

China Senior Housing and Health Care

Newsletter
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For internal review only

News Update

Shanghai Launches its Long-Term Care Insurance

In order to implement the requirements of the Ministry of Human Resources and Social Security (MOHRSS) concerning launching its Long-Term Care Insurance (LTCI), combined with Shanghai's Thirteenth Five-year Plan, Shanghai Municipal Government formulates and issues the LTCI's pilot scheme, which prescribes that Shanghai will start its pilot approach at Xuhui, Putuo and Jinshan districts from January, 2017. The following is a brief description of the policy.

➤ **LTCI's Positioning**

LTCI is positioned as a mandatory and independent insurance providing basic protection as the sixth basic social insurance tied with pension, medical, unemployment, employment injury and maternity insurance, which will effectively solve the problem of raising and use of fund. MOHRSS (the Municipal Medical Insurance Office) will be responsible for drafting and unified management of LTCI and supervision and management of the fund.

➤ **The Assessment of Senior Care Needs**

People who are over 60 and should apply for the basic pension of urban workers as well as those who are over 60 and participate in the basic medical insurance for urban and rural residents will enjoy LTCI if they are determined as Grade 2 to Grade 6 via senior care needs assessment.

Senior care needs will be classified from Grade 1 to Grade 6 after assessment depending on the self-care ability and disease severity. Self-care ability includes the abilities of daily living (ADL), instrumental activities of daily living (IADL) and cognitive competence while disease severity mainly includes 10 kinds of diseases of which the prevalence rates are relatively high among the senior. The maximum valid period of the assessment is 2 years. Assessment of senior care needs will be the "gatekeeper" of LTCI.

➤ **LTCI's Benefit**

The benefit of LTCI is specifically divided into care provided by community home care, nursing homes and hospitals.

The service providers of community home care include aged care homes and the health care institutions at a basic level, e.g. nursing stations, out-patient departments (OPDs), community health centers and nursing homes. The services are provided by way of home care and community care, principally for basic life care and medical care services that are closely related to basic life. 90% of the fees will be paid by LTCI which means individuals will afford only 10%.

Care by nursing homes refers to the basic life care and medical care services which are closely related to basic life provided by the agencies for insured people who live in there. 85% of the fees are paid by LTCI and individuals need to bear the remaining 15%.

Care by hospitals refers to the medical services provided by the designated medical institutions with the senior care functions for inpatients who are the insurance participants. The specific treatment is still subject to the provisions of the current basic medical insurance system.

➤ **LTCI's fund raising**

The fee of LTCI are paid by employers and employees at the rate of 1% of the basis of the medical insurance and 0.1% of the basis of the medical insurance respectively. People who are insured by the basic medical insurance for urban and rural residents will have lower paying standards than those for the employee medical insurance participants. Individuals only have to pay 15% of the fees and the rest will be shared by the city and district finance.

During the pilot term, employers and individuals will not need to pay the fees, and the funds LTCI need will be transferred from the balance of medical insurance.

➤ **LTCI's service providers**

LTCI's designated care institutions include nursing homes, community aged care homes, grass-root medical care services organizations, nursing beds belonging to some secondary medical institutions which have the senior care functions. At the same time, LTCI encourages development of nursing stations with medical qualification and life care stations without medical qualification. To become LTCI's designated care institutions, the organizations need to submit applications, go through a series of evaluations and then sign service agreements with the City Medical Insurance Center.

The LTCI that Shanghai have launched this time is a basic social insurance essentially reflects the guiding ideology of "protect the basics and hold the bottom line". Moving forward with the pilot scheme, Shanghai will constantly learn from experience and improve the LTCI system to meet the needs of long-term care services in the aging society. ■

A Nation-wide Special Action for Nursing Homes Services Quality Construction is Rolling Out

In order to intensively deploy President Xi Jinping's advocate for "carrying out quality improvements activities" at the Central Economic Work Conference and the important speech spirits of improving the nursing homes services quality (NHSQ) at the 14th Central Finance Leading Group Meeting, to strengthen the quality supervision of nursing homes, departments of Ministry of Civil Affairs (MCA)、Ministry of Public Security (MPS)、National Health and Family Planning Commission (NHFPC)、General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)、Standardization Administration (SA)、National Aging Office (NAO) decide to carry out special action of NHSQ construction nationwide.

➤ **Background**

With China gradually stepping into the aging society, people pay more and more attention to the senior care. In recent years, the country has introduced a series of policies to strengthen the construction of services for the elderly. It is undeniable that the number of elderly people in China has been very large, facing the growing demands for high-quality, safe and credible nursing homes. Rectifying the current problems which exist in nursing homes has become an imminent request. under such context, the

special action which intends to improve the services quality of the senior care industry all over the country comes into being.

