INSTITUTO UNIVERSITÁRIO DE LISBOA

Development of a Business Model Reflecting the Impact of the Fourth Industrial Revolution: the Case of the Chinese Pharmaceutical Companies

Kexing Wang

Master of Science in Business Administration

Supervisor:

Prof. João Manuel Vilas-Boas da Silva, Assistant Professor,

ISCTE Business School, Department of Marketing, Operations and General Management

April 2022

Development of a Business Model Reflecting the Impact of the Fourth Industrial Revolution: the Case of the Chinese Pharmaceutical Companies

Kexing Wang

Master of Science in Business Administration

Supervisor:

Prof. João Manuel Vilas-Boas da Silva, Assistant Professor,

ISCTE Business School, Department of Marketing, Operations and General Management

April 2022

Acknowledgment

First and foremost, I would like to thank my supervisor, Prof. João Manuel Vilas-Boas da Silva, not only for his patient guidance and support throughout the whole research process but also for his priceless efforts in this dissertation.

Second, I would like to thank the training of ISCTE-IUL (Portugal), KU Leuven (Belgium), Southern Medical University (China), and KEDGE Business School (France). The experience in different countries and universities helped me finally finish this dissertation.

Third, I would like to thank my mentor, Prof. Yue Yang, and colleagues at Tsinghua University (China) for their support in the research period.

Finally, I would like to thank my family for their constant support. They always stayed by my side when I was down and gave me the faith to stand up again.

I deeply love the pharmaceutical area and will devote all my life to this industry to save more lives, help more people keep fit, and make the world a better place.

Abstract

This dissertation aims to systematically summarize the efforts and attempts of ten leading Chinese companies in order to propose a Canvas Business Model that can be applied as a reference for change in all the Chinese pharmaceutical companies that are conservative about Industry 4.0.

The three research questions that were introduced provided guidance to the literature review and to the development of a final canvas business model that fully satisfies the initial research curiosities. This summary model was based on ten intermediate Canvas ones developed from the secondary data concerning the change processes of ten leading Chinese pharmaceutical companies.

The most important findings of this research are, as follows: i) identification of the eight technologies more used within an Industry 4.0 approach; ii) specification of the structural change to be engaged by the Chinese pharmaceutical companies addressing a digital technology push; and, iii) description of the expected advantages for Chinese pharmaceutical firms from the related transformation process.

In summary, the literature confirms the interest in the empirical canvas model developed in this thesis by supporting it. Finally, the research outcomes should be further studied despite already being relevant to both researchers and practitioners. In fact, Chinese pharmaceutical companies can establish their own transformation strategies according to their *status quo* by referring to this business model.

Keywords: Business Model, Chinese Pharmaceutical Companies, Industry 4.0.
JEL Classification System: O33; L65

Resumo

Esta dissertação visa resumir sistematicamente os esforços e tentativas de dez empresas chinesas líderes a fim de propôr um Modelo de Negócio do tipo CANVAS que possa ser aplicado como referência de mudança em todas as empresas farmacêuticas chinesas que são conservadoras sobre a Indústria 4.0.

As três questões de investigação que foram introduzidas orientaram a revisão da literatura e o desenvolvimento de um modelo final de negócio do tipo CANVAS que satisfaça plenamente as curiosidades iniciais de investigação. Este modelo resumo foi baseado em dez modelos intermédios desenvolvidas a partir dos dados secundários relativos aos processos de mudança de dez empresas farmacêuticas chinesas líder.

As conclusões mais importantes desta investigação são: i) identificação das oito tecnologias mais utilizadas numa abordagem I4.0; ii) especificação da mudança estrutural a ser empreendida pelas empresas farmacêuticas chinesas, endereçando um impulso tecnológico digital; e, iii) descrição das vantagens esperadas para as empresas farmacêuticas chinesas envolvidas num processo de transformação deste tipo.

Em resumo, a literatura confirma o interesse no modelo emírico de negócio do tipo CANVAS desenvolvido nesta tese, apoiando-o. Finalmente, os resultados da investigação devem ser posteriormente investigados, apesar de já serem relevantes tanto para investigadores como para profissionais. De facto, as empresas farmacêuticas chinesas podem estabelecer as suas próprias estratégias de transformação de acordo com o seu *status quo* e tendo como referência o modelo de negócio desenvolvido e apresentado nesta dissertação.

Palavras-chave: Modelo de negócio, Empresas Farmacêuticas Chinesas, Indústria 4.0.

Sistema de classificação JEL: O33; L65

Contents

List of Figures

List of Tables

List of Abbreviations and Acronyms

AI	-	Artificial Intelligence
API	-	Active Pharmaceutical Ingredient
AR	-	Augmented Reality
BMC	-	Business Model Canvas
C2M	-	Customer-to-Manufacturer
CAR-T	-	Chimeric Antigen Receptor T Cell
CM	-	Continuous Manufacturing
CPS	-	Cyber Physical System
ERP	-	Enterprise Resource Planning
ICH	-	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICT	-	Information and Communications Technology
IoT	-	Internet of Things
IPR	-	Intellectual Property Right
JY	-	Jinyu Bio-technology Co., Ltd.
JZ	-	China Resources Jiangzhong Pharmaceutical Co., Ltd.
KL	-	Hunan Kelun Pharmaceutical Co., Ltd.
LES	-	Laboratory Execution System
LIMS	-	Laboratory Information Management System
MAH	-	Marketing Authorization Holder
MES	-	Manufacturing Execution System
MIIT	-	The Ministry of Industry and Information Technology
NCP	-	North China Pharmaceutical Company Ltd.
NEP	-	Northeast Pharmaceutical Group Co., Ltd.
OMO	-	Online-Merge-Offline
PAT	-	Process Analytical Technology
QR	-	Quick Response
RFID	-	Radio Frequency Identification
RQ	-	Research Question
TCM		Traditional Chinese Medicine
TJT	-	Sinopharm Tongji Tang (Guizhou) Pharmaceutical Co., Ltd.
TRT	-	Beijing Tong Ren Tang Technologies Co. Ltd.
TSL	-	Tasly Pharmaceutical Group Co., Ltd.
UP	-	Xinjiang Uygur Pharmaceutical Co., Ltd.
VR	-	Virtual Reality
WMS	-	Warehousing Management System
WTEPIM	-	Written Team of Intelligent Manufacturing Exploration and Practice
XX	-	Guangzhou Xiangxue Pharmaceutical Co., Ltd.

1. Introduction

1.1 Context

The first industrial revolution began in the 1800s and brought the transition from manual to mechanical work. The second industrial revolution achieved industrialization and mass production based on electrification. The third industrial revolution aimed to introduce automation and digitalization to Industries (Rojko, 2017).

Industry 4.0 could be regarded as the 4th Industrial Revolution and it brings together the emerging technologies to achieve independent self-organizing manufacturing (Arden et al., 2021). Industry 4.0 was first used in 2011 at the Hannover Fair and the Germany Government decided to develop it to enhance the competitiveness of the Germany Industry in 2013 (Vogel-Heuser & Hess, 2016; Kagermann et al., 2013). It is based on the integration of the business and manufacturing processes, as well as the integration of all actors in the company's value chain (Rojko, 2017). The technology trigger of Industry 4.0 is Information and Communications Technologies (ICT) including cyber-physical systems (CPS), Internet of Things (IoT), embedded systems, cloud computing, etc (Xu et al., 2018).

The reasons for the birth of Industry 4.0 originate from both inside and outside the industry. On the one hand, the industry needs to face new market challenges represented by the individual needs of customers. On the other hand, the traditional manufacturing industry is transforming toward a digital business model. The external impetus for Industry 4.0 comes not only from new technologies such as CPS and IoT but also from the country's strategic need to focus on improving manufacturing competitiveness (Peng, 2016).

Unlike the developed countries, the emerging countries will face more unpredicted difficulties when they are trying to apply Industry 4.0 since they might need to take the third industrial revolution and fourth industrial revolution as a continuous process (Dalenogare et al., 2018). This difference could be also observed between Germany and China. After World War II, Germany relied on U.S. aid and used significant resources to develop research in the fields of education and science. This effort helped Germany become a world industrial power. Compared to Germany, on the eve of the introduction of Industry 4.0, China was lagging behind in terms of the start of industrialization and cutting-edge technologies and manufacturing levels (Li & Zhou, 2013).

In the context of the obvious gap between the world's advanced level and the current situation, China proposed a ten-year plan called "Made in China 2025" in 2015. By implementing this plan, China can build on its strengthened industrial base to promote the integration of information technology and industrialization, gain sustainable core competitiveness, and ultimately transform itself from a manufacturing country to a manufacturing power. The plan also focuses on the development of biomedical and high-performance medical devices, setting out new requirements and support measures for the development of related industries (The State Council of China, 2015).

Over the past year or so, COVID-19 has swept the world, making medicine and drugs one of the topics of daily discussion. In the process of fighting against COVID-19, Industry 4.0 would play a role in providing new ways of quarantine, accelerating drug development and manufacturing, and conducting telemedicine (Javaid et al., 2020).

Under the influence of Industry 4.0, the pharmaceutical might find another novel operating paradigm with digitization, automation, and real-time data integration, which would be better than six sigma (Arden et al., 2021). With the new paradigm, the pharmaceutical industry could apply interconnectivity, AI (artificial intelligence), big data, and robotics to its operation (Binggeli et al., 2018).

1.2 Research Motivations and Purposes

Although the application of emerging technologies can lead to more robust and flexible manufacturing processes, reduce disruptions in drug production and delivery, and ensure high product quality while reducing production costs, the process of embracing new technologies typically takes longer than in other industries because the pharmaceutical or biopharmaceutical industry follows a more stringent regulatory pathway (Chen et al., 2020). This is mainly due to the fact that the entire lifecycle of drug development, manufacturing, distribution, and use is under regulation, and the smart manufacturing transformation process will inevitably involve adjustments to equipment or processes resulting in a complex risk assessment and change process afterward. Moreover, pharmaceutical companies are often cautious to participate in the smart manufacturing process because the short-term benefits are not obvious (MIIT & CPEA, 2020).

Nevertheless, a number of Chinese pharmaceutical companies are already involved in the Industry 4.0 process, driven by Chinese policies, enhanced quality regulation, and quality requirements, and the growing need to improve manufacturing efficiency. Therefore, this dissertation aims to systematically summarize the efforts and attempts of these companies and propose a business model by using the Business Model Canvas (BMC) that can be applied in the transformation process to provide a reference for Chinese pharmaceutical companies that are conservative about Industry 4.0.

The following RQs and objectives were formulated according to the gaps found and reported in section §1.1.

1.3 Research Questions and Objectives

In order to achieve the purposes of this dissertation, the following Research Questions (RQs) will be investigated:

RQ1: What are the technologies applied from the Fourth Industrial Revolution in Chinses pharmaceutical companies?

Objectives: Describing the current state-of-the-art technologies applied from Industry 4.0 in Chinese pharmaceutical companies to construct key activities in business model canvas.

RQ2: What competitive advantages do the Fourth Industrial Revolution bring to Chinese pharmaceutical companies?

Objectives: Assessing the organizational enablers for pharmaceutical companies gained from Industry 4.0 to construct value proposition, cost structure, and revenue stream in business model canvas.

RQ3: What changes do Chinese pharmaceutical companies need to make, in order to take advantage of the technologies applied from the Fourth Industrial Revolution?

Objectives: Filling the remaining parts of the business model canvas framework to obtain a business model to guide the transformation of embracing Industry 4.0 for pharmaceutical companies in China.

By solving the research problems one by one, a business model can eventually be obtained to satisfy the research purpose.

1.4 Research Methodology

To achieve the objectives of this dissertation, this research will build on the literature to first review the application of Industry 4.0 in the pharmaceutical industry, compare the research results of different researchers guided by the RQs and summarize the propositions that are found from the in-depth literature review based on the different blocks (Customer Segments, Value Propositions, Channels, Customer Relationships, Revenue Streams, Key Resources, Key Activities, Key Partnerships, and Cost Structure) of the BMC (Osterwalder, 2017) (Chapter 2). They will be discussed by comparing the summary from gathering empirical data (Chapter 5). Then, this dissertation will illustrate its research methodology in chapter 3 in order to pursue its defined purpose.

This dissertation will be based on secondary data provided by literature and books related to target companies. Depending on the main business, this dissertation will select two companies individually focusing on Chinese Patent Medicines (Traditional Chinese Medicine (TCM)) and Preparations / Medicines and one company focusing on pharmaceutical retailing, health care products, Uyghur Medicines, Active Pharmaceutical Ingredients (API) and Biological Products (10 companies in total) to conduct the application research. The secondary data to be collected will focus on the dimensions related to business model building, e.g. the specific technologies applied, the value chain segments covered, and the competitive advantages gained, among others (Chapter 4).

Moreover, based on the application status, this dissertation will build a business model for each company using Business Model Canvas. This dissertation will also map the application of Industry 4.0 technologies based on the model in Chapter 4, and build a reference business model for Chinese pharmaceutical companies to explore the competitive advantages gained through joint analysis. Finally, this assignment will summarize the competitive advantages for

Chinese pharmaceutical companies facing the transformation of Industry 4.0 and illustrate a comparison of outcomes between literature review and empirical research (Chapter 5).

1.5 Research Structure

Chapter 1 provides an overview of this dissertation. Then, the literature review will be presented in Chapter 2 to show the efforts that pharmaceutical companies made to embrace Industry 4.0. Chapter 3 will illustrate the research methodology of this dissertation. In terms of the secondary data, the efforts of 10 Chinese pharmaceutical companies will be summarized in Appendix A to J and the respective business models are presented in Chapter 4 as the analysis of the findings. The discussion chapter will report the consolidation of the findings for the researched Chinese Pharmaceutical Companies and discuss the investigation outcomes concerning the research questions that will be addressed in Chapter 5. Ultimately, this dissertation will give conclusions to answer the research questions proposed in Chapter 1 in Chapter 6.

2. Literature Review

2.1 Introduction

This chapter presents a literature review guided by the RQs presented in Chapter 1. Propositions are formulated and supported by existing studies to facilitate comparison with the subsequent research results of this dissertation. This chapter identifies the contents related to the research topic of this dissertation based on the "5W1H Model" as Table 1 shows.

