Design and Implementation of an Ontology-based Product Traceability System: An Empirical Study of a Domestic Biotechnology Company

Ming-Shang Huang
mshuang@mail.npust.edu.tw

Yimin Sun,
swimming@mail.hwai.edu.tw

May-Yi Lin
D98010066@mail.hwai.edu.tw

Abstract

Recently consumers and producers gradually pay more attention to the traceability information of products in the biotechnological industries. Based on the increasing needs of the traceability information of biotechnological products, this research develops an ontology-based traceability system that keeps the complete electronic records of product traceability information since from the suppliers of raw materials to the manufacturing processes. Therefore, consumers can access the information of product traceability easily and quickly. To ensure the safety of biotechnological products, a traceability information system can provide consumers the traceability information about the biotechnological product. Consequently, producers of biotechnological products will possess better competitive advantages due to providing consumers the traceability information of products openly and transparently. This research proposes a framework of the ontology of constructing a traceability system for biotechnology companies according to the procedures specified by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). An empirical study was conducted in a biotechnology company in south Taiwan. A product traceability system was developed in a biotechnology company and surveys of application performance were conducted by way of the questionnaires delivered to the respondents who take in charge of traceability information on biotechnological products. In this study, we used the AHP method to compute the weights of evaluating indicators for the application performance of a production traceability system. The results of this survey indicated that the major dimensions of evaluating the application performance of a product traceability system were ranked as follows: system quality (63.6%), operation performance (25.5%), and information and knowledge applications (10.9%). In summary, an ontology-based traceability information system can be used to reduce the workloads and reductions of total costs, and improve the quality of work and operational efficiency. Besides, a production traceability system also provides producers and consumers the comprehensive traceability information for the purposes of decision making.

Keywords: Ontology, Traceability Systems, PIC/S, AHP
Design and Implementation of an Ontology-based Product Traceability System: An Empirical Study of a Domestic Biotechnology Company

I. INTRODUCTION

In recent years, total values of output including production incomes, OEM incomes, service incomes and license incomes, etc. created by the biotechnological industry grow dramatically in Taiwan. According to the statistics by the official organization, the total production values of biotechnology created by the 390 biotechnology producers in Taiwan amount to 6514 million NT dollar. Fig. 1 shows the production value and growth rate from 2008 to 2009.

![Fig. 1. Total values of output and growth rates from 2008 to 2009.](image)

This research proposes an ontology-based production traceability system which meets the needs of GMP specified by the pharmaceutical inspection convention and pharmaceutical inspection co-operation scheme (PIC/S) and develops a product traceability system that provides important decision information to the customers and producer. Therefore, producers can effectively control the manufacturing quality using the above information. In addition, customers can assess the production information and transportation information via the Internet. Thus, the purposes of this paper are: (1) to investigate key issues on developing a product traceability system, (2) to propose a framework for developing a product traceability system based on the ontology for the application of a product traceability system, and (3) to examine the applicability and practicability of proposed framework using a case of a domestic biotechnology company. This research develops an ontology-based production traceability system to resolve the problems mentioned above.

II. LITERATURE REVIEW

2.1 Basic concept of ontology

According to the concept of ontology, there are different domain knowledge in the real world, different domain knowledge constitutes the domain, and many related basic things is composed of the basic thing (Guarino, 1998; Bunge, 1977). In general, ontology can be
separated into the following types: (1) top level ontology: describes the most common concepts and relationships between those concepts such as time, space, event, behavior which are not related with the application, (2) domain ontology: knowledge is acquired via the verification from some specific domain, (3) task ontology: operational knowledge developed from the specific task and behavior, and (4) application ontology: knowledge for modeling the specific domain knowledge, is the combination of domain ontology and task ontology (Guarino, 1998; Chandrasekaran et al., 1999). Basically, the ontology of concepts are composed by the following components (Guarino, 1995, 1998; Gruber, 1993): (see Fig. 2) (1) Entities or classes, concepts, or general things, etc.: there are tangible or intangible things such as people, role, time, and so on; (2) Instances or particular things: for instance, some specific person called Tim, Tom, or Kim; (3) Attributes, properties or property values: it is used to describe the characteristics of an entity such as color, weight, etc. (4) Relations: it is used to describe the rules and relationships between the entity and another entity, and (5) Constraints: there are used to describe the limitations and rules for main bodies.

