
New Challenges for Global Clinical Trials: Managing Supply Logistics in an Expanding Clinical Trial Universe

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Introduction

Under pressure to jumpstart productivity and reduce the time and cost of shepherding new drugs from laboratory through licensure, the biopharmaceutical industry began aggressively globalizing clinical trials about 15 years ago. Lured by lower research expenses, rapid patient recruitment and the opportunity to establish footholds in developing markets, the migration of studies to countries such as China, India and Russia proved to be a resounding success. Today, half of all clinical trials are conducted offshore and in more developing countries than ever before, profoundly increasing the complexity of supply chain logistics.^{1, 2}

Emerging markets in Asia, Latin and Central America, the Middle East, Africa and Eastern Europe -- many of which didn't make the short list for trials in the past -- are fast becoming sought-after study locations. Their newfound popularity comes at a time when drug development costs are higher than ever and competition is emerging from some of the very markets to which trials migrated nearly two decades ago, primarily China, India and even Korea.^{3,4,5,6,7,8,9,10}

ClinicalTrials.gov, the registry of clinical trials in the United States and around the world, documents the ongoing shift. In late 2012, the website listed more than 136,000 clinical trials taking place in 181 countries, a number that has been climbing steadily. About 40% of clinical trials took place in emerging nations of Asia, Latin America and Africa in 2012.²

While an enlarged clinical trial universe certainly benefits patient recruitment and diversity, it also multiplies the operational and strategic obstacles that clinical trial professionals must circumvent:

- In addition to inexperience in conducting trials and differing quality standards, there are wide spread differences from country to country in Customs knowledge, experience and laws.
- Many developing countries are also evolving Regulatory requirements about the conduct of clinical trials and protection of research subjects.

Introduction (continued)

- Other challenges include the need to manage logistics complicated by countries with limited infrastructure, especially outside major cities. The growth of studies testing temperature-sensitive biologics with special handling and transportation needs presents additional logistical challenges across the supply chain.
- Finally, there are regional idiosyncrasies -- differences of language, both spoken and unspoken, working patterns, culture and religion -- that add another layer of complexity. While challenging, none of these obstacles is insurmountable. Navigating them successfully, however, requires a well-defined, sustainable process capable of mitigating risk from the beginning to the end of the supply chain.

Fisher Clinical Services, a recognized leader in supply chain management, is exclusively focused on serving the packaging and distribution requirements of clinical trials across the world. In addition to having the largest global footprint in the clinical supply chain industry, Fisher Clinical Services continuously invests in facilities, technology, people and training across the world. This paper discusses the challenges of conducting clinical trials in emerging markets and how to navigate them.

New Challenges for Global Clinical Trials

The Escalating Cost of Drug Development. The globalization of clinical trials began as a prescription for stagnating output and rising research and development (R&D) costs. Some 15 years later, those same economic pressures continue to plague the biopharmaceutical industry.

Factoring in failures, the average capitalized R&D costs per new drug and biological product licensed between 1980 and 2008 exceeded \$1.2 billion, according to the Tufts Center for the Study of Drug Development. This compares to a previous Tufts estimate of \$900 million. ⁴

THE HIGH COST OF FAILURE

Development costs for New Molecular Entities (NMEs) and Biological products approved between 1980 and 2008:

	DIRECT COSTS (\$US Millions)		CAPITALIZED COSTS (\$US Millions)	
Basic Research through Preclinical	\$60	17%	\$186	15%
Clinical through Regulatory Approval	\$109	34%	\$189	15%
Allocated Failures	\$166	49%	\$866	70%
Total per Approved Drug	\$335		\$1,241	

Source: Tufts Center for the Study of Drug Development at Tufts University



Multiple factors are responsible for the escalating per-drug price tag. Among them are increased regulatory requirements for licensure and for recruiting across a broad range of patients.