Table 1 Structuring of the Literature Review Based on the "5W1H Model"

<table>
<tr><th>Dimension</th><th>Content</th><th colspan="2">Note</th></tr>
<tr><td colspan="4">Known</td></tr>
<tr><td>Who</td><td>Pharmaceutical Companies</td><td colspan="2">Related to RQ1, 2 & 3</td></tr>
<tr><td>When</td><td>up to now</td><td colspan="2">Related to RQ1, 2 & 3</td></tr>
<tr><td colspan="4">Unknown</td></tr>
<tr><td rowspan="2">Where</td><td>at Which Segment in Lifecycle</td><td rowspan="2">Related to RQ1, 2 & 3</td><td rowspan="2">Providing content of key activities</td></tr>
<tr><td>at Which Level of Industry 4.0 Deploying</td></tr>
<tr><td>What</td><td>What technologies brought by Industry 4.0 can be applied in the pharmaceutical industry?</td><td>Related to RQ1</td><td>Providing content of key activities</td></tr>
<tr><td>Why</td><td>Why should pharmaceutical companies embrace Industry 4.0? / What competitive advantages can the application of Industry 4.0 bring to pharmaceutical companies?</td><td>Related to RQ2</td><td>Providing content of value proposition, cost structure, and revenue stream</td></tr>
<tr><td>How</td><td>How pharmaceutical companies should make changes to embrace Industry 4.0?</td><td>Related to RQ3</td><td>Providing content of remaining blocks of the business model canvas</td></tr>
</table>

China proposed a ten-year plan called "Made in China 2025" in 2015. (The State Council of China, 2015) Under the guidance of this plan, although China's pharmaceutical equipment has been moving towards the goal of intelligence, the pace of development is still slow (Yi et al., 2021).

In order to identify the propositions to state the chosen paths to address the RQs, the review in this chapter will not be limited to China but will be specific to the Chinese context when examining the answers to the "What", "How" and "Why" related questions. The answer to "Where" will be described in §2.2 and the answer to "What" will be described in §2.3. However, the key activities will be concluded with a more detailed illustration in §2.5. Besides, the answer to the question "Why" is described in §2.4. The answer to "How" will be described in §2.5. Finally, §2.6 will summarize the results of the literature, formulating a business model as the proposition to be compared in the following chapters.

2.2 The Application Levels and Segments of Industry 4.0

The supply chain from drug discovery to consumption when studying the IoT is depicted in Figure 1 (Jain & Sharma, 2020). This model links the R&D and using segment and presents a clear industrial chain in the pharmaceutical area.

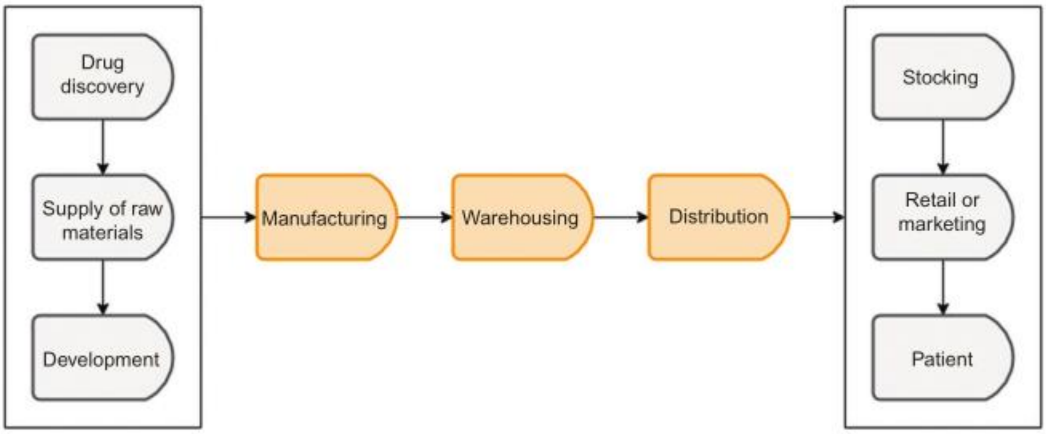

Figure 1 Pharmaceutical Supply Chain for IoT Application (Developed by Jain & Sharma (2020))

MIIT & CEPA (2020) believe that intelligent manufacturing can empower the whole life cycle management of drug R&D, manufacturing, quality management, logistics, etc., and support the continuous optimization of pharmaceutical operations management on this basis. Based on this, R&D management, manufacturing management, logistics management, and the two modules (quality management and operational management) covering them could be considered as the core of the application of Industry 4.0 in Chinese pharmaceutical companies. These modules are implemented on the basis of a digital system and an organizational system as well as project management. In addition, these modules need to meet the regulatory requirements as well as the information security requirements. In order to guide Chinese pharmaceutical companies, there is an intelligent manufacturing system framework had been proposed (Figure 2).

Compared with Figure 1, Figure 2 highlighted the importance of operations management and quality management covering the whole industrial chain and reflecting the characteristics of the pharmaceutical industry. Moreover, Figure 2 also implied the application patterns of Industry 4.0 in the pharmaceutical area.

Figure 2 Intelligent Manufacturing System Framework for Pharmaceutical Companies (Developed by MIIT & CEPA (2020))

Furthermore, Sharma et al. (2020) identified the IoT application in the pharmaceutical value chain (Figure 3). It obtained similar results compared to Figure 1 and provided some application scenarios of IoT.

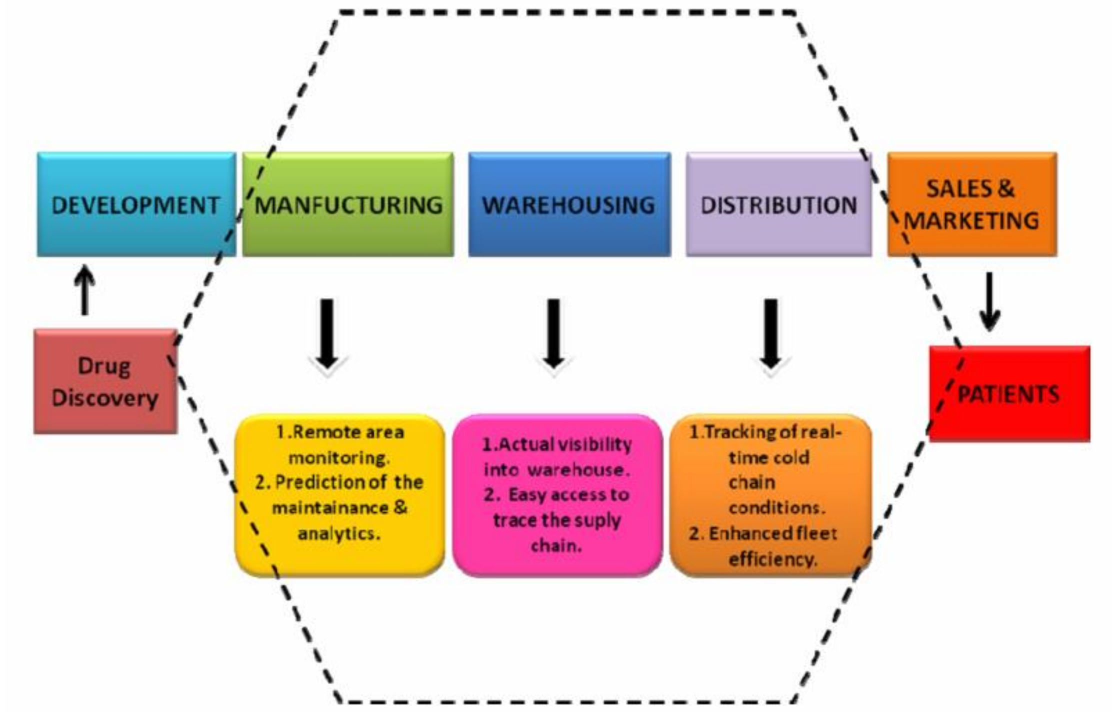

Figure 3 IoT Application in Different Pharmaceutical Processes Across the Value Chain (Developed by Sharma et al. (2020))

In summary, R&D, Manufacturing, Warehousing, Quality, Distribution, and Sales & Marketing could be the vital segments in the transformation process. Besides, there are four application levels (Operations Management Level, Department Level, Control level, and Field Level) of Industry 4.0. The following research of this dissertation will be based on these illustrations to present results.

2.3 The Applications of Industry 4.0 in Pharmaceutical Industries

Silva et al. (2020) believe that CPS and IoT are the most fundamental applications of Industry 4.0 in the pharmaceutical industry. Based on the application of these two technologies, big data, AI, cloud computing, robots, 3D printing, virtual reality (VR), augmented reality (AR), and radio frequency identification (RFID) tags or quick response (QR) Code all have different degrees of application. Jain & Sharma (2020) confirmed the application of cloud computing and IoT based on the unique identification number, real-time location system, sensors, and communication technologies in the manufacturing segment. Besides, in the distribution segment, the RFID-based smart warehousing management system plays an important role. Yi et al. (2021) combined the robots and machine learning technology to solve the four challenges of aseptic control, tiny particle detection, flexible gripping, and collaborative control of multi-process, multi-task, and multi-machine in the pharmaceutical manufacturing process. Except for the AR, VR, and Cloud technologies before, Reinhardt et al. (2020) highlighted the application of data mining and process analytical technology (PAT). In another paper (Reinhardt et al., 2021), 3D printing, digital twins and simulation, CPS, and big data were also identified as applications in the pharmaceutical industry. Moreover, Ganesh et al. (2020) emphasized the important contribution of PAT and continuous manufacturing (CM) for pharmaceutical companies to understand the digitalization of process operations. Finally, Arden et al. (2021) held that machine learning and machine vision technology are the representatives of AI and the full automation has reflected the application of PAT. Furthermore, for some technologies mentioned before, they provided a framework to illustrate (Figure 4).

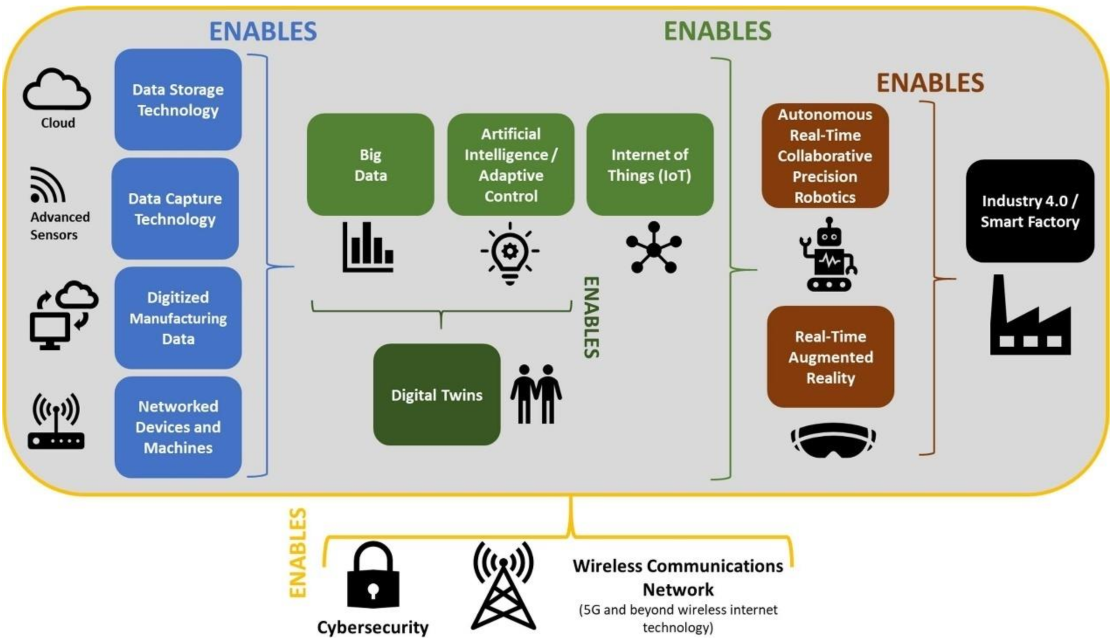

Figure 4 The enabling technologies of an Industry 4.0 smart factory (Developed by Arden et al. (2021))

Table 2 shows the summary of the potential technologies that could be applied to pharmaceutical companies to embrace Industry 4.0.

Table 2 Potential Technologies Applied to pharmaceutical companies to Embrace Industry 4.0

Technologies		Silva et al.	Reinhardt et al.	Jain & Sharma	Yi et al.	Ganesh et al.	Arden et al.
Foundation	CPS	O	O				
	IoT	O		O			O
Other	Big Data	O	O				O
	AI (Including machine vision technology)	O					O
	Cloud	O	O	O			O
	Robots	O			O		O
	3D Printing	O	O				
	VR	O	O				
	AR	O	O				O
	RFID	O		O			
	QR	O					

	Data Mining		O				
	Machine Learning				O		O
	Digital Twins and Simulation		O				O
	PAT		O			O	O
	CM					O	

2.4 The Competitive Advantages Brought by Industry 4.0

By adopting Industry 4.0, pharmaceutical companies can reap many benefits. These benefits can be seen in the value proposition, cost structure, and revenue stream of the Business Model Canvas (BMC).

2.4.1 Value Proposition

(1) Products

1) Customization: Customization of Lines and Products (Silva et al., 2020)

2) Product Performance: Quality Improvement (Hariry et al., 2021; MIIT & CEPA, 2020; Sharma et al., 2020; Silva et al., 2020; Wang & Chen, 2021; Yi, 2021);

3) Risk Reduction: Reduction of Errors Linked to the Human Condition and Attenuates Ergonomic Risks (Silva et al., 2020; Wang & Chen, 2021) Fewer Errors (Arden et al., 2021; Sharma et al., 2020) Reduction of Quality Risk (MIIT & CEPA, 2020) Deviation Detection (Kumar, 2020)

(2) Services

1) Convenience / Usability: Accessed to content on the streaming platform. (Okano et al., 2021)

2) Accessibility: Productive Data Integrity and Traceability (Silva et al., 2020)

(3) Products and Services

1) Newness: New Product Launch / Greater Availability of Products on the Market (Hariry, 2021; Silva et al., 2020; Wang & Chen, 2021); New Models (MIIT & CEPA, 2020; Silva et al., 2020)

2) Price: Reduction of Prices Practiced in the Market (Silva et al., 2020).

(4) Manufacturers:

1) Company Performance: Productivity (Silva et al., 2020; Yi, 2021), Management Efficiency (Silva et al., 2020; Yi, 2021) Flexibility (Better Meeting Deadlines / More Agile Service to Delivery Times (Sharma et al., 2020; Silva et al., 2020) More Flexibility and Agility; Fewer Drug Shortages (Arden et al., 2021))

2) Environment Protection: Waste Reduction; Environmental Benefits (Ding, 2018; Rezepa, 2021; Silva et al., 2020)

2.4.2 Cost Structure

(1) Variable Costs Decreased: Operating Cost Reduction; Market cost reduction (MIIT & CEPA, 2020; Silva et al., 2020); Energy Cost Reduction (Rezepa, 2021); Manufacturing Cost Reduction (Sharma et al., 2020)

(2) Variable Costs Increased: Labor cost for the new model (Okano et al., 2021)

(3) Infrastructure Investment Increased: High Investment Level (Okano et al., 2021; Silva et al., 2020)

2.4.3 Revenue Stream

The following revenue streams were identified by the author based on the value proposition mentioned before.

