

## Medical Device Regulation in China and the US: A Comparison and A Look Forward

Spring Sun  
*Stanford University*

### Abstract

This paper explores the history and development of medical device regulation in both the United States and China. Through a detailed investigation of the path each country undertook to arrive at its current state of medical device regulation, it reveals the political and societal barriers each encountered and how these barriers forced regulation in the two countries to develop in two different ways. Due to situational and cultural circumstances, both countries have reacted to both domestic and international stimuli in some very similar and other vastly different ways. Strengths and weaknesses of the regulatory policies and agencies that have emerged in reaction to these stimuli are evaluated in hopes of revealing how much influence situational circumstances have upon a fundamentally identical technology. Ultimately, we formulate a critical understanding of what must be required for China's medical device industry to "catch-up" to international expectations.

### Introduction

The growing sophistication and prevalence of medical devices have heralded the need for more stringent and well-defined regulation of these technologies. The United States and China serve as two representative models for medical device regulation in our current society. More importantly, they demonstrate the development and considerations required for regulation policies at different stages in medical device growth experienced in different global landscapes. While the international-nature of current technologies has led to increased synergy between countries and their regulatory policies, fundamental differences between cultures and impetus for development have allowed the two to grow both cohesively as well as uniquely.

This paper explores the history and development of medical device regulation in both the United States and China. A detailed investigation of the path each country undertook to arrive at its current state of medical device regulation, will reveal the political and societal barriers each encountered and how these barriers forced regulation in the two countries

to develop in two different ways. Due to situational circumstance and more importantly, cultural circumstance, both countries have reacted to both domestic and international stimuli in both similar and different ways. This paper will also evaluate the strengths and weaknesses of the regulatory policies and agencies that have emerged in reaction to these stimuli in hopes of revealing how much influence situational circumstances have upon a fundamentally identical technology, as well as formulate a critical understanding of what must be required for China's medical device industry to "catch-up" to international expectations.

### Definition

According to the most recent definition of medical devices issued by Chinese regulatory agencies, a medical device is:

Any instrument, apparatus, appliance, material, or other article whether used alone or in combination, including the software necessary for its proper application. It does not achieve its principal action in or on the human body by means of pharmacology, immunology or metabolism, but which may be assisted in its function by such means; the use of which is to achieve the following intended objectives: 1. Diagnosis, prevention, monitoring, treatment or alleviation of disease; 2. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap conditions; 3. Investigation, replacement or modification for anatomy or a physiological process; 4. Control of conception ("Regulations," 2012).

In comparison, the United States' regulatory agencies define a medical device to be:

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: 1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, 2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or 3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes" ("Is the Product," 2010).

As a whole, the general structure and content of the two are fairly similar; the US definition contains a larger array of clearly defined agents and does not explicitly mention contraception or injury and handicap. More striking, however, is the explicit restriction of a US medical device as one that is "recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them". Any similar regulation is absent from the Chinese definition. This difference indicates a few important points. Firstly, medical devices in the US must be nationally recognized while no such

requirement is present in China. The reason for this is most likely due to China's lack of stable, well-trained and reliable departments or groups that could undertake the task of "recognizing" all medical devices. Secondly, this difference indicates the emphasis the US places upon domestically approved products. As one of the oldest regulators of medical devices, the United States has good reason to place emphasis and trust in domestic products. In China, on the other hand, medical device development and regulation is still relatively new. Currently, much of the Chinese medical device industry relies upon imports from countries like the United States. As a result, China does not and, most likely, cannot have the capacity to emphasize domestic approval and regulation. Differences aside, however, the general definitions are extremely similar in nature. The primary reason behind this similarity is due to China's adoption of the European Union's 1993 standard definition of medical devices. At the same time, the EU no doubt took the US model of medical device regulation into consideration when it developed its own definition almost 20 years later. China's act of adopting the EU's definition signals an attempt to align Chinese medical device regulation as well as development with international standards. This trend will become more and more apparent through the continued changes in medical device regulation in China.

