

Analysis of the Construction and Application Path of International GMP Training Model for Pharmaceuticals under the Background of China-Africa Cooperation

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ABSTRACT

This paper conducts an in-depth analysis of the actual situation of GMP training cooperation between China and Africa in the pharmaceutical industry, and clearly points out the numerous challenges it faces in terms of one-way output, content fragmentation, and mechanism sustainability. Based on this, relevant research focuses on establishing a brand-new international training model that takes co-construction and sharing as its core concept, systematization as an important principle, and sustainable development as its core pursuit. This model actively advocates multiple paths such as specific measures for pilot construction, the establishment of regional networks, and the deep integration of systems, to promote cooperation to no longer merely remain at the stage of simple knowledge imparting, but to shift towards the direction of co-building capabilities, thereby fully stimulating the intrinsic driving force for the development of the African local quality system itself. Ultimately, it will provide continuous and powerful support for ensuring the safety of drugs and promoting the development of industrial cooperation.

KEYWORDS

China-africa cooperation GMP; International training application path

1 Introduction

In the current era of continuous integration in the global pharmaceutical industry, Good Manufacturing Practice (GMP) for drugs has become an important cornerstone for ensuring drug safety and enhancing their efficacy^[1]. The cooperation between China and Africa in the medical and health field has been continuously deepened, which has brought a historic opportunity to enhance the capacity of drug supply security and the level of localized production in the African region^[2]. Promoting the international training of GMP standards for drugs is not only a way of technology transfer but also a crucial support for building an internal drug quality assurance system on the African continent. It has a very profound significance for achieving a healthy and beautiful vision of common development between China and Africa. The existing training cooperation models have encountered many challenges, and their effectiveness has not yet fully met the long-term development needs of African countries. The traditional approach has room for improvement in terms of sustainability, systematization, and integration with practice. Therefore, it is extremely urgent to explore and establish a brand-new, more resilient and more synergistic international training model.

2 The current situation of GMP training cooperation between China and Africa for pharmaceuticals

2.1 One-way Output Feature Analysis of Training Cooperation

At present, the cooperation on GMP training for drugs between China and Africa has a distinct one-way output feature, which has affected the cooperation effect. In this model, the Chinese side is the main provider of knowledge and technology, and has a strong leading role in the setting of training agendas, the development of course content, and the selection of lecturers^[3]. Most African participants are at the knowledge receiving end, and it is difficult for their local practical experience and specific national conditions to be integrated into the initial stage of training design. Although this preset standardized scheme ensures transmission efficiency, it may reduce the actual fit of the training content with the differentiated regulatory environments, industrial foundations and cultural backgrounds of various African countries.

A careful study reveals that this unidirectionality is reflected at the course level and also exists throughout the entire process of cooperative interaction. The feedback generated by non-trainees during the training period, the unique challenges they encountered, and the local knowledge they accumulated failed to play an optimizing role in the subsequent cooperation. This is a supply-oriented working approach, and the two cooperating parties have not formed a true knowledge co-creation relationship. In the long term, this mechanism is difficult to fully mobilize the enthusiasm and internal motivation of African institutions to build their own capabilities, affecting the effectiveness and sustainability of knowledge transfer and causing the depth of cooperation to hit a bottleneck. Therefore, it is particularly important to

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explore a more balanced cooperation model that emphasizes two-way communication.

2.2 Review of the Fragmentation of Training Content

At present, the GMP training cooperation between China and Africa is also confronted with another very prominent challenge, that is, the training content shows a distinct fragmented feature^[4]. Most of the existing training programs are carried out with specific themes or single dosage forms as the core, such as training on tablet production or sterility assurance, etc. However, they lack a systematic design concept that runs through the entire chain, from quality risk management, pharmaceutical quality system construction to data integrity management. As a result, the knowledge points imparted are like isolated islands, failing to establish an organic connection with each other. This makes it very difficult for trainees to form a profound understanding of the GMP standards in terms of their overall and logical aspects. Moreover, training arrangements are often driven by short-term projects rather than based on the career development of African trainees or the long-term plans for upgrading the quality system of their institutions. This further makes the learning content random and fragmented.