Another significant element, however, is double-digit growth in the number of studies for biological products requiring controlled temperature conditions during shipment and storage. The economics associated with the complexity, manufacturing and clinical

New Challenges for Global Clinical Trials (continued)

development of biologics makes these products significantly more expensive to develop than small-molecule therapies. More than a third of Fisher Clinical Services' projects, for example, involve controlled-temperature products, a proportion that continues to rise.

A CHANGING GLOBAL FOOTPRINT: THE EVOLVING CLINICAL TRIAL MARKET. As drug development costs escalate, so do the number of emerging markets that are hosting clinical trials. In 2012, as many as 4 out of 10 clinical trials were conducted in emerging nations of Asia, Latin America and Africa.²

The uptick in the number of emerging markets with clinical sites is a consequence of both the continued high cost of drug development and a competitive evolution.

In the years since they became favorite locations for clinical trials, China and India established global reputations as generic drug producers. Now both are poised to compete with U.S. and European companies for a share of the global biosimilars market, which is projected to reach \$26.8 billion by 2022.^{3, 4, 5}

New competitors hail from other sectors and countries, one of which is Korea. Korea is rapidly establishing a nascent biopharmaceutical industry that intends to compete in Asia, Europe and South America. To compensate for their biopharmaceutical inexperience, some Korean firms are partnering with established American and Japanese firms.^{8,9,10}

As global competition grows, the migration of trials to new corners of the world is altering the global clinical trial footprint:

- China & India. It is no surprise that each has experienced robust growth in the last five years, a period during which they were crowned the most desirable sites for clinical trials, according to consulting firm A.T. Kearney.¹ China experienced a 28% growth rate per year, while India enjoyed a 25% annual rate of growth.² In actions aimed squarely at the biopharmaceutical industry, China and India have each

New Challenges for Global Clinical Trials (continued)

created Free Trade Zones. Establishment of these zones permitted the countries to simplify import/export procedures, thus attracting greater shares of manufacturing and distribution businesses as well as foreign currency. Now these Asian powerhouses are widely perceived as established, rather than emerging, markets with their own biopharmaceutical infrastructure, proprietary products and substantial export muscle.³

More than 50 Chinese companies are producing or planning to produce biosimilars, while in India 10 companies are already marketing dozens of biosimilars. Among the latter are agile global players: Dr. Reddy's Laboratories, Biocon, Zydus, Cadila, Cipla and Ranbaxy, a majority share of which is owned by Japanese drug maker Daiichi Sankyo.^{3,4,5}

Both countries also continue to be among the leading destinations for clinical trials, something that is unlikely to change in the near future.

- Other Asian nations. Asia topped the list of regions in which clinical trials are expected to grow the most, based on an informal poll conducted by Fisher Clinical Services. Countries that had been minor players in clinical trials are expected to grow the most, among them the Philippines, Taiwan and Japan.
- Although Japan can hardly be classified as an emerging market, it was not a common site for global clinical trials until recent years. Previously, country specific protocols and procedures were required. However, in recent years new regulations facilitated the inclusion of Japan in global protocols. In addition, Japan has become more accepting of conducting clinical trials. The inclusion of Japan in global studies can go a long way to helping biopharmaceutical companies reduce costs and bring products to market faster. It is also worth noting that many Japanese biopharmaceutical

New Challenges for Global Clinical Trials (continued)

companies are choosing to run global trials in other parts of Asia.

- Latin American & Central America. These regions have enjoyed tenfold growth since 2000, largely due to significant economic advances made by countries such as Brazil, Mexico, Argentina and Colombia.
- Middle East & Northern Africa (MENA), excluding Israel. A relatively small number of trials took place in MENA five years ago. In the coming decade, however, tenfold growth in clinical trials is expected. Turkey, Egypt, Jordan and Lebanon, as well as Israel, are gaining popularity as locations for clinical trials. In addition to offering large patient pools for the study of many infectious diseases, government-sponsored research facilitates unique types of trials in Sub-Saharan Africa. South Africa in particular is well established for clinical research and is often used as a gateway to other African countries.

