Practice and Thinking on the Construction of Provincial Professional Drug Inspector Team—Taking the Construction of Shandong Drug Inspector Team as an Example

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Abstract
Promoting the construction of professional drug inspectors is an important measure to improve the drug regulatory system in China. At present, 31 provinces have basically completed the establishment of professional drug inspectors. In order to use and manage this team well, all provinces have carried out active exploration and hard practice in the construction of professional drug inspectors, and accumulated valuable experience. This paper summarizes Shandong's exploration and experience in recent years in terms of institution building, personnel allocation, capacity improvement, incentive mechanism, assessment and evaluation, integrity building, system building, etc. It analyzes the difficulties encountered in the construction of professional drug inspectors in terms of hierarchical and classified management, professionalization process, assessment and evaluation system, salary and treatment mechanism, etc. On this basis, it puts forward the establishment of evaluation standard system, positive incentive mechanism A series of measures such as optimizing the management system are expected to provide decision-making reference for the construction of professional drug inspectors at the provincial level in the future.

Keywords
Drug administration, professional drug inspectors, team construction

Introduction
In recent years, central committee of the Communist Party of China and the State Council has attached great importance to the construction of a professional drug inspector team. In 2019, the General Office of the State Council issued the Opinions on Establishing a Professional and Professional Drug Inspector Team, which comprehensively kicked off the establishment of a professional drug inspector team. By the end of 2020, 31 provinces have basically completed the formation of professional drug inspector teams. In order to make good use of and manage this contingent, all provinces have carried out active exploration and hard practice in the construction of professional drug inspector teams, and have accumulated valuable experience. This paper summarizes the exploration and practice of the construction of professional drug inspectors in Shandong Province in recent years, analyzes the difficulties encountered in the process of team building, and puts forward some thoughts on how to better build a provincial-level professional drug inspector team, aiming to provide decision-making reference for the provincial-level professional drug inspector team.
1. The practice of Shandong Province in the construction of professional inspector teams

1.1 In terms of expanding the ranks of inspectors

In 2019, Shandong Provincial Organization Committee Office approved the establishment of 150 professional drug inspectors. From 2020 to the end of 2021, Shandong Province adopted the talent introduction policy of "urgent before slow, classified policies", and recruited more than 100 professional inspectors in three batches. The first batch of personnel were transferred from the original drug supervision system at the city and county levels, and these personnel have inspector qualifications, rich experience, outstanding practical ability, and can directly engage in inspection work, which solves the problem of inspector shortage in a short period of time. The second batch of recruitment for the society, covering three levels: high, middle and junior, most of the senior personnel have research and development experience in pharmaceutical companies or work experience in the drug supervision system, and at the same time, the introduction of technical talents including computer, accounting and other majors. The third batch is open to the public to recruit high-educated young talents as a reserve army for the construction of the inspector team.

1.2 In terms of improving the competence of inspectors

Shandong Province adopts various forms to carry out professional inspector training. Including: the use of pre-job training, on-the-job teaching, continuing education, practical training and other methods to improve inspectors' inspection skills. Pre-job training mainly teaches the policies, regulations, comprehensive knowledge, and basic operational skills of inspection work, and improves the comprehensive ability and quality of adapting to the work of inspection posts. Teach by post, select senior inspectors with outstanding ability and "pair" with new inspectors to carry out one-on-one training. Continuing education, in-depth cooperation with universities and scientific research institutes, jointly holding inspector capacity improvement training courses, and carrying out special training courses on traditional Chinese medicine knowledge and drug clinical trial inspection; The daily training adopts the mode of "two-way learning and two-way improvement", and carries out the activity of "my business I will talk about my business" when inspectors go to the podium. Practical training uses the "immersive" training mode to improve practical skills, establishes a regular cooperation mechanism with many medical institutions and pharmaceutical manufacturers, and regularly organizes inspectors to study. In addition, business backbones are regularly selected to the State Food and Drug Administration and related units, provincial bureaus for temporary training.

