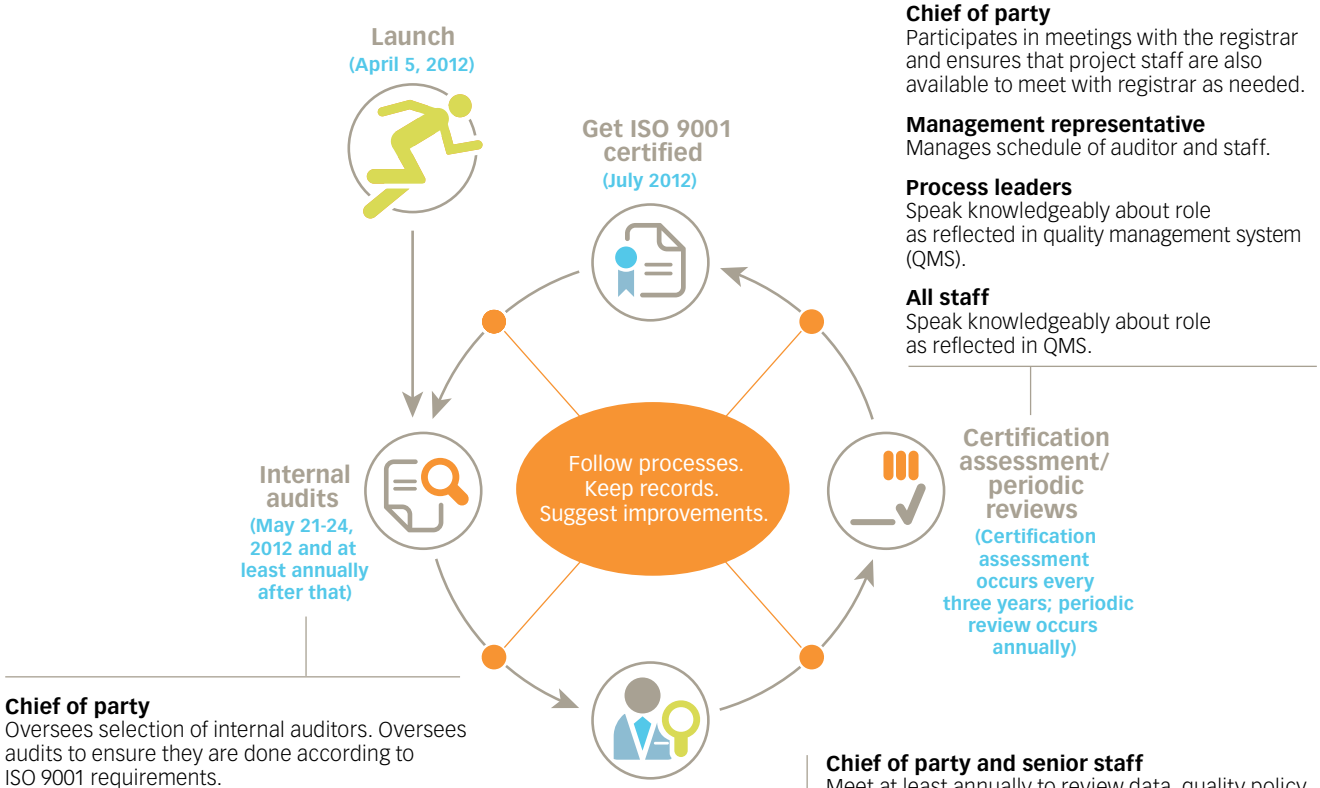
The decision to implement an ISO 9001-certified QMS was driven by the desire to create a systematic approach for supply chain practices to ensure continual improvement of services to the Kenyans served across the 225,000-square-mile country.

Setting the stage

Kenya Pharma operates a demand-driven (pull) distribution system with 169 facilities submitting orders to the central warehouse. In partnership with DHL-Kenya for distribution and with Phillips Healthcare Services Ltd. for warehousing, Kenya Pharma effectively engages the private sector in the developing world to deliver results.