(1) Usage Fee: Introduction of intelligent manufacturing model to other pharmaceutical companies.

(2) Asset Sale: More revenue due to the productivity increase; More revenue from new products.

(3) Other revenue in terms of the introduction of new models.

2.5 The Efforts from Pharmaceutical Companies for Applying Industry 4.0

This section further refines the key activities of pharmaceutical companies based on the literature and completes the remaining part of the business model canvas.

2.5.1 Key Partners

Equipment Companies (Identified by Author)

Software Companies (Identified by Author)

Medical Associations and Societies (Okano et al., 2021)

2.5.2 Key Activities

(1) Application Level (Identified in §2.2):

Manufacturing Execution System (MES) (Department Level), Warehousing Management System (Department Level), Enterprise Resource Planning (ERP) (Operations Management Level), Laboratory Information Management System (LIMS) (Department Level).

(2) Technologies (Identified in §2.3):

Since the IoT and CPS are the foundation, this dissertation will merely consider other technologies as follow:

Big Data, AI (Including machine vision technology), Cloud, Robots, 3D Printing, VR, AR, RFID, QR, Data Mining, Machine Learning, Digital Twins and Simulation, PAT, CM.

(3) General Activities:

1) Digitization Basics (Arden et al., 2021; MIIT & CEPA, 2020)

2) Interconnection of devices and integration of information among different levels and devices (Arden et al., 2021; MIIT & CEPA, 2020).

3) Automation control in different departments (Arden et al., 2021; MIIT & CEPA, 2020)

4) Online Platforms: Lectures (Okano et al., 2021)

5) Introduction of AI Applications (Arden et al., 2021; MIIT & CEPA, 2020)

6) Cross-Organizational Interconnection (MIIT & CEPA, 2020)

2.5.3 Key Resources

(1) Physical Resources: New Infrastructure; Equipment and Technology Integration (Silva et al., 2020)

(2) Financial Resources: High Investment Level (Arden et al., 2021; Silva et al., 2020)

(3) Human Resources: Qualified Professionals (Okano et al., 2021; Silva et al., 2020;)

(4) Intellectual Resources: Industrial Software and ERP software (Identified by Author)

2.5.4 Customer Relationships

(1) Personal Assistance: Customized transformation plan to solve: Lack of strategies and maturity for implementation (Silva et al., 2020).

(2) Automated Services: Presenting exclusive content, being easier to search for information, connecting professionals in the same area, and identifying new demands (Okano et al., 2021).

2.5.5 Channel

(1) Data Sharing: Data traceability (Arden et al., 2021)

(2) Digital Platforms (Okano et al., 2021)

2.5.6 Customer Segments

Mass Market: (1) Other Pharmaceutical Companies (Identified by Author) (2) Purchasers, Payors, Healthcare Providers, And Patients (Arden et al., 2021; Okano et al., 2021)

2.6 Summary

This chapter organized the results of the existing literature on the transformation of pharmaceutical companies based on Industry 4.0 via the "5W1H Model" and answered the "What", "Why" and "How" questions by using the blocks of the business model canvas. By organizing these blocks, a business model (Figure 5) derived from the literature review was obtained for this dissertation.

Since there is no research on the business models of Chinese pharmaceutical companies transforming based on Industry 4.0, the subsequent part of this dissertation will summarize the current business models of Chinese pharmaceutical companies transforming based on Industry 4.0. This summarizing will be through empirical research based on secondary data and compare them with the business models obtained in this chapter. Through the comparison, this dissertation can verify the applicability of the business model proposed in this chapter to

Chinese pharmaceutical companies. In response to the differences, this dissertation will fully explore and determine whether the business model obtained in this chapter needs to be revised.

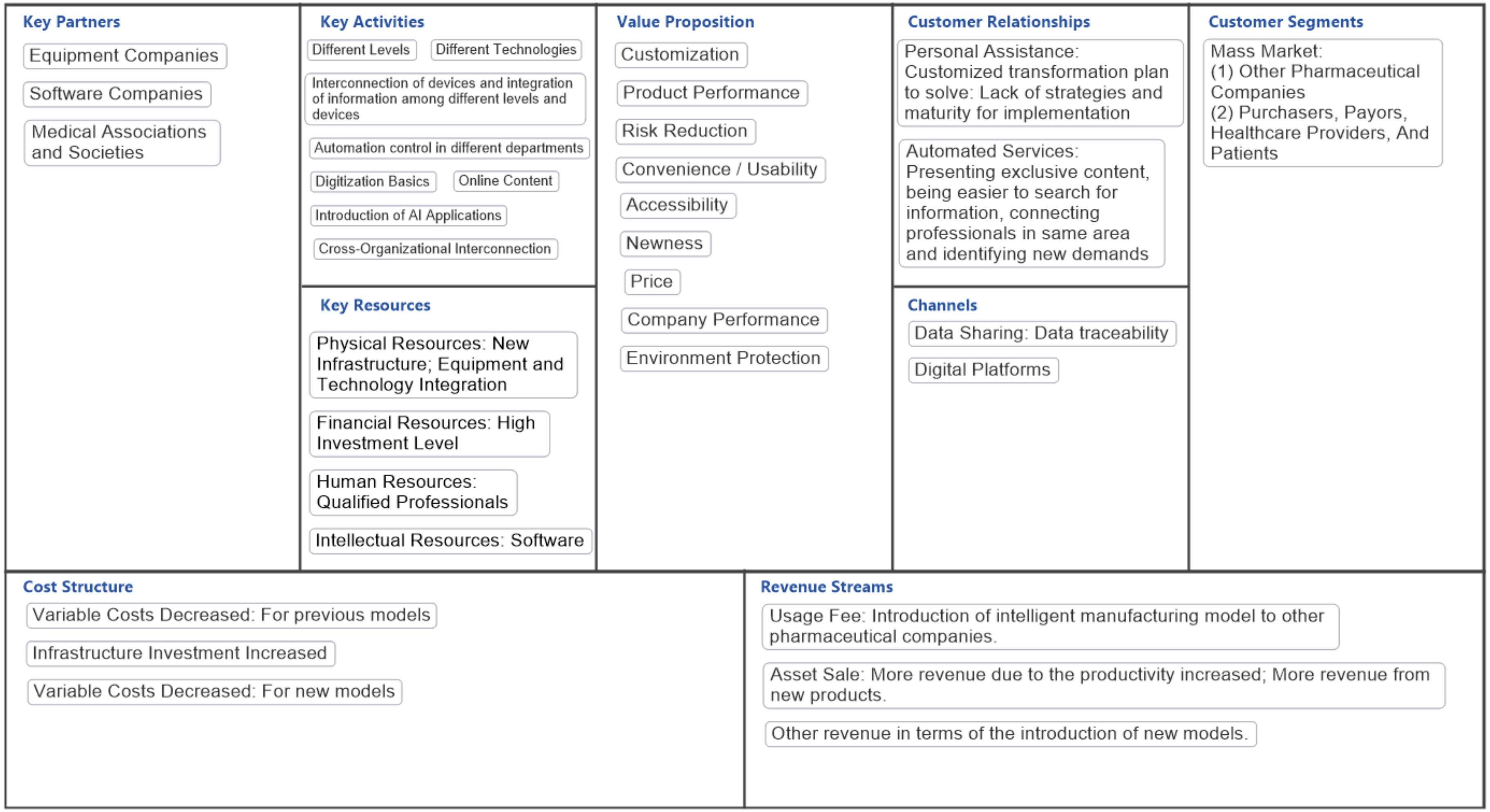

Figure 5 Business Model for the Transformation of Pharmaceutical Companies Based on Industry 4.0

3. Research Methodology

Through the literature review, there is a hypothetical model proposed in the last chapter that can be tested (Figure 5). In order to further determine whether this hypothetical model truly reflects the application of Industry 4.0 by Chinese pharmaceutical companies, this dissertation will later conduct an empirical study based on exemplary Chinese pharmaceutical companies under the guidance of RQs.

The Ministry of Industry and Information Technology (MIIT) of China published one book named "Intelligent Manufacturing Consumer Goods Industry Solution: Pharmaceutical Industry" in December 2020. Since 2015, MIIT has identified a number of smart manufacturing pilot model projects for support. In order to summarize the achievements, promote the experience and advance the development of smart manufacturing in the consumer goods industry, MIIT has assembled the outstanding cases into this book. This book includes 25 cases of Chinese pharmaceutical companies, summarizing the current status of Chinese pharmaceutical companies for the application of Industry 4.0 as an important reference (MIIT, 2020) and could be regarded as secondary data. This dissertation utilized these secondary data to analyze and improve the proposed model in the last chapter. Besides, in order to obtain more relevant information, this dissertation referred to the other two books published in 2020 edited by the Written Team of Intelligent Manufacturing Exploration and Practice (WTEPIM) as supplements. Table 3 shows the targeted companies selected.

Table 3 Targeted Companies of Empirical Research in This Dissertation

Area	Company Name	Abbreviation	Sources of Secondary Data
TCM - Chinese Patent Medicines	Sinopharm Tongji Tang (Guizhou) Pharmaceutical Co., Ltd.	TJT	MIIT (2020)
TCM - Chinese Patent Medicines	Tasly Pharmaceutical Group Co., Ltd.	TSL	MIIT (2020), WTEPIM (2020b)
TCM - Retails	Beijing Tong Ren Tang Technologies Co. Ltd.	TRT	MIIT (2020)
TCM - Services	Guangzhou Xiangxue Pharmaceutical Co., Ltd.	XX	MIIT (2020), WTEPIM (2020b)

TCM – Health care Products	China Resources Jiangzhong Pharmaceutical Co., Ltd.	JZ	MIIT (2020), WTEPIM (2020b)
Uyghur Medicines	Xinjiang Uygur Pharmaceutical Co., Ltd.	UP	MIIT (2020)
Preparations / Medicines	North China Pharmaceutical Company Ltd.	NCP	MIIT (2020), WTEPIM (2020a)
Preparations / Medicines	Hunan Kelun Pharmaceutical Co., Ltd.	KL	MIIT (2020), WTEPIM (2020a)
APIs	Northeast Pharmaceutical Group Co., Ltd.	NEP	MIIT (2020)
Biological Products	Jinyu Bio-technology Co., Ltd.	JY	MIIT (2020)

The collected secondary data will be summarized in the Appendix (A to J) following a brief introduction, efforts for embracing Industry 4.0, key partners, technologies applied, and performance evaluation from these books mentioned above. In the course of the empirical study, this dissertation will continue to base its discussion on the nine dimensions covered by BMC and explain their business models through BMC individually based on the information from Appendix (A to J) in the analysis of findings section.

Finally, this dissertation will discuss the commonalities and differences between the findings of different companies based on each block of BMC and compare them with the model obtained from the literature review. Through the above research, this dissertation will finally present a comprehensive model in the discussion as the final research outcomes of this dissertation to achieve the research purpose of this dissertation: Systematically summarize the efforts and attempts of these companies and propose a business model by using the business model canvas framework that, later on, might be applied in the transformation process to provide a reference for Chinese pharmaceutical companies that are conservative about Industry 4.0.

4. Analysis of Findings

Based on the collected secondary data presented in Appendix A to J, this dissertation establishes ten business models for each company, which are presented in this chapter. These models will be discussed in the next chapter.

4.1 Sinopharm Tongji Tang (Guizhou) Pharmaceutical

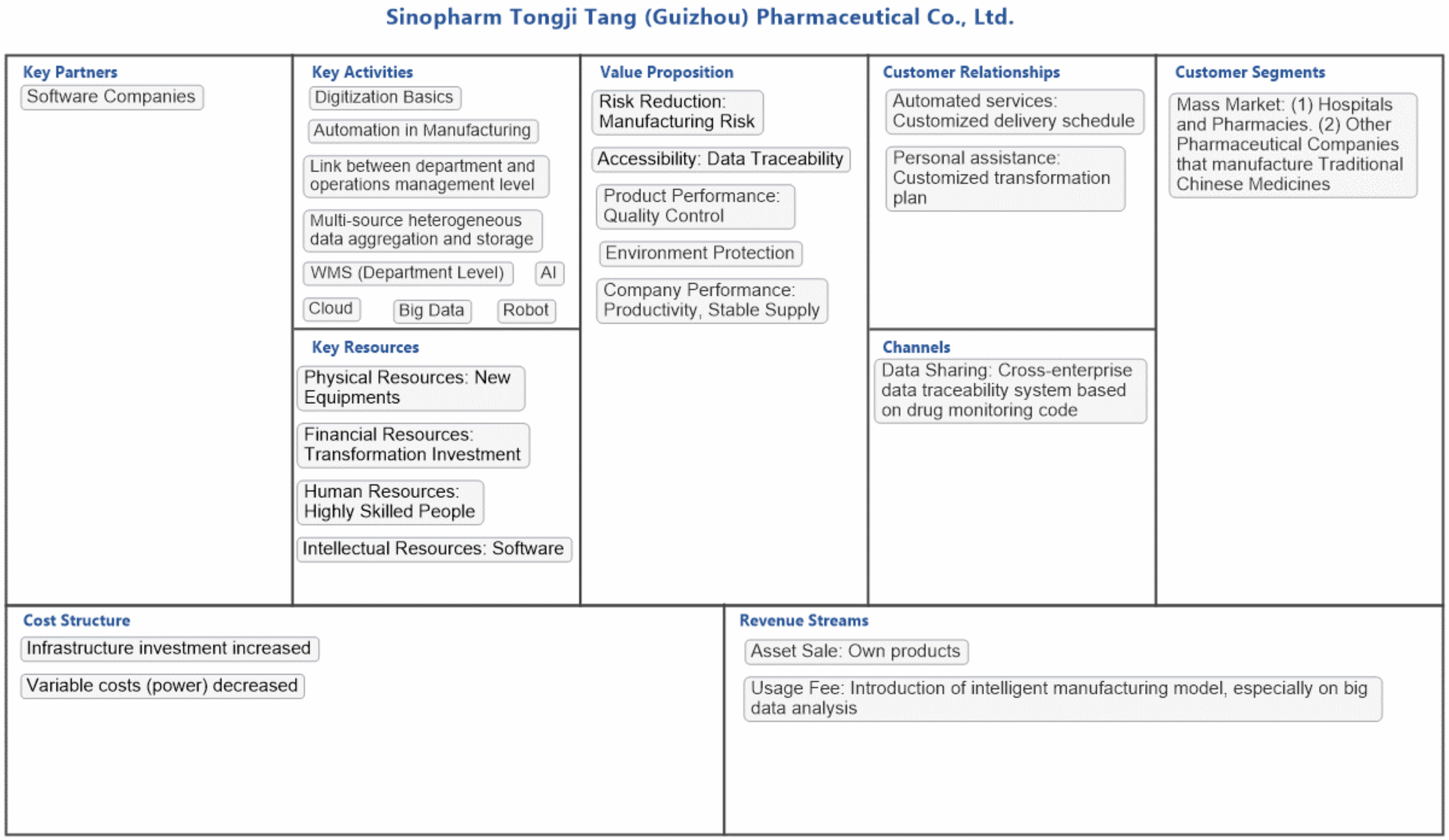

Figure 6 Sinopharm Tongji Tang Canvas (vide Appendix A) (Developed by Author)