Fundamentally, developing an information system is a knowledge-intensive activity. Software project team members usually share knowledge with other member of the project teams during the project development process. Thus, ontology is a powerful tool to facilitate the project team member in developing software projects due to ontology has the following advantages: (1) increases the capacity and value of knowledge in an organization, (2) increases the competitiveness of an organization by applying the knowledge into the innovation of techniques, product and service, (3) improves the efficiency of knowledge acquisition by promoting the exchange of knowledge in an organization, (4) introduces a new direction of organization innovation, (5) facilitates an organization to develop core competence of technology, (6) improves project team members’ knowledge capabilities and potential creativities, and (7) contributes to share the business cultures and technological knowledge among project team members. In addition, Rosse and Mejino (2003) also illustrated the reference ontology for biomedical informatics which formulates the foundational model of anatomy. Therefore, applications of ontology in developing a production system are a promising research direction.

![Fig. 2. The ontology of concepts.](image-url)
2.2 The production traceability system

According to the regulation of food proposed by the European Union (EC), traceability is defined as follows: “The ability of monitoring, tracing, and survey information about the foods, fodder, animal foods or processing foods, etc.” Thus, EC defines traceability as follows: “An information retrieval about traceability, place, etc. to attend the following objectives: (1) transparency of material flows path, (2) recycles products according to assigned objectives, (3) provides information to the consumers and certification organization, (4) provides the contents of traceability as the evidence of certification, (5) supports the collection of disease information about health which is contributed to the development of techniques of risk management, and (6) provides correct information to the consumers which is helpful to carry out the transaction in fair.

Ministry of agriculture, forestry and fisheries of Japan defines food traceability system named as traceability of production and transportation as follows (Hu, 2005): “Collects information about the traceability (from down stream to upper stream), monitoring (from upper stream to down stream) of foods on production, processing, marketing, etc.” Codex (2004) defines traceability/production tracing as follows: “The ability of monitoring the movement of foods about the production, processing, transportation in the specific and multiple stages. So, a production traceability system is an information system that monitors the production and marketing information from the farm to table with quality assurance in transparent and traceability. In other words, a food production traceability system is an information system that monitors the information during the process of production, processing, and transportation, and selling. Food producers are strongly required to record, keep, and show the production traceability information in public, consumers can understand all related processes’ important information. Therefore, a production traceability system can trace the production process since from the producers to the consumers including purchases of materials, inspection, manufacturing, and transportation, etc. Once, when products occurs problems, a production traceability system can help the person in charge of production traceability in a food company to find the important cues of occurring the problems quickly and correctly, and reduce harms to the consumers in a minimum degree.

2.3 International pharmaceutical inspection standard

Until now, PIC/GMP certification is considered as the most rigorous specification of medicine manufacturing in the world. It is a comprehensive quality management system which monitors the quality of product since from the starting of production, therefore, detailed experimental records of medicines are strongly required. The advantages of implementing PIC/GMP certification includes: (1) ensures the high quality of medicines on research and development, manufacturing, and control, (2) promotes the consistency in issuances of license, (3) promotes the consistency and homogeneity of auditing procedures, and (4) contributes to reduce trade barriers of medical products.
According to the regulation of good medicines’ manufacturing process stipulated by the PIC/S GMP promulgated in 26th November, 2004. The classification standards of PIC/S GMP covers: (1) quality management, (2) personnel, (3) factorial facilities and equipments, (4) document, (5) production, (6) quality control, (7) OEM/testing, (8) complain/product recycle, and (9) self-check. In order to attain the objectives specified by the PIC/S GMP, a medicine company is required to implement the quality management including quality assurance (QA), good manufacturing practices, quality control, documents, and monitoring the results of manufacturing processes.

### 2.4 Evaluation of application performance of implementing a production traceability

For the purposes of investigating the application performance of implementing a production traceability system, several researchers have illustrated the evaluation indicators for performance evaluation. Table 1 is a summary of evaluation indicators. Three types of evaluation dimension are system quality, operation performance, information and knowledge application.

Table 1. A summary of evaluation indicators for application performance of a production traceability system.

