

## Breaking News on Outsourcing Pharma

Previous page : [China gets serious on drug GMP; safety pact with FDA imminent](#)

# China gets serious on drug GMP; safety pact with FDA imminent

By Kirsty Barnes

13/11/2007- **As of next year Chinese pharmaceutical manufacturers will face a tougher time gaining good manufacturing practice (GMP) certification after the country's regulator signalled new and stricter standards were on the way.**

Meanwhile, a six month series of talks on drug safety between China's State Food and Drug Administration (SFDA) and the US Food and Drug Administration (FDA) may soon bear fruit.

Effective 1 January 2008, the SFDA will no longer tolerate the detection of any "severe defects" during a GMP accreditation process, meaning that such a finding will result in automatic failure, it was reported in Chinese news outlet Xinhua.

Under the current system, certification is still granted if less than three severe defects are discovered during the manufacturing process, as long as the problem(s) are rectified within the required time limit.

An example of one such severe defect is falsifying application documents, although the SFDA did not elaborate any further.

The agency did say that the revised standards will contain 259 articles, an increase of 34, and the number of articles that are now considered "key" will also jump from 56 to 92.

An SFDA spokesperson told Xinhua that the changes mainly relate to matters of staff qualifications, production process, quality control and document verification.

It has only been since 2004 that China has required all its pharmaceutical manufacturers to comply with GMP regulations at all - before this, the country had introduced GMP certification in 1998, but did not insist upon adherence.

However, despite this earlier attempt at a regulatory crack down, China continues to be centre of numerous health and safety scares around the world and at home, involving pharmaceutical substances manufactured in the country.

Many will be hoping that the SFDA's latest attempt at regulatory scrutiny on its drug makers will significantly raise the bar for gaining the coveted GMP certification and in turn, the quality of the medicines its producers churn out.

Not least the FDA, which has been copping much criticism of late for its failure to inspect even a fraction of the foreign drug manufacturing facilities that export to the US.

This is a worrying scenario, considering that 75-80 per cent of all active pharmaceutical ingredients (APIs) used by US drug manufacturers are now imported, mainly from India and China, along with 40 per cent of finished dosage forms from various global locations.

According to a recently-released Government Accountability Office (GAO) audit report, China, which has the largest number of drug manufacturers eligible for FDA inspection (714) is earmarked for only 13 regulatory visits by the FDA this year, meaning only less than 2 per cent of the country's drug exporters will have their facilities examined.

As mentioned earlier, it is China of all places that should be subject to particular regulatory scrutiny due to its abominable track record on unsafe and counterfeit drug products, along with a smattering of corruption amongst some of the country's high-ranking regulatory officials.

However, it appears that progress is slowly being made. The FDA's department of human Health Services (HHS) has been involved in a series of bilateral meetings with its Chinese counterparts over the past few months in a bid to tackle the safety issue.

US food and drug regulators raised elevated concerns with China over the safety of its imports in May and requested "*rapid action*" over the establishment of better cooperation; better information; and establishment and enforcement of "*regulations that we can understand, with which we agree and in which we feel confident*".

*"Our US regulatory agencies are concerned about what they see as an insufficient infrastructure across the board in China to assure the safety, quality and effectiveness of many products exported to the United States"*, HHS secretary Mike Leavitt said in a statement in July.

*"I am hopeful that we can achieve two, strong, action-oriented documents by December"*.

This timeline is looking likely - last week the SFDA announced that the two countries will indeed seal a pact next month to cooperate on and improve drug safety.

Meanwhile, well aware of its dubious international reputation, the GMP clamp down is only the latest in a number of initiatives the agency has been launching all year in an attempt to reverse itself in the eyes of the international community.

In September the SFDA released a draft plan that would require manufacturers to recall drugs as early as 24 hours after they are discovered to be unsafe.

It also pledged to place a particular emphasis on the scrutiny of the manufacturing of injectable drug products by upping the number of its staff at such production sites, along with a crack down on wholesalers and distributors of pharmaceutical ingredients, checking the licenses of anyone who started operating as of 2006, and will also carefully monitor those involved at all stages of the supply chain of highly restricted substances.

Prior to this, China announced an initial \$1.7bn (€1.2bn) investment to bolster its currently questionable ability to effectively monitor the quality of the food and drugs manufactured within its borders.

And in June, China's top administrative body, the State Council, announced a series of regulatory reforms, vowing to place new controls on drug (and food) imports and exports by 2010 and to increase the proportion of such products that are subject to random inspections to 80 per cent - currently the figure is only 30 per cent.

In its reform efforts, the country is facing a mountainous task, however, it is a mountain well worth the climb.

**Copyright** - Unless otherwise stated all contents of this web site are © 2000/2007 – Decision News Media SAS – All Rights Reserved. For permission to reproduce any contents of this web site, please email our Syndication department: [contact our Syndication department](#). Full details for the use of materials on this site can be found in the [Terms & Conditions](#).

[contact the editor](#)

[Print](#)