Beyond their general definition, medical devices are also distinguished into 3 separate classes in both countries. In China, a medical device falls under: class I when their "safety and effectiveness can be ensured through routine administration", class II when further control is needed for safety and effectiveness, and class III when they are to be "implanted into the human body, or used for life support or sustenance, or pose potential risk to the human body and thus must be strictly controlled in respect to safety and effectiveness" ("Regulations," 2012). In the US, the three classes are distinguished as follows: class I devices present minimal harm to the user and are relatively simple in nature, class II devices are "more complex, higher-risk devices that are not life sustaining", and class III devices typically "support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury" (Pietzsch, 2008). In both cases, definitions for class I and II devices are vague. In comparison of class III devices, the Chinese classification specifically mentions the use of implants. This distinction reveals the different technological conditions from which both regulations emerged. The classification of medical devices in the US occurred when technology was still in its early stages; thus, implants were not widely used in medical practice. On the other hand, by the time China was able to classify its medical devices in 2000, implants were already fairly ubiquitous in the medical world. As a result, the Chinese definition is able to be more precise and better

reflect current practices. As a whole; however, classification of devices into the three classes remains quite vague and is often subject to case-by-case exceptions.

### History of Medical Device Regulation in the US

In the US, medical device regulation falls under the authority of the Food and Drug Administration (FDA). Official regulation of Medical Devices began in 1976 with the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA). Even prior to 1976, however, the FDCA had already taken substantial advances in regulatory developments, especially in the area of drug manufacturing and development, which would later proceed to affect medical device regulation. For example, in 1938 the FDCA only required pre-market *notification* of new drugs. It wasn't until 24 years later in 1962 that the FDCA determined that drugs must be reviewed for effectiveness and safety, thereby changing the original pre-market notification requirement to one for pre-market approval instead. Furthermore, the burden of proof was now placed upon drug makers to demonstrate safety and effectiveness. Prior to this shift in regulation, the FDA approved all drugs unless a drug could be proved unsafe.

The 1962 modification and tightening of the FDCA's regulations were largely in response to an international tragedy involving the use of the drug Thalidomide, which was developed in Germany and widely used in many countries by 1960 as a highly safe sedative that could even relieve morning sickness. When the drug was later found to cause phocomelia, which resulted in the growth of flipper-like limbs in newborns, the international sphere quickly took action to ban the drug in many countries (Fintel, Samaras, & Carias, 2009). This incident influenced the US's approach to drug development, tightening regulations as well as lengthening the drug approval process. In fact, many believe "that FDA reviewers are afraid of making decisions that could allow the marketing of "another thalidomide". Reviewers are said to be haunted by the spectre of 'being hauled up' before a congressional oversight committee and pilloried for a mistake that cost lives" (Merrill, 1994).

A large critique of the FDCA's regulation of drugs at this time involved the long approval process required, especially in comparison to prior processes. With the new fear of drug safety lapses, experiments during clinical trials would need to be repeated. Furthermore, Richard Merrill, former chief FDA counsel from 1975-7, noted: "Why didn't you do it this way? is a recurrent question, whose answer requires explanation, argument, [and] occasionally even appeal to supervisory judgment" (Merrill, 1994). As a result, the drug approval process became slower and more uncertain. The review process of Pre-Market Approval (PMA) applications also became more difficult. PMA applications were necessary to begin marketing a

new drug. In fact, by the early 1990s, “the number of PMA applications [had] risen faster than the FDA’s capacity to review them” (Merrill, 1994). Capacity in this sense refers not only to the number of people but also to the availability of people with the required expertise to review these cases as well as the financial and political support needed from the government.

Also in the 1960s, innovation in medical technology created a growing need for specific medical device regulation. Initial considerations for medical device regulation involved “[seizing] upon the [FDCA]’s expansive ‘drug’ definition to claim that certain diagnostic tools or other items of medical equipment were in fact ‘new drugs’ that required approval before they could be introduced” (Merrill, 1994). As a result, many of the considerations for medical devices were taken with the lessons learned from drug development regulation. It was not until 1976; however, that the FDA instituted the Medical Device Amendment. Despite lessons gained from drug regulation, the 1970s did not see medical devices much beyond tongue depressors. As a result, the pre-market approval stage of regulation was only required for a small number of devices, and was not required for devices approved before 1976 or similar in function to pre-1976 device (Merrill, 1994). Ironically, these provisions seem to mirror the ones that ultimately led to the Thalidomide tragedies; drugs that were originally perceived to be safe did not go through further regulation and testing but were ultimately found to be dangerous.