Through a hub-and-spoke distribution network, the 169 ordering points supply 626 antiretroviral therapy (ART) dispensing points, which generally provide a full range of HIV/AIDS prevention, treatment and care services. The ordering points also supply an additional 654 dispensing points that provide only prevention of mother-to-child transmission (PMTCT) services.

ISO 9001 certification process / FIGURE 1



BOXES CONTAINING HIV/AIDS medicines are loaded onto a taxi boat to ferry them from Mbita Point on Kenya's mainland to Sena Health Center on Mfangano Island.

By the end of 2012, the supply chain was serving more than 349,000 ART patients representing about 58% of the total treatment population in Kenya. The remaining population is supported mainly by a supply chain run by the Kenyan government.

Kenya Pharma began the process of building its QMS in 2011, obtaining ISO 9001 certification in the summer of 2012 (see Figure 1). The journey actually began in 2010, however, when Chemonics International achieved ISO 9001:2008 certification for its home office QMS, a unique distinction amongst international development companies.[1]

Chemonics' QMS spans proposal development to project management practices—the entire business cycle. Having an ISO 9001 approach in place at the company's home office meant the Kenya Pharma project could build on an established culture of entrepreneurship, employee ownership, systemization and continual improvement of best practices.

Chemonics currently implements more than 80 international development projects in 60 developing countries, working with donors such as USAID, the U.S. Department of Defense and the U.K.'s Department for International Development. In the company's $550 million USAID-funded Kenya Pharma project, Chemonics and its client, USAID, saw a unique opportunity.

Using ISO 9001 logically built on the approach for implementing the Kenya Pharma supply chain, which was based on employing private-sector, internationally recognized management practices that support supply chain operations to fight the spread of the HIV/AIDS epidemic in Kenya.

Implementation approach

The basics of how to build a QMS and obtain ISO 9001 certification are known across the quality industry:

- Document what you do—document control.
- Do it—product realization.
- Keep the proof that you've followed what you've documented—record control.
- Check to make sure you're doing what you documented and examine your work to make improvements and document them—measurement, analysis and improvement.
- Ensure your management team reviews progress, drives improvements and champions the system—management commitment.[2]

Chemonics' home office experiences also helped to provide a clear roadmap for implementing an ISO 9001-certified QMS. Often, however, the success of an implementation will hinge not on technical knowledge, but on the softer side of the equation. Effective change management, team ownership and executive commitment are equally—if not more—important. Ensuring the effort was grassroots and designed by and for the project staff was at the forefront of the approach.

On my first trip to Nairobi in early 2011, the Kenya Pharma team spent some time discussing what having a management system would mean

Check out the May episode of ASQ TV, which focused on supply chain management and the Kenya Pharma project. Visit **http://videos.asq.org/home** to see the entire May episode or the individual segment on the project.

JOSEPH ACHIENG, who lives in Kibera, a large low-income informal settlement in Nairobi, walks through a maze of footpaths and trenches to get to the Tabitha Medical Center to pick up his medication.

for the project. The quality policy the team developed—with its emphasis on the customer-focused result of an optimized, continually improving supply chain—says it all and carried the team through the entire process:

> Kenya Pharma is committed to using its ISO 9001 quality management system (QMS) to optimize a sustainable supply chain that provides commodities for prevention, care and treatment of persons with HIV/AIDS in Kenya. The goal of the Kenya Pharma QMS is to continually improve our ability to provide effective service and high-quality supplies to persons in need. We will do our job ethically and follow all statutory and regulatory requirements seeking to exceed our stakeholders' expectations. We shall always keep the welfare of our patients in mind, striving to add life to their days and days to their life.

In particular, three themes played a key role in the implementation process, making the project's ISO 9001-certified QMS a true operational foundation for the supply chain.

1. Play to your strengths. The Kenya Pharma project was operating with zero stock-outs—a rare feat in the developing world for a pharmaceutical supply chain. The project sought to take that quality and reliability of delivery, accuracy and cost-effectiveness to the next level. With clearly documented practices that staff adhered to repeatedly and were held accountable for, the project was able to get more from its margins.

