# AN ASSESSMENT OF ROSEMARY QUALITY MANAGEMENT IN ZHEJIANG PROVINCE, CHINA: A CASE STUDY OF HISUN ROSEMARY PLANTATION



A Research Project Submitted to Larenstein University of Applied Sciences in Partial Fulfillment of the Requirements for the Degree of Masters of Development, Specialization International Agriculture

Ву

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# LIST OF ABREVIATION

СВ	Certification Body
COS	Certificate of Suitability
EDQM	European Directorate for the Quality of Medicines
FDA	Pure Food and Drug Administration
ISO	International Organization of Standard
GCP	Global clinical practice
GMP	Good Manufacturing Practices
GLOBAL GAP	Global Good Agricultural Practices
GLP	Good laboratory Practice
HACCP	Hazard Analysis Critical Control Points
KLP	The key Laboratory of Forest Plant Ecology
QA	Quality Assurance
QC	Quality Control
QMS	Quality management system
GCP GMP GLOBAL GAP GLP HACCP KLP QA QC QMS	Global clinical practice Good Manufacturing Practices Global Good Agricultural Practices Good laboratory Practice Hazard Analysis Critical Control Points The key Laboratory of Forest Plant Ecology Quality Assurance Quality Control Quality management system

# ABSTRACT

Nowadays, it is a trend that people takes more and more plants (especially horticultural plants) extract products in their daily life. Rosemary is widely used as a culinary herb, especially in Mediterranean dishes, and is also used as a fragrant additive in soaps and other cosmetics. Zhejiang Hisun Pharmaceutical Co. Ltd. owns a 38 ha rosemary plantation and they plan to enter the international market with rosemary product.

The objective of this study is to assess the compositeness of rosemary production of Hisun, by providing insight into the main components of KLP (Hisun's plant R&D Centre) quality management so as to enable the formulation of beneficial interventions.

The research has a quantitative and qualitative approach which is based on the survey, case study, empirical data, literatures and documents. Field level survey of farmer workers in the plantation and staffs from Hisun Pharmaceuticals is done by semi-structured questionnaires. Further within KLP, the existing situation of quality management system concluded by senior manager and extension staff is studied till the technical experts' level by interview and GAP quality management system checklist.

It was found that farmer workers can not implement well on quality control points, according to the training from experts. Compared with GLOBALGAP checklist, the preparation of Hisun is insufficient that document control, training and produce handling are the main problems. In supply chain, Hisun selects vertical integration strategy, which may both benefit and loss in the quality management performance.

Following recommendations are made to make Hisun's quality management improved, consult a objective tree: Design training program; Document and records control; Lower prejudice.

#### Keywords

Rosemary flower, quality management, GLOBALGAP standards



# CHAPTER 1 INTRODUCTION

# 1.1 Significance of the Study

Due to limited nature resources, some European Union countries are looking for new or unique extracts or chemical constituents for new applications of known ingredients from third parties. This offers an opportunity for a number of companies in developing countries to exploit this chance. However, most of the European Union customers are not interested in intermediates or products without any patent and without any quality certificates. This has forced producing organizations to obtain certification schemes like ISO, HACCP and Global Gap to enable entry into the European market. Hisun Pharmaceuticals plans to gain entry into the lucrative European market but this is only possible with the right quality certification. This desire by Hisun Pharmaceuticals highlights the importance of this study for it assesses the ability of the company's quality systems to meet the requirement under Global gap along with recommendations for improvement.

#### 1.2 Hisun Plantation

The medical plants plantation base of Zhejiang Hisun Pharmaceutical Co., LTD lies in Xialian village, the Fuyang city, Zhejiang province. N 30°00', E119°09', belong to Tianmu Mountain, the average altitude is 300m, in this area, different topography distribute different soil type, at plain the soil mainly are yellow meadow soil and meadow peat, but at hill and mountainous are arenaceous red soil and conglomerate red soil. The annual rainfall is 1435 mm; relatively humid is 70% and mean temperature is 16.2. Total area of the medical plants plantation is 38 ha, for rosemary is around 33 ha.



Figure 1 Xialian Village in the map of Fuyang city (red point)

Xia Lian village(red point in the map above) located in Zhejiang province, China, and this village belongs to Xu Kou Town, Fuyang city. In this village, Hisun pharmaceuticals bought usufruct of around 40 ha of the land for using them as their Plant Base. Besides, Hisun pharmaceuticals also hire farmers as their worker. Xia



Lian village has a subtropical climate with four distinct seasons.



Overlook of Hisun medical plants plantation

Xia Lian Village has arable land for 65 ha, hilly land for 493 ha including 400ha ecospecific forest. In average 0.04-0.05 ha of arable land and 0.13 ha of hilly land were occupied by per person. The population of Xia Lian village is 1761(503 households) in register.

# 1.3 **Problem Statement**

The Key Laboratory of Forest Plant Ecology (KLP) is a consultancy organization in partnership with Hisun Pharmaceuticals, which is the biggest rosemary producer in China. KLP is in charge of all quality management activities at farmer level on behalf of Hisun Pharmaceuticals such as provision of quality planting materials, cultivation supervision and post harvest management.

Recently Hisun Pharmaceuticals decided to initiate the process of becoming a Global Gap certified rosemary producer. However there are concerns about the ability of the organization's current quality system to meet the Global gap certification requirements.

# 1.4 Research Objective

The objective of the study is to assess the ability of the rosemary quality management program at the plantation to meet the Global gap requirements and formulate beneficial interventions in case of deficiencies.

# 1.4.1 Central Research Question 1

What are the crucial elements of Hisun's quality management program in relation to rosemary production?

# Sub Questions

- i. What is the organizational structure at the Research and Development Department of Hisun Pharmaceuticals and how does it influence quality management of rosemary production?
- ii. What is the position of Hisun's plantation in the rosemary supply chain?
- iii. How is the quality control process of Hisun's rosemary production implemented?



# 1.4.2 Central Research Question 2

How developed is the plantation quality management program under KLP in achieving Global gap certification?

Sub Questions

- iv. What is the core issues under the Global gap Quality Management Systems that require improvement and how should it be implemented?
- v. To what extent is KLP prepared to apply GLOBALGAP quality assurance?

# 1.5 Research Outline

This study is organized into five main chapters. Chapter 1 offers an overview of rosemary farming in China and the importance of the plant extract to humans. It further describes the research objective and links the research problem with two main research questions. In Chapter 2 the importance of the rosemary industry in China is reviewed. The chapter ends by documenting the concept of total quality management and quality certification. Chapter 3 deals with the research methodology elaborating the research area, tools used and the data analysis procedure that was used.

Chapter 4 consists of the empirical findings of the research and Chapter 5 covers the discussion of these findings. The report ends with Chapter 6 that formulates the conclusion and recommendations of the study.

#### 1.6 Research Terminologies

In the writing of the thesis report, the flowing words were used according to the context as described below.

#### i. Quality management system

Quality Management System (QMS) can be defined as a set of policies, processes and procedures required for planning and execution (production / development / service) in the core business area of an organization. QMS integrates the various internal processes within the organization and intends to provide a process approach for project execution. (Wikipeida, accessed on 02,Oct. 2008)

#### ii. Farmer Worker

A farmer worker is temporary worker in the Hisun plantation, working with no employment contract and on temporary arrangements. In addition, they are also private farmers of vegetables and other crops.

#### iii. Expert

Expert in different specialization(research direction) of Plant Science of KLP



#### CHAPTER 2 LITERATURE REVIEW

#### 2.1 Background of the Rosemary Plant

Rosemary (*Rosmarinus officinalis*) is a woody, perennial herb with fragrant evergreen needle-like leaves. It is native to the Mediterranean region.



It is a member of the mint family Lamiaceae, which also includes many other herbs. Forms range from upright to trailing; the upright forms can reach 1.5 m tall, rarely 2 m. The leaves are evergreen, 2-4 cm long and 2-5 mm broad, green above, and white below with dense short woolly hairs. The flowers are variable in colour, being white, pink, purple, or blue.

Rosemary is easily pruned into shapes and

has been used for topiary. When grown in pots, it is best kept trimmed to stop it getting too straggly and unsightly, though when grown in a garden, rosemary can grow quite large and still be attractive. It can be propagated from an existing plant by clipping a shoot 10-15 cm long, stripping a few leaves from the bottom, and planting it directly into soil. (Willett Garden of Learning, accessed on 29, Sep. 2008)

Rosemary, Rosmarinus officinalis L. (Lamiaceae) is an aromatic evergreen shrubby herb highly distributed in the Mediterranean region. It was introduced into China in 1981 by Institute of Botany, Chinese Academy of Sciences. Rosemary is widely used as a culinary herb, especially in Mediterranean dishes, and is also used as a fragrant additive in soaps and other cosmetics. Traditionally, rosemary has been used by herbalists to improve memory, relieve muscle pain and spasm, and stimulate hair growth, and support the circulatory and nervous systems. It is also believed to affect the menstrual cycle, act as an abortifacient (inducing miscarriage), relieve menstrual cramps, increase urine flow, and reduce kidney pain (for example, from kidney stones). Recently, rosemary has been the object of laboratory and animal studies investigating its potential in the prevention of cancer and its antibacterial properties. (Zu,2007)

# 2.2 Rosemary Farming

Rosemary can be grown outdoors in climates where winter temperatures do not drop below -2.7°C; -5°C for the alba variety. Although rosemary is drought tolerant outdoors, it is sensitive to both drought and over watering indoors. Note that 'drought tolerant' relates to survival, not to the rate of growth under drought stress; good production requires adequate water. Since it is attractive and tolerates some degree of drought, it is also used in landscaping, especially in areas having a Mediterranean climate. It can in fact die in over-watered soil, but is otherwise quite easy to grow for beginner gardeners. It is very pest-resistant.



# 2.2.1 Propagation and Care

Growth Environment: Rosemary does well in full sun in well-drained soil with a pH of 6.0 to 7.5. Warm, dry summer climates are ideal; rosemary does not do well where winters are cold and wet unless it grows in a protected site. Good drainage is essential, as roots easily develop root rot (Savio, 1992).

Cuttings and layering: Cuttings and layerings from established plants make the best propagation material. Root cuttings in a sand/loam/leaf mold mixture in a cold frame or cool greenhouse.