The direct consequence of this fragmented state is that the effects achieved through training are difficult to be effectively accumulated, and thus it is hard for them to be transformed into actual capabilities. After returning to their posts, trainees, although they have mastered some specific skills, most of the time they are unable to integrate these scattered knowledge and apply them to solve the overall quality control problems faced by their factories. There are inherent gaps in the knowledge system itself, which makes them feel powerless when promoting systemic changes, and the marginal benefits obtained from training investment also show a decreasing trend. Essentially, such a training design approach that lacks continuity and advancement cannot effectively support African countries in establishing a self-evolving and continuously improving drug quality assurance system.

2.3 Analysis of the Causes of the Weak Sustainability of the Cooperation Mechanism

At present, the sustainability of the GMP training cooperation mechanism between China and Africa is relatively weak, and this situation is particularly evident in terms of resource input. Most projects rely on short-term foreign aid funds or single project grants to maintain operation, lacking stable and diverse financial support plans. When a specific project cycle comes to an end, the related training activities and technical support may be interrupted, making it difficult to achieve a long-term and consistent capacity-building effect.

The more intractable problem lies in the deficiency of the support system. In terms of the construction of the core teaching staff, there are certain deficiencies. Chinese experts are often temporarily selected and dispatched, and the training mechanism for local African lecturers has not yet been systematically established. As a result, it is difficult for the teaching force to maintain a continuous and stable situation. In addition, an effective tracking and evaluation process is largely lacking. There is a lack of corresponding feedback and subsequent support on the application effectiveness of post-training knowledge by trainees and the quality improvement of their institutions. This results in the inability to form a closed loop for the transformation of training outcomes, which in turn affects the self-sustainability and development capacity of the cooperation mechanism.

3 The application path and implementation strategy of the new model

3.1 Pilot project construction and infrastructure support

To ensure the effective implementation of the new training model, the first step is to select countries with a solid foundation of cooperation to jointly build training centers with exemplary significance. Such pilot projects can no longer merely remain at the traditional level of simple teaching venues. They should be fully developed into comprehensive ability incubation platforms with distinctive features. In terms of the supporting infrastructure, it is essential to break through the conventional scope of classrooms and teaching materials, and focus on building pilot production lines or simulation workshops that meet international standards. This will enable trainees to further deepen their understanding of relevant theories in real scenarios and effectively exercise their practical skills at the same time.

In addition to hardware investment, the core function of the pilot project should be more reflected in the construction of soft capabilities. One of the very crucial links is to systematically implement the trainer training program, and to work hand in hand with Chinese regulatory authorities and leading enterprises, so as to cultivate a local core lecturer team for African countries. It is equally important to create a digital resource center that integrates multilingual courses, classic cases and a regulatory library, so as to facilitate continuous knowledge accumulation and sharing in this way. All these measures have jointly laid a solid foundation for the sustainable future of the training system, which shifts from relying on external support to self-sustaining.

3.2 Regional Promotion Strategies and Collaborative Network Construction

After the pilot project has been running smoothly and accumulated effective experience, the key point of the next stage lies in systematically promoting its successful model to a broader area. The realization of this process requires actively leveraging the influence of regional organizations such as the African Union and the African Medicines Agency to gradually upgrade the demonstration center into an industry benchmark institution that can serve the entire African continent. By participating in the formulation of regional training standards and qualification certification frameworks, the authority and mutual recognition of training outcomes can be significantly enhanced, thereby breaking through national limitations and promoting the flow and sharing of quality management talents within the region.