➤ **Contents**

This special action basically covers the following 9 key aspects:

- (1) Reflection and rectification of national NHSQ;
- (2) Accelerating the standardization and certification construction of NHSQ;
- (3) To carry out medical and health services;
- (4) To strengthen the safety management of nursing homes;
- (5) To improve the capability of senior care staff;
- (6) To establish the national nursing home business management system;
- (7) To actively promote the special action of NHSQ;
- (8) To honor awards to nursing home for outstanding performance; and
- (9) To strengthen the supervision of NHSQ.

Generally speaking, the above aspects are in two-folds — the rectification of current status and the improvement of the services. Needless to say that it is only through deep and comprehensive investigation into the problems and defects of NHSQ, can the nursing home implement rectification towards a clear direction. During this process, a comprehensive set of rating criteria to NHSQ needs to be established. Meanwhile, nursing homes should also actively introduce professional staffs with senior care qualifications and improve their capacity of medical and management service to meet the variety of customer demands, including the disabled elderly. In order to encourage nursing homes to participate in the action, some awards will be honored. Those nursing homes who achieve remarkable success will be rated as models and be recommended preferentially and widely. The government will set up hotline platforms to unite the public and strengthen the supervision over nursing homes. For the nursing homes who have conducted severe illegal activities and refused to rectify or even cause some accidents, related departments should punish them strictly and reveal the same to the public. Last but not least, the whole society should actively safeguard the legitimate rights and interests of the elderly to prevent abuse activities.

➤ **Targets**

The special action starts from 2017, tentatively continues for four years. By the end of 2017, the national unified rating standard and certification system of NHSQ is expected to be taking shape. More than 50% of nursing homes shall be able to provide medical and health services for the elderly in different forms and a batch of high-quality and high-level professional nursing homes will emerge.

By the end of 2020, the construction work of the system mentioned above is expected to be almost full-fledged. The standard of nursing home services will be improved and the majority of nursing homes have the capacity to provide medical and health services for the elderly in different forms. It is expected to emerge a number of chain nursing homes with distinctive brands, comprehensive service functions as well as first-class service quality.

➤ **Highlights**

One of the highlights of the special action is that it formulates 115 specific assessment criteria with respect to established qualification, service staff, equipment, management standard, different levels of basic life services and emergency response measures, etc. There is no doubt that the 115 criteria will be a unified guidance for nursing homes all over the country to follow, giving them a specific and practical direction to rectify and improve. It can save a lot of time through the learning curve and ensure the efficiency of the implementation of this action. ■

Legal Insight

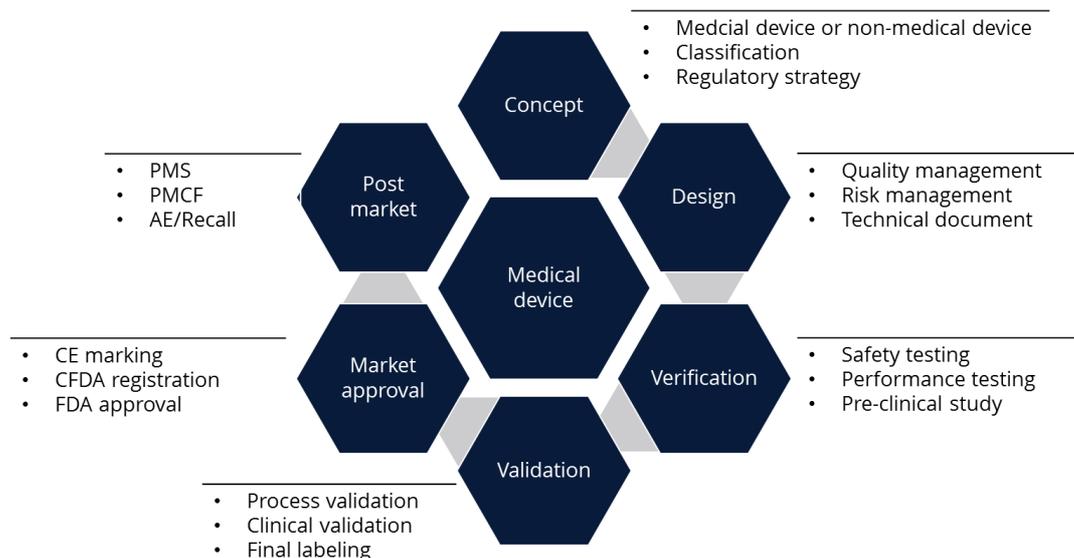
A comparative view on medical device regulations -- *When West meets East*

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Introduction

Conforming to the local regulatory requirement is essential in introducing medical devices into a market. The medical regulations often permeate throughout the whole product life cycle, from the hatching of a concept, to design and development, to verification and validation, to market approval check, and to post market phase. Having a sound regulatory strategy from the very beginning of the product life cycle and carefully execute the regulatory conformity plan at each stage will ensure the company a competitive advantage in the medical device market.