Set 90cm apart outdoors in the same type of soil. Fertilize infrequently or if soil is poor; too much fertilizer reduces flowering and fragrance. Rosemary can be started from seed, but germination rates are very low, even at an optimum of 2.5Cfor 14-21 days; and it takes up to three years to produce a bush sizable enough for harvesting.

In addition, plants grown from seed are not as robust as cuttings and layering: stems are softer, branches are weaker, and leaf color lacks sheen and intensity (Savio, 1992).

# 2.2.2 Post harvest Handling

Harvesting can be done throughout the year, but care should be taken to not remove more than 20 percent of the growth at a time. Volatile oils are most potent just before blooming. To dry leaves, cut individual branches and strip the leaves from the branches onto screens or paper in a shady place with good air circulation, or dry whole or partial branches for decorative use (Savio, 1992).

Increased use of fresh rosemary for culinary and other purposes has also increased the demand for high quality. The successful marketing of high quality fresh rosemary requires extreme care and attention to post harvest handling conditions.

All the post harvest principles that apply to leafy green tissues apply to the handling of fresh rosemary. Temperature is the single most important factor in maintaining quality after harvest. Despite the diverse botanical origin of the fresh rosemary, the optimum post harvest temperature for it is 0 C. Under controlled conditions, a shelf life of 3 to 4 weeks can be achieved at this temperature. With a temperature of 5 C, a minimum shelf life of 2 to 3 weeks can be expected. If rosemary is harvested early in the morning, the need for cooling is minimized. If harvested later, the appropriate cooling method depends on the type of herb. Most respond favorable to room and forced air cooling. Herbs have also been successfully vacuum-cooled. A simple forced air pre-cooler can be constructed for small operations that require only an adequate cool room, a fan, and some simple carpentry.

After temperature, prevention of excess moisture loss is the second most important post harvest factor affecting the quality and shelf life of rosemary. Most herbs respond favorable with very high humidity (>95%). Water loss in most can best be controlled by packaging and maintaining high humidity in the environment. Lowering the holding temperature to the recommended levels also greatly reduces water loss (Cantwell, 1986).



Rosemary can be packaged in bags designed to minimize water loss. When rosemary is packaged this way, it is particularly important to maintain constant temperatures, to reduce condensation inside the bag and the consequent risk of fungal or bacterial growth. The bags may be partially ventilated with perforations, or may be constructed of a polymer that is partially permeable to water vapor. The relative humidly in the packing area, cold rooms, and transport vehicles should be maintained at a high level (>95%) where practical (Cantwell, 1986).

Ethylene gas is another factor which limits the shelf life of leafy tissues. Ethylene causes yellowing of leaves, and an increased rate of deterioration. It is possible to routinely find one to three ppm ethylene in the environment surrounding fruits and vegetables during commercial handling. Young growing herb tissue responds to ethylene (5 ppm), whereas little effect was observed in mature herb cuttings. In addition, holding the herbs at the recommended temperatures also greatly reduces their ability to respond to ethylene in the environment (Cantwell, 1986).

Careful handling to avoid physical injury to the leafy tissue of the fresh herbs is also important. Rigid clear plastic containers such as those sometimes used for sprouts may be used for rosemary. "Pillow packs" (plastic bags which are partially inflated when sealed) may be an alternative packaging technique. Careless handling results in tissue discoloration, as well as increasing sites for pathogen attack. Growth of microorganisms can also be reduced by proper temperature management and good hygienic practices in the field and packing station. (Cantwell, 1986)

# 2.3 Marketing of Rosemary and Rosemary Products

There is a significant and growing interest in plant medicine amongst Western consumers. The health service has for many years been the sole provider of treatment for disease, but now patients are beginning to take more and more responsibility in this area. In fact, patients now decide, through information gathering via the Internet and other means, as to what treatment there is for their particular disease. Consequently, the traditional knowledge about plants and their effect on disease has experienced a comeback.

Most of the Eureapean companies are not interested in intermediates or products without any patent and without any official certificates. GAP, GMP, GLP and GCP must be certified too. Because of limited research capacities, they are looking for new or unique extracts or chemical constituents or for new applications of known ingredients from third parties. Nevertheless, even the widely distributed green tea and rosemary extracts would be of interest, if they fulfill quantitative and qualitative demands at a much lower price.

The market for rosemary extracts is already healthy. Suspicion over chemical-derived synthetic preservatives has pushed food makers to source natural preservatives such as rosemary extract instead, and market analysts Global Information pitch the global food preservative market at  $\in$  422.7 billion, reaching  $\in$  522 billion by 2008 (Zu, 2007).



# 2.4 Zhejiang Hisun Pharmaceutical Co.Ltd

# 2.4.1 General introduction about Zhejiang hisun Pharmaceutical Co.Ltd

Zhejiang Hisun Pharmaceutical Co.Ltd (hereinafter referred to as "Hisun Pharmaceutical") situated in Taizhou, a port city in southeastern China, was founded in 1956 and after 50 years of steady development, has became one of the most competitive manufacturers of generic medicine in China. Product range includes a series of medicines for oncology, cardiovascular, anti-infection, anti-parasite, endocrine regulation, immunosuppressant and antidepressant. Over 80% of sales revenue comes from exporting to more than 30 countries and regions in both Europe and America.

At present, the Company owns total fixed assets of RMB 5 billion, covers an area of 900,000 square meters(not including the medical plant plantation base), and employs over 2500 staff. Since July 2000, Hisun high-tech Stock A has been listed on the Shanghai Stock Exchange.

# 2.4.2 Technology

The Company boasts a large technology center occupying an area of 16000 square meters, which employs 300 R&D researchers and contains over 50 individual labs. Its R&D scope covers a diversified range, namely biotechnology (microbial fermentation and genetic engineering), chemical synthesis, and natural plant medicine and formulation development. The Company maintains good co-operative relations with over 30 research institutes in China and has established labs in several universities. It conducts joint R&D programs in new medicines with American, Japanese and European research organizations. It spends about 8% of its sales revenue annually in research and development. Hisun Pharmaceutical has successfully conducted several key science and technology projects at the request of the Chinese government, registered over 20 new medicines in China, and applied for over 30 patents.

The Company's factories are designed and constructed strictly in accordance with GMP regulations. The company invests over RMB 300 million annually for upgrading production facilities using advanced production equipment. It uses the newest production equipment, control systems, and testing instruments in its GMP production facilities, test and analysis centre, and R&D centre.

The Company adopts advanced quality management concepts and carries out GMP requirements throughout the whole process from raw material purchasing, production processes, Quality control testing and storage, to sales and distribution. Strict Quality Assurance and Quality Control, qualified managerial team and excellent quality testing equipment provide reliable assurance of product quality. Currently, 12 products have obtained FDA (Pure Food and Drug Administration) approval and 10 products have obtained COS (Certificate of Suitability) from EDQM (European Directorate for the Quality of Medicines).



# 2.5 The Key Laboratory of Forest Plant Ecology (KLP)

#### 2.5.1 Affiliation between Hisun Pharmaceuticals and KLP

Zhejiang Hisun Pharmaceutical Co. Ltd. Co-operate with The Key Laboratory of Forest Plant Ecology Ministry of Education, they built Research and Development Centre, which located in Northeast Forestry University, Harbin, China. Research and Development Centre does research and develop new plant extract products that can be used into medicine, food, and other areas. For plant extracts field, the Key Laboratory of Forest Plant Ecology (KLP) as the only R&D centre playing an important roll in this enterprise. Further more, rosemary extract is the main product of extension, and KLP takes charge of the quality management of the plantation, including rosemary products.

#### 2.5.2 Background of KLP

The key Laboratory of Forest Plant Ecology (KLP) was formed in 1992. The KLP is sponsored by Ministry of Education, P.R. China and it is supported by Northeast Forestry University. It is located in Harbin City, the capital of Heilongjiang province, China, on the Songhua River. KLP covers 6286 square meters and it employs 20 permanent staffs and has 15 master students and 15 PhD students for research works.

In its first decade, much of the Laboratory's activity centered around contents from its forest plant research fields of Botany, Ecology and Molecular Biology such as Synecology, Molecular Ecology and Calculation Ecology (using the method of Nonlinear plant ecology model to design transport mechanism of ecology.) Since 2004, KLP cooperate with Hisun pharmaceuticals and takes charge in quality management of the medical plant plantation. Besides, KLP also doing research on plant extract.

Forest Plant Ecology always is their main research field. In recent years, their main focus is on Forest vegetation Ecological Conservation and Biology Resources Ecological Use.

#### 2.6 Supply Chain

#### 2.6.1 Definition and concepts

There seems to be a universal agreement on what supply chain is. Luning et.al., 2002 defines supply chain as 'all stages of the entire process from raw materials to final product'.

A typical supply chain begins with ecological and biological regulation of natural resources, followed by the human extraction of raw material and includes several production links, for instance; component construction, assembly and merging before moving onto several layers of storage facilities of ever decreasing size and ever more remote geographical locations, and finally reaching the consumer. (Wikipedia, Accessed on 13, September, 2008)

A supply chain is only as strong as its links. Different relationships exist between organizations involved in the separate stages of the chain-whether it is in the



structuring of product distribution, arrangements for payment and arrangements for handling, or in storing the product. At the heart of these relationships is the way in which people treat each other. Long-term business relationships need to be based on honesty and fairness-parties to a trading agreement need to feel that they are getting a fair deal (Teigen, 1997)

# 2.6.2 Rosemary supply chain in China

Supply Chain of rosemary in China is not well defined and is still unorganized owing to the reason of low volume of production coupled with the problem of unawareness of rosemary's usefulness from the end section of the supply chain. Most of rosemary production is concentrated on cosmetics as fragrance extract. In recent years, with the gradual increase in production and improved technology of many processing companies, demand as sanitarian food and food additive has emerged from the customer.

#### Primary producers

Since EU customers such as the Netherlands(Zu, 2007) is not interested in product without a quality assurance, primary producers of rosemary in China are organizations but no individual farmers. Because of its natural characteristics, rosemary is mostly planted in the 6 provinces in South east of China: Zhejiang province, Jiangxi province, Hunan province, Guizhou province, Guangxi province and Hainan province. The dimension of rosemary plantations is much larger in Guangxi province when compared with others. (See Figure 2.)