4.2 Tasly Pharmaceutical Group

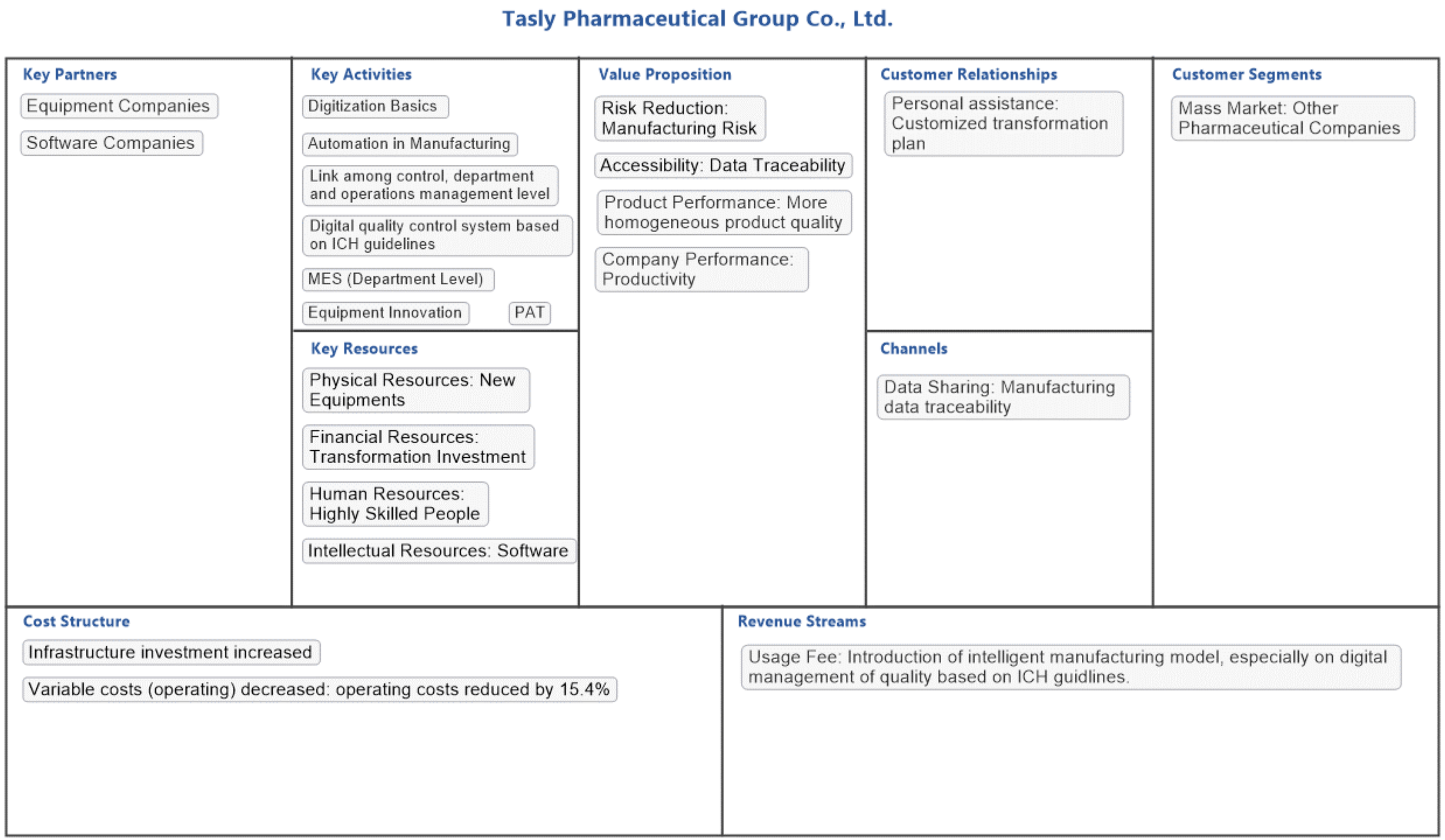

Figure 7 Tasly Canvas (vide Appendix B) (Developed by Author)

4.3 Beijing Tong Ren Tang Technologies

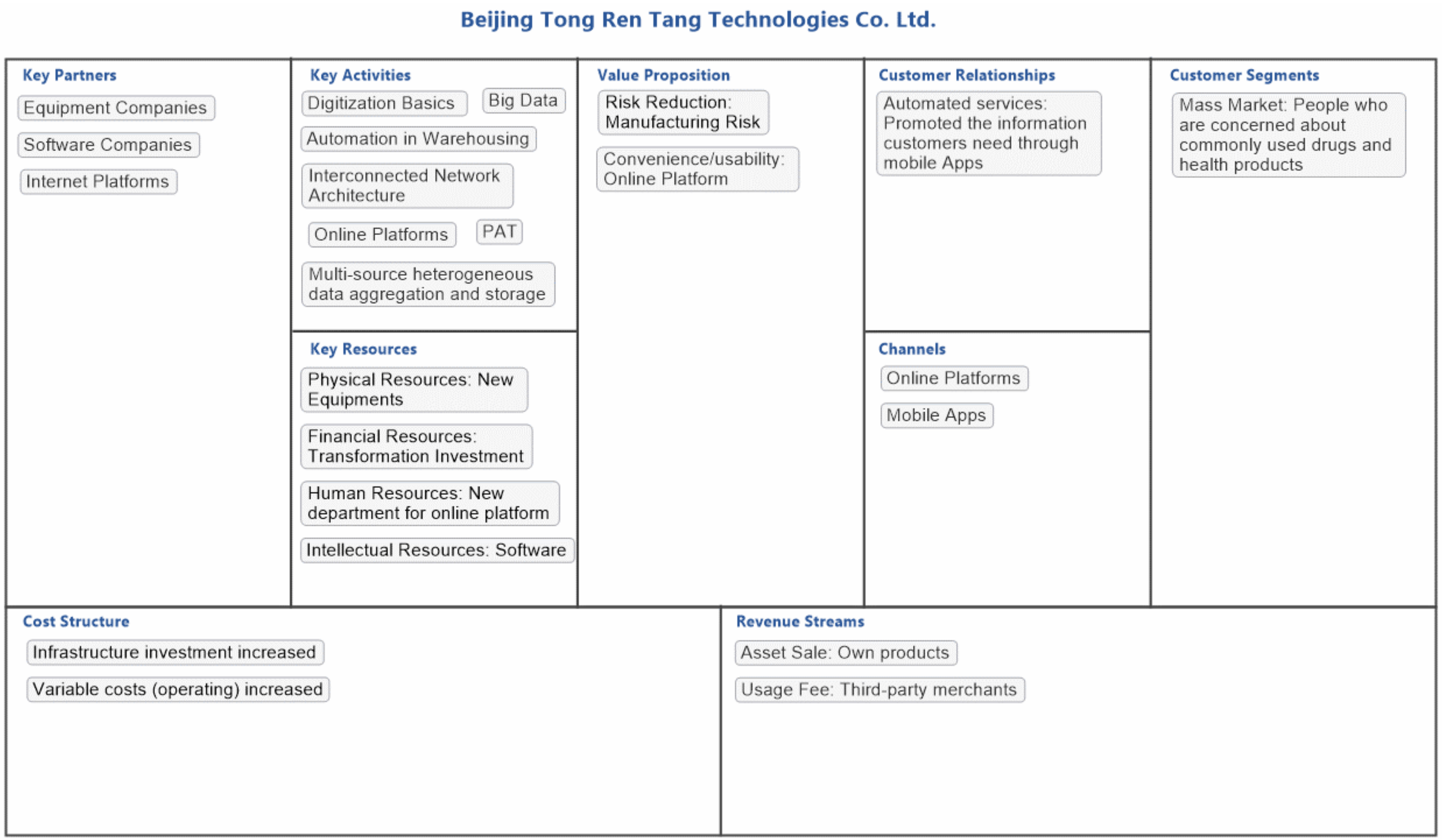

Figure 8 Tong Ren Tang Canvas (vide Appendix C) (Developed by Author)

4.4 Guangzhou Xiangxue Pharmaceutical

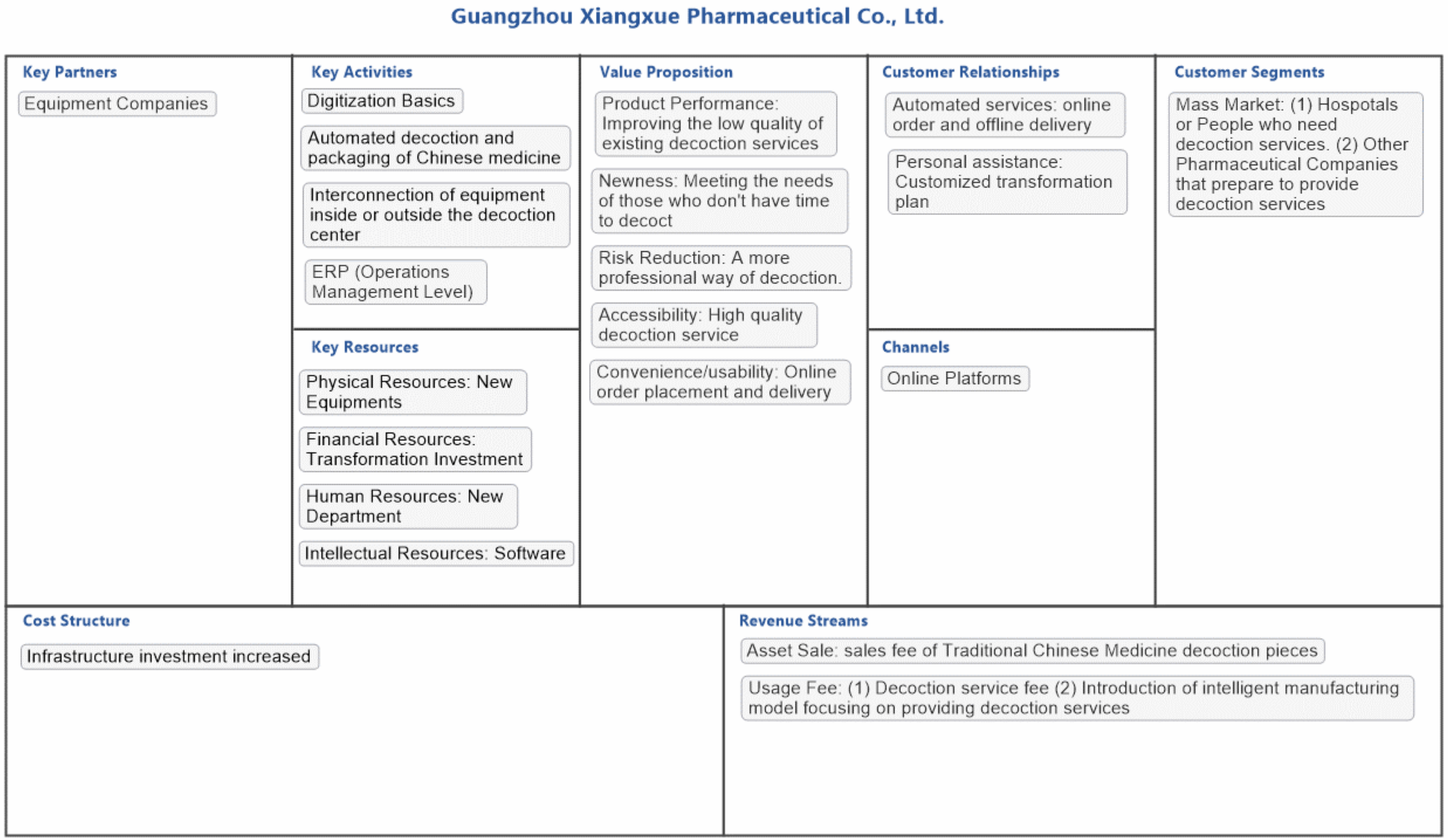

Figure 9 Xiangxue Canvas (vide Appendix D) (Developed by Author)

4.5 China Resources Jiangzhong Pharmaceutical

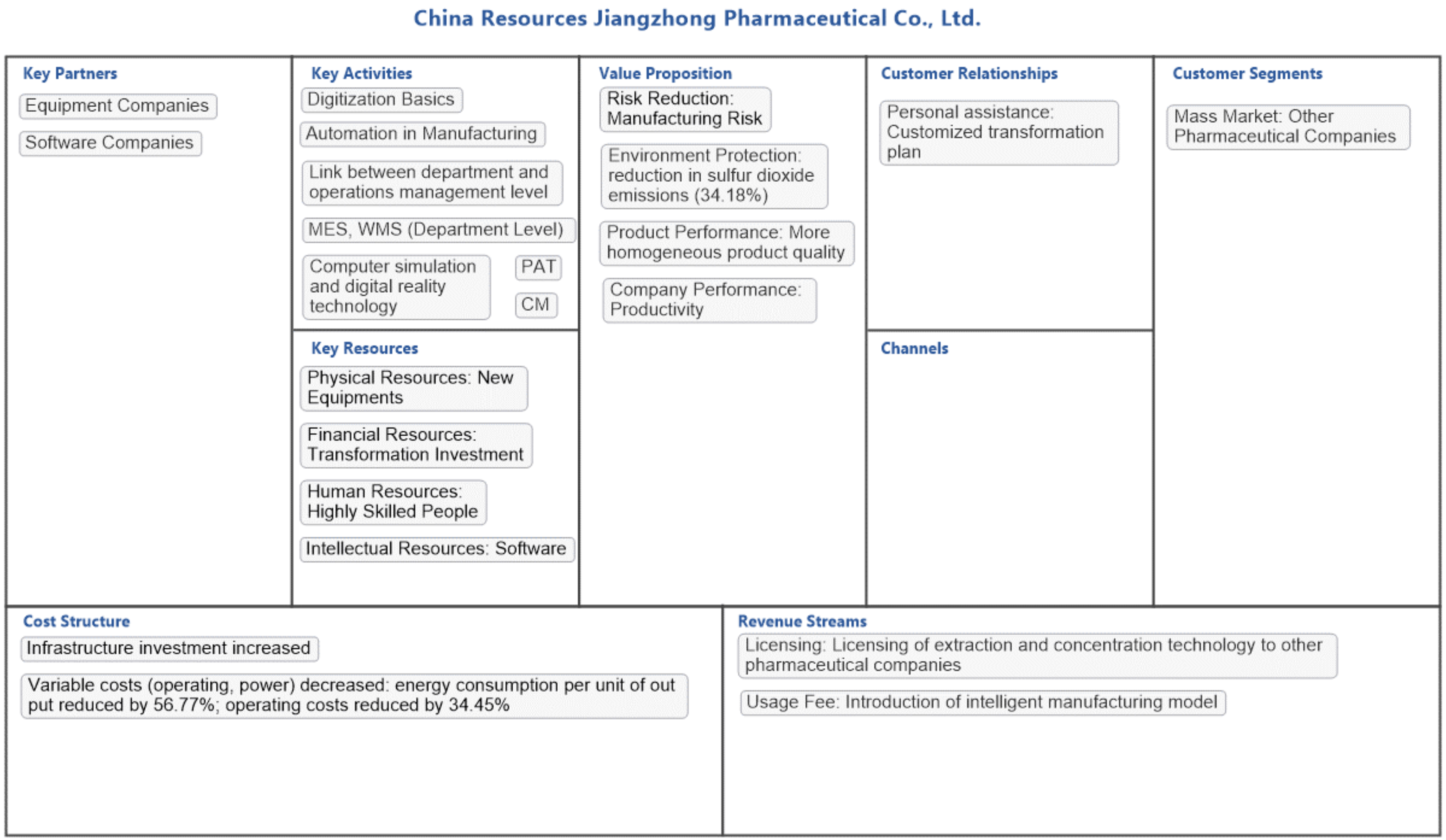

Figure 10 Jiangzhong Canvas (vide Appendix E) (Developed by Author)