In 1978, the FDA declared that the Current Good Manufacturing Practices (CGMP) regulations would need to be applied to medical devices as well. The CGMPs would ensure that manufacturers “establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications” (“Quality System”, 2011). In later years, the FDA also adopted the Quality System Regulation (QSR) in 1996, which added design control requirements authorized by the Safe Medical Devices Act of 1990 as well as harmonized certain requirements with international standards set by the International Organization for Standards (ISO) (Rizzi & Beaver, 2010). Thus we can see a relatively swift adoption of CGMPs for emphasis on quality in the US as well as continued quality regulation additions 15 to 20 years after initial regulations for medical devices were put into place. The ability for swift adoption was due in part to the US’s already well-developed safety standards required for other areas of FDA authority such as drug development. The short two year gap between the Medical Device Amendment and the adoption of CGMPs for quality control also indicate the emphasis the US places on quality design in their considerations for domestic medical device development.

A Comparison of Medical Device Regulation History in China

In China, medical device regulation began in 1994 under the State Pharmaceutical Administration of China (SPAC). Over the next 18 years, the jurisdiction, nature, as well as motivations for medical device regulation changed greatly. In 1998, as a result of government restructuring, the SPAC merged with the Department of Drug Administration of the Ministry of Health (MOH) and formed the State Drug Administration (SDA). In 2000, the SDA issued the “Method of Medical Device Manufacturing Enterprise Quality Assessment” for the registration and inspection of Class II and III medical devices in attempts to prevent the work of “small, workshop-type manufacturers without suitable production controls” (Rizzi & Beaver, 2010). The first article of this “Quality Assessment” document of 2000 states: “These Regulations are hereby formulated with a view to strengthening enterprise quality control and administration of Medical Devices, ensuring patient safety, and enforcing the Regulation for the Supervision and Administration of Medical Devices” (Zheng, 2000). Critics insisted that these regulations only affected the process involved in creating the final device, whereas the general production processes were still largely unaltered.

The conditions for medical devices in China between 1994 and 2000 are similar to the conditions in the US before 1976. In fact, it might be more appropriate to say that conditions in China between those 7 years are closer in form to the conditions for drug regulation in the US between 1938 and 1962. While medical devices fell into official government authority by 1994 in China, much of this authority merely required registration of medical devices before placing them on the marketplace. This is similar to the requirement for pre-market notification of drugs prior to 1962 in the US. In terms of official documentation for medical device regulation, especially with respect to quality and effectiveness, it would be suitable to take the Medical Device Amendment implemented in the US in 1976 and compare it to both the “Regulations for the Supervision and Administration of Medical Devices” and “Method of Medical Device Manufacturing Enterprise Quality Assessment” in China which went into effect in April and June of 2000, respectively. Both documents serve as essentially the first official, published documents for the direct regulation of quality of medical devices. In the US, the document was experimental in nature, since there was little to no international precedent available for medical device regulation. As a result, the document was only able to rely on experience from drug regulation. This is most evidently seen in the document’s belief that effectiveness controls were only required for Class III devices since the government at the time was unable to imagine the potential harms of lower class devices. In contrast, the Chinese documents were created in a time when the international landscape had already made significant advancements towards medical device regulation. As a result, the SDA

was able to look to international regulatory processes already in place for medical devices. Thus, the “Regulations for the Supervision and Administration of Medical Devices” already contains requirements for safety and effectiveness of all three classes of devices. Another obvious contrast between the documentation of the two countries is that the Chinese document distributes authority for the 3 medical device classes to differing levels of governmental authority. For example, approval of class I medical devices lies within the jurisdiction of the municipalities while approval of class II devices fall under the “drug regulatory authorities of provinces, autonomous regions and municipalities directly under the central government” and class III device approvals are governed by the State Council (“Regulations,” 2012). This breakdown of authority is not seen in the Medical Device Amendment, which is reasonable considering the different governmental structures of the two countries.