Figure 2 Distribution of Rosemary Plantation in China



#### Rosemary processor

For the reason of lower the cost and reduce hazard within the chain, normally the processor collect and purchase rosemary raw material themselves. There are hundreds of rosemary extracts processors in China, however, most of them are medium and small sized enterprises. Figure 3 shows the distributions of the processors.





#### Rosemary advanced processor

Some enterprises process semi-manufactured products and take advanced processing. Advanced processor can be any type of manufacturers: pharmaceutical firms, cosmetic compaies, or food companies, to name only a few. They may buy rosemary extract oil or rosemary extract powder or rosemary food additives from rosemary processor and manufacture their own product, such as sanitarian food, shampoo, sauce, etc.

# 2.6.3 Vertical integration in supply chain

Vertical integration is the degree to which a firm owns its upstream suppliers and its downstream buyers. Contrary to horizontal integration, which is a consolidation of many firms that handle the same part of the production process, vertical integration is typified by one firm engaged in different aspects of production (e.g. growing raw materials, manufacturing, transporting, marketing, and/or retailing).

There are three varieties: backward (upstream) vertical integration, forward (downstream) vertical integration, and balanced (horizontal) vertical integration.

- In **backward vertical integration**, the company sets up subsidiaries that produce some of the inputs used in the production of its products.
- In **forward vertical integration**, the company sets up subsidiaries that distribute or market products to customers or use the products themselves.
- In balanced vertical integration, the company sets up subsidiaries that both supply them with inputs and distribute their outputs. (Wikipedia, Accessed on 13, September, 2008)







# Figure 4 Proportion of vertical integration enterprises in rosemary supply chain

# 2.7 Quality management

# 2.7.1 The Quality Management Concept

#### Quality management

Quality management is a method for ensuring that all the activities necessary to design, develop and implement a product or service are effective and efficient with respect to the system and its performance. Quality management can be considered to have three main components: quality control, quality assurance and quality improvement. Quality management is focused not only on product quality, but also the means to achieve it. Quality management therefore uses quality assurance and control of processes as well as products to achieve more consistent quality. Quality Management is all activities of the overall management function that determine the quality policy, objectives and responsibilities and implement them by means such as quality control and quality improvements within a quality system. (Wikipedia, Accessed on 28, June, 2008)

# **Quality Control**

Quality control has been described as the ongoing process of evaluating performance and taking corrective action when necessary (Evans and Lindsay, 1996). It is generally considered as that part of the quality management system which is focused on operational techniques, and the processes applied to fulfill quality requirements. (ISO, 1998)

#### Quality assurance

The objective of quality assurance is to guarantee that quality requirements, such as product safety, reliability, service etc., are realized by the quality system. On the other hand quality assurance should provide confidence to customers and consumers that quality requirements will be met (ISO 1998). A quality system is defined as the organizational structure, responsibilities, processes, procedures and resources that facilitate the achievement of quality management.

# <u>GLOBAL GAP</u>

GLOBALGAP is a private sector body that sets voluntary standards for the certification of agricultural products around the globe. The GLOBALGAP standard is primarily designed to reassure consumers about how food is produced on the farm by minimizing detrimental environmental impacts of farming operations, reducing the use of chemical inputs and ensuring a responsible approach to worker health and safety as well as animal welfare.





Figure 5 Stages in Production of Produce covered by EUREPGAP CPCC (Source: GLOBALGAP, 2005)

Rosemary inspection follows standards of Fruit and Vegetables in GLOBALGAP. There are several documents related to Fruit and Vegetables Certification, the inspection of GAP will be carried out of four checklists that based on four main documents. Three of them are about control point and compliance criteria, the other one gives the standard of quality management system itself.

According to the checklist, the Inspection for quality management system is carried out on following aspects: Administration and structure, Management and organization; Management and organization, Competency and training of staff, Quality manual, Document control, Records, Complaint handling, Internal audit and inspection, product traceability and segregation, Sanctions and non conformance, Withdraw of certified product and Subcontractors.

See Appendix 2 for standards and requirements of quality management system in GLOBALGAP.

# ISO

ISO standards that provide requirements or give guidance on good management practice are among the best known of ISO's offering. ISO amis to achieve uniformity in product and/or services and to prevent technical barriers to trade through out the world. It requires the establishment of all acivities and handling procedures, which must be followed by ensuring clear assignment of responsibilities and authority. (Luning, Marcelis, Jongen, 2006)

# HACCP

HACCP aims to assure the production of safe food products by identifying and controlling the critical production steps. It uses a systematic approach to the identification, evaluation and control of those steps in food manufacturing that is critical to food safety (Luning, Marcelis, Jongen, 2006).



# <u>GMP</u>

GMP aims to combine procedures for manufacturing and quality control in such a way that products are manufactured consistently to a quality appropriate to their intended use. GMP consists of fundamental principles, procedures and means needed to design a suitable environment for the production of food of acceptable quality. GMP can be applied in a horizontal or a vertical supply chain and focuses on technological aspects. It creates the basic environmental and operating conditions for food production (Hoogland, et. al., 1998; IFST, 1991)

# Quality improvement

Quality improvement actually embodies the need for change, breaking though the status quo. It implies that the firm has to "learn". It requires facilitating structures, such as means of communication, procedures and reward systems, focused on identification of changes in internal and external business environment and on avoiding routine and rigid structures in the firm. There are many methods for quality improvement. These cover product improvement, process improvement and people based improvement.

# 2.8 Concepts of organization configuration: Professional bureaucracy

Professional bureaucracy configuration relies on the standardization of skills rather than work processes or outputs for its coordination and so emerges as dramatically different from the machine bureaucracy. It is the structure hospitals, universities, and accounting firms tend most often to favor. Most important, because it relies for its operating tasks on trained professionals-skilled people who must be given considerable control over their own work-the organization surrenders a good deal of its power not only to the professionals themselves but also to the associations and institutions that select and train them in the first place. As a result, the structure emerges as very decentralized. CHAPTER 3 METHODOLOGY



# 3.1 Scope of the study

The scope of the study was quality management at the Hisun Pharmaceutical rosemary plantation in Xialian village. The study restricted its focus to only the production section of the rosemary supply chain i.e. from reception of young plants to their harvesting. The study decided to limit its scope as mentioned above to ensure that the research could be successfully concluded within the allotted time for field work. The study was done on the basis of quality management practice which is composed of three main branches, namely; quality control, quality assurance and quality improvement.

#### 3.2 Research Framework

The research was conducted in Xia Lian Village, Fu yang city, Zhejiang Province, China and Harbin city, Heilongjiang Province China. The two areas are related to the quality management system of Hisun's rosemary plantation: the preceding area has been considered as cultivation base; the latter is the headquarters. The study was carried out from 11<sup>th</sup> July 2008 until 09<sup>th</sup> August 2008. The study involved a qualitative approach based on empirical data, literature and documents. The research used a quantitative and qualitative approach based on the employment of a survey, case study, literature and document reviews. Different publications like reports, journals, books and internet sites relevant to the study were used and reviewed.

Respondents referred in this study included the stakeholders within the quality management system of the rosemary plantation of Hisun pharmaceuticals. These are namely; the plantation workers, KLP experts and KLP senior managers. The research was focused on the implementation of quality control, results from inspection of the quality management system and quality improvement based on Global gap standards.

#### 3.2.1 Survey

The survey was carried out on rosemary farmer workers in Xia Lian village which is the rosemary producing base of Hisun Pharmaceuticals. The farmer workers selected have an experience ranging from 1 to 4 years. The researcher interviewed a total of 20 farmer workers to obtain a detailed understanding of how quality control in implemented with rosemary production. Field survey of farmer workers in the plantation was done by semi-structured questionnaires. Twenty (20) workers were randomly selected out of the Farmer Leader's list and questionnaires in the local language used to collect data. The semi-structured questionnaires focused on quality control aspect of their work during rosemary production and problems that they face in relation to quality assurance (*Related to Sub Questions 2 and 5*)



# 3.2.2 Case study

A case study of the quality management system at the Hisun rosemary plantation was conducted through a number of interviews. The researcher interviewed the senior manager of KLP and extension staff as technical informants on the quality management situation. Interview sessions were guided by the use of the Global gap Quality Management System checklist. Interviews involved four (4) senior members of Management at KLP, two (2) extension staff and the Global gap Project Manager, Asia. Interviews addressed issues related to; the organization structure and it impact on quality, quality control process in rosemary production, the supply chain position of Hisun plantation, core issues under the Global gap Quality Management Systems for improvement and the preparedness of KLP to apply Global gap quality assurance. (*Related to Sub Questions 1, 2, 3, 4, and 5*)

# 3.3 Data analysis

The data collect by the research was summarized into Microsoft excel sheets and analyzed according to the research objective. The results were then compared with related and relevant literature to enable formulation of recommendations for improving and integrating appropriate quality management systems.

# 3.4 Limitations of the study

The study was conducted during July to August 2008 which is the off season for farmer workers and rosemary plants were not in the harvest stage Therefore the survey and case study were done on a recall basis by the respondents. This could have affected the answers of some of the respondents especially those who had difficulty in recalling past information.



#### CHAPTER 4 RESULTS

# 4.1 Management of the KLP Research and Development Centre

The structure of KLP is considered as a matrix structure in relation to quality management because it combines the functional and divisional structure. This is done by have an employee reporting under the two – boss system. Since KLP has many projects within the rosemary plantation, these projects are worked out by experts who are given considerable control over their own work. In addition the research found that the Department of Finance and Human Resource provide service support.

#### 4.1.1 Organizational Structure of the Hisun R&D Centre

The research revealed that the Key Laboratory of Forest Plant Ecology (KLP) as Hisun's research and development centre has four departments. The departments are namely; Department of Quality Control, Department of Technology, Department of Finance and the Department of Human Resource. The Key Laboratory of Forest Plant Ecology has three (3) levels of managerial coordination for the over 50 staff members within the organization. The Director is the highest level in the whole centre and KLP, two vice directors are on the second level, each vice director responses for two departments (See Figure 6). Three Assistants assist the Director by managing projects which cooperated with Vice Directors; besides, Assistants are responsible for administration office formally. And Assistants are on the third level of leadership of this organization.



Figure 6 Organizational Structure of the Hisun R&D Centre

The two vice directors play the role of Department Managers in the normal functioning of the organization. One vice director is responsible for the Technology Department and Quality Control Department. The Technology department is one of equipment design, new product research and development while the Quality Control Department is concerned with how to fulfill international quality standard, feedbacks on quality etcetera.



