

Introduction

The Pfizer Global Health Fellows Program is an international corporate volunteer program. Through the GHF program, Pfizer colleagues are paired with leading international development organizations in short-term assignments in key emerging markets designed to transfer their professional expertise in ways that promote access, quality and efficiency of health services for people in greatest need.

This annual essay collection illustrates how Pfizer's Global Health Fellows are working together with partner organizations in underserved communities to solve global health challenges.

To learn more about the Pfizer Global Health Fellows Program please visit www.pfizer.com/ghf.

The Importance of Animal Vaccines

GALVmed's role in underserved countries is helping to protect livestock and saving human lives and livelihoods, by making livestock vaccines, diagnostics and medicines accessible and affordable to the millions in developing countries for whom livestock is a lifeline. Healthier livestock can provide a pathway out of poverty and enhance food security. Livestock is a considerable, but often overlooked, economic driver in the developing world. GALVmed's goal is to create sustainable animal health systems that will allow rural livestock farmers to identify and diagnose disease outbreaks, access vaccines and administer treatments. These systems will improve the overall health and economic viability of these communities for years to comeⁱ. There is a simple truth for nearly 700 million of the world's poorest people: survival and prosperity are almost entirely dependent on the health of their livestock.ⁱⁱ

As a Supply Chain Fellow with GALVmed, I worked to strengthen all of the engineering-related quality systems including calibrations, preventive maintenance and commissioning and qualification systems in LANAVET Laboratories Cameroon. LANAVET is a government-owned facility responsible for making animal health vaccines for the Central and West African regions. To date, the facility manufactures a total of 19 different animal vaccines and one human vaccine. When the facility opened in 1981, it was equipped with all the usual good manufacturing practices (GMP) and systems. However, due to lack of adequate funding and resources these systems now no longer represent current manufacturing or quality assurance practices.

With funding from the European Union's VACNADA projectⁱⁱⁱ, GALVmed will develop manufacturing procedures and management capacity in eight animal health vaccine manufacturing laboratories in the African region including LANAVET. This is a very broad and ambitious program. The laboratories selected make vaccines for local and neighboring markets that are not generally manufactured in developed countries. The laboratories are located in Cameroon (LANAVET), Mali, Ghana, Senegal, Democratic Republic of Congo, Ethiopia, Kenya and Botswana. The project not only aims to re-equip the facilities with modern processing equipment but it also aims to train staff in current good manufacturing procedures (cGMP). This approach to improving the manufacturing side of each of these facilities will help to improve the standards and quality of the vaccines being produced. The real innovative thinking behind the VACNADA project is to train the laboratory staff in modern marketing and management procedures. It is envisaged that exposing the management staff to modern marketing techniques will enable the laboratories to expand their markets and increase revenue. The ultimate goal will be for each facility to become a commercially viable entity supporting larger market regions with the vaccines necessary to support livestock and subsequently improve livelihoods.

Quality Assurance and Quality Control Challenges in Vaccine Manufacturing Process

Through discussions with the staff at LANAVET, I learned that a lot of the key quality assurance systems and procedures generally associated with pharmaceutical manufacture are no longer effective; these systems would normally include maintenance, calibration, learning, quality investigation procedures, change control and batch records systems. The facility has a quality assurance department, but it isn't fully staffed or fully operational. In developed countries product manufacture is strictly controlled and well-documented, whereas at LANAVET and other laboratories in developing regions the normal manufacturing procedure for a batch of product is frequently completed from the memory of the operators, there are no records of batch manufacture with the exception of the documentation of the testing carried out on the final product. Quality control is often not as high a priority as you would normally expect from a pharmaceutical manufacturer. I observed instances of where sterility was compromised; cross contamination was a distinct risk and vaccine instability due to the storage and manufacture in extreme heat conditions. Any or all of these issues would make the efficacy of the vaccine by the time it reaches the end user questionable at best.

The problem is not that staff does not want to improve quality; they do, but lack of knowledge and available training combine with a lack of resources and adequate funding to make it very difficult for the facilities to improve without direct intervention from outside agencies such as GALVmed.

Manufacturing Process Issues Further Compounded by Other Key Challenges

Equipment maintenance and record keeping

One of the biggest problems facing manufacturing facilities is the availability of spare parts. The unavailability of something as small as an O-ring can render a piece of manufacturing equipment unusable and thus hinder production in the facility. The lack of detailed record keeping dramatically hinders the possibility of process improvement. In developed country markets, process improvement is usually driven by the need to reduce costs. Process improvements result in higher yields and increased quality of the final product, and this in turn increases availability of the vaccine to the market. It must be noted that it is extremely difficult, if not impossible, to implement production process improvements without detailed records of current processes that allow detailed review to identify inefficiencies and other problems currently limiting yield and compromising quality.