4.6 Xinjiang Uygur Pharmaceutical

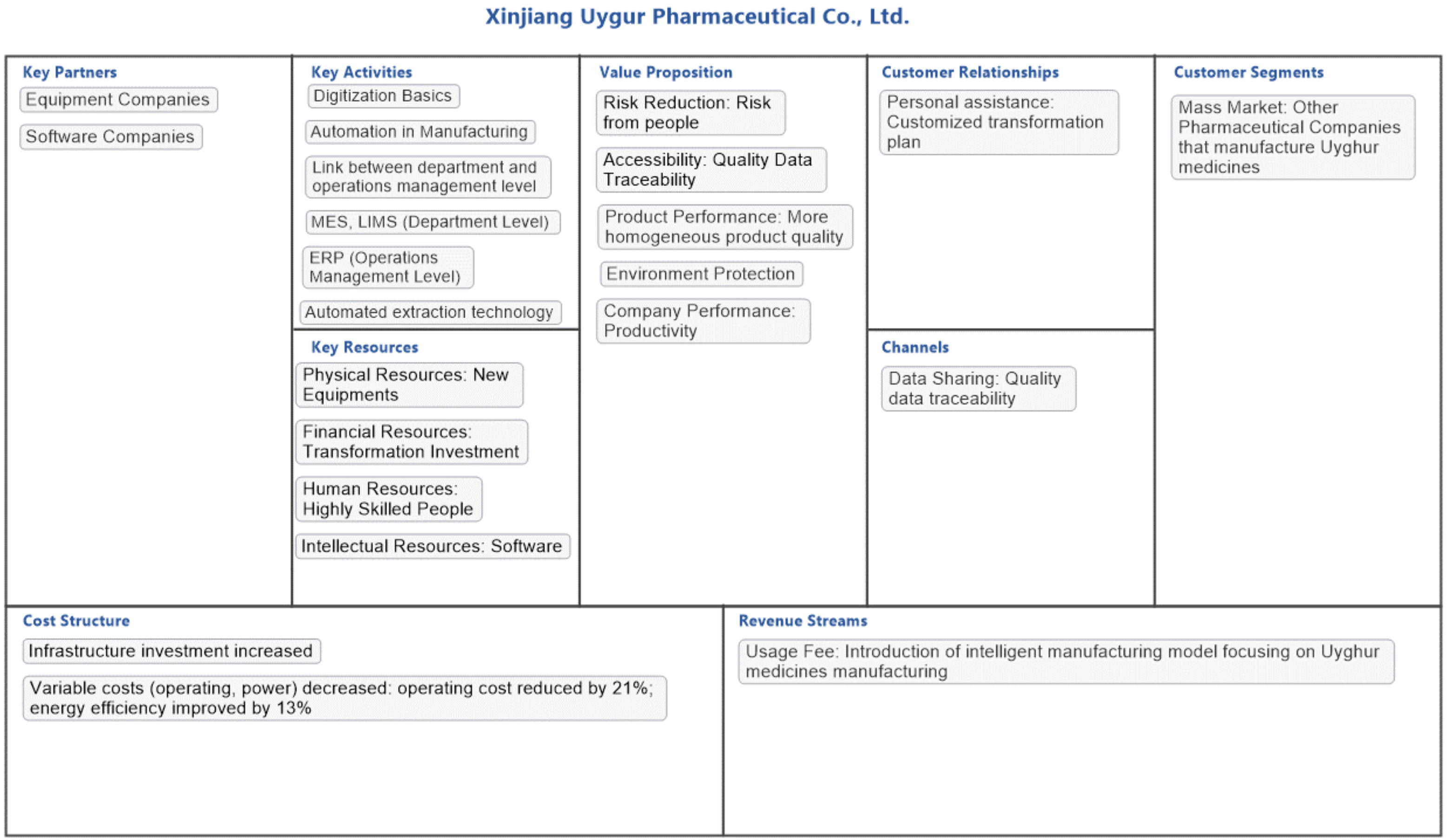

Figure 11 Xinjiang Uygur Pharmaceutical Company Canvas (vide Appendix F) (Developed by Author)

4.7 North China Pharmaceutical

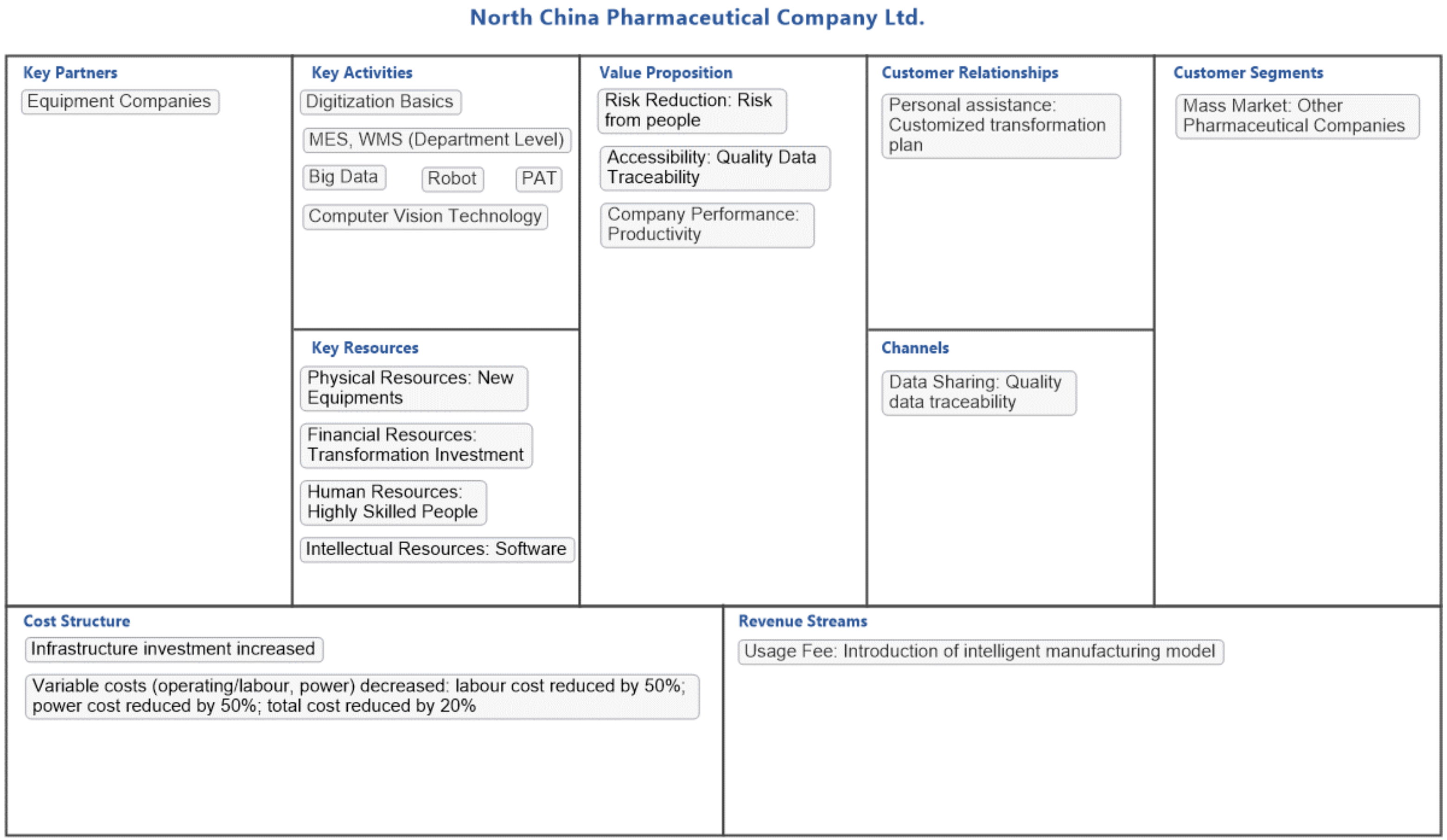

Figure 12 North China Pharmaceutical Company Canvas (vide Appendix G) (Developed by Author)

4.8 Hunan Kelun Pharmaceutical

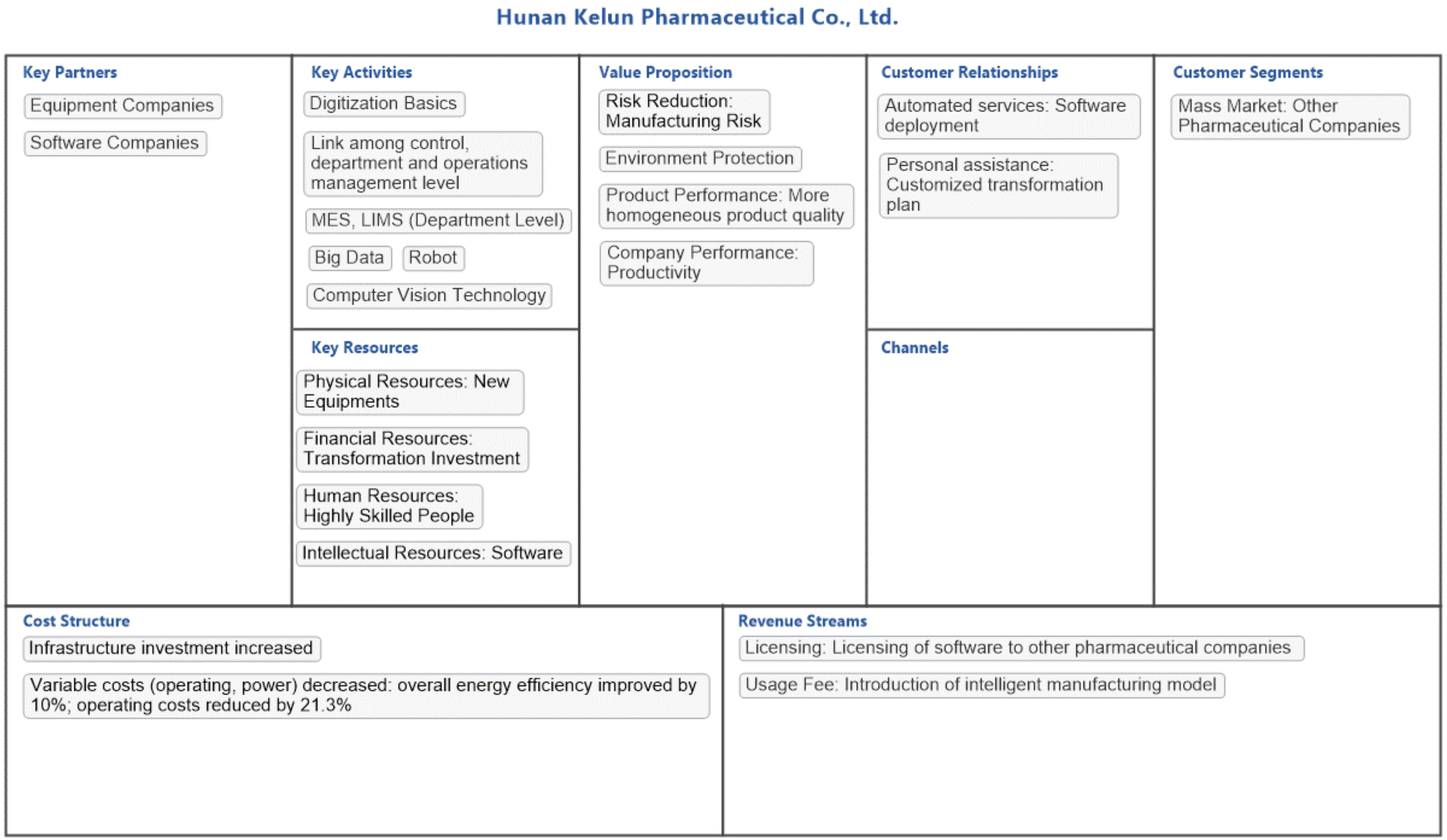

Figure 13 Kelun Canvas (vide Appendix H) (Developed by Author)