Although these countries have become attractive sites for clinical trials for many reasons -- including ready access to patients for key indications, such as heart disease -- they are indisputably in a learning phase with respect to the conduct of clinical trials.

Strategies to Address Operational Challenges

The continued globalization of clinical trials has precipitated a spike in the operational and strategic obstacles faced by clinical trial professionals. These challenges include a rising volume of global clinical trials of greater logistical complexity, shorter study start-up times and escalating regulatory pressures, as well as the imperative to focus on better, more strategic utilization of resources to minimize costs.

Let's take a closer look at some of the challenges facing clinical trial professionals and strategies for addressing them.

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The Changing Regulatory Environment

The Changing Regulatory Environment

Faced with a sudden influx of clinical trials, many emerging markets are addressing the need to establish or evolve Regulatory infrastructures.

- *Some emerging markets are developing Regulatory structures, often for the first time.*
This includes establishing laws about every aspect of trials, from the process of obtaining approval for initiating trials locally to those aimed at safeguarding research subjects. China, Turkey and the Philippines are among countries that are in the process of developing regulatory structures.
- *Many such countries are adopting U.S./European standards.*
The shift toward global alignment of controls and standards is good news for clinical trial professionals responsible for managing global trials involving dozens of countries across multiple regions. India is an example of a country moving toward global alignment.
- *A handful of nations have no Regulatory requirements or requirements that are inadequate. In some cases, these countries are adopting laws that are unique to them.*
The absence of laws or enactment of unique requirements impact supply chain logistics by increasing the challenges of managing trials. Here are examples from three regions of the world:

The Changing Regulatory Environment (continued)

- *Turkey: No process for granting GMP licenses*
Although Turkey has been a desirable location for clinical trials for some time, its Regulatory structure is still under development. For example, Turkey neither requires distribution facilities to hold Good Manufacturing Practice (GMP) licenses, nor has a process by which depots can request and obtain GMP certificates. In 2010, however, government officials impressed with what they saw during a visit to a regional depot in Istanbul, subsequently issued a Good Manufacturing Practice (GMP) certificate to that facility. This caused a perception that competitors were not on equal standing until they too secured GMP certificates. The story has a happy ending in that it led to improved quality standards at all Turkish facilities handling clinical trial materials.
- *Taiwan: No export of leftover trial materials*
In 2011, the Taiwanese government approved a new regulation mandating that all clinical trial materials remain in the island nation during the entire duration of a study. At the same time, authorities ceased issuing export licenses, which meant that all returned Investigational Medicinal Products (IMP) had to be destroyed in country. Supply chain managers were faced with an immediate need to arrange storage and destruction of leftover drug at substantial additional cost.
- *Costa Rica: No clinical trial law, no new trials*
Until recently, clinical trials were conducted in Costa Rica under standard pharmaceutical law. In 2012, however, Costa Rican authorities announced that no new clinical trials would be permitted to begin until a clinical trial law was enacted. This effectively put an end to plans for conducting additional trials in Costa Rica. Clarification is expected in 2013 on a clinical trial law that will permit new studies to begin in Costa Rica. One major pharmaceutical company, confident that this will happen, has recently opened a depot there.

The Changing Regulatory Environment (continued)

The following steps are recommended for remaining current on changing Regulatory requirements and ensuring that those requirements are met:

- Establish & maintain a knowledge database. This repository should contain up-to-the-moment information about Regulatory requirements for clinical trials in every country. Beyond mere Regulatory requirements, the database should reflect real-life experience and intelligence, much of it provided by personnel on the ground in local markets.
- Rely upon a cadre of local partners & staff. Carefully vetted local partners and in-country staff are among a supply chain professional's greatest assets. In addition to speaking the local language and providing hands-on support, they maintain key relationships with Regulatory and Customs officials while keeping the knowledge database current. Local partners and staff can also provide early warnings about proposed or impending changes that can impact clinical supply logistics and budgets.
- Establish & engage reliable information sources. It's critical to cultivate and maintain relationships with Regulatory bodies via frequent email, phone and – where appropriate – face-to-face interactions. Regular monitoring of Ministry of Health resources, particularly websites, is also recommended. In Belize, for example, the Ministry of Health website includes up-to-date guidance on Regulatory requirements.
- Distinguish between legislation, requirements & expectations. Consider what is required from a legal perspective versus what is expected, but not absolutely necessary. Some countries are flexible so long as patient safety is not compromised.
- Know import license requirements & how to meet them.
 - Is a single or umbrella license required? Is it for multiple use?
 - For how long is the license valid?
 - Are there restrictions regarding import license applicants?
 - May only certain parties, such as the sponsor company, submit applications for license approval?