The second Vice Director is in charge of the other two Departments namely; the Finance Department and Human Resource Department. Tasks of Finance Department and HR Department are the same as their tiles imply as showed in figure 6 above. Administration office is charged by three Assistant who contact with business partners and the government, to arrange project process schedules.

The research was able to map the organizational structure of KLP as revealed in figure 6 above. It was noted by the researcher that the organizational structure under KLP is highly centralized with most of the powers under the Director.

# 4.1.2 KLP Quality Management Work Flow

The researcher noted in interviews at the Headquarters of Hisun's marketing department that work flow within the organization followed the flow chart as shown in figure 7 below. The process of quality management starts with the meeting of the directors who are responsible for the distribution of the projects to the different employees within the organization.



Figure 7 KLP quality management work flow

The work flow was noted to be influenced by the organizational structure of KLP and Hisun Pharmaceuticals. In some aspects the structure of the organization played a benefiting role but in others it was limiting. For example the researcher found that 4 managers out of the 4 interviewed felt that having a department in charge of quality allowed for the needs of the quality program to be well represented. Three staff members out of seven interviewed were of the opinion that the incorporation of quality control into all projects, as a result of the matrix structure, allowed for quality concerns to be addressed more properly.



# 4.2 **Position of Hisun pharmaceuticals in Supply Chain**

The research observed that the Hisun's rosemary plantation produces rosemary raw material but does not carry out any further processing of the harvested plants. It was noted that after harvesting, the raw materials is transported to the Hisun's manufacture factory. In the factory the useful component of rosemary is extracted to make rosemary oil and rosemary powder. The rosemary oil and powder are then sold to other actors in the chain who use it for the manufacture of medicine or in the food industry. The research mapped the rosemary supply chain as revealed in figure 8 below.



Figure 8 Supply Chain of Hisun Pharmaceuticals

Hence the study was able to establish that the Hisun plantation plays the role of producer in the Hisun Pharmaceutical supply chain. This is a very important position in the perspective of quality assurance because the quality of the rosemary raw material impacts on the processed oil and powder quality.



# 4.3 Implementation of Quality Control at the Hisun Plantation

In determining how the quality control process in Hisun rosemary production is implemented, the research used selected indicators. The research selected eight (8) indicators based on the academic magazine termed Yunnan Agriculture and these were used to determine the current state of quality control in the Hisun plantation. The indicators used were; farmer's knowledge of cultivation, seeding, cutting propagation, temperature control, fertilizer and pesticide, watering, weeding and post harvest. The results of the study are presented in table 2 below.

Control point Indicator	Positive aspects	Positive aspects Negative aspects	
1.Awareness about working procedure	Every farmer interviewee has a high awareness on things need to be done	Not clear about specific seeding standards;	
2. Seeding	Every farmer has a clear idea about method of reproducing	2 farmer interviewees gave wrong answers on "proper growing condition"; 4 farmers are unaware of it	
3. Cuttings indicator	Farmers implement what the experts train	Not clear about the reproduce indicators (length of caulis; plant space between; length of caulis and branches per caulis)	Farmers are not participate in decision making
4. Temperature	5 farmers well understand temperature control method (Canopy)	1 farmer has no idea of controlling temperature	8 farmers considered watering is a good way of controlling temperature (including 2 of those who well understand the use of Canopy)
5. Fertilizer and Pesticide	Each of farmers are well informed that it is not allowed to use Chemical fertilizer and pest side		Here they use manure from animals which processing by KLP itself

Table 1 Findings about the implementation of Quality Control at the Plantation



			PART OF WAGENINGEN UK
6. Water	Farmers will water		Farmers has not been
	them when experts or		trained about watering,
	farmer leaders ask		which may to they work
	them to		as temporary worker
			or there is another
			person who takes
			charge in watering
7. Weeding	All farmers use		
	traditional method for		
	weeding (sometimes		
	hoe, sometimes hand		
	weeding)		
8. Post		No standardization	Have not yet link to the
Harvest		on harvesting from	market
		farmers knowledge	

# 4.4 Core issues within quality improvement

The research was undertaken in a bid to assess how prepared the quality system under KLP was for the implementation of Global gap. Hence the Global gap quality standard of Fruits and Vegetables was used as the second checklist by the study. It was found that against the core issues of the global gap standard, there were ares that the current KLP program was in compliance. However its was noted by the research that five (5) out of the eight (8) core issues that the research selected were not developed as the global gap demands. The Control Points and Compliance Criteria for Integrated Farm Assurance was used to generate the findings in table 2 below.

Table 2	List of	core	issues	for	quality	/ im	provem	ent
				-				

No	GLOBAL GAP Control Point	Level	Findings
1	Has a hygiene risk analysis been performed for the harvest and pre-farm gate transport process?	Major Std.	No.
2	Are documented hygiene procedures for the harvesting process implemented?	Major Std	Was not developed yet
3	Have workers received basic instructions in hygiene before handling produce?	Major Std	Not yet but plans to do so.
4	Are the containers and tools used for harvesting cleaned, maintained and protected from contamination?	Major Std	Yes. No further improvement needed.
5	Do harvest workers that come into direct contact with the crops have access to clean hand washing equipment?	Major Std	No
6	Are produce containers used exclusively for produce?	Major Std	Yes. No further improvement needed.
7	Is packing material used for in-field packing, stored to protect against contamination?	Major Std	Does not apply.
8	Are signs clearly displayed instructing workers to wash their hands before returning to work?	Major Std	No



The above findings of the research allow the study to examine areas that did not perform well basing on the global gap standard and will require improvement to satisfy the market. This is because the research considers quality improvement a means to increase customer satisfaction, by achieving higher quality levels.

# 4.5 GLOBALGAP based assessment of Hisun's quality management system

In an attempt to determine the extent to which the KLP managed quality system is prepared to implement the GLOBALGAP quality assurance standard, the study carried out a SWOT of the KLP quality system. The SWOT tool was guided by the GLOBALGAP checklist on Quality Management Systems. The findings on the strength and weakness of the current quality system are listed in section 4.5.1 and 4.5.2 respectively.

# 4.5.1 Strength of the Hisun's quality management system

This study compared the information that got from interviewees and the requirements from the checklist of GLOBALGAP quality management system. The study of the Hisun Pharmaceuticals quality management system resulted in a list of areas that offer strength as follows;

- i. Availability of sufficient capital to invest into the quality program development
- ii. Presence of professional employees involved in the cultivation of rosemary
- iii. Obtained certification for water and soil aspects of the plantation

# 4.5.2 Weakness in the Hisun's quality management system

This study compared the information that got from interviewees and the requirements from the checklist of GLOBALGAP quality management system. The study of the Hisun Pharmaceuticals quality management system resulted in a list of areas that offer weakness as follows;

- i. The entire rosemary crop is not registered for GLOBALGAP certification yet.
- ii. The duties and responsibilities of all personnel in Hisun involved with the compliance of GLOBALGAP requirements are not yet documented. Training and qualifications for key staff are not yet documented as per requirements laid down in the GLOBALGAP standard.
- iii. The internal auditor(s) and inspector(s) have not undergo training and evaluation e.g. by documented shadow audits to ensure consistency in their approach.
- iv. Hisun pharmaceuticals have not documented a quality manual yet. Procedures for the identification and evaluation of non-compliances to the quality management system (QMS) are not documented yet.
- v. A copy of all relevant documentation is not available at any place where the QMS is being controlled. The records from the QMS related to compliance of GLOBALGAP requirements are not kept on-line or electronically valid.
- vi. There is not a documented procedure that describes how complaints are received, registered, identified, investigated, followed up and reviewed. There is no record of the internal audit plan, audit findings and follow up of corrective actions.



- vii. Internal inspectors are not approved by the CB during the external inspections yet
- viii. The internal auditor has not yet completed a short (2 days) internal auditor-training course related to QMS.
- ix. Hygiene risk analysis and risk assessment has not been documented.
- x. Workers have not received basic instructions in hygiene before handling produce.
- xi. Signs are not clearly displayed in the packing facilities with the main hygiene instructions for workers and visitors.



#### CHAPTER 5 DISCUSSION

#### 5.1 Quality Management and the Administration of the KLP Centre

The structure of KLP is considered as a matrix structure in relation to quality management because it combines the functional and divisional structure. This is done by have an employee reporting under the two – boss system. Since KLP has many projects within the rosemary plantation, these projects are worked out by experts who are given considerable control over their own work.

It was encouraging to note that under the current structure of KLP, the function of quality control was housed within a department of its own under a vice director (Ref: figure 6). This kind of structure offers a number of advantages in implementing of quality control programs within the organization. This is mainly because by having a departmental presence in the organization; quality control is able to be in control of its financial budget which impacts greatly on quality programs. In some organizations, quality control is absorbed within the various departments such as manufacturing, engineering, etc. The problem in such cases is then that the quality control problems or challenges are not attended to in as a single approach but rather is pieces under the different departments. This does not happen in KLP because the quality function is all placed into a single department which is then charged with the coordination of quality operations within all other aspects of the company.

However the danger with the model in KLP is that because the quality management function is all placed under a single department, there is bound to be a feeling in other departments that quality is the responsibility of only the people working in that department. Yet quality matters are better attended to when its looked at as a team effort which means that all people in the company should look at quality in their activities. The research did not detect evidence that this was happening at KLP and it is my opinion that its related to the fact that KLP is a small organization hence it is easy to build a team spirit across the entire organization.

The structure of KLP has a weakness at the Human Resource Department. The Department is the smallest in the organization and is managed by a single member of staff. The fact that KLP is a science based organization, majority of the staff are under the Quality Control and Technology Departments. However its important to mention that the Human Resource department is in charge of drawing up the training program of the organization's staff and in addition managing staff affairs to ensure their productivity. Unfortunately the Human Resource Department has not been promoted under the current system. This weakness in the department has resulted in the training program of the organization not being well developed.

KLP is a professional bureaucracy and due to that the parent company Hisun Pharmaceuticals offers the technical experts under its technology department a lot of individual powers. This structural design has a major disadvantage in that the technical experts are not easy to coordinate by KLP were their work is carried out. It was noted that the technical experts due to a lot of powers were able to carry out their duties according to their wishes and a times not as KLP would have preferred. This situation is caused by the current power distribution between KLP and the technical experts. Coordination of the technical experts would have been more effective if the structure of the organization allowed for the technical experts to be better managed by KLP.