However, navigating through the web of regulations and stay conformity can be a headache to many medical device manufactures, especially given the fast-changing landscape of medical device industry. In EU, manufacturers are beginning a hectic transition from the old Medical Device Directive (MDD) towards the new Medical Device Regulations (MDR). In China, the overhaul of medical device regulations started in 2014 doesn't seem to stop there, and CFDA has been ever since continuously updating and renewing its regulatory framework.

For many, the question remains, what has changed? And what are the implications? In this article, we look at both the EU regulatory changes and the new CFDA regulatory development through the following lenses:

- Regulatory scope
- Supervision
- Responsibilities
- Transparency & traceability issues
- Clinical requirements
- International alignment

1 Wider, Clearer Scope

As in many cases, rewriting legislation gives the opportunity to revisit the particular scope of the piece of legislation under review.

In EU:

In EU, the revision comes only after several decades, and so over time several items were posted on the wish list for change. As a result, some products will in the future be covered by the MDR, whilst others will be removed.

To start with the latter, most clearly this relates to products with viable substances, such as products containing lactobacilli used to restore natural conditions in patients with vaginosis and vaginitis. Over time various authorities have tried to remove such products selectively from their market as medical device, but ultimate success was not achieved. The current revision is looking to clarify what authorities over time have tried to reach. In addition, several products containing substances that over time have been banned from having health claims under the food regulations. Manufacturers currently marketing such products should not only look at strategies to register their products under the regulations as applicable, but they should also discuss with their notified body the opportunities to keep the products on the market during the transition period.

Secondly, the scope will be enhanced with new medical devices containing non-viable human materials from other sources that currently allowed human blood derivatives. Needless to say, that as there will be a consultation involved with human tissue agencies, rapid construction of technical documentation, and applying for conformity assessments will be key for these products. But manufacturers will be happy, as it will bring them a much clearer regulatory route to the EU market.

Lastly, we see the inclusion of non-medical implants, for example non-correcting contact lenses, in annex XV. These products will be reviewed as if they are medical devices, but their conformity assessment will largely focus on risk mitigations. Here, manufacturers will need to start building technical documentation whilst at this stage the final expected requirements are not fully clear. No CTS will be available for a while, and notified bodies will need to strongly adjust to focus on risk separately, as opposed to their regular work looking at the risk-benefit ration, so comparing residual risks to proven

clinical benefits.

The good news is that the classification system does not change under the MDR, but as expected there will be some reclassification, all leading to products shifted into higher classes, mainly into the highest class III, i.e. selective orthopedic implants, products using or containing nano-particles, and certain life sustaining active devices.

As the Active Implantable Directive is integrated into the MDR as well, these products become class III by default. But one should be careful to realize that their accessories are class III as well, in contrast to accessories of any other device that will be classified in its own right.

Debates on substances that are Ingested, inhaled, or administered rectally or vaginally and absorbed by or dispersed in the human body have continued throughout the negotiations. A stratified system with some elements of a consultation process will be brought in place.

Software was granted a whole new rule (ad interim numbered 10a), that will ensure software can be classified in all available risk categories as needed.

In China:

Likewise, the shift from the 2000 medical device regulatory scheme to the new 2014 scheme saw a significant extension of scope also. Previously not considered and regulated as medical devices are included in the landmark regulation No.650 published by State Council in 2014, such as IVD reagents, devices with the purpose of life support or maintenance.

Furthermore, the scope is constantly modified by the CFDA on a case-to-case basis. For instance, in 2015 alone CFDA has issued consecutively several notifications, such as notification No.49, No.69, No.75, and No.104, in which CFDA has clarified in total 474 devices, adjusting their classification to higher or lower class, or reconsidering their status as medical devices. In the latest notification published in July 2016 (notification No.480), penis enlargement device, whose classification as well as status as a medical device in China have long been debated, has now been officially declared by the CFDA as a Class III medical device in China.

For foreign medical device manufacturers, it is thus important to be aware of this top-down and bottom-up combined regulatory scheme: top-down, legislation of high level regulation, bottom-up, tinkering on a case-to-case basis. A practical message for the foreign manufacturers is that, besides the normative regulations on the top level, do look out for the CFDA announcement and CFDA notifications, and see if those informative documents affect the market entry strategy in China.

EU	China
<p>Scope extensions</p> <ul style="list-style-type: none"> - Products manufactured utilizing non-viable human tissues or cells, or their derivatives, that have undergone substantial manipulation - Certain implantable / invasive products without a medical purpose - Clarification towards: products that contain or consist of viable biological substances <p>food covered by Regulation (EC) No 178/2002</p>	<p>Scope extensions:</p> <ul style="list-style-type: none"> - definition of medical devices has expanded in the 2014 version, compared with 2000 version. - Scope modification on a case-to-case basis - Individual medical device's classification defined and clarified by CFDA through notifications.