The Changing Regulatory Environment (continued)

In other words, who is responsible for doing what and when? A clear understanding of roles and responsibilities is essential to avoid confusion, redundancies, mistakes and delays.

- Re-confirm everything in advance. Going the extra mile to re-confirm arrangements and details may appear to be overkill, but doing so prevents last-minute surprises and provides peace-of-mind. Clearing clinical trial materials through Customs requires substantial advance preparation, including a thorough knowledge of the laws, proper documentation and a clear and well-defined process.

Differing Customs Requirements

Despite the substantial progress being made toward global regulatory alignment, Customs requirements continue evolving and may differ significantly amongst even neighboring countries. The following steps are recommended to avoid Customs chaos.

- First and foremost, establish a clear process. A well-defined process agreed well in advance of shipping clinical trial supplies is the top recommendation for avoiding Customs delays. The more parties involved in the trial, the greater the need for the sponsor to make the process as transparent and seamless as possible.
- Understand the role of Importer of Record. The Importer of Record (IoR) is a legal entity responsible for ensuring that imported goods comply with local laws and regulations, filing completed duty entry and associated documents, and paying assessed import duties and other taxes on these goods. However, the role of the IoR varies from country to country; in some, the sponsor is the only entity that can assume the role of IoR, while in others, the IoR can be a third party, such as a Clinical Research Organization (CRO) or a distributor. That's why it is important to understand the role of IoR in every country to which clinical supplies will be shipped. In many cases, this will form part of the tax strategy and the IoR will be able to reclaim tax on behalf of the Sponsor.
- Ensure that documentation includes required details. Necessary documentation often includes invoices pro-forma or commercial -- the Certificate of Analysis and Origin Certificates. Such documents must detail all of the information required by Customs.

Differing Customs Requirements (continued)

The following should be kept in mind:

- In many developing countries, Customs officials require original documents. Whenever possible, provide original documents printed in color – this avoids the appearance of photocopies – and bearing an official stamp where appropriate.
- Before shipping materials, consider seeking pre-approval of documentation with the importer or Customs broker.
- Include a precise value for CT materials on the invoice; a rounded-up number could draw the attention of Customs officials by appearing to be an arbitrary value.
- Have a Certificate of Analysis available for any and all comparator product. Include as much information as possible so Customs officials know exactly what materials are included in the shipment, particularly when the shipment contains commercial drugs.
- Include details about proposed packing materials, particularly for biological products. For example, if plans include the use of insulated shippers with temperature monitors, inform Customs officials in advance so they understand the need to maintain materials in original packaging during transport and storage.
- Bear in mind the importance of Origin Certificates for trials being conducted in Arab countries. These documents are required in order to prevent importation of materials of non-approved (i.e. Israeli) origin. A further note: Gelatin-coated tablets or gel caps are not used in Muslim countries because they contain pork byproducts.