The study noted that the organization structure influenced the quality control role that it undertakes. As earlier mentioned work flow in KLP is organized under a matrix system i.e. one expert reporting to more than one superior. The advantage of this structural arrangement within the organization is that it allows it to keep the cost of its operations low hence very competitive in the market. The different projects under the organization are able to share expert staff who are paid according to the number of days worked rather than the number of projects worked upon. Hence this is an area were the structure of the organization influenced its quality program.

# 5.2 The Hisun Plantation and the Rosemary Supply Chain

The study was able to establish that the Hisun rosemary plantation is involved in the chain as a producer of raw material. The plantation employs agro suppliers like seeds in producing the mature plants that are then harvested and taken to the Hisun factory for further processing in the supply chain as revealed in figure 8. The rosemary supply chain has six different actors hence is still short due to the fact that the rosemary plantation has been in production for only the last four (4) years.

According to the concept of vertical integration Hisun's rosemary plantation is at the bottom part of Hisun pharmaceuticals' vertical integration. Within the vertical integration, Hisun pharmaceuticals belong to the category of balanced vertical integration that produce some of the inputs used in the production of its products. Hisun plantation plays the role of producer in the Hisun Pharmaceutical supply chain. This is a very important position in the perspective of quality assurance because the quality of the rosemary raw material impacts on the processed oil and powder quality. In addition, in quality management operations, it is always better to have prevention of a problem rather than to depend on correction of the problem once it has occurred. Given the position of the Hisun plantation, it is vital to mention that the quality of the rosemary stage of the supply chain. This is mainly due to the fact that once the raw material is of low quality, then the final product will normally be of equally low quality. Therefore the position of the plantation in the rosemary supply chain and the role that it plays makes it very important to the GLOBALGAP plans of Hisun Pharmaceuticals.

Benefit in proper quality management are numerous such as; lower transaction costs, stronger product traceability, lower uncertainty risk and easier documentation management. In addition proper quality management avoid s loss in quality that may result into; higher exit costs of switching to other suppliers/buyers and too much risk within one industry

# 5.3 Implementation of Quality Control at the Hisun Plantation

The study considered eight (8) indicators in assessing how the quality control program at the Hisun plantation is implemented. These indicators selected were namely; farmer's knowledge of cultivation, seeding, cutting propagation, temperature control, fertilizer and pesticide, watering, weeding and post harvest as mentioned in table 2.

During the research it was noted that the farmer workers could not describe properly what they had been trained about quality. Lack of awareness about basic quality



indicators in rosemary cultivation and harvest shows a weakness in the training program. On the other hand the trainers feel that it's difficult to train the farmer workers. The causes of problems in the training of farmer workers are due to the following identified issues;

- Temporary workers. Farmer workers come from the whole area of the village to work as temporary workers and they are paid by the hour. This means that there is a constant change in the workers since they are not permanent. Hence a need for constantly training new farmer workers who join the company.
- Hierarchy prejudice. During the field work of this study, both experts and farmer workers were complaining with each other, there might be hierarchy prejudice existing between the two categories of employees. Experts considered their way of cultivation as the only and best way, whereas farmer workers insist using the method they used on their crops before. This creates a situation were the farmer workers are less interested in learning from the experts.
- Language problem. All experts speak fluently Chinese mandarin, but not all farmer workers fluently speak and understand Chinese mandarin. This language problem leads to weak communication, which causes difficulties in training. This is return affects the quality implementation program of the plantation.
- Labor shortage. Zhejiang province in which the Hisun plantation is located is a rich region of China were the people enjoy a higher than average domestic income. In recent years, most of the young people in the region have gone to the cities hence the labor shortage. Most of young people go to the city for non-agricultural jobs that pay better so as to support their family in finance. The rest of the villagers i.e. aged women and children are not willing to work as labor for agricultural activities. The labor market in this village is therefore an employee market because the farmer workers have the bargaining power and they prefer to choose the cultivation quality method which they are used to, instead of the new methods that the experts trained them. The Hisun plantation has to accommodate their demands due to the need for labor.

# 5.3.1 Farmer's Knowledge of cultivation

Cultivation of rosemary involves a number of tasks and normally the tasks are changing depending on the season, e.g. in March is seeding, Post harvesting mostly in November, and the rest months are for watering & weeding. However, all the farmer workers did not have a clear idea about seeding standards in a specific way and even the two farmer leaders. It was interesting to note that the quality control experts mentioned that the farmer workers had been informed about the seeding standards. This situation reveals a danger in that according to requirements from GLOBALGAP, each worker's task and responsibility should to be clearly identified and the worker should be aware of his task. Hence although all farmer workers interviewed had high awareness on their tasks for the whole working day, they were not well informed on the seeding standards.



# 5.3.2 Seeding

During the interview with the 20 farmer workers on the issue of seeding, it was revealed that 14 workers out of the 20 interviewed gave correct answers. However two (2) farmer workers gave wrong answers while another four (4) were not aware of it. The interview therefore tuned up a success rate of 70% correct answers but under the GLOBALGAP standard the interview was supposed to obtain an 100% success rate. In other wards when interviewed, the responses from the different farmer workers should have been as per the documented standards. The fact that more than 70% of the responses were successful shows that the farmer workers clearly understand the seeding issues related to quality management. This implies that the training work that has been done under this topic in the past is quite successful but there is still some way to go in able to make it to the GLOBALGAP level.

# 5.3.3 Cutting propagation

During the session of interviews concerning the cutting propagation, none of the 20 interviewed was able to give the correct response. When asked what the recommended length of cutting was, they used their fingers and hands to make the measurement. However it should be noted that the fingers differed among the different farmer workers hence giving different measurements. However it was positive to note that the farmer workers were trying to implement what the experts trained them. It's the opinion of the researcher that some of these problems concerning the knowledge of the cutting propagation standard are based on the fact that during training the experts should use common measurements like centimeters rather than using fingers. In addition the experts once having trained the farmer workers, they do not make a follow up to check how the farmers are performing. The farmers depend on their leaders in the field to make the right decisions but these farmer leaders equally are not sure about the cutting propagation requirements.

# 5.3.4 Temperature control

During interviews concerning temperature control, it was noted that five (5) farmer workers well understand the usefulness of canopy in temperature control while one (1) farmer worker doesn't know anything about temperature controlling. Eight (8) farmers workers considered watering is a good way of controlling temperature, including two (2) of those who well understand the use of Canopy. The GLOBALGAP standard would require that all the farmer workers should be aware of the importance of temperature control. Its important for the farmer worker to be aware of temperature control because its once of the most crucial elements during the winter. In addition higher temperature control leads to the multiplication of fungi which reduces the quality of the rosemary. Therefore its important for the farmer worker to be aware of the importance of temperature control because if they are not, then they are most likely going to work in the opposite was which the leads to loss of quality and even a times loss of the entire plant.

Temperature is the single most important factor in maintaining quality after harvest. If rosemary is harvested early in the morning, the need for cooling is minimized. It is particularly important to maintain constant temperatures in packaging. (Cantwell, 1986) Since Hisun's rosemary plantation has not a cooling room, their harvesting always carries out in the early morning. Normally rosemary will be packaged with paper box, which may cause fungi. Lowering the holding temperature to the recommended levels 0C-5C also greatly reduces water loss in the transport vehicle.



# 5.3.5 Fertilizer and Pesticide

The use of fertilizers and pesticides is very sensitive in the cultivation of rosemary. In the case of the Hisun rosemary plantation, it's not allowed to use fertilizer and pesticides. It was discovered during the interviews that al the farmer workers were aware of the instruction that fertilizer and pesticides were not used in the plantation. This was a very encouraging finding because it showed that the previous training sessions by the experts had been successful in creating awareness on the issue. In addition to make sure that there were no mistakes in the use if fertilizer and pesticide, the management of the plantation through the farmer leader ensure that no fertilizer or pesticides are kept at the farm. In the place of inorganic fertilizers, the Hisun plantation uses manure too maintains the fertility of the soils. However it's interesting to note that some farmer workers felt that the organization should use inorganic fertilizer to get better results. In the opinion of the researcher, this is mainly because the farmer workers do not understand the meaning of organic production. This could therefore be a risk in future and the Hisun plantation should consider the importance of training farmers on the meaning of organic cultivation and its benefits.

# 5.3.6 Watering

The area where Hisun's rosemary plantation is located is rarely affected by natural disasters but seasonally drought and water logging of the fields affect agricultural activities. The area has different topography and there are different soil types distributed all through out the area. At the plains the soil is yellow meadow soil and meadow peat, but at the hilly area and mountainous parts, there are arenaceous red soil and conglomerate red soil. Hisun's rosemary plantation is partly located in the hilly areas and the plain areas as a strategy to avoid water problems during the drought and rainy seasons.

During the study it was noted that farmer workers water the rosemary plants only when experts or the farmer leaders ask them to. The study further noted that the times of watering depended on the weather and seasons. The farmer workers pointed out that water used in watering is obtained from the canal. The canal comes from the hilly area of the region and was built before Hisun and KLP started managing the fields.

Proper watering of the rosemary is very important because if not well carried out, then the rosemary plants stand a high possibility of drying. In some cases the rosemary plants will not die completely but the quality of the extract from poorly grown plants will not be good. Hence it's very important to have all the farmer workers aware of the importance of watering in rosemary quality control.

# 5.3.7 Weeding

All farmer workers use traditional method for weeding: sometimes hoe, sometimes hand weeding. They bring the weeding facilities themselves, and the frequency of weeding also depends on weather and season, in the dry season, they can remove grass once a month, but in the raining season they have to weed twice a month.

During the study, the farmer workers were asked about the use of pesticides in rosemary farming. It was encouraging that all the farmer workers who were asked



about use of chemicals mentioned that chemicals should not be used in the growing of rosemary. Therefore in regard to weeding, the farmer workers scored 100% and this is as per the requirements under the GLOBALGAP standard. It also revealed that on this aspect that farmer workers and listen to the advise from the experts who had been involved in the earlier training. An area of further research and maybe discussion is why the farmers seem to be very aware of the impact of using chemical weeding on rosemary production and the same number was not seen in the other quality indicators of implementation, this is in the light that the training ion rosemary growing are conducted by the same experts yet some lessons seem to stick and others not so much.