For example, a notable innovation of the Kenya Pharma project from its onset in 2009 is its field service representative (FSR) model. FSRs operate throughout the country, serving a similar function to that of pharmaceutical sales reps: acting as customer service liaisons, but without a sales function. Their role is to regularly engage with each of the 169 ordering sites that the project serves to monitor the ordering and receipt process, receive feedback on expired or nonconforming product and provide advice on appropriate storage.

The percentage of orders received on time has increased from 61 to 78% due in part to the FSRs' work. In this way, the project improved on its already-effective services by using ISO 9001—paired with a strengths-based approach—to have the greatest impact for beneficiaries. Although the project was already strong, ISO 9001 brought the following advantages:

- The record control guidelines pushed the staff to reach the next level to institute records naming conventions and centrally store its records. This saved staff time in the long run by making these documents easier to find and making the staff's internal operations more efficient.
- It brought a level of formality to process management and improvement with a set vocabulary and rubric to put structure around what was already working well.
- It allowed staff members working at different points in the supply chain to understand each other's roles better.

2. Make it collaborative. The process of document-

ing supply chain practices was intensely collaborative. It was a cohesive effort among multiple teams at Chemonics, including our Washington, D.C.-based quality management unit (QMU) and Kenya Pharma project management unit (PMU), the Nairobi-based Kenya Pharma field office staff and two QMS specialists from our Washington, D.C., office, who spent months at a time working with project staff in Nairobi.

A smaller team was formed from within the Kenya Pharma field office staff to lead the process, supported by the QMU and QMS specialists with oversight and coordination from the PMU. All worked together to develop the project's quality policy, and supply chain process leads were assigned from among the project staff to take charge of designing their process documentation using tools, templates and trackers adapted from Chemonics' home office ISO 9001 implementation process.

Many interactive process mapping and process review sessions were held involving anyone who was part of a particular process—no matter how small his or her role might be. This provided some key benefits:

- Diverse perspectives were included, enhancing the accuracy and utility of the final product.
- Players from different parts of the supply chain—from quality assurance to quantification to procurement—were able to understand parts of the supply chain they had not necessarily been previously exposed to, fostering a deeper appreciation for each other's work along with empathy for the types of issues co-workers experienced.
- This collective learning opened the door for innovative suggestions for how to streamline supply chain operations.

Through this process, all were learning together. For example, those who knew ISO 9001 well were learning supply chain operations and vice versa. Everybody had a role to play.

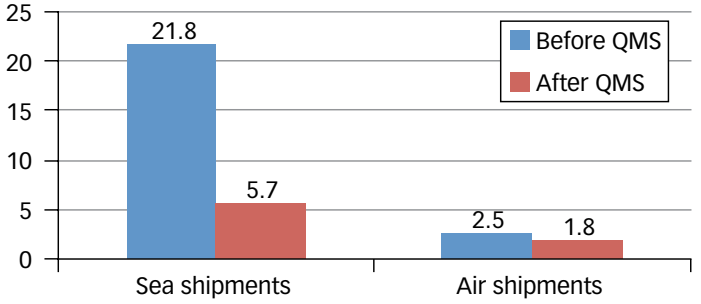
3. Results, results, results. As project staff documented processes, it was critical to keep the end in sight: the client, USAID, and the project's beneficiaries: the patients. The project's performance management plan includes 43 detailed output and outcome indicators across the supply chain, including customer satisfaction, quality assurance and transportation. These were purposely woven into each process and documented at the appropriate steps so staff has results and targets in mind as it executes processes.

Each indicator includes detailed instructions for data collection, processing and reporting, ensuring consistent monitoring and evaluation over time, and also for facilitating continual improvement of supply chain management and performance. Indicator data include definitions, units of measure, disaggregation types, management utility, data collection methods, data sources, cost to collect data, data acquisition schedules, limitations and formats for data presentation.

The project also adheres to World Health Organization (WHO) treatment guidelines and a series of industrywide technical standards in procurement, distribution and warehousing. These also were purposefully woven into the documented processes to ensure the supply chain and all of its industry and technical requirements were captured and reinforced by the QMS.

