別添 3-1　結果要約表（英文）

Summary

Evaluation conducted by: Foundation for Advanced Studies on International Development (FASID)
Report date: June 2009

1. Outline of the Project		
Country: People's Republic of China		**Project Title:** China-Japan Friendship Project on the National Center for Safety Evaluation of Drugs
Issue/Sector: Health		**Cooperation Scheme:** Technical Cooperation
Division in Charge: Health Personnel Development Team, Human Development Department		**Total Cost:** 901 million yen
Period of Cooperation	July 1, 2000 - June 30, 2005	**Partner Country's Implementing Organization:** State Food and Drug Administration, National Institute for the Control of Pharmaceutical and Biological Products
		Supporting Organization in Japan: National Institute of Health Sciences, Pharmaceuticals and Medical Devices Agency, and Others
Related Cooperation		

1-1. Background and Summary of the Project

The lack of assurance for the safety of pharmaceutical drugs in China had posed health concerns over its people. In addition, issues were being raised about how to increase or promote the safety and reliability of China's domestically manufactured drugs that were exported overseas. Consequently, to meet the international standards of "Good Laboratory Practice (GLP)", the standards applied to nonclinical studies assessing the safety of pharmaceutical drugs, the Chinese Government requested the technical cooperation of the Japanese Government concerning "National Center for Safety Evaluation of Drugs (NCSED)".

1-2. Project Overview

(1) Overall Goal

To ensure the safety of drugs in China.

(2) Project Purpose

To establish the capability of the National Center for Safety Evaluation of Drugs to meet the international standard of GLP.

(3) Outputs

1. To comply with the GLP standard in management and operation.
2. To improve the level of experimental techniques through staff training.
3. To place and utilize experimental equipment, machinery and materials appropriately.

(4) Inputs

Japanese Side:

Long-term Experts:	8 persons	Equipment:	279,978,000 Yen
Short-term Experts:	92 persons	Local cost:	54,400,000 Yen
Trainees received:	22 persons	Others:	10,364,000 Yen

Chinese Side:

Counterpart:	63 persons	
Construction/Research Costs:	67,150,000 Yuan	(957,088,000 Yen)
Administrative Costs:	25,330,000 Yuan	(361,053,000 Yen)

Land and Facilities:	Safety Evaluation Center etc.		
2. Evaluation Team			
Members of Evaluation Team	Evaluation Analysis: Naomi Okada (Director, Department of Planning and Program, FASID) Evaluation Analysis: Rie Fusamae (Program Officer, Department of Planning and Program, FASID) Analysis Assistant: Zhao Haidong, Jiang Xinwei		
Period of Evaluation	March 22, 2009 - April 11, 2009 (Including two other ex-post evaluation studies)	**Type of Evaluation**	Ex-post

3. Project Performance

3-1. Performance of the Project Purpose

The Project Purpose has been achieved, since, in comparison to when the Follow-up Cooperation Study had stated its anticipated realization, (1) cases of GLP testing have increased dramatically (31 cases in 2006 increased to 79 in 2008), (2) the audit system is functioning with the quality assurance program within/outside NCSED, (3) staff numbers have risen (59 members increased to 83), and (4) the budget is also sufficient with increasing incomes from sponsored tests (4.90 million Yuan increased to17.34 million).

3-2. Achievements related to the Overall Goal

It is hard to assess whether the overall goal of "ensuring the safety of drugs in China" has been accomplished. This is because firstly, the overall goal is not in line with the indicators denoted in the PDM, moreover, no specific numerical targets were set. Secondly, although not presented in the indicators in the PDM, in recent years, numerous drug-related accidents from the usage of Chinese pharmaceutical drugs had been reported both domestically and abroad.

Furthermore, judging from the duration and the content of the project, it is thought that the targeted Overall Goal was too high. It is suggested that the overall goal be amended to "the improved precision of nonclinical studies at evaluation institutions within the country" to make it more feasible; if the amended goal were adopted, it can be declared that this Project has contributed to its realization.

3-3. Follow-up of the Recommendations of the Terminal Evaluation Study

The table below presents the suggestions proposed to NCSED and at what stage of implementation they are at.