4.9 Northeast Pharmaceutical Group

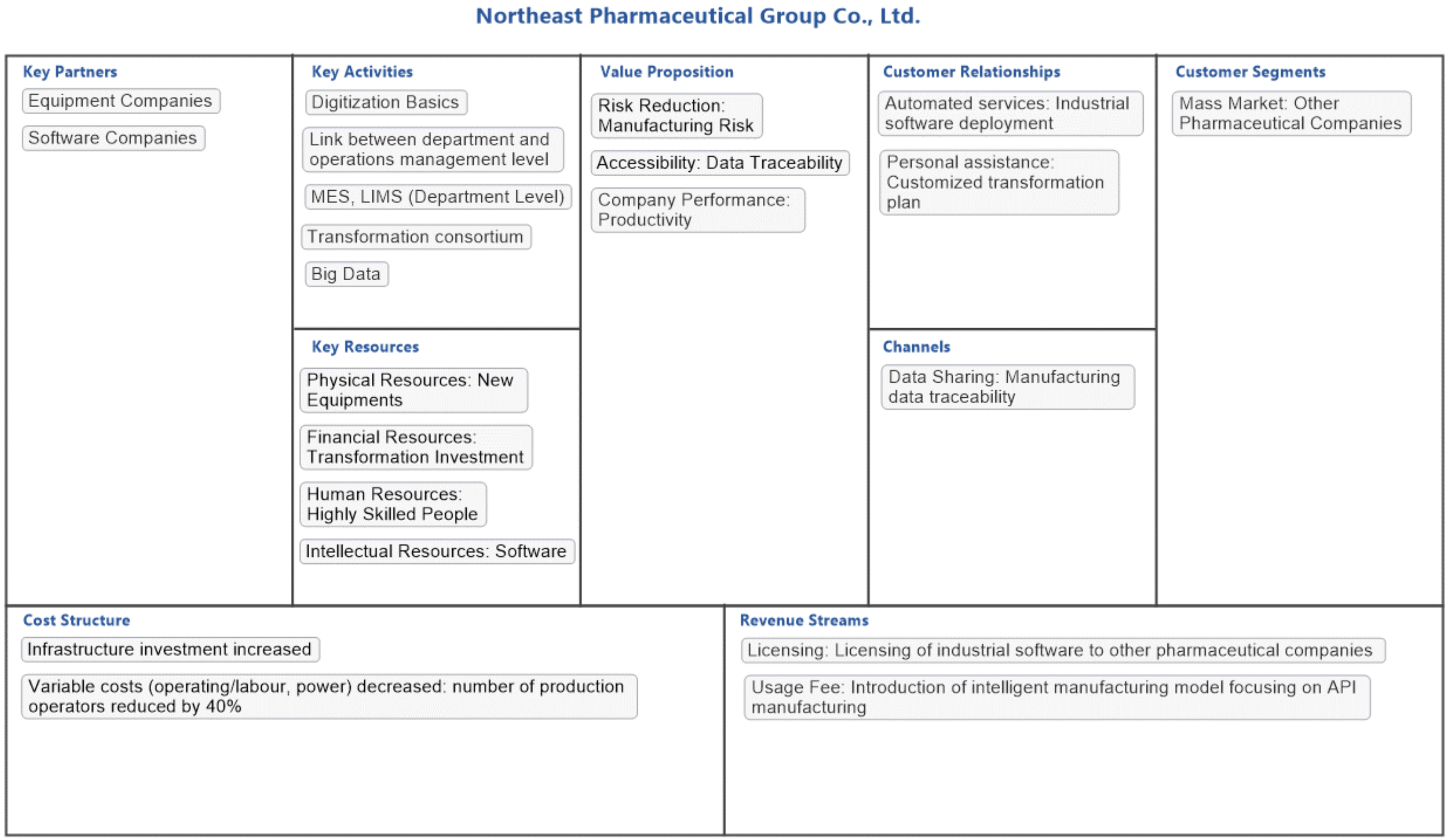

Figure 14 Northeast Pharmaceutical Group Canvas (vide Appendix I) (Developed by Author)

4.10 Jinyu Bio-technology

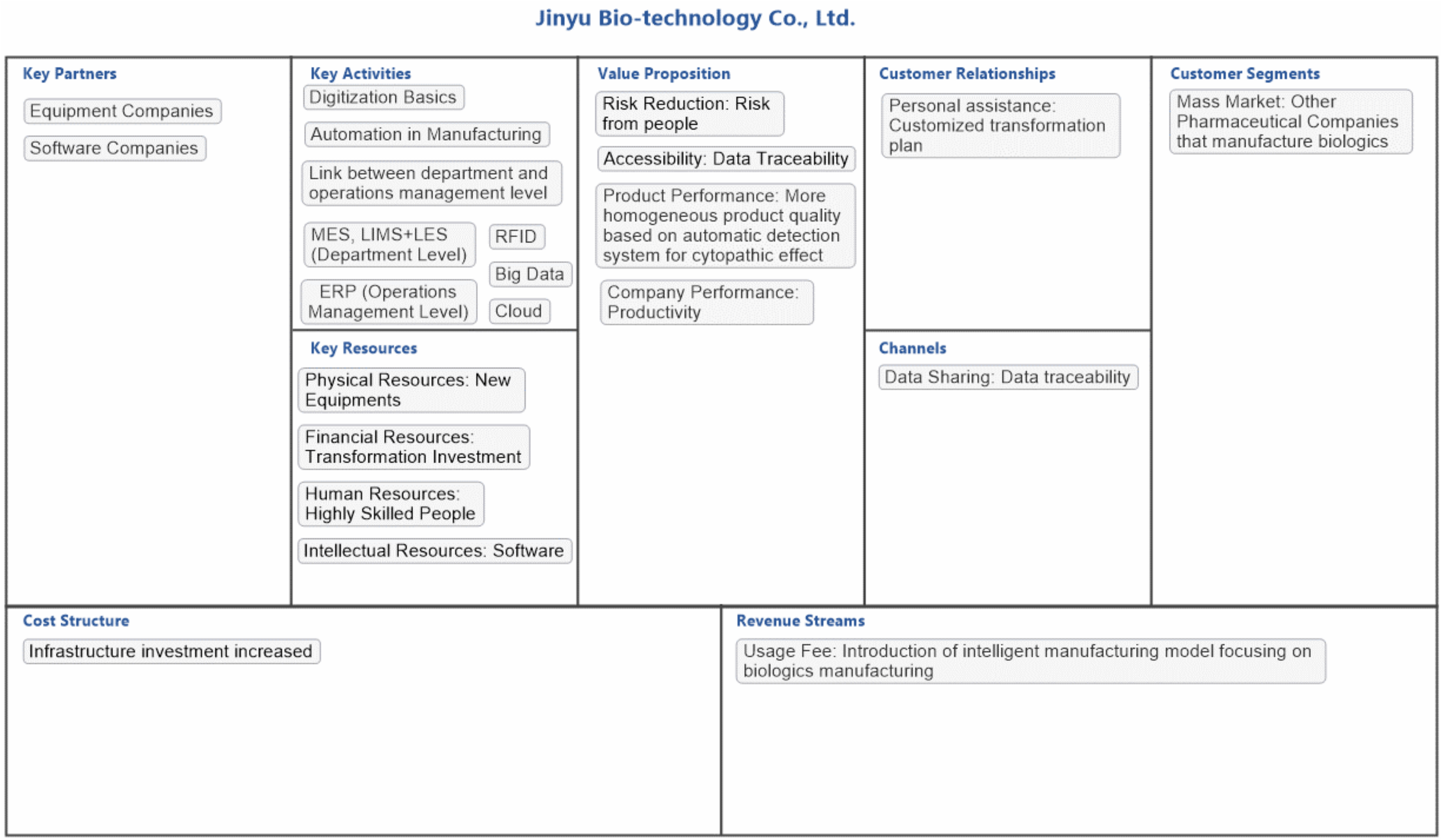

Figure 15 Jinyu Canvas (vide Appendix J) (Developed by Author)

5. Discussion

In the previous research work, this dissertation identified eight Chinese pharmaceutical companies that have introduced Industry 4.0 in their existing operating models and two Chinese pharmaceutical companies that have opened up new operation models by applying Industry 4.0 technologies. In this chapter, the analysis of results will be synthesized to achieve the objectives proposed in Chapter 1 and compared with the propositions obtained from the literature review.

5.1 Technologies Applied Identified from Empirical Research

5.1.1 Application Level

As Figure 16 shows, the department level is the most introduced level of Industry 4.0 in Chinese pharmaceutical companies. In addition, the ERP, MES, LIMS, and WMS proposed in §2.2 are observed to be applied in Chinese pharmaceutical companies. This means that Chinese pharmaceutical companies can build their transformation strategies for Industry 4.0 based on these systems. These applications will cover multiple functional areas such as R&D, manufacturing, logistics, quality control, and operations management.

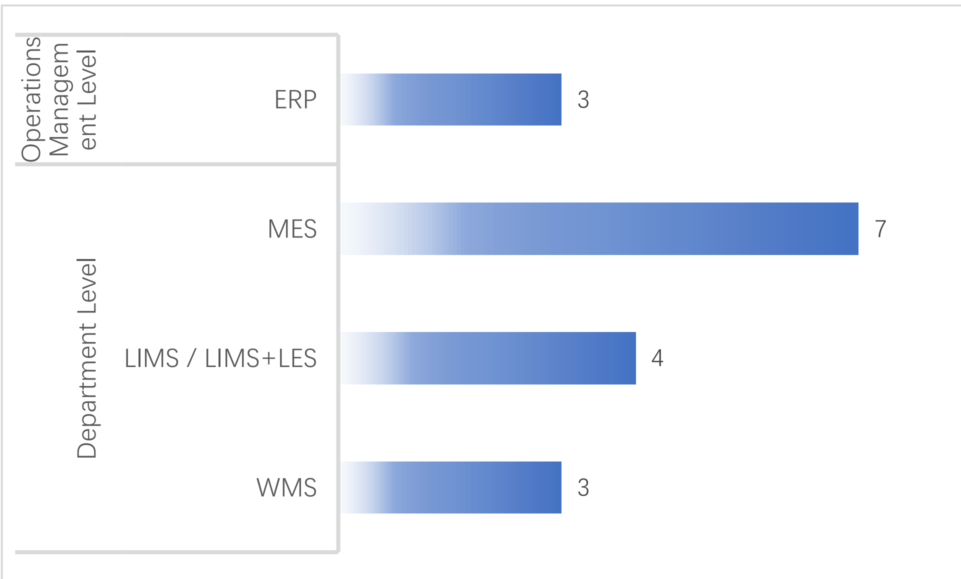

Figure 16 Number of Applications in Different Levels

5.1.2 Technologies

As Figure 17 shows, the eight technologies identified in §2.3 were observed in the empirical research. Among them, digital twins and simulations can simulate the construction and operation of production lines in advance and identify possible difficulties in the construction and manufacturing process. Robots play a huge role in manufacturing and warehousing; RFID becomes the basis for digital management of materials, equipment, people, and environmental systems within the company; PAT technology reduces the discontinuity of manufacturing processes and provides the basis for the implementation of CM technology. Moreover, based on empirical research, it is observed that the application of AI is mainly focused on computer vision technology.

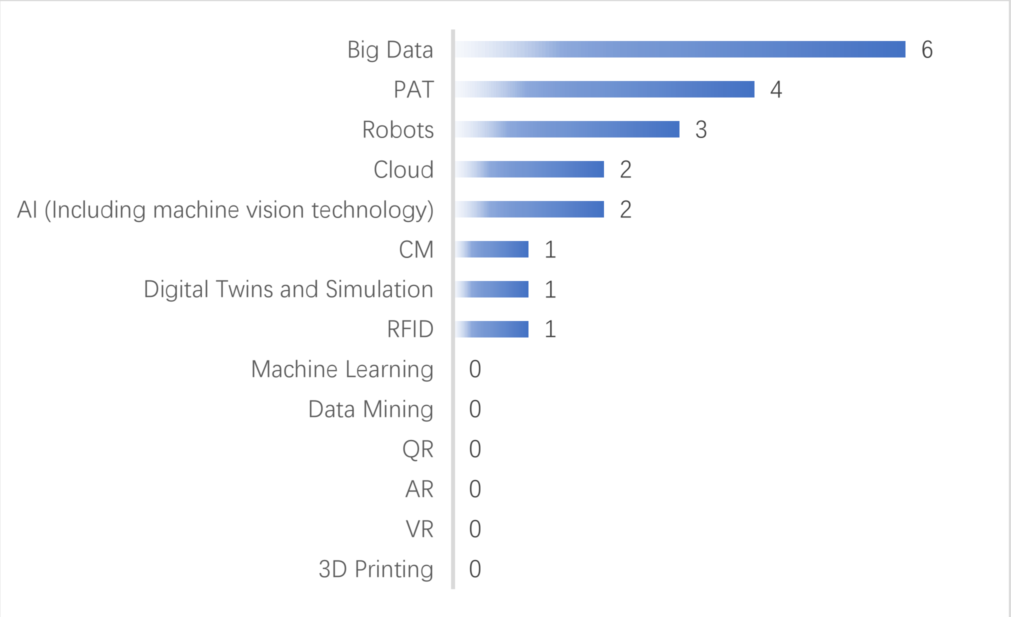

Figure 17 Numbers of Different Applications of Technologies of Industry 4.0

5.2 Competitive Advantages from Empirical Research

The value proposition, cost structure and revenue streams in the business model canvas reflect the competitive advantages that Industry 4.0 can bring.

5.2.1 Building Block #1: Value Proposition

As Figure 18 shows, seven of the techniques identified in §2.4 were observed in the empirical research.

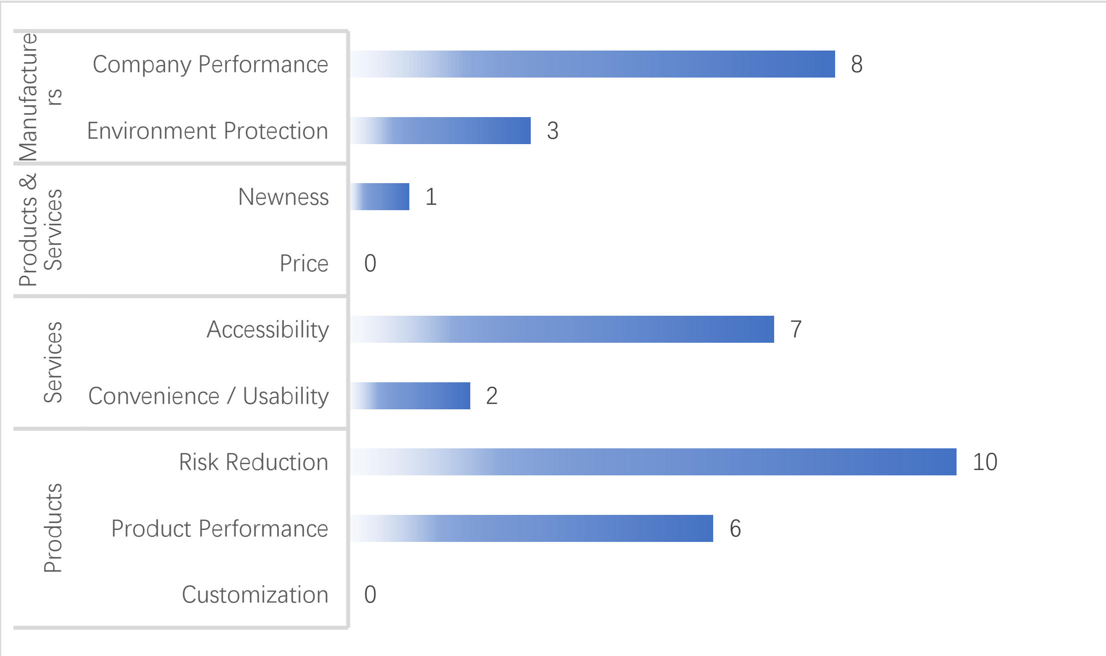

Figure 18 Numbers of Value Proposition Brought by the Transformation of Industry 4.0

In the empirical research, this dissertation did not observe a significant decrease in the price of the company's products like Silva et al. (2020) mentioned before after the introduction of the technology of Industry 4.0. This may be related to the characteristics of the pharmaceutical products themselves. In China, the "Drug Volume-based Purchasing" refers to the centralized procurement of drugs organized by the Chinese government for Chinese Marketing Authorization Holders (MAHs) or Chinese entities that fulfill the obligations of MAH for MAHs outside China. This policy gives a reference procurement price and achieves a significant reduction in drug prices by exchanging volume for the price (The State Council of China, 2019). Additionally, the Chinese pharmaceutical companies in the empirical research have not yet introduced a customized value proposition. This may be related to the fact that the main business of these companies is facing the mass market. However, in recent years, cell therapy technologies are developing rapidly, and CAR-T (Chimeric antigen receptor T cell) technology, as a representative technology in cell therapy, is a customized therapy (Shamansky, 2018). As Industry 4.0 is further promoted in the pharmaceutical industry, customization as a value proposition will also play an important role in the future. Furthermore, the value proposition of convenience/usability was realized by two Chinese pharmaceutical companies experimenting with the new model through an online platform. This value proposition is also evidenced in the streaming platform mentioned by Okano et al. (2021). Besides, the decoction center created by XX identified the potential demand of customers for professional decoction services with newness.