# 5.3.8 Post harvest

The management of the rosemary plantation has been under the management of Hisun and KLP for the last four years period. Post harvest is another point at which the quality of the rosemary product is greatly affected if its not well handled. During the study it was discovered that a number of the farmer workers did not know the correct length of rosemary caulis at harvesting. A number of the workers simply gestured using this hands but were not very sure of the exert length requirement to ensure proper product quality. This in the opinion of the researcher is quite a serious issue that has to be resolved as far as the implementation of the quality program at the rosemary plantation is involved. It would be unfortunate to observe quality control during all the other operations involved in cultivation the plants and then lose it at the harvesting stage.

# 5.4 Quality concerns that require improvement

The research considered the Global Gap standards in determining the core issues for quality improvement under the company's quality program. The Control Points and Compliance Criteria for Integrated Farm Assurance were used to generate the findings as revealed in table 2. Out of the eight selected GLOBALGAP critical points that were selected, it was revealed that only two control points had been implemented in the current quality program under KLP at the rosemary plantation. One of the selected eight areas of review did not apply to the operations of the plantation because it concerned the reference to whether packing material is used for in-field packing, stored to protect against contamination. This aspect did not have relevance to rosemary production under Hisun plantation because immediately the product is harvested, it is transported to the factory for processing and hence there is not field storage practiced. However it is concerning to note that majority of the critical control points that were selected had not been implemented by the current quality management program. The finding that showed that five out of the eight selected standards had not yet been implemented gives a very clear picture of the current standing of the quality management program against the requirements of GLOBALGAP certification. The management of the rosemary plantation is equally in agreement that there is a lot that requires to be done in order to prepare for certification under the GLOBALGAP standards. On an encouraging note, the management of the Hisun plantation was very positive about undertaking improvement on their current quality program. This was seen in the fact that they were soon going to start ensuring that farmer workers received basic instructions in hygiene before handling produce as per GLOBALGAP the standards.



In reference to how the improvements should be implemented, the researcher is of the opinion that improvements that are ranked as major considerations under the certification program of GLOBALGAP need to be considered first. On one hand its unrealistic to expect that the organization will be in position to implement all the quality improvements at once for there are considerations to be made about the time it takes to train the current group of farmer workers and the fact that there are financial consideration to bear in mind. However, a close examination at the eight selected areas that require improvements it can be noted that not all of them require a lot of funding for example being able to clearly display signs that require workers to wash their hands before returning to work on the harvested produce.

Most of problems within GLOBALGAP inspection propagation of Hisun's rosemary plantation come from the documentation system but not the procedure or critical control points. However, collecting and make documentations cost time; this may delay applying GLOBALGAP certification. Normally GLOBALGAP requires that data records been kept for at least 12 months, and in some cases for 2 years. A quality manual is the top-level document of the quality management system. The quality manual should be according to GLOBAL GAP requirements.

# 5.5 Hisun's quality management system

The SWOT analysis of the Hisun quality management system revealed a number of findings as covered in section 4.5.1 and 4.5.2 under strengths and weakness respectively. In line with part of the objective of the research which was, to assess the ability of the rosemary quality management program at the plantation to meet the GLOBALGAP requirements and formulate beneficial interventions in case of deficiencies, the SWOT analysis concentrated on only the strength and weakness. This was done on the understanding by the researcher that the strengths of the program who show how prepared the quality system was to date in undertaking GLOBALGAP certification while the weakness would reveal the areas that need interventions for improvement.

In regard to the strength of the current program, it was found that there were three aspects in which the quality program was well scored. Quality management programs require a commitment and willingness on the part of management to spend finances if they are to be improved. This sis because a number of the GLOBALGAP requirement involves purchase resources that will then be placed into the quality system and paying for training sessions that will be required to improve the capacity of the human resource. Therefore it was very encouraging to find during the study that the management of Hisun had sufficient capital to invest in the guality program development. According to the management of the Hisun, investing in quality was seen as an opportunity to gain access to markets in the European Union that demand GLOBALGAP certification. Hence there is motivation on the part of the management that the certification process will be able to provide returns on their investment by opening up access to high profit markets within the European Union. The fact that the organization has a number of experienced professional with years of professional experience in quality management operations was also considered strength on the part of the organization mainly because GLOBALGAP requirements are related in some areas to the requirements under the Chinese Government regulations for manufacturers. Hence the organization staff would require capacity building to be able to implement GLOBALGAP in an effective manner but they will not be staring form



knowing nothing about quality systems. It was also important to note that the current plantation ha already obtained certification for water and soil aspects of the plantation hence confirmation that the program had a starting point above zero.

However the research also revealed a number of weaknesses under the current quality program when assessed using the GLOBALGAP standard as listed in section 4.5.2. The areas of weakness are in a number of diverse subjects therefore the need for construction of a problem tree to link up the problems. This was considered as very important by the researcher for it allowed the relationship between the problems to be revealed and also an avenue to follow in terms of interventions meant to improve the quality program. Although the problems emerge from a number of aspects, all of them point to three core issues: implementation, administration and produce handling in supply chain as stated in figure 9 below.









# CHAPTER 6 CONCLUSION AND RECOMMENDATIONS

#### 6.1 Conclusion

The major influencing factors affecting the quality management of rosemary from the study can be concluded as:

Literature review of crop and propagation care of rosemary indicate control points during cultivation. Then the study on implementation of quality control by farmer's side was carried out on Knowledge of cultivation, Seeding, Cutting propagation, Temperature control, Fertilizer and pesticide, watering, weeding and Post harvest. The result shows that the effect of training from experts is below the expected level, "temporary workers", "hierarchy prejudice", "language problem" and "labor market" are the causes of this inefficiency training.

The requirement from Hisun processing factory are regulations mentioned in GAP fruit and vegetables checklist. The finding that showed that five out of the eight selected standards had not yet been implemented gives a very clear picture of the current standing of the quality management program against the requirements of GLOBALGAP certification.

After compare with GLOBAL GAP checklist on quality management system, this study figures out those insufficient subjects and considered "documentation" is the main problem but not the procedures. The study also point out that this problem may leads to the delay of GLOBAL GAP applying, because of the requirement of time on record keeping. This study mentioned that it is better to combine GLOBAL GAP with other quality assurance, such as HACCP and ISO, in order to provide more professional systematic service to fulfill customer's requirements and expectation. Besides, a discussion on fundamentality of quality manual is available to help Hisun rosemary plantation selecting the priority.

KLP is a professional bureaucracy and due to that the parent company Hisun Pharmaceuticals offers the technical experts under its technology department a lot of individual powers. This structural design has a major disadvantage in that the technical experts are not easy to coordinate by KLP were their work is carried out.

As the primary producer, the only "customer" is Hisun pharmaceuticals. According to its concept, this study classifies Hisun's integration as a backward vertical integration. The benefits in quality management of Hisun pharmaceuticals are: Lower transaction costs, stronger product traceability, Lower uncertainty risk, and Easier documentation management. Losses in quality management is analyzed as well, they are: Higher exit costs of switching to other suppliers/buyers and Taking too much risk within one industry.

#### 6.2 Recommendation

Based on the conclusion drawn as discussed in the previous section, following recommendations are made to make Hisun's quality management improved, consult the objective tree (See Figure 9):



#### 6.2.1 Design training program

Training program can be divided into two parts: one program focus on GAP standards (expertise) and the other for train farmers. Since this is the first time to apply GAP certification, experts reported that they do not get the awareness of GAP, only internal inspectors and auditor have the knowledge about it. Therefore, training program for experts should focus on GAP standards and requirements, in order to train and supervise farmers when they are working. It is better to invite an external expert who has GAP background to be the trainer.

The other training program should be designed as describe and practice the methods of training farmers. Training is a crucial issue in agriculture in developing countries, it links advanced technology into agricultural practice. There are many ways and methods of training, such as group farmers and train the group leader, or use the tool of participative development research, etc. To cooperate with an Agriculture training centre or an agricultural institute might be the primary choice.

Give allowance to the family which all the members working for Hisun can be considered and another method of effective training: For example, if children work as experts/staff and parents work as farmer workers. It is convenient for children to train their parents for the allowance.

#### 6.2.2 Document and records control

Chapter 4 shows that KLP as the Hisun's R&D centre have stored almost all documents on technical measures. However, those documents they missed are about the administration, such as documented process of documents control. Actually they have quality control measures or CCP points but they have not collect them and documented. Since GAP applying is taken charge by an internal project team, this paper suggests KLP to select a proper staff who has the quality management background within this project team for clear up and control documents.

Records should be taken by each expert when they are working, and it should be in details, the more details the better. Besides, it is necessary for KLP to input all the records into the computer and store it via internet. Thus the record can be check in time and renew momentarily. It is crucial to clarify responsibilities and distribute administrative works in details. Since the management structure of KLP is Adhocracy, every expert should record his/her own data, and the Assistant take charge in coordinating and record collecting and keeping.

As the most crucial documentation, lack of quality manual can not be ignored in the recommendation. Herewith A quality manual designing should be based on the requirements of Global GAP. See Suggested table of content of Quality Manual of KLP in Appendix 3.





Figure 10 Objective tree based on problem tree (yellow parts are out of consideration within this research)



# 6.2.3 Lower prejudice

Prejudice comes from both of the two sides: farmers and experts. Farmers get payment by working hours but the payment is not linked up with quality of rosemary they produced, so they do not have motivation on getting better relationship with experts. And since the farmers are temporary workers and they are not constant, it is also difficult to link the quality with their salary. Herewith it is more easy and practical to motivate experts to lower their prejudice on farmers. This paper suggests Hisun to consider the communication skill with farmers as one factor of the career inspection of experts, by carrying out survey on farmers in the village a periodically. It is also helpful to motivate farmer's group leader by profit sharing.

Both farmers and experts understand Chinese mandarin, but some farmers, especially farmers who over 45 years old, can not speak it. Instead, they speak dialect which all the farmers understand well but experts could not. Since language becomes a problem and it leads to a weak communication, it is better to coordinate working language between farmers and experts. To coordinate working language does not mean to force farmers to learn and speak mandarin or compel experts to learn the dialect. Here to coordinate language means to make more chance to encourage and excite farmers and experts talking and communicating. For example, Hisun could hold more social gathering/club in the village and invite local farmers, by doing so farmers may have more chance for practicing mandarin and experts may use to hearing local accent and understand some dialect words.