2 Stronger supervisions

For long authorities around the world have left the medical device field largely to the industry, as rapid developments, innovations, and complex technologies have been hard to regulate in detail upfront. As the sector takes the next steps in maturation, changes in legislation also call for stronger supervision and coordination of market surveillance activities.

In EU:

For Europe, the key point here is the supervision on notified bodies. For long, there has been a wish to level the playing field at a consistently high level, but harmonization efforts until recently were done only on a voluntary basis, which has proven to be very limiting in terms of enforcing the same expectations.

As most other legislations already have, the MDD will move into the new legal framework. That means EU will keep notified bodies and their conformity assessments central in the system, but with a broader base into the supply chain.

Current practice developed on joint supervision by the EU authorities on the notified bodies will remain in place, with annual monitoring by the country specific authority after successful designation and subsequent re-designations. For these designation phases, joint assessment teams will continue to do their work. And with sufficient training and experience at this stage, the next round is expected to be even more demanding to notified bodies than the first wave under the current regime. The good thing however, is that the expectations as derived from the Joint Assessment Manual, are now clearly available in the annex on Notified Bodies. So, the expectations are higher, but they have been clarified in much more detail than before.

In addition, the new regulations will also enable notified bodies to better do their work in stricter conformity assessment, including among others enhanced product testing, continuation of the unannounced visit programs and guidance in the form of common specifications.

A new system of clinical scrutiny will further enhance supervision; more on that in a subsequent part of this article.

In China:

China, unlike Europe who works with an accrediting system, has an autonomous, independent, and centralized regulatory authority, the CFDA. Since the start of medical device regulatory overhaul in 2014, a series moves by the CFDA has convinced the onlookers that China is taking regulating MedTech industry very seriously.

Firstly, CFDA has been keeping churning out new regulations and new standards following the landmark No.650. Notably are the new GMP (manufacturing), GDP (distributing), GCP (clinical). Many product standards are also renewed to be more in line with the internationally accepted standards.

Secondly, CFDA has speed up the frequency in dropping unannounced QMS inspections on its domestic manufacturers. And by the trend of it, the overseas QMS inspection on foreign manufacturers who have devices registered in China will very likely become a reality.

Last but not the least, a whopping 126,42% increase of budget intended for medical device related affairs within the CFDA department for 2016 compared with 2015 undoubtedly showed CFDA's commitment in living up to its role as the Chinese regulatory authority. All the signs point to the fact that there will be stronger and more powerful control over the market by the CFDA.

EU	China
<p>Stronger supervision on notified bodies</p> <ul style="list-style-type: none"> - System stays within New Legal Framework - Stronger supervision on Notified Bodies - Continuation of joint assessment; manual transcribed into NB annex - Scrutiny on high risk devices <p>More powers for assessment</p> <ul style="list-style-type: none"> - Thorough testing and regular checks on manufacturers - Unannounced factory inspections - Rotation of notified body staff involved in assessment - Adoption of common technical specifications 	<ul style="list-style-type: none"> - New regulations: e.g. new GMP, GDP, GCP since 2014; - New standards: e.g. 186 new product standards published in the first quarter of 2016 - More frequent CFDA inspections - Scrutiny on high risk devices - CFDA annual budget for medical device in 2016 almost doubled from 2015

3 Clearer responsibilities

Increasingly companies start working globally, and in more complex ways dividing work over many partners in a supply chain, the need is there to clarify in more details the requirements for the various stakeholders in the system of regulatory compliance.

In EU:

For Europe, streamlining and defining roles throughout the entire supply chain brings the medical device field in line with common EU regulations on the supply chain responsibilities and liabilities, although many argue that the liability for authorized representatives goes beyond the current EU legislation on that aspect.

The concept of a qualified person like in pharma did not fully make it, but the enhanced expectations on regulatory competence will be in place. Manufacturers will need to demonstrate in the future that their RA team has sufficient resources and know how.

Companies ahead of the curve identified in this aspect also that basically all labels will need to be revised, and in many cases that will mean revising the labels also for other jurisdictions outside of the EU; this could potentially also mean that modifications to existing market registrations outside of the EU will need to be taken into the implementation planning.

In China:

The responsibilities for regulatory authorities are getting clearer. CFDA central office will take the lead role in legislating, administrating and supervision of medical device related regulatory affairs. Center for Medical Device Evaluation (CMDE), a specialized department consists of product and technical experts will handle the technical review of all the Domestic Class III and Import Class II and III registration files.