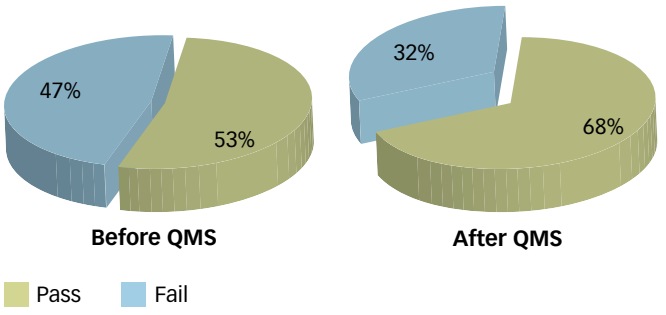
Using ISO 9001 requirements as an operational foundation for Kenya Pharma's supply chain was a strategic investment to holistically capture all aspects of the supply chain and serve as a playbook for staff and blueprint for success-

Pharmaceutical shipment: time to clear customs (in days) / FIGURE 2



QMS = quality management system

Results of health facility supply chain data quality audits / FIGURE 3



QMS = quality management system

How to use our QMS / FIGURE 4

Four steps to success

1 Follow processes

Make sure you are familiar with our process maps so we're all on the same page and clear about roles and responsibilities. Process maps embody best practices and proven methods for providing maximum value to our clients: USAID, SDPs, and ultimately, the Kenyan population touched by the Kenya Pharma supply chain.

2 Keep records

Each process map describes what records should be developed and kept. Records prove that our quality processes have been followed and provide historical documentation of our work on Kenya Pharma.

3 Participate in audits

There are two types of ISO 9001 audits: internal and external. Internal audits are conducted by a trained group of Kenya Pharma staff and are designed to identify process improvements and discover areas where we might not be following our processes or keeping records as our QMS specifies. External audits are conducted by our registrar, DNV. Our first audit to obtain our initial ISO 9001 certification will be this summer. The project will have periodic audits in the summer of 2013 and 2014. During both types of audits, you may be asked about the work that you do and your role on the project.

4 Suggest improvements

With our QMS, we now have a built-in mechanism to capture, assess and implement suggestions.

Corrective actions are submitted when you identify a problem with a business process or when you discover a trend that could be tied to one or more business processes.

Preventive actions are submitted when a business process is already functioning well, but you identify ways that Kenya Pharma can improve it or prevent potential problems.

QMS = quality management system
SDP = service delivery point
USAID = U.S. Agency for International Development

ful supply chain operations in the developing world.

This method, in turn, can be duplicated worldwide and potentially scaled up across diversified health commodities and pharmaceuticals that address issues such as malaria, tuberculosis, reproductive health, family planning and emerging pandemic threats, as well as equipment and medical supplies supporting lab services.

Reaping the benefits

In July 2012, DNV Business Assurance conducted the Kenya Pharma project certification audit, identifying no nonconformities. Richard Dreiman, Chemonics' CEO at the time, addressed staff, friends and partners at the certification celebration, emphasizing the real value of the process.

"The project was already operating with high standards of quality management even before seeking certification ... now we have an official, internationally recognized stamp of approval," Dreiman said.

He also noted the importance of Kenya Pharma as "one of the first USAID projects to become ISO 9001:2008 certified." The Kenya Pharma ISO 9001-certified QMS has created a robust foundation for supply chain operations—a home for the project's top-notch supply chain process documentation—which can be improved continually with the plan-do-check-act framework as part of the ISO 9001 approach.

The focus of ISO 9001 is on the customer—reinforcing and systematizing the Kenya Pharma quality policy—"…adding life to their [patients'] days and days to their life." On a daily basis, ISO 9001 helps ensure problems that do arise in the supply chain are systematically documented and addressed not only to correct an immediate issue, but also to gather data on larger trends impacting the project's ability to serve its customers through the corrective and preventive action process.

More specifically, integrating an ISO 9001 approach has delivered several key benefits for Kenya Pharma that will help lead to long-term successes:

Flexibility. Having used ISO 9001, it is possible to change supply chain operations more smoothly and quickly while maintaining consistency across the board. With ISO 9001 document control, and employee awareness and training requirements, the Kenya Pharma QMS provides a central system in which all work processes and change notifications are effectively captured. Process improvement becomes seamless, flowing through all aspects of the supply chain without the risk of being siloed.