There is a lot of support being given to facilities in the region under the VACNADA project, and this support includes training of all levels, but when the project ends (August 2011) the training ends. Unfortunately this is one of the drawbacks of the VACNADA project in that it is of fixed duration, which is not a problem for the equipment side of the project but training really needs to be recurring with metrics in place to measure the effectiveness of what skills are being transferred.

Supply chain issues

Cleverly, the LANAVET laboratory was established in the northern region of Cameroon, which is near enough central to where a lot of the family livestock for Cameroon, Chad, Congo and Nigeria are located, thus somewhat simplifying the supply chain for the vaccines. However, the vaccines are transported by road and the road network is in such poor condition that delivering the vaccines results in a significant amount of losses due to damage.

Distribution of vaccines

Animal vaccines are vital to maintaining both animal health and human livelihoods, but the lack of qualified veterinarians is a barrier to distribution. In Cameroon, for instance, an animal vaccine can only be purchased, delivered or sold by a veterinarian. The limited number of veterinarians severely restricts the availability of the vaccines to the local farmers. I have observed that some vaccines can be found at a local market but these would be considered as unsafe or ineffective due to the storage and display conditions.

Key Learnings

Collaboration between laboratories in Africa

[Pan African Veterinary Vaccine Center of the African Union \(AU/PANVAC\)](#)'s^{iv} mission is to improve quality and coordinate vaccine production between countries of the African Union. This organization has been in existence since 1983 but to date hasn't really been that successful mainly because of lack of funding, communication and clear direction. Through renewed funding from the European Union and the African Union, PANVAC is making greater efforts to standardize the quality, training and manufacturing procedures in African Union countries^v. It is also helping to improve communication between laboratories so that they can share expertise and experience. PANVAC also carries out additional quality control on the vaccine products from the different laboratories; this helps to facilitate the sale of vaccines to countries outside the country of manufacture.

The collaboration of laboratories through the PANVAC organization will be a big step forward for manufacturing and quality operations in the African Region. It is envisioned that it will help standardize manufacturing, quality control and quality assurance practices and procedures by utilizing a more efficient communication network and a philosophy of mutual support between the participating laboratories. I believe standardizing the production methods and improving quality using industry "best practices" will allow for a far greater supply of these vaccines. The vast majority of these diseases has been eradicated or don't occur in developed countries. Therefore it is not profitable for the pharmaceutical industry to manufacture vaccines or medications for their treatment.

Better training vs. better technology

Using highly technological pieces of equipment in the developing world does not help in the vast majority of situations because of the lack of suitable resources. There is not enough knowledge and material to run and maintain this type of technological equipment. I have seen many examples of new equipment just sitting idle because people don't fully understand how to use it, or they can't get a spare part. Vendors should provide training when they are supplying equipment to the developing market but unfortunately the training is not effective in many cases. Sustained, recurrent training of laboratory staff would be the key solution to improving quality and efficiency within labs. A clear business plan would enable progressive goals and metrics to be introduced to monitor progress and allow for growth, profitability, and sustainability of the supply chain industry itself. Long-term training would enable facilities to become self-sufficient commercial enterprises and allow them to cut their bonds to the relevant government funding. In the long term, once the laboratories become commercially viable they can reinvest profits back into their own facility thus further increasing sustainability.

Equal standards for developed and developing countries

One of the more frustrating observations that I have encountered several times during my fellowship is that companies who operate in both the developed and developing markets tend not to deliver the same quality of service or product in the developing world. While standards are sometimes much lower, this is not reflected in the cost of goods or services which remain expensive. Unfortunately, this is an easy way for the supplier to make a profit from the local facility and in many cases the facility's staff do not complain since they do not have sufficient experience or knowledge to deal with the situation. Corporate governance and responsibility really needs to play a part in stopping this practice. Companies doing business with developing countries should be reminded of professional etiquette, moral code of practice and not take advantage of situations in search of greater profits.

ⁱ <http://www.galvmed.org/about-galvmed>

ⁱⁱ <http://www.galvmed.org/why-livestock>

ⁱⁱⁱ http://ec.europa.eu/europeaid/how/finance/documents/eidhr/action-fiches-3_en.pdf

^{iv} <http://centaur.vri.cz/news/prilohy/pril735.htm>

^v <http://www.africa-union.org/root/au/memberstates/map.htm>