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Item of evaluation</th>
<th>Evaluation indicator</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>System quality (A)</td>
<td>Information quality (A1)</td>
<td>Consumers use the system correctly, reliably, completely, and contribute value to consumers.</td>
<td>Bharati and Berg (2005); DeLone and McLean (2003).</td>
</tr>
<tr>
<td></td>
<td>Usage quality (A3)</td>
<td>The quality of system usages such as efficiency, stability, response times, ease of operation, ease of learning, safety of usage and artistic of interfaces.</td>
<td>Bharati and Berg (2005); DeLone and McLean (2003); Hernon and Calvert (2005).</td>
</tr>
<tr>
<td>Operation performance (B)</td>
<td>Traceability of abnormal products (B1)</td>
<td>Improves the product traceability effectively</td>
<td>Juran (1989).</td>
</tr>
<tr>
<td></td>
<td>Reductions of total costs (B2)</td>
<td>Reductions of total costs (material cost, indirect cost, and labor cost)</td>
<td>Liu (2000).</td>
</tr>
<tr>
<td></td>
<td>Savings of seeking times (B3)</td>
<td>Reductions of total times in seeking information spent on the production traceability</td>
<td>Liu (2000).</td>
</tr>
<tr>
<td></td>
<td>Evaluation operation (B4)</td>
<td>Improves the performance of evaluation operation such as real time, correctly, and completely.</td>
<td>Agricultural committee of Executive Yuan; Food and medicine management bureau of Executive Yuan.</td>
</tr>
<tr>
<td>Information and knowledge (C)</td>
<td>Documents management (C1)</td>
<td>Compliance with the regulation by the PIC/S.</td>
<td>Agricultural committee of Executive Yuan; Food and medicine management bureau of Executive Yuan.</td>
</tr>
<tr>
<td>Knowledge management (C2)</td>
<td>Improves the operation of knowledge acquisition, knowledge process, and application.</td>
<td>Davenport and Prusak, (1998).</td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>------------------------------</td>
<td></td>
</tr>
<tr>
<td>Information sharing (C3)</td>
<td>Enhances the ability of information sharing using IT.</td>
<td>Davenport and Prusak, (1998).</td>
<td></td>
</tr>
<tr>
<td>Information application (C4)</td>
<td>Provides information retrieval and browsing the output of a production traceability system.</td>
<td>Davenport and Prusak, (1998).</td>
<td></td>
</tr>
</tbody>
</table>

### 2.5 Analytical Hierarchy Method

Analytic hierarchy process (AHP) was first proposed by Saaty (1980) and it is based on the analysis of expert surveys. AHP is a structured technique for organizing and analyzing complex decisions. Basically, users of the AHP first decompose a problem into a hierarchy of more easily comprehended sub-problems, each of which can be analyzed independently. The elements of the hierarchy can relate to any aspect of the decision problem. Once the hierarchy is built, the decision makes systematically evaluate its various elements by comparing them to one another two at a time, with respect to their impact on an element above them in the hierarchy. The decision makers use their judgments about the elements’ relative importance. The AHP converts these evaluations to numerical values that can be processed and compared over the entire range of the problem. A numerical weight is derived for each element of a hierarchy. In the final step of the process, numerical priorities are calculated for each of the decision alternatives. These numbers represent the alternatives’ relative ability to achieve the decision goal, so that they allow straightforward consideration of the various courses of action.

The basic assumptions of AHP are listed as follows: (1) a system can be separated into many classes and variables, therefore, it represents a directional hierarchical network, (2) The element in each layer is independent to another element, (3) the element in each layer can be evaluated using the element in the upper layer, (4) we need to transform the absolute value into a ratio value during the process of comparison after the process of pairwise comparison, (5) transitivity of law is applicable to the case of relation. For instance, A is superior to B, B is superior to C. Then, A is superior to C. Meanwhile, intensity is also applicable to transitivity of law, (6) it is allowed that dissatisfying the transitivity of law, but it is necessary to pass the test of consistency (7) the degree of priority is obtained by using the weighting principle, and (8) any element in the hierarchy, no mater what it is high or low, it is considered as related with the structure of evaluation.