In 2003, many of the original functions of the Chinese MOH were diverted to other departments and the SDA was renamed the State Food and Drug Administration (SFDA), the title that it holds to this day. The ultimate result of this restructuring allows for the SFDA to serve as a single drug regulatory authority for the Chinese government, which standardizes regulation in China and removes conflicts between the regulations created by provincial government agencies. Furthermore, this standardization acts as a response to the believe in a growing importance to cater to the international community. Having one standard set of regulations allows for foreign industries to more easily enter the Chinese market. Similarly, it allows Chinese industries to easily export products. Under the SFDA, an attempt to address the concerns raised with the 2000 “Quality Assessment” resulted in the proposal of the “Good Manufacturing Practices for Medical Devices”. It was not until 2007 that these GMPs were tested on 10 high-risk medical devices in 45 medical device manufacturing companies in 8 provinces (Rizzi & Beaver, 2010). In 2010, the Chinese government declared the Good Manufacturing Practice of Medical Devices (Interim GMP Regulations) and Good Manufacturing Practice of Medical Device Inspection (GMP Inspection Regulations), which went into effect in March of 2011. These regulate the methods, facilities, and controls for the “design, manufacture, packaging, labeling, storage, installation and servicing of all finished devices intended for human use” (Rizzi & Beaver, 2010). Thus, we can note an 11-year time gap between the first set of medical device regulation documentation in China and the final institution of GMPs. In contrast, the US included CGMPs into medical device regulation only 2 years after the Medical Device Amendments. While the Chinese time lapse to institute GMPs was much longer than the US, it cannot be attributable to lack of resources or even lack of knowledge of the applicability of GMPs to medical device regulation. We can observe

that GMPs were already proposed in the same year the “Regulations for the Supervision and Administration of Medical Devices” and “Method of Medical Device Manufacturing Enterprise Quality Assessment” went into effect. The 11 year time gap to put GMPs into effect reflects the slower nature of government improvement of medical device regulation in China. This implementation time lag also attests to China’s smaller need to institute tighter medical device restrictions due to their reliance on imports from countries that already have GMPs in place. Thus, in terms of availability for use, China does not have a pressing demand for domestically manufactured, high quality medical devices. Instead, the impetus for the GMPs could reflect a shift in governmental perception of the importance of domestic medical device manufacturing, which may not have been emphasized as highly in previous years. This shift in perception is due in part to growing health care demands in China as well as a shift in the general technological atmosphere to produce domestically, high quality products.

#### Motivations for Medical Device Regulation

From a political perspective, the Chinese government hopes to increase medical device regulation not only to address the concerns of the populace but also to boost domestic medical device manufacturing (Gross & Minot, 2009). Medical device regulation in China began more than 50 years later than regulation in the US. As a result, medical devices from other countries have higher standards, greater innovation and are more reliable. At its current stage, attempts to equip healthcare centers with higher quality devices must rely on international imports since the quality of domestic medical devices have not achieved internationally accepted standards. Thus, in order to “move up the value chain from low-margin, labor-intensive products to more sophisticated products and components” (Gross & Minot, 2009), the Chinese government now seeks to give more support for domestic production of medical devices that can compete in the international marketplace.

Aside from an international impetus for medical device regulation, domestic political considerations have also acted as strong influences. In December of 2008, the SFDA was placed under the authority of the Ministry of Health to “help restrain SFDA corruption” (Gross & Minot, 2009). The corruption refers to a set of incidents that were brought to public attention in 2007 regarding the illegal behavior of high officials in the SFDA. The landmark event in this set of investigations ended with the execution of Zheng Xiaoyu, head of the SFDA from 1998 to 2005, in July of 2007 when he was convicted of accepting bribes totaling over \$850,000 from eight large companies. More importantly; however, his actions “led to the approval of many medicines that should have been blocked or taken from the market,



including six fake drugs” (“Former SFDA”, 2007). In light of this event, the Chinese population, as well as the government, has placed considerable attention to the regulatory processes involved in drug development as well as medical device development. Effects of this added attention includes the slowing of the approval process for medical devices as well as the fear of device makers and the SFDA to continue the misdoings of Zheng. This situation is similar to the Thalidomide tragedy that affected the US in the 1960s where fear of repeating another Thalidomide incident placed considerable burdens on drug development. Other SFDA scandals including heparin and melamine recalls have posed international impacts. In both cases, authorities found tainted, Chinese-produced heparin and melamine, a chemical compound added to milk, and ultimately recalled from products distributed internationally. Cases such as these have caused the Chinese government to impose more stringent regulatory processes, especially to appease the watchful eye of the international community. We see from both the US and China, increased regulation by agencies, whether the FDA or SFDA, are often in response to events that have gained wide public or international attention. At the same time, these increased regulations often slow down the regulatory process, thereby inhibiting the countries from achieving maximal levels of innovation. For the US, this inhibition was not as detrimental for the country’s competitive position in the medical device industry as it held the advantage of being one of the leaders of medical device manufacturing and regulation. For China, on the other hand, this slowing down has placed it even more behind leading medical device manufacturers and countries. As a result, China has become forced to adopt the devices and products of other countries to ensure quality and reliability.