	Suggestions in Terminal Evaluation Report	Stage of Implementation
1.	The study audit of GLP testing and the enhancement of the application of GLP standards	• The Quality Assurance (QA) Unit in charge is leading the administration of GLP standards. In 2008, under the supervision of the director of NCSED, 4 special committees were formed across the organization ((1) Management of experimental animals, (2) Staff health and environment, (3) Management of GLP standards and (4) Academic contribution). • The director of NCSED and the QA personnel hold regular meeting twice a month, to share any issues or information, and deal with problems promptly.
2.	The study audit / the continual improvements to the SOP by the Safety Evaluation Center	
3.	Reinforcement of quality assurance for the study audit	
4.	The enhancement of a cooperation framework within NCSED for the study audit (QAU, evaluation).	
5.	The clarification of the procurement routes and procedures for large equipment and durable goods	• The norms of Japanese institutions for safety testing were met (as of November 2006).
6.	The acknowledgement of outstanding issues at project termination and related solutions	• N/A
7.	Improvements needed for the	• The standards of institutions for safety testing in Japan

	accomplishment of the Project Purpose － technical improvement related to the analysis of reagents and homogeneity － conduct of carcinogenicity tests － collecting background data －the stricter surveillance of test items and procedures related to GLP study	were met, as of November 2006, in the following 10 areas; ((1) Staff , (2) Quality assurance program, (3) Facility, (4) Equipment, (5) Reagents, (6) Standard Operational Procedures, (7) Management of experimental animals, (8) Test and reference items, (9) Study plan and conduct of the study, (10) Reporting and records) • At the time the above was confirmed, there were an additional 7 items pointed out to be improved; of these, the malfunctioning of the refrigerators / freezers and the installation of automated security alarms had been dealt with.

4. Results of Evaluation

4-1. Summary of Evaluation Results

(1) Relevance

China's pharmaceuticals industry was growing at a significant pace; it exported pharmaceutical drugs and medical equipment overseas and there was a high demand both domestically and abroad for the manufacturing and provision of safe drugs. Given the situation, the Chinese government developed several drug-related regulations; hence, the cooperation for the development of pharmaceutical drug safety was largely in line with China's policies and needs. Although this Project was not a major item in the health and medicine sector of Japan's Economic Cooperation Program for China, the Project did match the cooperation plan in that it placed importance on the promotion of reformation and openness (with the adoption of global standards) and assistance in private sector activities. Therefore, it can be concluded that the Project was highly relevant.

(2) Effectiveness

It can be observed from how the Project matched the OECD Principles of Good Laboratory Practice, that the Project was implemented with sufficiently necessary activities towards the accomplishment of its goals; There was a sufficiently high causal relationship between the Project activities and its purpose. However, due to the fact that the targeted Project Purpose had been set too high, the Purpose could not be achieved within the duration of the Project, hence the Effectiveness of the Project was evaluated as somewhat low.

(3) Efficiency

On the Japanese side, the required input of experts turned out to be less than what had been originally planned; furthermore, good cooperation was achieved from the private sector in the dispatch of experts. In addition, the experts' fields of expertise satisfactorily matched those of their Chinese counterpart personnel's. Regarding inputs of equipment, excluding 2 equipments, they were utilized and managed well. However, though the usage of these inputs were suited for the most part of the Project, because the targeted Outputs and also the Project Purpose had been set unfeasibly high, these goals were not sufficiently achieved within the duration of the Project and for that reason, Efficiency was evaluated as somewhat low.

(4) Impact

The Project has brought about numerous positive impacts other than the Overall Goal and no particular negative impacts.

It may be too early to see the impact of the Overall Goal, "to ensure the safety of drugs in China." Furthermore, because there are numerous external factors other than the Project's efforts that could affect the Goal, such as the successful conduct of clinical tests, medicine manufacture, the safety of traditional and imported drugs, etc., the Goal has yet to be achieved. However, NCSED has organized lectures and has

offered training courses targeted at other drug testing institutions including private companies. As a result, there has been an increase in authorized GLP test institutions, hence the Project has initiated a positive spillover effect on other institutions. Other effects include NCSED's promotion of international business ties, and the emergence of official assistance at the national level such as the drawing up of related regulations and the authorization of GLP institutions.