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# **APPENDIX 1**

# SEMI-STRUCTURED QUESTIONNAIRE

Name: Age: Gender:

#### **Quality Control:**

- 1. What is your working procedure? (How many things need to be done per day?)
- 2. Which is the proper growing condition for rosemary? Dry or wet?
- 3. How many centre meters should be kept as the reproduce plant?
- 4. When can rosemary branch be reproduced? And what is the plant space between?
- 5. Do you have different cultivation method in different season for keeping stable temperature?
- 6. How many times do you watering?
- 7. How many times do you weed? In which way do you weed usually?
- 8. How many years after first planting can you start rosemary harvest? How many times can u harvest per year? How long of the caulis should be kept when u start harvest?

#### Quality Assurance: performance:

- 1. Do you know what is GAP?
- 2. Have you ever been trained? If yes, what is the content?
- 3. Where does the water come from?
- 4. Before rosemary, what kind of product had been cultivated on this field?
- 5. What kind of crop have you cultivated before on this field? Have you use fertilizer and pesticide when you cultivate your own crop?
- 6. Do you use fertilizer for rosemary now? If yes, what kind of fertilizer?
- 7. How do you distribute your working area? What is your responsibility in your work?
- 8. Have you recorded/labeled rosemary branch? How do you label them?
- 9. What do you do when we talking about hygiene when you are working? Do you have toilet when u r working? Do you wash your hands when u harvesting?
- 10. Is any person who supervises you?
- 11. How many hours do you work per day? Do you get any welfare from hisun?

#### **Quality improvement:**

- 1. What is your idea about quality improvement on rosemary?
- 2. Has Hisun asked feed back from you?
- 3. What kind of communication channel do you prefer?



#### **APENDIX 2**

# CONTROL POINTS OF ROSEMARY CULTIVATION(TRAINED BY PLANT SCIENCE EXPERT)

**Seeding:** Seeding for 3 months, distance between each plant is 5cm×5cm Cutting propagation: rosemary plant can be reproduce when roots comes out from the caulis;10cm Length cutting, 4 leaves per branch, 40cm×40cm

**Temperature:**17C-20C (In the Spring and Autumn rosemary plants should be protected by the cover; In the Summer the cover need to be removed.) If temperature is below 5C and it lasting 5 days, rosemary plant would die. If temperature is above 35C the growth of rosemary plant would stop.

Fertilizer and Pesticide: No give fertilizer and pesticide

**Water:** Percentage of water in the soil should be within 40%-50%, leaves would fallen down if the plant were in the water in 24 hours, after 24 hours root would be rotten.

Weeding: traditional method

**Post Harvest**: Rosemary plant can be harvested when the Caulis achieves 20cm; it could be harvested 4 times per year, since the 3<sup>rd</sup> year of cultivating.



# **APPENDIX 3**

# DEFINITION OF PRODUCE GROUP CERTIFICATION (FROM WEBSITE OF GLOBALGAP)

#### Producer group

A producer group **is** a group of producers (with their respective production locations) seeking to be GLOBALGAP (EUREPGAP) certified. The structure of the producer group must enable the application of a Quality Management System across the whole group. The Quality Management System (QMS) in place must be sufficiently robust to ensure (and to demonstrate through audits) that the group's registered producer members/production locations comply in a uniform manner with the GLOBALGAP (EUREPGAP) standard requirements. The producer group registered members must be legally responsible for their respective production locations. The producer group must comply with the requirements set out in this document to qualify for Option 2 certification.

A producer group is **not** a multi-site operation where an individual or one organization owns several production locations or "farms", which in itself are NOT separate legal entities. This type of operation falls under Option 1 and every production location, farm or site must be inspected and covered under the scope of the certificate. **Only** if such an operation has a Quality Management System including internal annual inspections, and the QMS is included in the GLOBALGAP (EUREPGAP) certification, can it be certified as Option 1, while following the Option 2 rules for random external sampling of sites (minimum square root) based on the criteria as described in GR Part I, 5.2 Option 2 and Part II, Appendix II.3 Rules for Evaluating Option 2 Producer Groups, 6.1.2.

NOTE: The entire crop of a registered product must be certified. e.g. A GLOBALGAP (EUREPGAP) producer that is part of a producer group certified for strawberries, must include all the production locations with strawberries for certification. See Annex III.1 (Producer Group and Legal Entity) for further clarification of the legal entity

#### Administration and Structure

**Legality:** There shall be documentation, which clearly demonstrates that the applicant producer group is or belongs to a legal entity. The legal entity must have been granted the legal right to carry out agricultural production and/or trading, and be able to legally contract with and represent the group members. The group or legal entity must, as a group, be registered legally for example as a Cooperative, Producers Association, Packing Company, Trading Company, Farming Company, etc. (not consultancy companies, Non-Governmental Organisations, development agencies, agrochemicals distributor, etc). This legal entity must have ultimate responsibility over the production, handling and ownership of the products, thus it is responsible for the compliance with the GLOBALGAP (EUREPGAP) standard and General Regulations within the GLOBALGAP (EUREPGAP) producer group. The legal entity will enter into a contractual relationship with GLOBALGAP (EUREPGAP) through the signature of the GLOBALGAP (EUREPGAP) Sub-Licence and Certification Agreement with a GLOBALGAP (EUREPGAP) approved CB, and becomes the sole holder of the GLOBALGAP (EUREPGAP) certificate.



**Structure:** The administrative structure of the producer group shall be documented and clearly identify the relationship between the producers and the legal entity.

#### **Contractual Documentation**

There shall be written signed contracts between each producer and the legal entity. The contracts shall include the following elements:

- (i) Name or fiscal identification of the producer
- (ii) Contact address
- (iii) Details of the individual production locations
- (iv) Commitment to comply with the requirements of the GLOBALGAP (EUREPGAP) standard

(v) Agreement to comply with the group's documented procedures, policies and where provided, technical advice.

(vi) Sanctions that may be applied in case of GLOBALGAP (EUREPGAP) and any other internal requirements not being met.

#### Producer Register

A register shall be maintained of all GLOBALGAP (EUREPGAP) member producers, and of all the applicable sites used for production in accordance with the GLOBALGAP (EUREPGAP) standard.

All these member producers in the producer register must be registered individually on the GLOBALGAP (EUREPGAP) database according to the requirements of the General Regulations PART I; 4.8 Registration.

The register shall at least contain the following information for each producer:

- (i) Name of producer
- (ii) Name of contact person
- (iii) Full address (physical and postal)
- (iv) Contact data (telephone number and e-mail and/or fax number)
- (v) Other ID (VAT Number, ILN, UAID, etc) if required for the country of production (vi) Product registered
- (vii) Growing/Production area and/or quantity for each registered product
- (viii) Certification Body(ies) if a producer makes use of more than 1 CB (according to General Regulations PART I; 4.4.1.vi and 4.4.2.vi)
- (ix) Internal audit date

(x) Current GLOBALGAP (EUREPGAP) status (according to the statuses as indicated in Annex I.4)

NOTE: Those producers of the legal entity who do not apply for GLOBALGAP (EUREPGAP) certification must be listed separately and will not be registered in the GLOBALGAP (EUREPGAP) database (unless they have applied for option 3 or 4). This list is for management purposes within the producer group, and the disclosure of its contents externally is not required, unless it is needed for clarification of any issues raised for example on the effectiveness of the producer group's Quality Management System. All data protection rules shall be published and observed.

#### Management and Organization

**Structure** The producer group shall have a management structure and sufficient suitably trained resources to effectively ensure that the registered producers meet the requirements of GLOBALGAP (EUREPGAP) on their production locations. The organisational structure of the group shall be documented and shall include:



(i) GLOBALGAP (EUREPGAP) management representative - person or department responsible for managing the implementation of GLOBALGAP (EUREPGAP) in the group.

(ii) Internal inspector(s) – person(s) responsible for the internal inspections of each producer member of the group annually; complying with the GLOBALGAP (EUREPGAP) requirements set for an internal group inspector (Appendix III.1).

(iii) Internal auditor(s) – person(s) responsible for the internal audit of the Quality Management System, complying with the GLOBALGAP (EUREPGAP) requirements set for an internal group auditor (Appendix III.2).

(iv) Agricultural or livestock technical person/department – person(s) responsible for technical advice to the group.

(v) Quality Systems Management (QMS) person/department – person(s) responsible for managing the QMS.

NOTE: A group needs at least one internal auditor, who can cover the functions of internal group inspector and internal auditor (in case only one internal auditor who performs also the inspections, another person, identified in the QMS must approve the producer internal inspections; see Appendix III.2, 3.1.i and 3.4.2)

**Responsibility and Duties** The duties and responsibilities of all personnel involved with the compliance of GLOBALGAP (EUREPGAP) requirements shall be documented, and an individual who holds a position of sufficient seniority and resources to serve as the overall responsible person will be nominated for maintenance of the GLOBALGAP (EUREPGAP) certification (see 1.2.1.i).

#### Competency and Training of Staff

(i) The group shall ensure that all personnel with responsibility for compliance with the GLOBALGAP (EUREPGAP) standard are adequately trained and meet defined competency requirements.

(ii) The competency requirements, training and qualifications for key staff shall be documented and shall meet any defined competency requirements laid out in the GLOBALGAP (EUREPGAP) standard.

(iii) Records of qualifications and training shall be maintained for all key staff (managers, auditors, inspectors, etc.) involved in compliance with GLOBALGAP (EUREPGAP) requirements to demonstrate competence.

(iv) The internal auditor(s) and inspector(s) shall undergo training and evaluation, e.g. by documented shadow audits, to ensure consistency in their approach and interpretation of the standard.

(v) Systems shall be in place to demonstrate that key staff is informed and aware of development, issues and legislative changes relevant to the compliance to the GLOBALGAP (EUREPGAP) standard.

#### **Quality Manual**

(i) The operating and quality management systems related to the GLOBALGAP (EUREPGAP) standard shall be documented and contained in a Quality Manual(s).

(ii) Policies and procedures shall be sufficiently detailed to demonstrate the group's control of the principal requirements of the GLOBALGAP (EUREPGAP) standard.