Developing a set of hierarchy is an important task during the process of applying the AHP method. Basically, a set of hierarchy is a skeleton of the system structure. It can be used to analyze the interaction and their impacts between the elements in each layer. Therefore, we can decompose a system into several groups, each group is further decomposed into subgroups, continues to carry out the above process until the whole hierarchy is done. During the process of group analysis: (1) the top level of a hierarchy denotes the ultimate goal of a decision problem, (2) the approximately element are set in the same layer, (3) the number of
elements in each layer are limited, (4) the element in the same layer is independent to each other, and (5) the element in the lowest layer is the alternative.

In the following, we plan to explain the application of the AHP method:

(1) Theoretical background of AHP method

Assume $A_1, A_2, ..., A_n$ is the variable in a hierarchy, we use pairwise comparison to calculate the weight of each variable is $W_1, W_2, ..., W_n$. The relevant importance of $A_i$ versus $A_j$ is represented as $a_{ij}$. When a decision maker carries out pairwise comparison, words and predicate can be used (Table 2). We denote the comparison matrix as $A [a_{ij}]$ for the variable $A_1, A_2, ..., A_n$. If $W_n, W_1, ..., W_2$ is known, the pairwise matrix $A [a_{ij}]$ is represented as follows:

$$A = \left[ a_{ij} \right] = \begin{bmatrix}
    a_{11} & \ldots & a_{1n} \\
    \vdots & \ddots & \vdots \\
    a_{n1} & \ldots & a_{nn}
\end{bmatrix} = \begin{bmatrix}
    1 & a_{12} & \ldots & a_{1n} \\
    1/a_{21} & 1 & \ldots & 0 \\
    \vdots & \vdots & \ddots & \vdots \\
    1/a_{n1} & 1/a_{n2} & \ldots & 1
\end{bmatrix} \quad (1)
$$

When

$$a_{ij} \cdot W_j = W_i / W_j, \quad a_{ji} = 1/a_{ij}, \quad \text{Let } W = \begin{bmatrix} W_1 \\ W_2 \\ \vdots \\ W_n \end{bmatrix}, \quad i, j = 1, 2, ..., n \quad (2)$$

Among the $n$ variables, $a_{ij}, a_{jk}, a_{ik}$ to all variables $i, j, k$, the comparison of two variable comparison is consistent if the following conditions is satisfied:

$$a_{ij} \cdot \frac{W_j}{W_i} = 1, \quad i, j = 1, 2, ..., n \quad (3)$$

Then

$$\sum_{j=1}^{n} a_{ij} \cdot \frac{W_j}{W_i} = n, \quad i, j = 1, 2, ..., n \quad (4)$$

Table 2. The Satty rating scale.

<table>
<thead>
<tr>
<th>Intensity of importance</th>
<th>Definition</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Equal importance</td>
<td>Two alternatives contribute equally to the objective</td>
</tr>
<tr>
<td>3</td>
<td>Moderate importance</td>
<td>Experience and judgment slightly favor one over the other</td>
</tr>
<tr>
<td>5</td>
<td>Strong importance</td>
<td>Experience and judgment strongly favor one over the other</td>
</tr>
<tr>
<td>7</td>
<td>Very strong importance or demonstrated importance</td>
<td>Experience and judgment very strongly favor one over the other. Its importance is demonstrated in practice.</td>
</tr>
<tr>
<td>9</td>
<td>Extreme importance</td>
<td>The evidence favoring one over the other is</td>
</tr>
</tbody>
</table>
Intensity of importance | Definition | Explanation
---|---|---
2、4、6、8 | For compromise between the above values | When compromise is needed.

(Source from: Deng and Zeng, 1989)

(2) Test of consistency

In order to ensure the consistency of comparison, test of consistency is necessary when carries out the pairwise comparison. We consider pairwise matrix have complete consistency when \( \lambda_{\text{max}} = n \), if then else \( \lambda_{\text{max}} \geq n \). If \( \lambda_{\text{max}} \) is more close to n, the consistency is higher. Therefore, Consistency Index (C.I.) is defined as follows (Saaty, 1980):

\[
C.I. = \frac{\lambda_{\text{max}} - n}{n - 1}
\]  

(5)

According to the value of C.I., the comparison of the former and the latter is complete consistency when C.I. =0, the comparison of the former and the latter is discontinuous when C.I.>0, the comparison of the former and the latter has allowable bias when C.I. \( \leq 0.1 \), then, comparison matrix has consistency (Saaty, 1980). The value of Random Index (RI) is different according to the value of order. As shown in Table 3, ratio of value of C.I. and value of R.I. is called as the consistency ratio. The consistency of comparison matrix is satisfactory when C.R. \( \leq 0.1 \). The definition of consistency ratio is defined as follows:

\[
C.R. = \frac{C.I.}{R.I.}
\]  

(6)

Table 3. Table of random index.