On this basis, efforts should be made to build a collaborative network with multi-level characteristics and a three-dimensional trend, which is extremely crucial and important in relevant aspects. The core measures include jointly establishing a China-Africa GMP expert resource library, bringing together the wisdom of elite talents in the regulatory field, experienced senior scholars and industry experts from both sides, so as to provide corresponding intellectual and technical support for various rather complex issues. In addition, it actively encourages the establishment of a China-Africa Pharmaceutical Enterprise Quality Alliance, enabling enterprises from both sides to carry out practical cooperation in areas such as sharing best practices, conducting audits on supply chain quality, and even matters related to technology transfer. The high-level industry forums held regularly and a series of activities such as joint inspection simulation exercises can transform the originally static classroom knowledge into dynamic solutions based on real challenges. Such a deep interaction will eventually form a vibrant cooperative ecosystem, enabling knowledge, technology and experience to continuously flow and increase in value within this network, thereby effectively ensuring the vitality of the training model and its ability to adapt to changes in the external environment.

3.3 Deep Integration of Systems and Coordinated Leadership of Standards

After achieving the result of regional promotion, the ultimate goal pursued by the cooperation model is to promote the deep integration and coordinated development of the quality management systems of both China and Africa. At this stage, the focus of attention will gradually shift from the specific and simple aspect of technology transmission to building an industrial quality ecosystem that enables all parties to share the fruits and achieve common prosperity and development. The training activities themselves should not merely remain at the level of simple interpretation of the standard provisions, but should thoroughly analyze the inherent logical connections among international standards such as China's GMP, WHO, and PIC/S, as well as their relevant contents in terms of common requirements, with a focus on cultivating the trainees' ability to make quality decisions based on risk management. Such a process of benchmarking and mutual certification has laid a solid technical and conceptual foundation for China and Africa to carry out standard coordination work in the field of drug regulation and establish a mutual trust relationship in market access in the future. It can be regarded as an important step towards long-term cooperation.

The key to achieving system integration lies in effectively combining training with industrial investment. Chinese pharmaceutical enterprises operating in Africa should be encouraged to actively participate in training, serving not only as providers of technical resources but also as platforms for local talents to apply knowledge in practice. This can make the training more targeted and form a virtuous cycle in which industrial demands drive course design and talent cultivation contribute to industrial upgrading. To ensure the continuous operation of this complex system, it is necessary to explore the establishment of a diversified long-term support mechanism, such as integrating government development assistance, corporate social responsibility investment, project support from international organizations, and cost-sharing among beneficiaries. Relying on multi-level and networked collaboration, the ultimate goal is to stimulate the intrinsic driving force for the self-development of Africa's quality system, gradually transforming cooperation from the "teaching people how to fish" led by China to a "cooperative fishing" involving both China and Africa, and even reaching a new stage where Africa can independently carry out "pioneering fishing grounds", thereby laying a solid foundation for drug safety in Africa.

4 Conclusion

The analysis results of this study clearly indicate that it is necessary for the cooperation between China and Africa in GMP training for pharmaceuticals to break through the framework of the traditional auxiliary model and shift towards a strategic collaboration direction that focuses on capacity building. In terms of the current mechanism, it faces a series of challenges such as unidirectionality and fragmentation. Therefore, under such circumstances, it has become an indisputable and inevitable choice to build a new training model based on equality and mutual benefit and systematically designed. This new model focuses on achieving the goal of deep integration between knowledge transmission and local practice through pilot exploration and regional networked promotion methods. The core value of this transformation lies

in its ability to stimulate the intrinsic impetus for the development of Africa's quality system, and to gradually shift the focus of cooperation from short-term technology export to long-term capacity building. On this basis, the further efforts made by both China and Africa in terms of standard coordination and industrial integration will lay a lasting and solid foundation for ensuring the safety of drugs, promoting win-win cooperation in the industry, and further deepening health cooperation between China and Africa.

Funding

This work was supported by the Vocational Education Teaching Reform Research Project of Chongqing Municipal Education Commission "Development and Application of an International Training Course on GMP in the Context of China-Uganda Pharmaceutical Luban Workshop" (NO: Z2253461) and the Vocational Education Teaching Reform Research Project of Chongqing Medical and Pharmaceutical College (NO: YGZJG2025313).

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