Differing Customs Requirements (continued)

- Make Customs officials aware of the importance of clearing materials promptly. It may be worthwhile to brief and/or educate Customs officials in advance. In fact, educating everyone along the supply chain, from Customs officials to the staff at third-party depots, is well worth the effort. In the developing world, individuals who play roles in clinical trials are eager to learn and especially appreciate the opportunity to feel that they are part of the team. Visits, briefings and sharing of best practices and standard operating procedures (SOPs) are welcomed. Fisher Clinical Services has hosted visits of Chinese customs officers at its Beijing facility, where these appreciative guests learned about their roles in the testing and development of new medicines and vaccines. This practice is sometimes referred to as “network recognition” – that of ensuring in advance that everyone involved in the supply chain knows what materials are expected, how they are packed and their temperature and handling requirements.
- Know the export rules before importing. Note restrictions about returns and destruction of IMP, which differ amongst countries. Consider, for example, Taiwan’s prohibition on export of unused trial materials. Clinical sites neither have the desire nor the resources to deal with excess trial materials. Restrictions about returns and destruction exert additional pressure on sponsors to accurately forecast the quantity of drugs needed for each clinical trial, thereby minimizing waste.

Infrastructure Issues

A key advantage of conducting clinical trials in emerging countries is ready access to the patients for whom drugs are being developed. Egypt, for example, has an aging population with a high incidence of cardiovascular disease, obesity, cancer and hepatitis C.

However, many sponsors underestimate the challenges of conducting trials in countries whose underlying infrastructure, particularly outside major cities, is inadequate. Considering a country's infrastructure should be a major part of the trial planning process, especially if clinical sites are widely scattered.

- In Argentina, for example, about 75% of clinical trials take place in Buenos Aires, a capital city with a well-developed infrastructure.
- In steamy sub-Saharan Africa, clinical trials may be conducted from mobile units located outside major cities. The supply chain must be closely managed here due to the climate and study sites' general lack of experience in handling trial materials. Due to the inexperience of some distributors, it may make sense to establish a "hub model." In a hub model, a distribution facility located in one country services the needs of many other countries. In addition, the creation of an "air map" outlining distance and delivery time from the central hub to outlying countries, and the creation of a central database of import rules can prove invaluable.

The following measures can help ensure that trial materials are delivered to clinical sites safely and on time in countries with infrastructure concerns:

- Partner with & continuously train suppliers. Work closely with local suppliers to develop their capabilities by providing guidance and training on storage, handling and transportation of temperature-sensitive trial materials from receipt through dispatch and final delivery to patients. Virtual training is an option should face-to-face

Infrastructure Issues (continued)

instruction prove impractical. Importantly, ongoing training may be necessary due to staff turnover.

- Establish durable standards. Set standards that must be adhered to along the supply chain so trial materials are delivered on time and in full. This could mean, for instance, agreeing optimum delivery times with sites so they are prepared to accept delivery at specified times. Stress the importance of patient safety to all concerned. In some countries, such as those of the former Soviet Union, individual clinical sites are dedicated to a particular indication, such as cancer or cardiovascular disease.¹¹ Over time, strong links are typically established between sponsor, distribution partner and investigator site. Deliveries should be scheduled at times that suit the sites and coincide with planned recruitment volume. In other locations, such as North Africa and Asian countries, direct-to-patient distribution is an accepted route for trial materials. However, a high-touch service is often necessary -- and may require a technology investment -- to encourage patient compliance throughout the trial.

Technology/Data Management

Constant visibility is the single most essential element for an integrated supply chain. Maintaining 24/7 visibility across dozens of emerging markets requires a combination of tools, technology and a conscientious team around the clock in every region of the world.

Here are some recommendations for establishing -- and maintaining -- and integrated supply chain:

- Technology for tracking, tracing & monitoring. Thanks to the use of automated technology, much of it pioneered by other industries, it is now possible to achieve visibility, control and compliance across the supply chain. Some examples include: Interactive Voice Response (IVR) Technology, providing 24/7 transparency for study enrollment and clinical supplies; and bar coding and global positioning system (GPS) technology to track shipments from transit through delivery. With more cold chain products in development, technology to constantly monitor shipments and prevent temperature excursions from occurring is used widely.
- Customer Service Departments at local offices. Technology notwithstanding, nothing substitutes for local people on the ground with the knowledge, training and contacts necessary to intervene when trial material is in danger of going off-course -- a missed plane, customs delays, closed roads due to inclement weather. Customer service personnel provide ground support in them most remote regions, marshaling technology to maintain constant communication and to proactively track and trace shipments from dispatch to delivery. ²