<table>
<thead>
<tr>
<th>Order</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>R.I.</td>
<td>0</td>
<td>0</td>
<td>0.58</td>
<td>0.90</td>
<td>1.12</td>
<td>1.24</td>
<td>1.32</td>
</tr>
<tr>
<td>Order</td>
<td>9</td>
<td>10</td>
<td>11</td>
<td>12</td>
<td>13</td>
<td>14</td>
<td>15</td>
</tr>
<tr>
<td>R.I.</td>
<td>1.45</td>
<td>1.49</td>
<td>1.51</td>
<td>1.48</td>
<td>1.56</td>
<td>1.57</td>
<td>1.58</td>
</tr>
</tbody>
</table>

(source from: Saaty, 1980)

**III. RESEARCH METHOD**

In order to attain the objective of developing a production traceability system, we developed an ontology-based production traceability system. An empirical study was conducted in a biotechnology company in south Taiwan. To investigate the application performance of implementing a production traceability system, the AHP method was used to measure the weight of dimensions and evaluation indicators for the application performance of a production traceability system. Our research process is shown as follows: (see Fig. 3)
Step 1: Reviews the specification of PIC/S and conduct requirement analysis of a production traceability system.

Step 2: Proposes a process-oriented ontology for the application of a production traceability system.

Step 3: Develops a production traceability system for the case company.

Step 4: Conducts a survey of AHP questionnaires on the application performance of a production traceability system.

Step 5: Carries out the data analysis and discusses the results of data analysis.

Step 6: Summarizes the results of this research and completes the paper of this research.

IV. AN EMPIRICAL STUDY OF A DOMESTIC BIO TECHNOLOGY COMPANY

The ABC Company is an ISO 22000 and HACCP certified manufacturer of biotechnology products since 2003, located in the Tainan Industrial Park in the south of Taiwan. The ABC Company has been committed to making researches and development on biotechnology products for pharmaceutical, food, animal feed and agricultural applications. All of the biotechnology products produced by the ABC Company are particularly designed for solving environmental pollution problems, up-grading farming products, and offering completely natural and healthful food and beverage for human beings.

Table 4 is the major business processes of a production traceability process. Major businesses of a production traceability system cover purchase of raw materials, testing of raw materials, prescriptions design, registration of licenses, original equipment manufacturing (OEM), chemical examination of products, functional testing of products, applications of advertisement for products, and counseling services, etc. In this study, we develop a framework of the ontology for constructing a production traceability system (Fig. 4). The advantages of applying proposed ontology of a production traceability system into design of a production traceability system include: (1) collects comprehensive information of production traceability systematically, (2) reduces workloads and efforts spent on the tasks of managing the production traceability, (3) customers can inquiry the production traceability efficiently.
and transparently, and (4) reuses the historical data of similar production traceability. Therefore, improvements of system quality, total times and costs of project development can be reduced dramatically.

Table 4. The major business processes of a production traceability system.

<table>
<thead>
<tr>
<th>Business process</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchase of raw materials</td>
<td>Survey and selection of suppliers, quotation of raw materials, applying for purchases.</td>
</tr>
<tr>
<td>Testing of raw materials</td>
<td>Chemical analysis of raw materials, making specifications of regulations, preparing the records of testing results.</td>
</tr>
<tr>
<td>Prescriptions design</td>
<td>Prescriptions design of Chinese herbal medicine, western medicine, cosmetics, and health care products.</td>
</tr>
<tr>
<td>Registration of licenses</td>
<td>Registration of licenses for the Chinese herbal medicine, western medicine, cosmetics, and health care products.</td>
</tr>
<tr>
<td>Original equipment manufacturing (OEM)</td>
<td>Manufacturing of products according to the prescriptions design, OEM, customers’ commission of purchase.</td>
</tr>
<tr>
<td>Chemical examination of products</td>
<td>Chemical examination of products (analysis of principal ingredients of products, testing of specifications of regulations), customers’ commission testing of samples (analysis of principal ingredients of products, testing of specifications of regulations), customers’ commission testing of products (analysis of principal ingredients of products, testing of specifications of regulations).</td>
</tr>
<tr>
<td>Functional testing of products</td>
<td>Testing of products (penetration, stimulus, poison, pock-resistant, wrinkled-resistant, elasticity, human body, etc.)</td>
</tr>
<tr>
<td>Applications of advertisements for products</td>
<td>Assisting applications of advertisements for products.</td>
</tr>
<tr>
<td>Counseling services</td>
<td>Counseling services on production equipments, testing equipments, testing problem, regulations, etc.)</td>
</tr>
</tbody>
</table>