Consequences of China’s later position in medical device development can proceed in 2 potential directions: either China will consistently remain one step behind other countries, or at some point, it will be able to catch up. China holds the advantage that it has much precedent to refer to when considering medical device regulation and can easily learn from the mistakes of other countries. However, without the ability to quickly implement regulations such as quality controls, China will not be able to catch up even if they theoretically understand the actions required for future growth and development. In practice, China should be able to quickly achieve milestones in the regulatory evolution process when compared to other countries with well-established medical device regulations. However, there needs to be fundamental changes in perceptions of medical devices so that China realizes their importance to health care advancement. Without these changes along with realization of the pressing need for quality controls despite potential hindrance to immediate benefits, China’s medical device development will not be able to catch-up to the level of

current market leaders.

### Current State of the Medical Device Industry

As of 2011, the biomedical industry in China constitutes an \$11.8 billion industry with over 700 enterprises (Koh, 2011). While the main regulation of medical devices falls under the jurisdiction of the SFDA, other agencies involved in medical device regulation include the Ministry of Health (MOH), the general Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), as well as municipal and provincial governments. Thus, although medical device regulation in China has fallen primarily within the authority of one centralized entity, there is still more variation between the various agencies involved when compared to the model used in the US. Furthermore, while the medical device industry in China has gone through much development over the past decade or so, researchers hold the opinion that “many of China’s domestic enterprises still rely on government support to drive the overall industry” (Koh, 2011). As a result, the Chinese government not only needs to provide regulation, but also policy implementation and financial support. Currently, fund committees of the government have been shown to consider medical device development to have equal importance to new drug development (Koh, 2011). Reasons behind this shift in consideration include the growth of the medical device industry in the international sphere as well as the growing sophistication of medical devices to create direct life-changing impacts. Furthermore, medical devices present the advantage over drugs in their considerably shorter time for research and development.

China’s rapidly changing healthcare system has prompted a growth in medical device development as well created an increased need for regulation. Specifically, China hopes to expand coverage of their Basic Medical Insurance as well as New Rural Cooperative Medical Insurance (Gross & Minot, 2009). The government also seeks methods that allow for sustainability of their expansion programs. Measures that need to be taken include investment in higher quality drugs and medical devices as well as support of policies that maintain quality of devices in the market (Gross & Minot, 2009). In fact, in January 2009, the Chinese government committed to investing an additional \$124 billion for modernization and expansion of the healthcare system (Gross & Minot, 2009). This funding will not only support the use and development of medical devices, but also provide a boost in morale for medical device innovation and development. This additional funding symbolizes a commitment by the government to support future health care innovation and is important for shaping the political and societal landscape for medical devices. Likewise, the political and societal landscape has shaped medical device regulation. While increased attention on the healthcare system plays a large role in

medical device regulation, publicized scandals involving medical devices used both in China as well as in the international sphere have also served as an important driving force for necessary additional medical device regulation (Gross & Minot, 2009).

While medical device development is seeing growth and additional governmental support in China, its speed of growth and innovation does not seem to hold the same power as that found in the US. This is partially due to China's increased burden of monitoring international competition. For example, China keeps "close tabs on the approval status of analogous technology in the U.S." (Koh, 2011). This emphasis on US efforts in medical device development caused much governmental focus on supporting fundamental biomedical research rather than a promotion of the manufacture and marketing of medical devices. Thus, the recurring theme of China's attempts to balance both the drive for innovation with the pressure and competition from existing technologies as well as necessity for high quality and reliability appears yet again. This theme adds an additional fold to the complexity of the considerations for medical device regulation and more importantly future medical device growth in China. For China to "catch-up" to the level of other countries that are currently leading the medical device sector, it must balance the desire of the government to develop medical devices as well as the realized importance of quality controls. To be truly competitive, China must constantly monitor the status of these other countries as well. This additional concern is one that was not present as a hurdle for countries with earlier and more established medical device industries. Thus, despite current government realization of medical device importance as well as quality importance, how China will be able to maintain the balance between building a stronger basis for medical device development and taking a unique competitive position in the marketplace remains to be seen.