(5) Sustainability

From analyzing the organizational/institutional, technical and financial aspects of NCSED, it can be concluded that it is highly sustainable.

Firstly, from an organizational/institutional standpoint, there is high awareness on the importance of policies related to pharmaceuticals, reestablishing the significance of NCSED, and there are high expectations regarding GLP study. Secondly, regarding its technical aspects, NCSED plays a central role related to GLP studies, constantly improving on its own techniques and promoting the concept and the methodology of GLP nationwide. Even after the termination of the Project, NCSED has performed GLP testing and has organized various events such as lectures and workshops. Staff numbers have increased too. Thirdly, considering its financial aspects, NCSED has a sufficient yearly budget allocation, and an increasing income from sponsored studies.

4-2. Factors that have promoted the Project

One of the promoting factors of the Project lay in the external environment of pharmaceutical drugs. Although China's drug industry has been growing, drug-related issues including the use of fake drugs have been on the increase within the country and abroad, fostering the needs to manufacture and provide safe pharmaceutical drugs globally. Drug evaluation and the technology related to it has already been recognized internationally, and although Japan already possessed the necessary technical skills for drug evaluation, this was another contributive factor in carrying out the technical cooperation efficiently.

4-3. Factors that have inhibited the Project

Causal factors that did not necessarily serve as a deterrence for the Project but lowered its evaluation, lay not only in the fact that the targeted Project Purpose and Overall Goal were set too high, but also in that many existent external factors that were prone to affect the outcomes had not been clarified. The fact that the Project was not revised after its start caused this problem too. In the preliminary study of the project, it was estimated that the Project Purpose was capable of being achieved; however, analysis on possible external factors that would affect the accomplishment of the Overall Goal had not been satisfactorily performed. In the mid-term evaluation study, although the issue that the targeted objectives were unfeasible was brought up, no amendments were made to the objectives nor to their indicators.

4-4. Conclusion

Overall, although the Project has brought about numerous positive effects, Effectiveness, Efficiency and Impacts were evaluated as somewhat low. This is because, as mentioned above, the target objectives were set too high. However, NCSED has reached the point where it has fulfilled the international GLP standards and now plays a central role in China's pharmaceutical drug safety evaluation. As a result, authorized GLP study institutions have been increasing. In this way, the Project can be given credit for having a positive impact on drug evaluation in China. In conclusion, the Project has brought about numerous positive effects and impacts and these are expected to be sustained.

4-5. Recommendations

(1) Maintaining and enhancing the technical capability of GLP Testing

As well as performing advanced GLP testing, NCSED also needs to maintain the international reputation of China's GLP testing institutions. To achieve this, NCSED will need to continuously enhance

its technical capability by promoting academic exchanges with related overseas institutions, and also by securing funding for research in comparatively-less advanced areas within NCSED.

(2) Training of junior staff members

NCSED's scope of business has the potential to expand in the future. Although staff numbers are on the rise, they should not be concentrated in certain sectors of NCSED, and the training of junior staff members should be promoted so as to organize NCSED's personnel structure.

4-6. Lessons Learned

(1) Confirming the partner country's needs given the global environment

From its start, the Project has been able to maintain its high Relevance until today, because of high demands to enhance the safety of China's pharmaceutical drugs, from both within the country and from overseas. Such domestic and international demands were huge driving forces for the GLP study of pharmaceutical drugs.

(2) Precise setting and management of the objectives

The Project Purpose and Overall Goal explain what the Project will achieve and what the partner country needs to achieve after the Project. For JICA, these objectives also indicate how the cooperation should be done during the Project for its sustainability. Therefore, it is extremely important to set feasible and precise objectives and to also revise them when necessary, and the objectives should always be shared with a common understanding amongst the people involved in the Project.

(3) Situation analysis and Project planning with careful attention to external factors

Besides the setting of clear objectives, it is indispensable to pay attention to external factors which may affect the Project objectives, and also to how the partner country could deal with these factors. It is necessary to conduct an analysis not only on the staff members and their roles of a particular organization, but also on the society and related institutions.