Fig. 4. A Framework of the ontology for constructing a production traceability system.

Fig 5 is the system architecture of a product traceability system. There are two modules in the production traceability system. The first module is the updating of ontology data. Thus,
A production traceability ontology database is maintained. The second module is updating of production traceability data. So, a production traceability system database is processed. The major business processes of a production traceability system cover the following processes: (1) building the basic data of raw materials, (2) setting the level of safety stock, (3) purchase management of raw materials, (4) keeping the COA data value of raw materials, (5) testing management of raw materials, (6) keeping the basic data of a product, (7) product lot management, (8) defining the data value of a quality product, and (9) testing management of products. The product traceability system is belonging to the client-server architecture. ASP.net is the major development tools, and SQL Server is selected as the database of a production traceability system.

Fig. 5. The system architecture of an ontology-based product traceability system.

The operation process of a production traceability system is shown in Fig. 6. Four modules including generate raw material requirements, build basic data of raw material, lot management of products, and build basic data of product. Fig. 7 is the home page of a production traceability system. Fig. 8 is the web page of maintaining the raw materials and Fig. 9 is the web page of testing the products.

Fig. 6. The operation process of a production traceability system.
In order to investigate the application performance of implementing production traceability system, a framework for the evaluation of a production traceability system is proposed (See Fig. 10) and AHP is used to compute the weights of dimensions and evaluation indicators for evaluating the application performance of a production traceability system. Table 5 is the results of the application performance of a production traceability system. Total score of the application performance of a production traceability system is equal to 82.47. Results of the application performance of the production traceability system can be taken a reference for further improvements in the case company.
Table 6 indicates key issues in implementing a production traceability system in the case company. We summarize the encountering problem and countermeasure from the perspectives of people, management system, equipments & software, and technology.

Table 5. The results of the application performance of a production traceability system

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Weight of dimension</th>
<th>Evaluation indicator</th>
<th>Weight of evaluation indicator</th>
<th>Average scores</th>
<th>Weighted value of scores</th>
<th>Sub-total scores of dimension</th>
</tr>
</thead>
<tbody>
<tr>
<td>System quality (A)</td>
<td>63.6%</td>
<td>Information quality (A1)</td>
<td>63.5%</td>
<td>84.17</td>
<td>53.45</td>
<td>51.37</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Service quality (A2)</td>
<td>26.4%</td>
<td>73.33</td>
<td>19.36</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>System usage quality (A3)</td>
<td>10.2%</td>
<td>78.10</td>
<td>7.97</td>
<td></td>
</tr>
<tr>
<td>Operation performance (B)</td>
<td>25.5%</td>
<td>Traceability of abnormal products (B1)</td>
<td>55.2%</td>
<td>86.67</td>
<td>47.84</td>
<td>21.86</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reductions of total costs (B2)</td>
<td>21.6%</td>
<td>80.00</td>
<td>17.28</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Savings of seeking times (B3)</td>
<td>15.3%</td>
<td>93.33</td>
<td>14.28</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Evaluation operation (B4)</td>
<td>7.9%</td>
<td>80.00</td>
<td>6.32</td>
<td></td>
</tr>
<tr>
<td>Information and knowledge (C)</td>
<td>10.9%</td>
<td>Document management (C1)</td>
<td>52.1%</td>
<td>83.33</td>
<td>43.42</td>
<td>9.24</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Knowledge management (C2)</td>
<td>23.2%</td>
<td>86.67</td>
<td>20.11</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Information sharing (C3)</td>
<td>14.4%</td>
<td>83.33</td>
<td>12.00</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Information applications (C4)</td>
<td>10.3%</td>
<td>90.00</td>
<td>9.27</td>
<td></td>
</tr>
</tbody>
</table>

Total scores of the application performance of a production traceability system: 82.47
Table 6 Key issues in implementing a production traceability system in the case company.