### Criticism of Current Regulatory Process

Currently, experts criticize the current medical device regulatory process in China for being slow. Wang Fei, founder of Jiangsu Berkgen Biopharmaceutical Co., Ltd says that the biggest abuse of the system is the overly long approval time for clinical trials. According to Wang, the SFDA regulations state that the approval timeframe should be between 60 to 90 days. In reality, however, a majority of companies need to wait up to a year to gain final approval to move into clinical trials ("Biomedicine Industry", 2010). When compared to the approval time in the US by the Institutional Review Board of a maximum of one month, this extended length of time would greatly hinder China's competitive position in the international medical device sphere, disincentivize domestic research and development of medical devices, as well as discourage foreign companies from entering the Chinese

medical device market.

Wang Xiaochuan, CEO of Sundia Meditech, explains that there are 3 reasons why the approval process is so long in China. Firstly, he believes that the Zheng Xiaoyu execution incident has rendered people afraid of making mistakes. As a result, standards have been implemented to be as close to internationally accepted as possible. Thus, rather than a gradual evolution of the regulatory process, the standards have become too strict without allowing companies and regulatory agencies to develop appropriate. As a result, clinical trial approval times become longer while costs for research rise. Secondly, he believes that the approval instructions for medical devices are unclear and opaque; oftentimes applications need to be revised or redone, again wasting considerable time. Lastly, Wang Xiaochuan finds that political influence also affects the long approval time. While the average time to enter a clinical trial is 150-200 days in China, shorter times can be achieved through political connections. For example, an interview with a pharmaceutical subsidiary of a large domestic oil and gas corporation revealed that the time to enter a clinical trial is “usually dependent on how influential or close you are to the review board” (Koh, 2011). This signals not only the influence of politics on clinical trial approval, but also more significantly their influence on the ultimate success of medical devices. According to Xiaochuan, government support is also increased heavily for products that are able to proceed to the clinical trial stage of approval. From this perspective, clinical trials serve as a gateway for medical device production and manufacturing.

The regulatory timeframe for China’s medical device production is fairly opposite to the US’s. It is the opinion of Xiaochuan that in America, as long as there are no big problems, medical devices can be quickly approved for clinical trials. If during the clinical trials something goes wrong, then the process is terminated and the producing company takes responsibility for the failure. In China, on the other hand, gaining approval for a clinical trial takes is extremely slow and many pre-clinical tests are required. However, regulation beyond this point is minimal. In fact, Xiaochuan states that oftentimes, even if there is a problem, it gets overlooked (Koh, 2011). This discrepancy between the areas of relative strictness in the regulatory processes between the two countries indicates a major flaw in China’s model. Relaxing restrictions on any clinical trial or post-clinical trial process also allows for future quality issues to be compensated under the pretense that the device should be of sufficient quality for market. It is possible, however, that the reasoning behind the Chinese model emerges from the lack of expertise in the current regulatory staff. As a result, China is only capable of instituting regulation at the application level and not any further in the process. From a political standpoint, pressure for the production of a product and thus revenue, must

accommodate for the already-long initial approval process and thus can drive any processes beyond the clinical trial approval stage to work at a much faster and often less regulated pace.

### Conclusion

While the processes followed to develop medical device regulatory procedures in the US and China share considerable similarities, they also exhibit key differences that reveal the fundamentally different social, political and cultural landscapes that have shaped development. Both China and the US have relatively similar frameworks for medical device regulation, which is attributable to their presence within an international landscape. During implementation, both countries also lay victim to scandals in both the international and domestic spheres, which ultimately hinder their regulatory processes. Despite these similar hindrances, however, historical differences in medical device regulation between the two countries as well as cultural and societal barriers leave the two in very different positions within the medical device industry.

In terms of regulatory framework, China holds the advantage of international precedent to better develop its policies and rules without having to overcome the same hurdles as the US medical device pioneers. On the other hand, these hurdles have allowed the US to be a leader in development and innovation. Where this advantage becomes most evident is in its acquired experience with quality regulations and requirements. This advantage has allowed the US to remain ahead in the medical device industry despite setbacks from international and domestic scandals. At the same time, China's advantage of international precedent often acts as a double-edged sword; while China has not yet developed the expertise and formalized procedures for medical device regulation, international pressures to achieve quality targets well beyond China's current capabilities render the country's medical device industry in a weak competitive position. This lack of development can be most readily seen with Chinese medical device companies' dependence upon government support for successful introduction of new medical devices. The heavy dependence further fuels the capacity of the medical device industry in China to be subject to corruption, and thus even poorer quality products.