Technology/Data Management (continued)

- Objective Performance Metrics. The use of technology to collect data and objectively analyze performance metrics de-risks the supply chain by enabling selection of shippers, couriers or even routes based on individual strengths and track records. In this way, for instance, the courier most suited to transport temperature-sensitive materials to Argentina receives this assignment, not a courier whose strength lies in continental Europe or Asia.
- Consistent interaction & training. Frequent communication and training on SOPs and best practices are among the most effective ways to ensure that everyone works as a team to deliver product in good condition to patients on time. Compressed budgets have prompted an increase in the use of virtual training, as well as training via Skype, videoconference and telephone. It is worth noting that the quality of telephone technology differs widely around the world. In Africa, for example, mobile phones are more reliable than land lines.

Regional Idiosyncrasies

Regional idiosyncrasies are among the greatest challenges in developing nations, where language differences are merely the most obvious of obstacles. Research can help avoid costly missteps, miscommunications and misunderstandings.

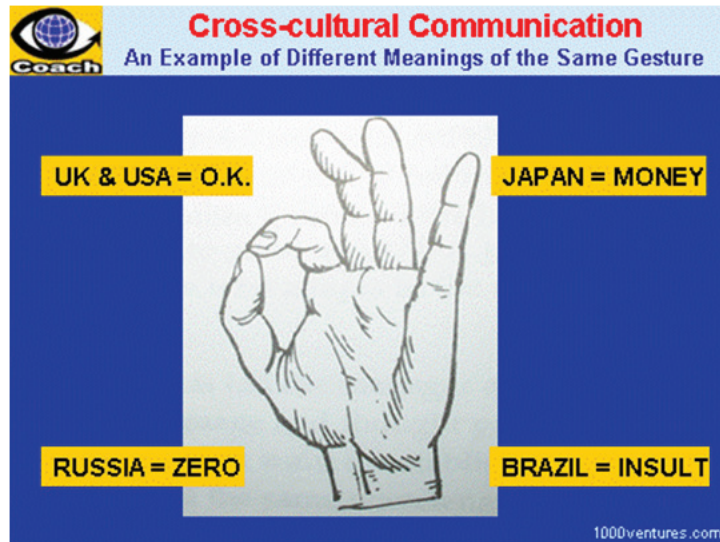
Here are some obvious and not-so-obvious issues about which to be aware.

- Language – Communicating with individuals who speak different languages can present obvious difficulties, potentially slowing processes along the way. Consider Russia, for example, where residents of Moscow and St. Petersburg may speak proficient English, but citizens living outside such major cities may not. The same circumstances exist in other countries, so it can be valuable to keep the following precautions in mind.
 - Predict and plan for delays along the way. Be prepared to invest additional effort when communicating along the supply chain to ensure an optimal outcome.
 - Whenever possible, go beyond mere words by providing visual instructions or preparing an instructional video as guidance for specific packaging instructions, for example. Visual instructions or a video can go a long way in compensating for language shortcomings.

Regional Idiosyncrasies (continued)

- Communication Styles – Even when individuals speak proficient English, there are instances in which the same word or phrase conveys different meanings. It is helpful to be knowledgeable about styles of communication from one country to another.
 - In Japan, for example, where it is culturally unacceptable to say “no”, common use of the expression “it is very difficult” in response to a request or question is equivalent to a polite denial.
 - Russians, known for their forthrightness in expressing themselves, rarely ask questions, even when they are not sure they understand what has been said.
 - In Latin America, it is common for 15 minutes of casual conversation -- about family, education, employment history, and accomplishments -- to take place before a business matter is discussed. Importantly, the Latin American contact must be the one to shift the conversation to the topic of business.
- Non-Verbal Communication – Aside from words, we all communicate in many non-verbal ways using looks, expressions and gestures. How we do so differs from country to country. Be aware, for example, that the same hand gesture can have vastly different meanings depending upon the country.

