PHARMSOL NEWS

A PERSPECTIVE ON CHANGING REGULATORY LANDSCAPE IN CHINA PHARMA INDUSTRY

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With the structural adjustment in China's domestic policies, the process of internationalization and the stringent international policies on Pharmaceuticals, Chinese pharmaceutical companies are facing new challenges in GMP compliance.

Policy Perspective:

Cost control, quality, innovation and compliance are the main themes of current China's pharmaceutical industry.

Since 2015, China has started the consistency evaluation of generic drugs. At the end of 2018, the National Medical Insurance Administration issued the policy of “4+7” centralized procurement of drugs, aiming to exchange quantity for price. From then on, generic drugs entered the era of quality and competitive cost which will boost the industry.

According to the policy of generic drugs consistency evaluation, " the generic drugs manufactured by Chinese domestic manufacturer which is approved for sale in EU, USA and Japan, can be regarded as passing the consistency evaluation”, arouses the enthusiasm of pharmaceutical companies for internationalization.

In June 2017, China officially confirmed NMPA to join ICH as its eighth global regulatory agency. This means that China's pharmaceutical industry will compete in a global landscape.

In 2019, GMP/GSP certification were cancelled in the newly revised "Drug Administration Law”. The concept of supervision has been clarified: from static nodal supervision to dynamic and whole process supervision and continue to maintain GMP compliance.

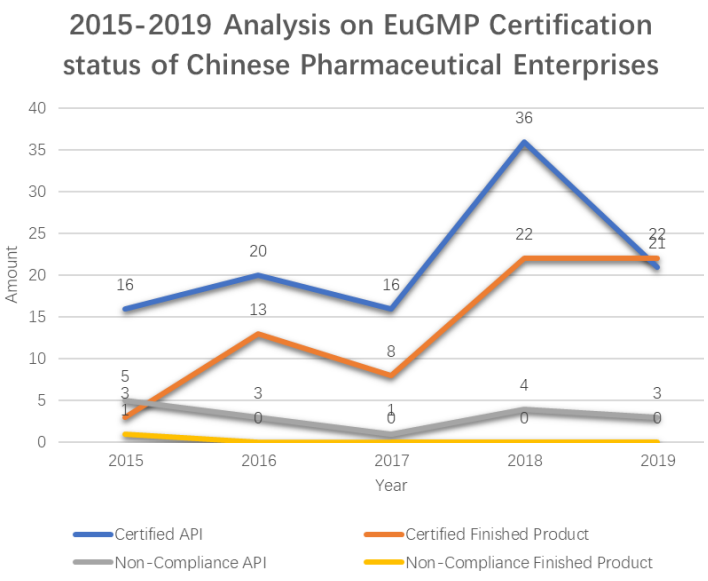
Meanwhile, both FDA and EMA have never relaxed their supervision on data compliance of pharmaceutical companies. According to statistics, US FDA issued a total of 102 GMP warning letters in fiscal year 2016, 114 in fiscal year 2017, and 127 in fiscal year 2018. Among them, the number of warning letters received by manufacturers from China is the largest and on the rise year by year: 15 in fiscal year 2016, 17 in fiscal year 2017, and 24 in fiscal year 2018.

Compliance Trend Perspective:

According to the GMP database of Eudra GMDP, from 2015 to 2019, a total of 200 (for human use) EUGMP certification of Chinese pharmaceutical enterprises were obtained.

Item \ Year		2015	2016	2017	2018	2019	Total
Certified	API	16	20	16	36	21	109
	Finished Product	3	13	8	22	22	68
Non-Compliance	API	5	3	1	4	3	16
	Finished Product	1	0	0	0	0	1

From the chart analysis, the API pharmaceutical enterprises are still the ones that have passed the EU certification, but the number of pharmaceutical enterprises that have passed the EU certification has increased. The decline in 2019 is linked to Brexit. And the GMP management of formulation has higher requirements.



The key deficiencies in the 2018-2019 EU non-conformance report are QA system, Manufacturing controls, Sterile production, Data integrity and QC.

The analysis of FDA warning letters in 2019: 92 warning letters in 2019 contained 292 deficiencies. Among them, there are 97 deficiencies in QA system, 94 deficiencies in QC system, 70 deficiencies in production, 21 deficiencies in equipment, 1 deficiency in label packaging and 11 deficiencies in material system.

Main findings of 2017 NMPA GMP follow-up inspection: Quality Control and Quality Assurance section are the most prominent, with a total of 1,205 defects, accounting for 28%, followed by document management, accounting for 16% of the total, and then by equipment defects (ranking the third), accounting for 10%.

Quality Culture Perspective:

Quality culture refers to the habits and cognition of employees' daily behaviors that have been maintained from the top to the bottom within the company. The core of quality culture is the quality concept that the enterprise and employees hold in the operation activities.

Starting at the top, a quality culture is most effective when management leads by example. The quality culture is included in the company culture, imperceptibly influenced in the daily work, and the quality is transformed into the habit and cognition of the daily behaviors of the employees by adopting different forms of continuous publicity。

A mature quality culture remains the key to fully achieving strong data integrity. In recently released guidance on data integrity, FDA stated directly that "the responsibility of senior management in pharmaceutical companies is to create a culture of quality that enables employees to understand that data integrity is a core value of the organization and encourages employees to identify and report data integrity issues in a timely manner."

Technical Perspective:

With the integration of the industrial chain, the demand for enterprise informatization is getting higher and higher, and information management tools have become an important means for pharmaceutical enterprises to perform regulations efficiently and promote drug compliance production. Drug production management is complex and rigorous, manual management is time-consuming, precision is difficult to control, drug production cycle is extended, the whole process needs electronic procedures to promote the implementation. The drug management process based on GMP standard is faced with the characteristics of compliance, complex procedures, multiple links and long cycle, which requires more flexibility and synergy of the system.

Conclusion:

Overall, with the increasingly strict GMP compliance environment, the ability to analyze gaps with regulatory requirements, the execution ability of documents and the formation of quality culture are in urgent need of improvement.

PharmSol, through its vast experience in providing solutions to the Pharmaceutical industry envisages the issues through a systemic project handling and helps companies for a smooth and successful EUGMP inspection.

Compliance, post inspection is expensive and compliance before inspection is a great experience and learning.

PharmSol