Overall, national objectives towards medical device development also constitute an important difference between the two countries. In the US, emphasis is placed upon domestic recognition, while in China the current medical device market is dominated by products imported from other countries. This difference is largely due to the previously mentioned inability of China's current departments to provide for stable, well-trained and reliable regulation. Furthermore, a cyclic relationship is formed between China's dependence on imported

devices and the resulting lack of impetus for domestic emphasis on GMPs which forces the country to be ever-more dependent upon international imports. As China seeks to strike a balance between international expectations for quality and a growing domestic need for more innovative medical devices and their associated revenue, it inevitably falls behind US medical device companies as its quality institutions are already well established.

Both the history of development and national view of medical device regulation in the US and China naturally differentiate the two countries. However for the two to ultimately stand together, fundamental changes to China's societal views on the fundamental use of medical devices not merely as revenue generators but as domestic tools for improving the health of its citizens is necessary. Without this basic change in attitude toward the medical device industry, it seems difficult to envision a future where the two countries share the same space in the development of medical devices.

## References

- Biomedicine industry faces restrictions: Why approval for new drugs is so slow. (2010). [www.emed.cc](http://www.emed.cc). GHmed. Retrieved March 19, 2012 from [http://www.ghmed.cn/Contents/20110815/35100\\_1.html](http://www.ghmed.cn/Contents/20110815/35100_1.html)
- Fintel, B., Samaras, A.T., & Carias, E. (2009). The Thalidomide tragedy: Lessons for drug safety and regulation. *Science in Society*. Northwestern University. Retrieved March 19, 2012 from <http://scienceinsociety.northwestern.edu/content/articles/2009/research-digest/thalidomide/title-tba>
- Former SFDA chief executed for corruption. (2007). *China Daily*. China Daily Information Co. Retrieved March 19, 2012 from [http://www.chinadaily.com.cn/china/2007-07/10/content\\_5424937.htm](http://www.chinadaily.com.cn/china/2007-07/10/content_5424937.htm)
- Gross, A. and Minot, J. (2009). China drug and device regulatory update 2009. *FDLI Update Magazine*. Pacific Bridge Medical. Retrieved March 19, 2012 from [http://www.pacificbridgemedical.com/publications/china/2009\\_China\\_Drug\\_Device\\_Reg\\_Update](http://www.pacificbridgemedical.com/publications/china/2009_China_Drug_Device_Reg_Update)
- Is the product a medical device? (2010) U.S. Food and Drug Administration. U.S. Department of Health and Human Services. Retrieved March 19, 2012 from <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm>
- Koh, C. (2011). Medical device research now a high priority for policy makers in China. *Lux Populi*. Lux Research. Retrieved March 19, 2012 from <http://www.luxresearchinc.com/blog/2011/09/medical-device-research-now-a-high-priority-for-policy-makers-in-china/>
- Merrill, R. A. (1994). Regulation of drugs and devices: an evolution. *Health Affairs*, 13(3), 47-69. Retrieved March 19, 2012 from <http://content.healthaffairs.org/content/13/3/47.full.pdf>
- Pietzsch, J. B. (2008). Review of U.S. medical device regulation. *Journal of Medical Devices*, 1, 283-292.
- Rizzi, S. J. & Beaver N. A. (2010). China publishes regulations on medical device GMPs and inspection requirements. *FDLI*, 2. Retrieved March 19, 2012 from <http://www.foley.com/files/Publication/8ebf64f6-4122-48b4-9980-25847f2870fd/Presentation/PublicationAttachment/ffb9cdde-336c-4736-8b55-28cc630b1558/update342010.pdf>
- Quality system (QS) regulation/medical device good manufacturing practices. (2011). U.S. Food and Drug Administration. U.S. Department of Health and Human Services. Retrieved March 19, 2012 from <http://www.fda.gov/medicaldevices/deviceregulationandguidance/postmarketrequirements/qualitysystemsregulations/default.htm>

Regulations for the supervision and administration of medical devices.  
(2012). www.SFDA.com. Wellkang Group of Companies. Retrieved  
March 19, 2012 from <http://www.sfda.com/medical-device.html>  
Zheng, X. Medical device manufacturing enterprise quality system  
inspection method. (2000). China-US Medical Business Consultation.  
Whitney Consulting Limited. Retrieved March 19, 2012 from  
[http://www.whitneyconsulting.net/publications\\_02a\\_02.htm](http://www.whitneyconsulting.net/publications_02a_02.htm)