Regional Idiosyncrasies (continued)



- Holidays & Religious Observances – Working globally requires awareness, appreciation and respect for the calendar of events in each country. Christmas is an example of a holiday that is celebrated internationally, but on different days depending on the Christian denomination. December 25th is a public holiday for the celebration of Christmas in many countries, including the United States and United Kingdom. However, it's important to bear in mind that about 200 million Orthodox Christians around the world celebrate Christmas on or near January 7th. In some countries, businesses are closed on Christmas Eve or December 24th. Some are closed for an extended period of time during the holiday season. For example, many U.S. biopharmaceutical companies remain closed from Christmas Eve through New Year's Day. Of course, Christmas is not a universal holiday. Christmas is not celebrated in some countries, including Muslim nations, Israel and the People's Republic of China. Christmas is but one holiday among many. It's important to be aware of other holidays or religious events -- including but not limited to Ramadan and Chinese New Year -- during which businesses may be closed all or part of the time. During Ramadan, for example, people may work but only in the morning.

Regional Idiosyncrasies (continued)

- Working Patterns – It is also important to understand the differences between working patterns in various parts of the world. In the Middle East, for example, companies work through the Western weekend of Saturday and Sunday. For most Israelis, the work week begins on Sunday and ends on Thursday or Friday at noon to accommodate the Jewish Sabbath, which begins Friday night. Thus, it may be necessary to have staff available during Western weekends to accommodate business being transacted in these countries.
- Engaging with People – When conducting business in developing countries, one should understand the style of manner in which people engage. This is particularly important in countries with hierarchical structures. One such country is Japan, where people expect to conduct business with those at the same level. It often takes time to establish credibility, but consistent and professional communication will win acceptance and result in a positive working relationship moving forward.

Differing Quality Standards

Quality standards are increasingly global, with most developing countries adopting those of the European Union or the United States. While the rules may be identical, however, the manner in which they are implemented can vary widely in and across countries.

It is worthwhile noting the necessity of observing both clinical trial laws and any local regulations. Here are some suggestions about maintaining quality standards in emerging markets.

- Establish and operate to GMP and Good Distribution Practices (GDP) standards, demonstrating consistency and adapting locally as appropriate. Such international standards are welcomed by personnel in local facilities, who frequently work hard to over-achieve them.
- Maintain a global quality standard, by training and developing suppliers, sharing best-practice expertise on GMP/GDP standards, and providing guidance and processes.
- Engage everyone, including brokers and couriers, to maintain a global quality standard. Quality is an ongoing commitment requiring the cooperation of the entire team to ensure maintenance of high standards.
- Empower all partners to work to GMP/GDP standards by including them in training. Training helps secure the supply chain by making all team members aware of what constitutes proper handling through shipment and delivery.
- Once procedures and standards are in place, continue to validate. Continue conducting due diligence, validating performance over time to ensure that procedures and standards are being followed and that local staffs appreciate the need to continue to do so consistently.
- Periodically re-train new -- and retained -- staff. Staff can turn over frequently in some countries, among them India, and retained staff can always benefit from refresher training.

Rules of Success

RULES FOR SUCCESS: WORKING IN THE DEVELOPING

WORLD. Once again, overcoming the challenges of conducting clinical trials in emerging markets requires a well-defined, sustainable process that mitigates risk from beginning to end.