What is noteworthy is that, the collaboration and inter-relations between different regulatory authorities also become apparent under the new regulatory scheme. For instance, National Health & Family

Planning Commission (NHFPC), a ministerial level agency like CFDA directly under the supervision of the State Council, has been seen playing an important role in co-legislating the new GCP for medical device trials. The recently enacted regulation in prohibiting non-medical needs related prenatal sex discernment and gender-selective pregnancy termination (NHFPC, NO.9, 2016) has far reaching impact into the administration and supervision of medical devices as well. For instance, the manufacturing, distribution, sales and use of ultrasound diagnostic devices and chromosome testing devices will bear strict scrutiny by the CFDA.

Last but not the least, the responsibilities for all the stakeholders along the product life cycle, including the manufacturer, the distributor, the user organizations, the clinical investigators etc., have been reflected in a series of new regulations including the new GMP, GDP, GCP etc.

In short, the current regulations are pushing towards a more holistic and inclusive view in ensuring the general public's health and interest.

EU	China
<ul style="list-style-type: none"> - Clearer responsibilities for manufacturers, importers and distributors - Also applicable to diagnostic services and internet sales - Establishing a 'qualified person' in manufacturer or authorized rep. - Relabeling and repackaging clarified 	<p>Clearer responsibilities <i>in and among</i> the regulatory authorities:</p> <ul style="list-style-type: none"> - Roles for CFDA central office, CMDE, NHFPC etc. are defined; <p>Responsibilities for other stakeholders:</p> <ul style="list-style-type: none"> - Renewed GMP, GDP, GCP since 2014 - Give clearer responsibilities for stakeholders along the whole product life cycle

4 More transparency & traceability

With stakeholders including patients becoming globally used to have instant access to large amounts of data and information, it is logical that also the legislation will seek to enhance transparency in availability of key data; and will also allow for better traceability to coordinate further authority and stakeholder's efforts to have clear and transparent follow up in cases of problems with products in the market.

In EU:

The critical basis for enhancing transparency in Europe will be EUDAMED, the big central database that captures all information relevant to authorities, clinician, patients, and the general public. In the period of legal negotiations, the model has shifted, and the EUDAMED database will focus on 4 key pillars.

The first 1 is on the certificates issued, suspended, withdrawn, refused, and restricted by the notified bodies

The second is capturing the vigilance data, field safety corrective actions and field safety notices, as well as associated corrective actions

The third pillar is key to include data on clinical investigations, covering among others the sponsor details and purpose, status, approval or rejection of the trial and a summary of it.

The last one is on market surveillance, detailing measures taken by member states on non-complaint medical devices as well as the preventive health measures they bring in place.

Key to linking all data in EUDAMED will be the Unique Device Identifier UDI. Details will be included on how to generate these, but the system is complex. Registrations to get a single registration number for notified bodies, and to register notified bodies are not the simplest of all. The good thing however is that implementation will become effective stepwise and not in the first few years of transitioning. So further details and guidance might well be in place in a timely manner.

At this stage, manufacturers will need to follow what is happening, will need to budget for a UDI project, and in re-developing labels will need to already include space for future UDI barcodes.

So, UDI implementation will be tricky. Starting to use UDI to enhance traceability would need timely implementation, as is the use of UDI in EUDAMED registrations.

In China:

Since the overhaul in 2014, CFDA has shown adamant resolution in pushing towards more transparency and traceability. It is manifested in the CFDA’s effort in making several databases accessible to the general public, including the registration database where the public can search for devices that are approved by the CFDA.

The results of announced QMS inspections on domestic manufacturers, random sampling inspection on product quality after the market approval, etc. have been periodically published on the CFDA websites. What’s more, since early 2016 CFDA has started publishing annual summary reports on medical device registration and annual Adverse Events report, in which many interesting numbers and figures were shown to the public to put the Chinese MedTech industry into perspective.

The above mentioned is only a few initiatives that CFDA has taken since 2014. Compared to the development in Europe and US, with the initiating and implementing safety and performance database and UDI, China in many aspects is still lagging. Nevertheless, the momentum that CFDA has built so far for bettering the Chinese MedTech industry doesn’t seem to stop here.

EU	China
<p>Extended Eudamed database</p> <ul style="list-style-type: none"> - Registration of devices and economic operators - Comprehensive information on products available on the EU market - Non-confidential data will be publicly available - Summary of safety and performance <p>UDI</p> <ul style="list-style-type: none"> - Better traceability of medical devices throughout the supply chain - Swift and effective response to safety problems (e.g. recalls) - Unique Device Identification (UDI) 	<p>Available:</p> <ul style="list-style-type: none"> - Database: Medical device registration database; classification catalogue; industry standard database; advertisement approval database - Publication: recall, QMS inspection result, device random inspection result; - Publication: annual report on registration; annual report on AEs.

5 Stricter requirements for Clinical Evidence

The most critical technical changes in legislations around focus on the actual evidence of the devices performing in their clinical settings. Consequently, getting clinical evidence in place as part of the products verification and validation globally is increasingly requiring efforts from manufacturers, both to bring new products on the market as well as to keep the existing once available.