This has been especially significant to Kenya Pharma because the project must be sensitive to policy shifts and regula-

tory requirements from external sources: WHO, USAID, the U.S. government and the Kenyan government. It can now push out information and updates faster to remote FSRs who work around the country and, in some cases, in very remote locations. Additionally, the Kenya Pharma supply chain has improved measurably in a number of other areas since the QMS implementation: The average time for sea and air shipments to clear customs decreased from 21.8 days to 5.7 days, and 2.5 days to 1.8 days respectively (see Figure 2, p. 23). The percentage of health facilities passing supply chain data quality audits increased from 53 to 68% (see Figure 3, p. 23), and significant improvement was seen in the project's performance in forecasting future costs to manage and operate the supply chain.

Sustainability. "We are focusing on ensuring that this operation is sustainable," explained Kenya Pharma Chief of Party Steve Hawkins. "Chemonics' model is 'build, operate and transfer.' ISO certification helps us achieve that model."

The resulting benefits from this process were not only to strengthen the supply chain against staff turnover and be malleable in the face of client shifts or changes at the global health policy level, but also to transfer supply chain operations to local Kenyan counterparts at project end in 2014. In effect, Chemonics was hired to work itself out of a job—a different context from what most businesses face, but one that we, as an international development company, encounter on every project.

This challenge has valuable lessons for any context. Design your system with these questions in mind: "Could I turn our supply chain over to someone else to run? Can I teach them how to do what I do?"

If the answers are yes, you can be confident in the sophistication of your QMS and knowledge that you have reaped the benefits of an ISO 9001 approach. Asking these questions and examining supply chain operations from this angle puts a fresh perspective on your business operations and ensures you develop a robust system that is attuned to the micro and macro features of your supply chain upstream and downstream.

Project culture. An anecdote shared by project staff in Nairobi—a team of about 40 people, all but two of whom are Kenyans—is that this process brought staff members together as a team and made them more invested in their work on Kenya Pharma. The continual improvement process created a culture in which everyone had a voice, was learning and had a role in innovating and improving. See Figure 4 for a condensed version of a handout used to educate team members about the QMS.

This effective teamwork could be seen from the beginning and in the launch week for the QMS. Launch week was constructed with each day having a theme—document control, record control, internal and certification audits and continual improvement. Every session was taught by a team of two people—one from our Washington, D.C. office and one from our Nairobi-based operations.

By the end of the week, it was important that the in-country staff members were the go-to people and viewed that way by their counterparts. Every session opened and closed with Q&A contest on material previously covered, with prizes for the winners.

And—most importantly—everyone from the receptionist to the project drivers to the project director participated. This strengthened the project's culture of inclusiveness—the softer side of business operations, which goes a long way in the end to achieving results. Kenya Pharma's management representative, Jackson Kariithi, said, "The process of rolling out and putting the QMS in place has created significant cohesion within the entire team. We now put quality at the forefront of our every activity."

For supply chains around the world, there's no question ISO 9001 will provide a solid backbone for capturing operational nuances. Operational efficiency is a challenge for any supply chain to effectively serve its customers and meet financial expectations. For Kenya Pharma, its quality anthem developed by project staff provides a testament to how interlinked quality is with the project's mission of delivering HIV/AIDS commodities to Kenyans:

Well, well, well, we're Kenya Pharma
Well, well, well, we're here to serve
Well, well, well, we're Kenya Pharma
Quality is our job. QP

REFERENCE AND NOTE

1. Tiffany Darabi, "Getting a Boost From Quality Tools," case study, ASQ, January 2012, http://rube.asq.org/2012/01/social-responsibility/quality-tools.pdf.
2. For a step-by-step guide to implementing ISO 9001, see John Orthaber's "Get Your Ducks in a Row," *Quality Progress,* October 2010, pp. 40-46.

TIFFANY DARABI is the director of the quality management unit at Chemonics International Inc. She has worked for Chemonics since the fall of 2003, spearheaded the development of Chemonics' ISO 9001-certified quality management system, and oversaw the Kenya Pharma ISO 9001 certification process. An ASQ member, Darabi holds a bachelor's degree in international relations from John Hopkins University in Baltimore.