<table>
<thead>
<tr>
<th>Problems and countermeasure Dimension</th>
<th>Encountering problem</th>
<th>Countermeasure</th>
</tr>
</thead>
</table>
| People                                | Key users are unfamiliar the new process and operation of a production traceability is difficult. | • Education and train courses are arranged and executed.  
• Commitments and supports from the management.  
• Communication is helpful to implementation of a production traceability system. |
| Management system                     | New process is fitness for the needs of the production traceability. | • Reviews of new processes of the production traceability. |
| Equipments & software                 | Selection of hardware and software systems | • Arrangements for review |
| Technology                            | Migration of legacy systems, new technology is feasible, easy of learning. | • Preapres a comprehensive migration plan and feasibility analysis is conducted. |

V. CONCLUSION AND FUTURE RESEARCH

Based on the above discussion, ontology is an important concept in developing a production traceability system. In this research, we propose a process-oriented ontology for production traceability in developing a production traceability system. In summary, the contributions of this research are summarized as follows: (1) proposes an ontology for developing a production traceability system according to the requirements of business process in a biotechnology company and PIC/S, (2) develops a production traceability system for a biotechnology company providing information services covering the process of production. So, customers can use the developing production traceability system to inquire the production traceability information quickly. It is helpful to protect the product safety for customers through the production traceability system.

Furthermore, this research uses the AHP method to evaluate the benefits and costs of a production traceability system. Findings of this research show that major factors affecting the application performance of production traceability system is ranked in the following sequence: system quality, operation performance and information and knowledge application. Findings of this research provide constructive references to the company in implementing the production traceability. Future research is suggested on these topics: (1) integrating data mining techniques with business intelligence to analyze the data of a production traceability system, (2) developing an integrated framework for constructing a universal ontology for the biotechnology industry, (3) an empirical study of implementing a production traceability system in a large-scale biotechnology company in Taiwan, and (4) a methodology of building
an ontology for the application of production traceability in the biotechnological industries using object-oriented approach.

REFERENCES

5. CODEX STAN 244-2004 STANDARD FOR SALTED ATLANTIC, site: foodmate.net.
10. Food and medicine management bureau of Executive Yuan, PIC/S GMP instructional manual.

以本體論為基礎之生產履歷系統之設計與導入
——以國內某生技公司為實證分析對象
黃明祥
mshuang@mail.npust.edu.tw
孫逸民
swimming@mail.hwai.edu.tw
林眉儀
D98010066@mail.hwai.edu.tw

摘要
國內目前消費者與生產者對於生物科技產品的生產履歷資訊日益重視。有鑑於此，本研究針對生技產業的需求，建立一套以本體論為基礎之生產履歷系統，舉凡產品的生產從產地到消費者，都能留下完全歷程的電子紀錄並透過分類快速查詢，將所有的生產資訊公開與透明化，生產記錄可追溯性消費者保障制度，確保產品的安全性，使消費者對於產品的生產歷程與成分充分了解並產生信心，據以提升市場競爭優勢。

本研究依據國際藥廠稽查公約組織(Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme, PIC/S)的規範以及生技公司的生產作業流程，建構一套以本體論為基礎之生產履歷系統來提供客戶相關資訊的查詢服務，以確保生技產品之安全性與品質保障工作。本研究是以國內某一家生技公司為實證分析對象，為了解導入生產履歷系統的應用效益，採用問卷調查法蒐集資料，問卷發放的對象是個案公司負責生產履歷作業負責與相關人員，本研究是採用層級分析法（AHP）計算生產履歷系統之效益評估準則的權重值。根據個案公司評估問卷結果，發現生產履歷系統的應用成效的主要因素為系統品質(63.6%)，其次是作業效益(25.5%)，最後是資訊及知識
應用(10.9%)。本研究分析的結果如下：以本體論為基礎的生產履歷系統可以大幅度降低生產履歷的工作負荷與成本，提升作業品質與工作效率。同時，該系統可提供生產者與消費者完整的生產履歷資訊，作為決策之用途。

關鍵詞：本體論、生產履歷、國際藥廠稽查公約組織、層級分析法