In EU:

One of the most critical changes is the enforcement to largely rely on one's own clinical data. Many products currently are on the EU market based on the practice of stapling equivalence data, and that is precisely where changes will be expected.

The new guidance document MEDDEV 2.7.1 revision 4 will already focus all away from matrices of partial compliance to a system with one key equivalent device only, but the MDR will move beyond that, with further restrictions such as using only data from peer reviewed journals, linking the clinical evidence to the use of the device in practice as opposed to the intended purpose.

Class III and implantable devices will largely must rely on their own clinical studies, and a manufacturer can only for line extension base themselves on full or partial equivalence to their own marketed products.

Much detail is added to include annual summary updates, continuous inclusion of market surveillance data, and continuous monitoring of the risk benefit ratio and remaining residual risks.

Manufacturers will rapidly should upgrade their existing clinical evaluation reports, reduce their reliance on broad equivalence, and plan to change their quality management system to enhance the elements of active and systematic analysis of data on quality, performance, and safety.

Secondly, the law will enhance continuous improvement and will lean heavily on PMS and PMCFU. So, in addition, plans and budgets will need to be raised to ensure active updating of documentation, for example also the periodic safety update reports, that include volume of sales, population of users and frequency of use.

In China:

CFDA has been seen very active in updating its clinical requirements for medical devices. The renewed GCP, two clinical trial exemption lists for class II and class III medical devices, clinical trial site accreditation scheme and the clinical trial on-site inspection plan all demonstrated CFDA's emphasis on the devices' safety and effectiveness, and more importantly, provide safeguard to the patients in terms of rights, safety, and welfare.

What is noteworthy is that China seems to take the attitude of 'learning from the best practice', and incorporating and adopting many internationally accepted standards and practices into its own regulations. For instance, the renewed GCP is a positive step towards the alignment with the ISO 14155. The Chinese GCP is comparable to the ISO 14155, but not identical. Nevertheless, this is no call for panic. Both the Chinese GCP and ISO 14155 are in place not only to ensure the credibility of the clinical data generated in the investigation, but also (equally importantly) to ensure patients' interest and rights are always protected throughout the trial. Therefore, on the ethical ground and on good science practice ground, the Chinese GCP and the ISO 14155 are similar. Some differences lie in, but not limited to, for instance the submission requirements to the Ethics Committee, the concept of multi-center investigation, the statutory selection of at least 2 clinical trial sites in China etc.

Clinical evaluation and clinical trial for medical device registration in China will increasingly become a backlog for foreign manufacturers who wish to establish their presence in the Chinese market.

EU	China
<ul style="list-style-type: none"> - Stricter requirements for clinical evidence to support assessments <ul style="list-style-type: none"> o Interventional clinical performance studies o Studies with invasive procedures or other risks - Sponsor introduced - Database for clinical studies - Ethical consent detailed 	<ul style="list-style-type: none"> - A series regulations and guidance published by CFDA since 2014 <ul style="list-style-type: none"> o Renewed GCP o Expanded clinical trial exemption list o Guidance on clinical evaluation o Clinical trial site accreditation o Clinical trial on-site inspection - High-risk class III device clinical trial requires CFDA approval - More and more in line with the international requirements on clinical evidence

6 More internationally aligned

With the global community becoming more like one big group, further international harmonization is essential, and as previously countries provided their best practices for others to benefit from, in legislative revisions it is essential to also re-adjust existing legislation to international best practices and agreements.

In EU:

In EU, more central oversight will be created with a central governance group, the MDCG.

In addition, the coordination of market surveillance activities, currently done under the wing of the COEN (Compliance Enforcement group), will continue.

Thirdly the joint assessment of notified bodies will be further streamlined into the new regime.

A final element is the push to register especially implantable devices into registries, to collect further clinical data that may contribute to a better coordination also in setting the bar and providing common specifications.

This cooperation allows better presentation of the European market data internally in EU, but also in relation to other countries in the world.

This is further supported by efforts to align classification, essential principles and other guidances from the Global Harmonization Task Force (GFTF) and its successor International Medical Devices Regulators Forum (IMDRF) into the system.

In China:

With the trend of internationalization and globalization, more and more companies and industries are operating across borders and across continents, in hope of tapping the global market. The medical device regulations and legislations, from around the globe, are also converging towards patient safe, trade friendly, internationally accepted standards.

China is no stranger in adopting the ‘best practice’ from overseas and gives it a Chinese feel. For instance, many of the newly published 186 industry standards in the first quarter of 2016 are translated from the ISO standards.