Moreover, risk reduction in terms of human risk reduction, company performance in terms of productivity improvement and stable supply, accessibility in terms of enhanced data traceability, and product performance in terms of enhanced product quality homogeneity are the four most mentioned value propositions in the empirical research. Additionally, Industry 4.0 also brings the value proposition of environmental protection to Chinese pharmaceutical companies due to the reduction of energy use and pollutant emissions.

5.2.2 Building Block #2: Cost Structure

All three cost structures identified in the literature review were present in the empirical research.

In terms of fixed costs, all 10 Chinese pharmaceutical companies in the empirical research invested in the infrastructure required for the deployment of Industry 4.0-related technologies.

In terms of variable costs, TRT's operating costs were elevated as a result of trying out a new operating model. However, it is worth noting that the secondary data on XX does not clearly indicate whether the introduction of the new model of decoction center led to an increase in operating costs. However, XX was profitable in the year it completed the introduction of the new model, with a 37% margin profit. In addition, seven Chinese pharmaceutical companies achieved a reduction in variable costs after the introduction of Industry 4.0 technology based on their original operating models. With the role of "Drug Volume-based Purchasing", the reduction of variable costs will become an important way for Chinese pharmaceutical companies to improve their profits and will become an important competitive advantage.

5.2.3 Building Block #3: Revenue Stream

The empirical research mainly identified three revenue streams, namely, usage fee, asset sale, and licensing. Among them, XX and TRT have increased the revenue streams of usage fees and asset sales respectively through the new operating model. This is exactly the revenue generated through the introduction of the new operating model as mentioned in the literature review. In addition, the empirical research identified a new revenue stream named licensing. During the transformation process of Chinese pharmaceutical companies based on Industry 4.0, two Chinese pharmaceutical companies (KL & NEP) developed software to meet the demand and one Chinese pharmaceutical company (JZ) invented a new patent. Through the licensing of IPRs (Intellectual Property Rights), the Chinese pharmaceutical companies were able to gain new sources of revenue. Moreover, because the subjects of the empirical research are exemplary in China, the model established by their transformation can be replicated by other Chinese pharmaceutical companies. By guiding other pharmaceutical companies in their transformation based on Industry 4.0, these pharmaceutical companies can gain usage fees for promoting the transformation model at this stage.

5.3 The Efforts from Empirical Research

By refining the business model canvas, this dissertation will provide a reference for Chinese pharmaceutical companies to transform their business models based on Industry 4.0. This section will complete the remaining blocks to obtain a complete business model description.

5.3.1 Building Block #4: Key Partners

In the empirical research, nine Chinese pharmaceutical companies noted the importance of collaborating with equipment companies. And eight Chinese pharmaceutical companies noted the importance of collaborating with software companies. Both of these collaborations are reflected in the literature review. However, Okano et al. (2021) emphasized the role of medical associations and societies in building a streaming platform. TRT, which also introduced a new operational model, needs to utilize other third-party Internet platforms for promotional activities.

5.3.2 Building Block #5: Key Activities

According to §5.1, Chinese pharmaceutical companies will conduct transformation activities based on Industry 4.0 from two levels, Operations Management Level and Department Level. Of these, RFID, digital twins and simulation, CM, AI, cloud, robots, PAT, and big data all have application scenarios in the transformation process.

Moreover, based on the results from the literature review, this dissertation classifies the key activities in the empirical research as follows.

(1) Digitization Basics (TJT, TSL, TRT, XX, JZ, UP, NCP, KL, NEP, JY)
(2) Interconnection of devices and integration of information among different levels and devices: Link between department and operations management level (TJT, JZ, UP, NEP, JY); Link among control, department, and operations management level (TSL, KL); Multi-source heterogeneous data aggregation and storage (TJT, TRT,); Interconnection of equipment inside (XX).
(3) Automation control in different departments: Automation in Manufacturing (TJT, TSL, JZ, UP, JY); Automation in Warehousing (TJT, TSL, TRT); Automation of Services and Packaging (XX).
(4) Online Platforms (TRT)
(5) Introduction of AI Applications: Computer Vision Technology (NCP, KL)
(6) Cross-Organizational Interconnection: Interconnection of equipment outside (XX)

In summary, digital twins and simulation can simulate the construction and operation of a production line in advance to identify accidents and risks. RFID and robots can be used as the basis for automation control. Digitization basics together with IoT and CPS which are the base technologies, enable the interconnection of devices and integration of information. The integrated information will be stored in the cloud for analysis using big data. The current application of AI in Chinese pharmaceutical companies is still focused on computer vision technology. But by combining with big data, AI will be observed to be more widely used in the future.

5.3.3 Building Block #6: Key Resources

In the empirical research, all four resources mentioned in Chapter 2 (vide §2.5) were observed. Financial resources are used to purchase physical resources or to explore new models. The use of physical resources requires the support of software (intellectual resources). As Industry

4.0 brings new technologies, Chinese pharmaceutical companies need to hire people (human resources) that can help them implement the daily application of these technologies or participate in the new models.

5.3.4 Building Block #7: Customer Relationships

The two customer relationships elaborated in the literature review were demonstrated in the empirical research. Five Chinese pharmaceutical companies and eight Chinese pharmaceutical companies presented automated services and personal assistance customer relationships, separately. In terms of automated services, the introduction of Industry 4.0 brings customized delivery schedules (TJT), providing needed information to customers via mobile Apps (TRT), online orders with offline delivery (XX), and the deployment of software with proprietary IPRs in customer companies (KL, NEP).

In terms of personal assistance, the Chinese pharmaceutical companies in the empirical research, due to their exemplary role, can summarize their successful experience as a model for transformation in the face of Industry 4.0 and thus help other pharmaceutical companies to customize their transformation solutions (TJT, TSL, JZ, UP, NCP, KL, NEP, JY).

5.3.5 Building Block #8: Channel

The two channels described in Chapter 2 (vide §2.5) were demonstrated in the empirical research. The digital platform is presented in two companies that introduced the new model, specifically online platforms and mobile Apps. Besides, Data sharing, represented by data traceability, is observed in six companies.

5.3.6 Building Block #9: Customer Segments

In Chapter 2, both types of customers belonging to the mass market are presented in the empirical research. The transformation model of the Chinese pharmaceutical companies in the empirical research can be replicated by other pharmaceutical companies with similar main businesses. In addition, hospitals (Healthcare Providers), pharmacies (Healthcare Providers), patients, and people in need of health care (Purchasers) are also a type of mass market.

5.4 The Proposed Model

In a nutshell, Table 4 shows the comparison of different blocks established by the literature review in Chapter 2 and empirical research in Chapter 4.

Table 4 Comparison of Different Blocks Established by Literature Review and Empirical Research

Block		Literature Review	Empirical Research	Difference
Key Partners		3	3	Basically Same
Key Activities	Application Level	4	2	The department level includes the other two levels.
	Technologies	14	8	Except Machine Learning, Data Mining, QR, VR, AR, 3D Printing
	General Activities	6	6	Basically Same
Key Resources		4	4	Same
Value Proposition		9	7	Except Price, Customization
Cost Structure		3	3	Same
Revenue Streams		2	3	The empirical research identified Licensing as a novel revenue stream.
Customer Relationships		2	2	Same
Channels		2	2	Same
Customer Segments		1	1	Same
Note: Basically Same means there are differences between literature review and empirical research, but the difference is not essential and could be regarded as the same.				

Through empirical research, this dissertation confirms and explores the contents proposed in the literature review in each block of the business model canvas. With the modification of the empirical research, this dissertation can propose the current business model of Chinese pharmaceutical companies for transformation in the face of Industry 4.0 (Figure 19).

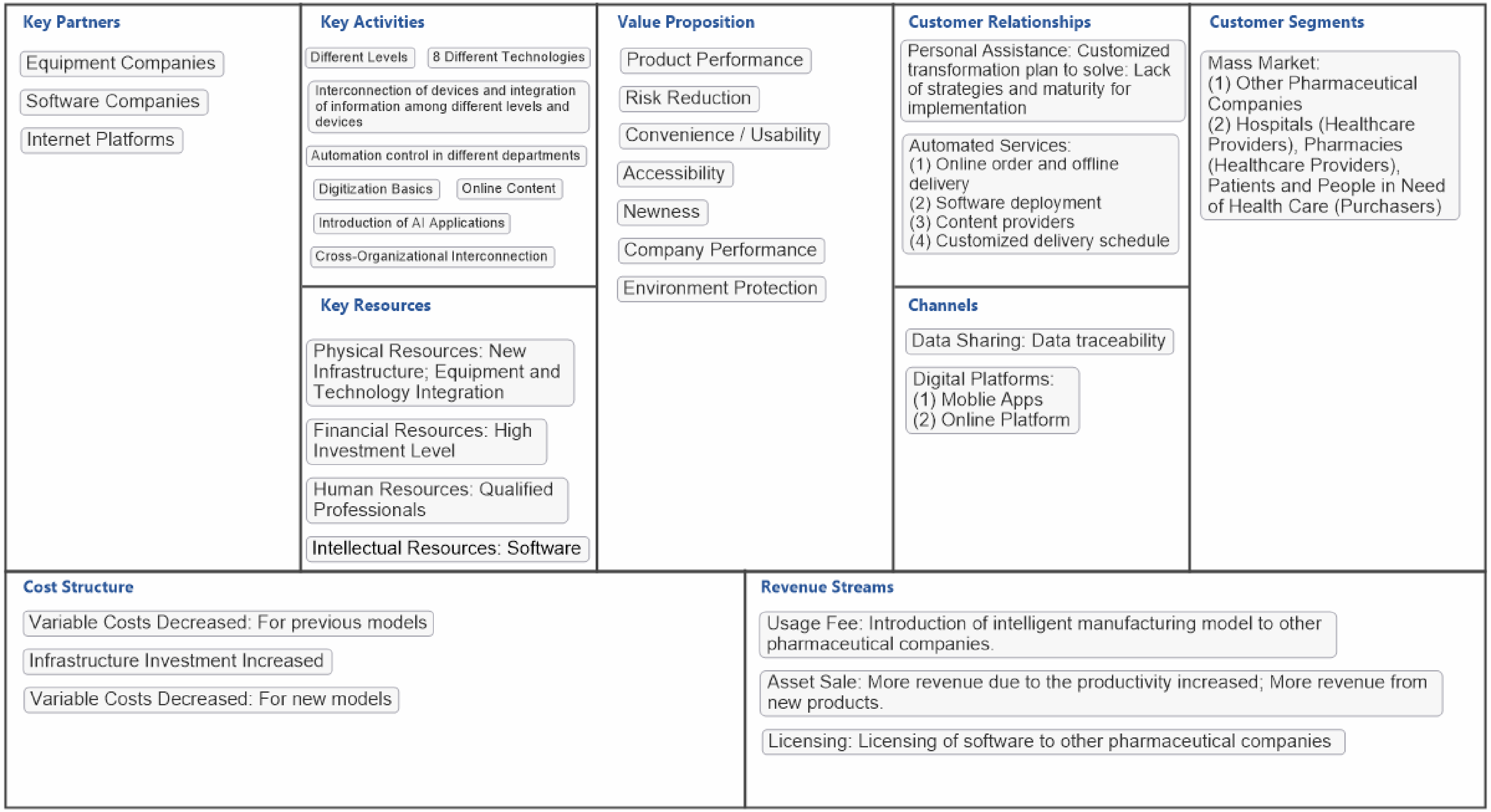

Figure 19 Business Model for the Transformation of Chinese Pharmaceutical Companies Based on Industry 4.0

6. Conclusions

Due to the lack of literature on the status of Chinese pharmaceutical companies applying Industry 4.0, this dissertation first reviewed the findings of studies on worldwide pharmaceutical companies deploying Industry 4.0 and conceptualized the relevant content to form a business model derived from the literature (Figure 5). Subsequently, a series of business models of ten Chinese pharmaceutical companies that are exemplary in the face of Industry 4.0 transformation are obtained through secondary data. In the discussion, this dissertation synthesized the analysis of results, discussed the commonalities and differences between the empirical research results and the business model developed in the literature review within each block of the business model canvas, and finally obtained a business model that can be referred to by Chinese pharmaceutical companies (Figure 19). This business model, based on propositions derived from the literature, was generated to meet the research objectives and can be used as a basis for answering the research questions. At this stage, this business model is of practical reference and can provide guidance to Chinese pharmaceutical companies in their business model transformation based on Industry 4.0 technologies.

6.1 Revisiting the Research Questions

(1) RQ1: What are the technologies applied from the Fourth Industrial Revolution in Chinses pharmaceutical companies?

In the empirical research, a total of eight technologies were identified in the literature review. These technologies are big data, PAT, Robots, Cloud, AI represented by computer vision technology, CM, Digital Twins and Simulation, and RFID. However, it is worth noting that IoT and CPS are the basis of all technology applications. Therefore, these two technologies are also widely used in the transformation process of Chinese pharmaceutical companies in the face of Industry 4.0.

In this way, the current state-of-the-art technologies applied from Industry 4.0 in Chinese pharmaceutical companies to construct key activities in the BMC were described. These technologies have been widely applied at different levels such as department or control to achieve the interconnection of devices and the integration of information. Moreover, those applications of technologies include automation control in different departments, digitization basics, online content providing, the introduction of AI Applications, and cross-organizational interconnection.

(2) RQ2: What competitive advantages do the Fourth Industrial Revolution bring to Chinese pharmaceutical companies?

The competitive advantages of the fourth industrial revolution are reflected in the value proposition, cost structure, and revenue streams of the business model canvas.