1.3 In terms of motivating inspectors

In November 2021, the Shandong Provincial Food and Drug Administration and the Human Resources and Social Security Department of Shandong Province jointly issued Several Measures on Further Strengthening the Construction of the Provincial-level Professional Drug Inspector Team, proposing to establish a professional title evaluation committee to carry out the professional title review of drug inspectors, and set up three majors: drug inspector, medical device inspector and cosmetics inspector. In terms of optimizing the personnel management of drug inspectors, the post of chief inspector is established according to the categories of drugs, medical devices and cosmetics, and an annual salary system can be implemented for them. Shandong Province organizes and carries out professional skills competitions such as the province's drug inspection skills competition to mobilize the enthusiasm and initiative of drug inspectors to perform their duties and enhance their sense of professional honor.

1.4 In the evaluation of inspectors

Shandong Province has promulgated the "Inspector Assessment and Evaluation Management System" to comprehensively evaluate inspectors from the aspects of inspection attendance, professional behavior, ability level, and integrity and discipline. The provincial-level inspection agency has established an inspection report quality management committee to regularly evaluate the quality of on-site inspection reports and improve the level of inspection quality management. In addition, Shandong implements the work of "quantification of drug inspection work", scientifically calculates the inspection workload, and accurately grasps the on-site inspection efficiency.

1.5 In terms of building the integrity of inspectors

Shandong Province has carried out a systematic prevention and control mechanism to achieve closed-loop man-
management of integrity risks. The "four systems" are implemented for various inspections: the system of interviews before the departure of inspection teams, the system of random inspections during on-site inspections, the system of return visits to inspected enterprises, and the system of regular clean government education for inspectors. Adopt the working mode of "interview letter inquiry plus investigation and verification plus discipline inspection and supervision proposal", select relatively specific and verifiable problem clues, and issue disciplinary inspection and supervision proposals to emerging problems found through conversation letter inquiry and investigation and verification, so as to achieve closed-loop management of integrity risks.

1.6 In terms of promoting the construction of a long-term development mechanism for the team of inspectors

In 2021, Shandong Province launched the "Excellent Project" action plan for professional and professional drug inspectors, which is a talent training project specifically for inspectors. Including the construction of pharmaceutical mechanization training content, the development of training resources, the establishment of inspection workflow specifications, and the construction of use management system, 22 projects. In terms of training, four professional knowledge manuals such as the "Compilation of Post-market Change Documents for Drugs" for training were compiled; There are 21 review and inspection points such as "Key Points for Drug Re-registration" and "Guidelines for On-site Inspection of Surgical Shadowless Lamps in Shandong Province". More than 80 courses covering registration, production, marketing and other links have been developed; A faculty expert database of more than 400 people has been established in 22 disciplines. In terms of work process, 7 procedural documents such as "Technical Review Work Procedures for the Filing of Chinese Medicine Formula Granules" and "Emergency Inspection Work Procedures" have been newly formulated, and 24 system documents such as "Drug Production License Inspection Work Procedures" and "Medical Institution Preparation License Inspection Work Procedures" have been optimized.

2. Shandong Province has encountered difficulties in building a professional inspector team

2.1 It is difficult to classify inspectors

At present, the grading and classification of inspectors in Shandong Province is still in its early stage, and it is difficult to promote the management measures for inspectors' grading and classification. The reason is that in order to establish an effective grading and classification evaluation system for inspectors, it is necessary to carry out targeted research in combination with the actual work and professional characteristics of inspectors. At the same time, in order to ensure the scientificity and effectiveness of the grading and classification work, it is necessary to guide the basic theories such as human resource management and statistics, and establish a scientific and complete evaluation standard system with visual and quantifiable data.

2.2 Inspectors are not sufficiently professionalized

The occupational definition of professional inspectors was proposed in 2019 and is a new occupational group. Compared with traditional professions such as police officers and doctors, its long history of construction makes it have its own unique professional characteristics (Yin Baohua, 2008). The construction of the inspector team is still in its infancy, and the cultivation of professional awareness, professional skills, professional ethics and professional status is still very lacking (Qiu Ji, 2012), and there is still a lot of work to be done to achieve true professionalism.