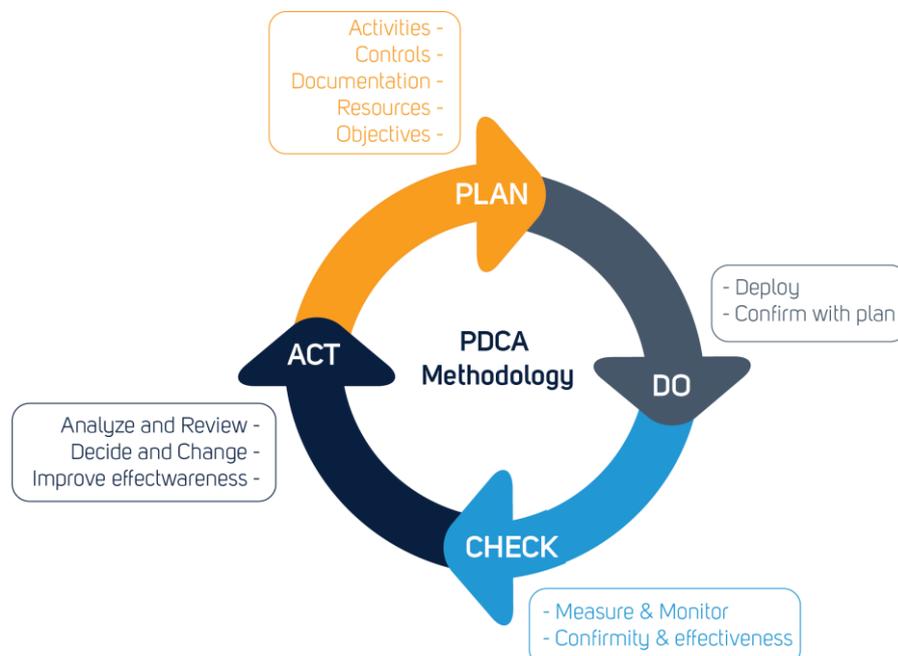
With the recent enacted ‘Priority Approval Process for Medical Devices’ (CFDA No.168 2016), China plans to put the registration of certain medical devices which can fulfil urgent or special clinical needs onto the ‘express registration lane’. It will give manufacturers (incl. the foreign manufactures) whose devices can fill in the clinical gap (e.g. treatment or diagnosis of rare disease, cancer, elderly care, and pediatric care etc.) undoubted advantage during the registration process. What’s more, this new proposal also seems to put China ahead of the curve in allowing fast track product review where patient need is high.

China is not only looking outwards by learning and adopting ‘best practice’ from its international counterparts, but also looking inwards judging by the ambitious ‘Made in China 2025’ plan, a policy that aims to encourage indigenous innovation, including the innovation in the medical device field. This policy will gradually shift the high-end MedTech industry in China from an import dominated state to a more domestic innovation supported industry. In a long run, the Chinese market is prepared to favor more and more its domestic procedure, cutting its reliance on foreign suppliers.

EU	China
<ul style="list-style-type: none"> - International guidelines to be incorporated into EU law <ul style="list-style-type: none"> oGHTF classification system oGHTF guidance 	<ul style="list-style-type: none"> - Outwards looking: adoption of ‘best practice’ - Inward looking: strengthening domestic innovation, lowering reliance on overseas supplies. - Ahead of curve: fast track approval procedure for devices fulfilling urgent clinical needs

Coping with changes in MedTech industry

So what should you be doing now? Start today if you haven’t done so already, applying for example the well know PDCA methodology!



In the PLAN phase, you must get buy-in from management on the regulatory compliance projects, get first budgets in place, then continue with more detailed impact assessments; which changes affect me? and what will the changes mean to my products and business? In the budget one should not forget to factor in the costs of translations, and the costs of the impact in the global registrations, induced by for example changes to formal claims, IFU, labeling and certifications.

In the DO phase, you should identify which products you wish to keep on the market, which are key to the continuation of the company, both inside EU as well as those that rely for market registration on underlying CE certificates.

You must ensure enough resources are available for the implementation, to provide training and a smart schedule is needed to optimally use available internal and external resources.

And you should ensure enough budget is allocated for the full implementation, not forgetting to detail potential impacts on global labeling and global registrations as that may have a huge impact on the project scope and costs.

For the CHECK phase, project monitoring and internal audits are essential, as might be mock audits.

In final phase the notified body will come in and time should be allotted for further improvement at that stage, well before the end of any transition period.

So, usually in QMS terminology the ACT comes last, but I believe we might strongly say it should be the first! You will need to ACT NOW! ■

About the authors

Dr. Gert Bos is an expert in European regulations based on 15 years hands-on working in the field, as auditor, product reviewer, regulatory specialist, and Head of notified body. He has been leading the Notified Bodies in Brussels for many years, and has strongly supported the regulatory debate with the EU Commission, EU Parliament and the EU Council of Ministers. He combines strong experience in quality, compliance, and regulations with a pragmatic, result driven approach at both operational and strategic level. From his PhD in Biomaterial Sciences, and PostDocs in controlled release of drugs and gene therapy, he has dealt as technical reviewer with a large range of devices mostly in the non-active device area. For his contributions to the regulatory profession over the last 15 years he has been awarded as Fellow of RAPS. Dr. Gert Bos currently serves as executive director and partner of the Qserve Group and is CEO of Qserve China Ltd.