(iii) Relevant procedures and policies shall be available to the producer group registered members and key staff.

(iv) The contents of the Quality Manual shall be reviewed periodically to ensure that it continues to meet the requirements of the GLOBALGAP (EUREPGAP) standard and those of the producer group. Any relevant modifications of the GLOBALGAP



(EUREPGAP) standard or published guidelines that come into force must be incorporated into the Quality Manual within the time period given by GLOBALGAP (EUREPGAP).

#### Document Control

#### **Quality Management System (QMS) Documents**

All documentation relevant to the operation of the Quality Management System (QMS) for GLOBALGAP (EUREPGAP) compliance shall be adequately controlled. This documentation shall include:

(i) The Quality Manual

(ii) GLOBALGAP (EUREPGAP) operating procedures

(iii) Work instructions

(iv) Recording forms

(v) Relevant external standards, e.g. the current GLOBALGAP (EUREPGAP) normative documents.

#### Quality Management System Document Control Requirements

(i) There shall be a written procedure defining the control of documents.

(ii) All documentation shall be reviewed and approved by authorised personnel before issue and distribution.

(iii) All controlled documents shall be identified with an issue number, issue date/review date and be appropriately paged.

(iv) Any change in these documents shall be reviewed and approved by authorised personnel prior to its distribution. Wherever possible an explanation of the reason and nature of the changes should be identified.

(v) A copy of all relevant documentation shall be available at any place where the QMS is being controlled.

(vi) There shall be a system in place to ensure that documentation is reviewed and that

following the issue of new documents, obsolete documents are effectively rescinded.

#### Records

(i) The group shall maintain records to demonstrate effective control of the GLOBALGAP (EUREPGAP) Quality Management System requirements and compliance with the requirements of GLOBALGAP (EUREPGAP) standard.

(ii) Records from the QMS related to compliance of GLOBALGAP (EUREPGAP) requirements shall be kept for a minimum of 2 years.

(iii) Records shall be genuine, legible, stored and maintained in suitable conditions and shall be accessible for inspection as required.

(iv) Records that are kept on-line or electronically are valid. If a signature is required, this can be a password or electronic signature that ensures the unique reference and authorization of the person signing. If a written signature of the responsible person is needed then this must be present. The electronic records must be available during the CB inspections. Back-ups must be available at all times.

# Complaint Handling

(i) The group shall have a system for effectively managing customer complaints.

(ii) There shall be a documented procedure that describes how complaints are received, registered, identified, investigated, followed up and reviewed.

(iii) The procedure shall be available to customers as required.

(iv) The procedure shall cover both complaints to the group and against individual producers.



#### Internal Audits and Inspections

Internal audit systems shall be in place both to assess the adequacy and compliance of the documented QMS and to inspect the producers and farms against the GLOBALGAP (EUREPGAP) standard.

#### **Quality Management System Audit**

Internal auditor(s), complying with the GLOBALGAP (EUREPGAP) requirements set for an Internal group auditor (Appendix III.2), will do the internal audit of the QMS. (i) The QMS for the GLOBALGAP (EUREPGAP) scheme shall be audited at least annually.

(ii) Internal auditors shall be suitably trained and independent of the area being audited.

(iii) The CB will evaluate the competence of the internal auditor during the external audit by checking compliance with Appendix III.2.

(iv) Records of the internal audit plan, audit findings and follow up of corrective actions resulting from an audit shall be maintained and available.

NOTE: It is permitted for the same person to initially develop the QMS within the group, and then undertake the required annual QMS audit, however the person responsible for the day-today ongoing management of the QMS is not allowed to undertake the required subsequent annual internal QMS audits (see Appendix III.2, 3.4.3).

#### **Producer and Production Location Inspections**

Internal inspectors, complying with the GLOBALGAP (EUREPGAP) requirements set for an internal group inspector (Appendix III.1) will be responsible for carrying out the farm inspections.

 (i) Inspections shall be carried out at each registered producer and production location at least once per year against the GLOBALGAP (EUREPGAP) Control Points and Compliance Criteria, based on the GLOBALGAP (EUREPGAP) Checklist. All Major and Minor Musts as well as Recommended control points must be inspected in full.
 (ii) There shall be a process for the review of the inspection reports and producer

(ii) There shall be a process for the review of the inspection reports and producer status.

(iii) New members of the group must always be internally inspected prior to them entering into the GLOBALGAP (EUREPGAP) registered producers list.

(iv) The original inspection reports and notes shall be maintained and available for the CB inspection as required.

(v) The inspection report shall contain the following information:

a) Identification of registered producer and production location(s)

b) Signature of the registered producer

c) Date

d) Inspector name

e) Registered products

f) Evaluation result against each GLOBALGAP (EUREPGAP) control point

g) All Major Musts in the Checklist must include details of what was verified in the comments section of the checklist, in order to enable the audit trail to be reviewed after the event.

h) Details of any non-compliances identified and time period for corrective action.

i) GLOBALGAP (EUREPGAP) status

(vi) The internal auditor (or audit team; see Appendix III.2) will make the decision on whether the producer is compliant with the GLOBALGAP (EUREPGAP) requirements, based on the inspection reports presented by the internal inspector.



# **Non-Compliances and Corrective Action Systems**

(i) There shall be a procedure to handle non-compliances and corrective actions which may result from internal or external audits and/or inspections, customer complaints or failures of the QMS.

(ii) There shall be documented procedures for the identification and evaluation of noncompliances to the QMS by the group or by its members.

(iii) Corrective actions following non-compliances shall be evaluated and a timescale defined for action.

(iv) Responsibility for implementing and resolving corrective actions shall be defined.

#### **Product Traceability and Segregation**

(i) Product meeting the requirements of the GLOBALGAP (EUREPGAP) standard and marketed as such shall be traceable and handled in a manner that prevents mixing with non- GLOBALGAP (EUREPGAP) approved products.

(ii) There shall be a documented procedure for the identification of registered products and to enable traceability of all product, both conforming and non-conforming to the applicable production sites. A mass balance exercise must be carried out to demonstrate compliance within the legal entity.

(iii) For Fruit and Vegetables certification: the produce handling site shall operate procedures which enable registered product to be identifiable and traceable from receipt, through handling, storage and dispatch.

(iv) Effective systems and procedures shall be in place to negate any risk of mis-labeling or mixing of GLOBALGAP (EUREPGAP) certified and non-GLOBALGAP (EUREPGAP) certified products.

#### Sanctions and Non-Conformances

(i) The group shall operate a system of sanctions and non-conformances with their producers, which meet the requirements defined in the GLOBALGAP (EUREPGAP) General Regulations.

(ii) Contracts with individual producers shall define the procedure for sanctions including the levels of Warning, Suspension and Cancellation.

(iii) The group shall have mechanisms in place to notify the GLOBALGAP (EUREPGAP) approved Certification Body immediately of Suspensions or Cancellations of registered producers.

(iv) Records shall be maintained of all sanctions including evidence of subsequent corrective actions and decision-making processes.

#### Withdrawal of Certified Product

(i) Documented procedures shall be in place to effectively manage the withdrawal of registered products .

(ii) Procedures shall identify the types of event which may result in a withdrawal, persons responsible for taking decisions on the possible withdrawal of product, the mechanism for notifying customers and the GLOBALGAP (EUREPGAP) approved Certification Body; and methods of reconciling stock.

(iii) The procedure shall be capable of being operated at any time.

(iv) The procedure shall be tested in an appropriate manner at least annually to ensure that it is effective and records of the test retained.

#### Subcontractors

(i) Procedures shall exist to ensure that any services subcontracted to third parties are carried out in accordance with the requirements of the GLOBALGAP (EUREPGAP) standard (see control point All Farm AF.3.6.1).

(ii) Records shall be maintained to demonstrate that the competency of any subcontractor is assessed and meets the requirements of the standard.



(iii) Subcontractors shall work in accordance with the group's QMS and relevant procedures and this shall be specified in service level agreements or contracts.



# **APPENDIX 4**

# SUGGESTED KLP QUALITY MANUAL

- 1. General
- 2. Management
  - Establishment of policy Strategy of KLP Quality policy Quality objectives and planning Acceptance from third parties
- 3. Organization and staff

Organizational chart Responsibilities and authorities Expertise and competences Quality responsibilities and management representation Explanation of function Personnel and training Communication

4. Administration (document and data)

Document structure Production Administration of internal en external documents Administration of data

5. Improvement

Complaints and improvements Project evaluation Evaluation by management Corrective and preventive measures Internal audits

- 6. Execution
  - Seeding Watering Weeding Postharvest Storage(if necessary) Contain and transport Traceability



#### **APPENDIX 5**

#### HISUN'S PLANTATION LABOR (FARMER WORKERS) ORGANIZING

All Farmer workers of Hisun rosemary plantation come from Xialian village where the Hisun's plantation located. Since most male villagers has migrated to nearby cities for non agricultural jobs (some working for Hisun factories), the rest people which are women and children becomes main source of agricultural labor in this small village.

Two farmer leaders have been selected by Department of Human Resource of Hisun Pharmaceuticals among 503 households in 2004, according to the suggestion from village leader. Farmer leaders estimated the rest available villagers who might work as labors and made a farmer workers list. According to this list, farmer workers have been selected and organized by two farmer leaders. Select process includes two steps: 1. Get comment from KLP expert (time, number of labor in need); 2. Contact farmers and make sure the available farmer workers.

Different stages of cultivation require different number of farmer workers. At the seeding stage in 2004, 50 farmer workers were selected for soil preparing, seeding and watering. After that, during the off season the plantation needs 8-15 farmer workers for weeding and watering. At the stage of harvest the plantation needs more labor than during off season but less labor than the seeding stage, which means around 20-25 farmer workers are in need.

In the field farmer leaders distribute working area for farmer workers averagely, according to the number of farmers. Farmer leaders also supervise working process of farmer workers in the plantation. Farmer workers work eight(8) hours in their working day, they usually start working at 6 am till 10 am in the morning, 3 pm till 7 pm in the afternoon (working time depends on season and weather, farmer leaders discuss this with farmer workers in the previous day). At the end of the working day farmer workers get payment from the two farmer leaders.

There is no paper contract between farmer workers and Hisun Pharmaceutical's, it is a temporary work and both of the two sides' activities are regulated by oral contract, in another words, they trust each other.