2.3 There is a lack of a scientific and reasonable assessment and evaluation system and remuneration mechanism for inspectors

At present, the evaluation of inspectors still follows the year-end evaluation mechanism of public institution personnel, and the salary and treatment of public institution personnel are also strictly implemented. The level of remuneration and treatment of inspectors is mainly related to the technical title positions they are hired, and is not linked to the amount of inspection tasks and the difficulty of inspection work. In view of the particularity of the inspection work, the assessment indicators are scientifically set, and an assessment and evaluation system is established that focuses on on-site inspection ability and risk control ability, and combines daily assessment with year-end evaluation, ability evaluation and performance evaluation.
2.4 Incomplete management system of inspector team

Although some provinces and cities have issued corresponding management measures for inspectors, the existing management standards for inspectors are generally rough, and most regulations or methods are not detailed, which makes it difficult to play the role of practical constraints and evaluation. How to carry out dynamic management of drug inspectors from the aspects of access, training, performance assessment, rewards and punishments, and career planning is a problem worthy of discussion. Interviews with inspectors showed that they did not have a systematic understanding of the existing drug inspector management system, and did not know what systems and norms were. Some of them even showed a negative attitude. They believed that it was the responsibility of the leadership to strengthen team building and develop management norms, so they did not need to know (Luo Xiao, 2021).

3. Thinking on the construction of the provincial-level professional inspector team

3.1 Build the foundation of a hierarchical classification system

3.1.1 Establish a scientific and reasonable hierarchical assessment standard system
The grading and classification level assessment standard system for professional inspectors shall fully consider the particularity of inspection work, scientifically set evaluation indicators, and establish a comprehensive evaluation system based on personal basic quality, inspection ability, inspection workload, scientific research level, etc., to achieve diversified and professional level assessment.

3.1.2 Pay attention to the orientation of hierarchical and categorical management methods
The formulation of hierarchical and categorical management measures shall fully consider the orientation and influence on inspectors' career planning and growth goals. The key to the formulation of hierarchical and categorical management measures is to effectively guide inspectors to establish correct professional values, improve inspection capabilities, and strengthen personal qualities (Du Peng, 2014).

3.2 Establish a vocational training system for drug inspection
Drug inspection is a highly professional technical work, and a corresponding training system should be established according to different categories, and a targeted drug inspection vocational education and training plan should be proposed, and the training object, goal, content, plan, time, method and training assessment system should be clearly stipulated (Liu Chenchen & Xing Zhanjun, 2013). Strengthen the management of the implementation of the training plan through the training plan, strengthen the management of the training site and the assessment of the training content, analyze and evaluate the training effect, and take the participation in the training and the training effect as one of the important conditions for the annual evaluation, rank promotion and reward and commendation of drug inspectors.

3.3 Formulate a scientific and reasonable assessment and evaluation system
Combined with hierarchical and categorical management methods, implement hierarchical and categorical assessment. In view of the particularity of the inspection work, scientifically set the assessment indicators, establish a diversified assessment and evaluation system with on-site inspection ability and risk control ability as the evaluation focus, combining daily assessment with year-end evaluation, ability evaluation and performance evaluation, and multi-dimensional assessment of inspectors' professional ethics, performance ability, professional skills, work performance, etc. The assessment and evaluation results are used as the basis for job recruitment, grade evaluation and promotion, salary and treatment adjustment, and the withdrawal of unqualified inspectors.

3.4 Establish and improve positive incentive mechanisms
Linking the level of inspectors' remuneration and benefits with the level of inspectors, the difficulty of inspection work and the amount of inspection tasks, fully considering the actual situation of inspection work, and building a salary incentive mechanism that is inclined to the front line of on-site inspection. Establish a performance-based salary increase mechanism for full-time inspectors, appropriately subsidize part-time inspectors with reference to the level of external experts hired in similar matters, and encourage more flexible salary distribution methods for high-level talents among inspectors. For drug inspectors with outstanding inspection ability, discovering or eliminating major risks and hidden dangers, and making outstanding contributions in emergency response, commendations and awards will be given to enhance their professional honor.
3.5 Optimize the inspector management system.

According to the categories of drugs, medical devices and cosmetics, the post of chief inspector is set up, and high-level professionals are introduced to provide professional technical guidance for drug inspection work. Reasonably approve the total performance salary of provincial-level drug inspection agencies, improve internal assessment and evaluation indicators, dynamically adjust the proportion of post establishment structure in public institutions, and recruit and introduce high-level talents with high-risk drug inspection skills and practical experience such as vaccines. Appropriately increase the structural proportion of senior professional and technical posts in provincial-level drug inspection institutions, and smooth the channels for talent promotion.

References