Ms. Xiaoli Gou is Qserve's expert on Chinese medical device regulations. She studied in Singapore and in the Netherlands, where she graduated in Biomedical Engineering (BSc) and in Management in Health (MSc). In the multi-national regulatory compliance projects that she supports, she skillfully combines knowledge and expertise from different fields and providing pragmatic solutions. She authors whitepapers and blogs on the Chinese CFDA regulatory requirements.

About us:

Law View Partners is a boutique law firm in China that specializes in providing services to foreign investors and companies in high-growth sectors. The firm's resources and services span foreign investment and trade, M&A and finance, construction and real estate, corporate compliance, as well as market-leading experience advising clients in corporate transactional advice, intellectual property and commercial litigation.

We understand that clients are looking for value beyond legal expertise. For years, our team has been focusing on advising foreign investors, emerging companies and investment funds, on, capital investment, mergers and acquisitions, business strategy and operation, etc. We focus on business—not just paperwork. We have a proven track record of unparalleled performance, working together with our clients to achieve business goals with our in-depth understanding of their industries, and have built a client roster that includes many of the world's most recognized and respected brands.

The Firm's strengths are in the fields of senior housing and healthcare; hospitality and retail real estate; foreign investment; advertising, technology and media ("ATM"); corporate compliance; and merger and acquisition (M&A).

Our Clients:

Real estate developer
Private equity investor
Operator
Banker and insurer
Architecture and design companies
Government agencies
Retail pharmacies and wholesale distributors
Medical device manufacturer and supplier

We represent providers across the continuum of senior living and care, including retirement living communities, assisted living and skilled nursing facilities, community centers and nursing station, home health, rehabilitation and specialty hospital.

Our services include:

- Advice on project regulatory feasibility and structuring of business models;
- Business incorporation and licensing, and negotiation with joint venture partners;
- Development and operation management contract;
- Draft and standardize documents for operation: resident contract, policies and procedures for residency, vendor contract, etc.;
- Senior housing assets development, acquisitions and dispositions;
- Advice on Public-Private-Partnership (PPP) structuring and documentation;
- Regulatory Compliance;
- Advice on finance and tax;
- Deal with issues involving intellectual property, liabilities and employment;
- Litigation and arbitration.

Our strengths:

--**Most renowned global team.** As early entrants as legal professionals in this industry, we understand the way the senior housing and healthcare industries works. We are trusted key advisors, with the experience and reach to advise at all stage of this business.

--**Outstanding track record.** Having represented international companies, from developers and aged care/hospital operators to institutional investors, in their entry into the Chinese market, we benefit our clients with our deep industry knowledge and experience, and with our creative, solution-oriented and responsive approach.

--**Industrial networking platform.** We are the chief editor of China Senior Housing and Health Care Newsletter. Our partners have participated in many senior care conferences in Asia, as chairperson, speaker and/or panelist, and have authored several articles and reports. Clients benefit from our industrial network in a wide variety of business.

--**Service covering the full life cycle of senior care project.** Providing sound service on the full spectrum of issues in project development which can arising during the site selecting, acquisition, feasibility studying, construction, financing, pre-opening preparation, post-opening operation and disposal of senior care or hospital facilities.

Speeches and publications:

Our partners have participated in several senior care conferences in Asia, as chairperson, speaker and/or panelist, and have authored several articles and industry report, including:

- American Chamber of Commerce, Hong Kong, September 2011.
- Retirement Communities World Asia, Hong Kong, October 2011 & 2012.
- Retirement Living World China, Shanghai, May 2012 & October 2013.
- Care Show China, Shanghai, August 2013. A half-day workshop on doing senior care business in China.
- International Association for Housing and Services for the Ageing (IAHSA), Shanghai, November 2013. A half-day workshop on doing business in China, with a focus on senior housing.
- The 4th Summit Retirement Living World China and the first Aged Care Service International Seminar 2014.
- ULI Mainland China Winter Meeting 2014, speech on the topic of “Hospital and Senior Care Facilities Development and Investment”.
- China Senior Living & Healthcare Design Debate 2015. Panel discussion on the topic of “Optimizing Design for better operational risk management”.
- Care Expo China, Shanghai, 2014 to 2016.
- Columbia-Fudan Global Summit on Aging and Health, Shanghai, October 2016. Panel discussion on the topic of “Public-Private Partnerships in the Elderly Care Industry”.
- Co-author with Rubicon a China Senior Care Report which includes in-depth analysis on new regulations specific to both senior housing and home healthcare.