Here are some guidelines about putting that winning process in place:

1. Know the local requirements: Establish a knowledge database -- reflecting regulatory requirements, real-life experience and intelligence gathering -- and keep it current with information and insights from local staff.
2. Prioritize relationship management: Cultivate and maintain relationships with regulatory authorities and local partners, who can help navigate issues that arise.
3. Plan for local infrastructure: Allocate extra time for infrastructure-challenged locations, particularly during inclement weather, and consult local partners who know the geography.
4. Help partners develop: Training and education are investments in people, performance and the pride of doing a job properly. Personnel who feel like they're part of the team usually act the part.
5. Consider the culture: Communication is more than mere words, and communicating effectively can achieve superior results. Research local customs and communication styles before plunging in and demonstrate respect at all times.
6. Provide the standards and processes: Establish high global standards, sharing SOPs and best practices to help staff and partners achieve and maintain them.
7. Maintain visibility of the supply chain: Marshal every resource -- tools, technology and a conscientious team -- to maintain supply chain visibility 24/7. Constant visibility is the single most essential element for an integrated supply chain.
8. Create contingency plans: Contingency planning is a good rule for life. Confirm everything, anticipate what could go wrong, and identify options -- every time.

More about Fisher Clinical Services

For more than 20 years, Fisher Clinical Services has exclusively focused on serving the packaging and distribution requirements of clinical trials across the world. As clinical trials require increasingly complex supply chain support, our purpose-built integrated facilities provide the global presence, information systems, and flexibility to allow unparalleled visibility and control of GMP activities from protocol design through to the investigator site. Our professional teams bring unsurpassed experience to the challenges associated with supporting clinical trials today. With exposure to large multinational trials and thousands of protocols every year across all therapeutic areas, Fisher Clinical Services has developed the industry's best practices in clinical supply chain management.

Fisher Clinical Services is a part of the BioPharma Services Division of Thermo Fisher Scientific, the world leader in serving science, enabling our customers to make the world healthier, cleaner and safer. With annual revenues of \$10 billion, we have more than 30,000 employees and serve over 350,000 customers within pharmaceutical and biotech companies, hospitals and clinical diagnostic labs, universities, research institutions and government agencies, as well as environmental and industrial process control settings.



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References

1. A.T. Kearney; http://www.atkearney.com/health/ideas-insights/article/-/asset_publisher/LCcgOeS4t85g/content/make-your-move/10192
2. ClinicalTrials.gov -- <http://clinicaltrials.gov/>
3. Health Research Policy and Systems; “Emergence of biopharmaceutical innovators in China, India, Brazil, and South Africa as global competitors and collaborators;” Rahim Rezaie, Anita M McGahan, Sarah E Frew, Abdallah S Daar and Peter A Singer*; <http://www.health-policy-systems.com/content/10/1/18>
4. Tufts Center for the Study of Drug Development press release: “Drug Company Executives Are Expanding Their Use of Strategic Partnerships”; http://csdd.tufts.edu/news/complete_story/rd_pr_january_2012
5. White paper -- Shaping the biosimilars opportunity: A global perspective on the evolving biosimilars landscape; IMS Health, December 2011 http://www.imshealth.com/ims/GlobalContent/Home%20Page%20Content/IMS%20News/Biosimilars_Whitepaper.pdf
6. Report on Biosimilars and Follow-on Biologics: World Market 2012-2022, www.visiongain.com
7. “Chinese Biosimilar Market,” Biosimilar News, August 15, 2011; <http://www.biosimilarnews.com/chinese-biosimilar-market>
8. Press release “Samsung Biologics and Biogen Idec announce formation of biosimilars joint venture Samsung Biopis, Feb. 27, 2012; http://www.biogenidec.com/press_release_details.aspx?ID=5981&ReqId=1666325
9. Press release “Establishment of Fujifilm Kyowa Kirin Biologics: Joint Venture of Fujifilm and Khyowa Hakko Kirin for the development, manufacturing and sales of biosimilars, March 27, 2012; <http://www.fujifilm.com/news/n120327.html>
10. “World’s first biosimilar antibody approved in Korea,” Biosimilar News, July 23, 2012; <http://www.biosimilarnews.com/worlds-first-biosimilar-antibody-is-approved-in-korea>
11. McGee, Patrick, Drug Discovery & Development, Vol. 9, No. 6, “Clinical Trials on the Move,” June 12, 2006; <http://www.dddmag.com/clinical-trials-on-the-move.aspx>