In terms of profit, by introducing the fourth industrial revolution, Chinese pharmaceutical companies can obtain a reduction in variable costs of their existing operating model. In addition, Chinese pharmaceutical companies can also earn guidance revenues or licensing fees at this stage by promoting their experience in the face of Industry 4.0 transformation or the software prescribed in the process, respectively. Companies can also earn more revenue when productivity rises or when technology spurs the creation of new products.

In terms of value proposition, Chinese pharmaceutical companies can gain competitive advantages in four dimensions. Regarding products, Chinese pharmaceutical companies can reduce the risks associated with their products and improve their performance through Industry 4.0 technologies. Regarding service, Industry 4.0 technologies bring accessibility and convenience to Chinese pharmaceutical companies. Regarding covering both product and service dimensions, Industry 4.0 offers Chinese pharmaceutical companies the possibility to introduce new operating models or acquire new products. Regarding the dimension of the company itself, Industry 4.0 improves the overall performance of Chinese pharmaceutical companies and contributes to the environmental protection dimension of the companies.

(3) RQ3: What changes do Chinese pharmaceutical companies need to make, in order to take advantage of the technologies applied from the Fourth Industrial Revolution?

In order to obtain the competitive advantages identified in answering RQ2, Chinese pharmaceutical companies should undertake the following efforts.

Firstly, Chinese pharmaceutical companies need to build on digital basics and a better level of automation control to establish interconnections among devices, and departments and to integrate the data or information obtained from various sources. Based on past data analysis, Chinese pharmaceutical companies can provide customized delivery services to their customers.

Secondly, Chinese pharmaceutical companies need to explore the new opportunities offered by digital platforms. These opportunities provide them with the opportunity to communicate directly with patients or product purchasers. On the one hand, they can become content providers through mobile Apps or other online platforms. On the other hand, they can also develop their own B2C services by taking orders online and delivering them offline.

Thirdly, Chinese pharmaceutical companies should be prepared to embrace cross-organizational interconnectivity. This makes it possible for them to automate collaboration with hospitals or pharmacies. At the same time, this enhances the data traceability of drugs. The regulator can establish a drug information traceability platform based on this interconnection to fully display to each customer the full life cycle information of the product from manufacturing to distribution.

Fourth, Chinese pharmaceutical companies should explore the application of AI technologies in their own operating models and be prepared for the arrival of more AI technologies.

Finally, Chinese pharmaceutical companies should actively promote their own successful experiences and provide customized transformation plans or deploy their own software developed during the transformation process for other Chinese pharmaceutical companies with similar main businesses.

To achieve the above process, Chinese pharmaceutical companies should invest (financial resources) and hire more professionals (human resources) to fully cooperate with equipment companies, software companies, and internet platforms at both the hardware level (physical resources) and software level (intellectual resources) for the transformation strategy of Industry 4.0.

6.2 Relevance and Contributions

6.2.1 Research

During the literature search, the author did not find any relevant studies grounded in the establishment of transformational business models for pharmaceutical companies in the face of Industry 4.0. Therefore, this dissertation supplements this point through a literature review. In addition, this dissertation verifies and corrects the results of the literature review through empirical research on Chinese pharmaceutical companies, so as to arrive at a business model applicable to the transformation of Chinese pharmaceutical companies based on Industry 4.0. This dissertation identifies, through the business model canvas, the industry 4.0 technologies that Chinese pharmaceutical companies can apply, the competitive advantages they can obtain, and the efforts they should make. The results systematically answer the questions of "what", "why" and "how" for Chinese pharmaceutical companies in the face of the fourth industrial revolution.

6.2.2 Practitioner

The birth of Industry 4.0 has effectively improved the productivity of manufacturing companies and reduced labor costs. As the national strategy of "Made in China 2025" continues to be implemented, Industry 4.0 will be fully deployed in China's pharmaceutical industry.

This dissertation summarizes the efforts of ten Chinese pharmaceutical companies that are currently exemplary in facing Industry 4.0 from the perspective of the business model. By referring to this business model, Chinese pharmaceutical companies can establish their own transformation strategies according to their own situations.

Additionally, as one of the most important economies and markets in the world, China has been the focus of attention for global pharmaceutical companies. This business model provides organizations outside of China with a more comprehensive understanding of the current state of the Chinese pharmaceutical industry. These references can help these companies effectively build business models that are adapted to the local environment in China with the help of Industry 4.0.

6.3 Limitations and Future Research

Even though this dissertation provides impressive insights into the deployment of Industry 4.0 in Chinese pharmaceutical company operations, this research is still done under some limited conditions.

Firstly, the business model obtained through the literature review of this dissertation may be of limited application due to the lack of literature related to the research topic and the lack of research results from the business model perspective. In order to solve this problem, future research should make full reference to relevant research results of similar industries (e.g., chemical industry) to obtain a more comprehensive consultation.

Secondly, in the empirical research, only ten Chinese pharmaceutical companies were used as the study subjects. Among them, only two pharmaceutical companies tried a new operation model using the technology of Industry 4.0. Although pharmaceutical companies all have similar characteristics, their main business is different. In order to obtain a more reliable conclusion, future empirical research should be based on a larger number of pharmaceutical companies with similar main business to conclude the business model applicable to this type of pharmaceutical companies.

Thirdly, limited by research resources, this dissertation chose to base its investigation on secondary data. However, these secondary data were not collected for the purpose of building business models. Although these data were also collected for the purpose of comprehensively summarizing the experiences of Chinese pharmaceutical companies' transformation based on Industry 4.0, they may still be missing some information disclosure due to the subjectivity of the data providers. To address this issue, future research should consider using multiple research methods (e.g., semi-structured interviews, distribution of questionnaires, etc.) to collect primary data in order to cross-corroborate the gathered data.

Eventually, this dissertation considers the activities of pharmaceutical companies as a holistic one. However, in reality, the scope covered by each pharmaceutical company in the chain may be different. Their distribution services and post-marketing monitoring may be assigned to outsourcing organizations. Many pharmaceutical companies will also not establish retail service teams belonging to themselves but will entrust third-party companies to do it for them. Therefore, in the future, it would be valuable to establish corresponding transformational business models based on Industry 4.0 according to various segments such as R&D, manufacturing, quality control, warehousing, logistics, and usage separately.

In summary, although there are still many limitations in the research of this dissertation, its research results are the best efforts made under the current research conditions. This research result is not only of academic value but also has certain guidance and reference significance to real world companies. Based on the results of this research, future research will likely further deepen in the above four areas and produce more valuable and practically meaningful results.

References

Arden, N. S., Fisher, A. C., Tyner, K., Yu, L. X., Lee, S. L., & Kopcha, M. (2021). Industry 4.0 for pharmaceutical manufacturing: Preparing for the smart factories of the future. *International Journal of Pharmaceutics*, 602, 120554. https://doi.org/10.1016/j.ijpharm.2021.120554

Binggeli, L., Heesakkers, H., Wölbeling, C., & Zimmer, T. (2018, July / August). *Pharma 4.0TM: Hype or Reality?* ISPE | International Society for Pharmaceutical Engineering. Retrieved October 28, 2021, from https://ispe.org/pharmaceutical-engineering/july-august-2018/pharma-40tm-hype-or-reality

Buket, A. K. S. U., & YEĞEN, G. (2021). Industry 4.0 Elements for Pharmaceutical Development and Manufacture. *Aurum Journal of Health Sciences*, *3*(1), 45-50.

Chen, Y., Yang, O., Sampat, C., Bhalode, P., Ramachandran, R., & Ierapetritou, M. (2020). Digital Twins in Pharmaceutical and Biopharmaceutical Manufacturing: A Literature Review. *Processes*, 8(9), 1088. https://doi.org/10.3390/pr8091088

Dalenogare, L. S., Benitez, G. B., Ayala, N. F., & Frank, A. G. (2018). The expected contribution of Industry 4.0 technologies for industrial performance. *International Journal of Production Economics*, 204, 383–394. https://doi.org/10.1016/j.ijpe.2018.08.019

Ding, B. (2018). Pharma Industry 4.0: Literature review and research opportunities in sustainable pharmaceutical supply chains. *Process Safety and Environmental Protection*, 119, 115–130. https://doi.org/10.1016/j.psep.2018.06.031

Ganesh, S., Su, Q., Nagy, Z., & Reklaitis, G. (2020). Advancing smart manufacturing in the pharmaceutical industry. *Smart Manufacturing*, 21–57. https://doi.org/10.1016/b978-0-12-820028-5.00002-3

Hankel, M., & Rexroth, B. (2015, April). *Industrie 4.0: The Reference Architectural Model Industrie 4.0 (RAMI 4.0)*. https://www.zvei.org/fileadmin/user_upload/Presse_und_Medien/Publikationen/2015/april/Das_Referenzarchitekturmodell_Industrie_4.0__RAMI_4.0_/ZVEI-Industrie-40-RAMI-40-English.pdf

Hariry, R. E., Barenji, R. V., & Paradkar, A. (2020). From Industry 4.0 to Pharma 4.0. *Handbook of Smart Materials, Technologies, and Devices: Applications of Industry 4.0*, 1-22.

Huang, C. (2021, August 6). Northeast Pharmaceutical “intellectual” transformation, polishing the “old” sign. *Shenyang Daily*. https://kns.cnki.net/kcms/detail/detail.aspx?dbcode=CCND&dbname=CCNDLAST2021&filename=SYRB202108060021&uniplatform=NZKPT&v=BiFksHLLZyiiSHzyh8rHgcOMnFMfAjmHeT5XzD8X9DXlKHoouELdfBQ6kG5_FNXmCg97SWRk7uA%3d

Jain, A., & Sharma, D. K. (2020). Transforming pharma logistics with the Internet of things. *An Industrial IoT Approach for Pharmaceutical Industry Growth*, 55–85. https://doi.org/10.1016/b978-0-12-821326-1.00003-6

Javaid, M., Haleem, A., Vaishya, R., Bahl, S., Suman, R., & Vaish, A. (2020). Industry 4.0 technologies and their applications in fighting COVID-19 pandemic. *Diabetes & Metabolic Syndrome: Clinical Research & Reviews*, 14(4), 419–422. https://doi.org/10.1016/j.dsx.2020.04.032

Kagermann, H., Wahlster, W., & Helbig, J. (2013). Securing the future of German manufacturing industry, recommendations for implementing the strategic initiative INDUSTRIE 4.0. Final report of the Industrie 4.0 working group, Frankfurt, Germany.

Kumar, S. H., Talasila, D., Gowrav, M. P., & Gangadharappa, H. V. (2020). Adaptations of Pharma 4.0 from Industry 4.0. *Drug Invention Today*, *14*(3).

Li, L., & Zhou, H. (2013). Manufacturing practices in China. *International Journal of Production Economics*, 146(1), 1–3. https://doi.org/10.1016/j.ijpe.2013.09.006

Liu, F. (2021). *Research on Financial Performance of Internet Transformation Effect of Beijing Tongrentang (Master Dissertation, Anhui University of Finance & Economics).*https://kns.cnki.net/KCMS/detail/detail.aspx?dbname=CMFD202102&filename=1021603556.nh

Ministry of Industry and Information Technology (MIIT). (2020). *Intelligent Manufacturing Consumer Goods Industry Solution: Pharmaceutical Industry* [E-book]. Publishing House of Electronics Industry. (In Chinese)

Ministry of Industry and Information Technology (MIIT) & China Pharmaceutical Enterprises Association (CPEA). (2020, August). *White Book of Intelligent Manufacturing in China's Pharmaceutical Industry.* http://www.cpema.org/uploadfile/2020/0831/20200831021710690.pdf (In Chinese)

Okano, M. T., de Castro Lobo Dos Santos, H., Ursini, E. L., Honorato, W., & Ribeiro, R. B. (2021). Digital Transformation as an Agent of Change in a Pharmaceutical Industry from the Perspective of Dynamic Capabilities. *2021 IEEE 11th Annual Computing and Communication Workshop and Conference (CCWC)*. https://doi.org/10.1109/ccwc51732.2021.9375838

Osterwalder, A. (2017). Business Model Generation (Chinese Only) (Chinese Edition) (1st ed.). China Machine Press. (In Chinese)

Peng J. (2016). *Digital transformation of manufacturing driven by Industry 4.0*. China Machine Press. (In Chinese)

Rezepa, S. (2021). Strategy and Planning and Implementation and Impact for the Pharmaceutical Industry with and by industry 4.0. *Stefan Rezepa, Jan Pekar ISBN*, 978-80.

Rojko, A. (2017). Industry 4.0 Concept: Background and Overview. *International Journal of Interactive Mobile Technologies* (IJIM), 11(5), 77. https://doi.org/10.3991/ijim.v11i5.7072

Reinhardt, I. C., Oliveira, D. J. C., & Ring, D. D. T. (2020). Current Perspectives on the Development of Industry 4.0 in the Pharmaceutical Sector. *Journal of Industrial Information Integration*, 18, 100131. https://doi.org/10.1016/j.jii.2020.100131

Reinhardt, I. C., Oliveira, D. J. C., & Ring, D. D. T. (2021). Industry 4.0 and the Future of the Pharmaceutical Industry. *Pharmaceutical Engineering*. 41. Online Exclusive.

Sharma, A., Kaur, J., & Singh, I. (2020). Internet of Things (IoT) in Pharmaceutical Manufacturing, Warehousing, and Supply Chain Management. *SN Computer Science, 1(4)*. https://doi.org/10.1007/s42979-020-00248-2

Shamansky, E. (2018). The Cancer Immunotherapy Pilot Program and Chimeric Antigen Receptor-T Cell Treatments. *Boston College Intellectual Property and Technology Forum*, 1, 1.

Silva, F., Resende, D., Amorim, M., & Borges, M. (2020). A Field Study on the Impacts of

Implementing Concepts and Elements of Industry 4.0 in the Biopharmaceutical Sector. *Journal of Open Innovation: Technology*, Market, and Complexity, 6(4), 175. https://doi.org/10.3390/joitmc6040175

The State Council of China. (2015, May 19). *Notice of the State Council on the Issuance of "Made in China 2025" (State Development [2015] No. 28)*_Government Information Disclosure Column. Http://Www.Gov.Cn/. Retrieved November 1, 2021, from http://www.gov.cn/zhengce/content/2015-05/19/content_9784.htm (In Chinese)

The State Council of China. (2019, January 17). *Notice of the General Office of the State Council on the Issuance of a Pilot Program for the Centralized Procurement and Use of Drugs by State Organizations (State Office [2019] No. 2)_Government Information Disclosure Column*. Www.Gov.Cn. Retrieved November 13, 2021, from http://www.gov.cn/zhengce/content/2019-01/17/content_5358604.htm (In Chinese)

Vogel-Heuser, B., & Hess, D. (2016). Guest Editorial Industry 4.0–Prerequisites and Visions. *IEEE Transactions on Automation Science and Engineering*, 13(2), 411–413. https://doi.org/10.1109/tase.2016.2523639

Wang, S., & Chen, Y. (2021). How Technological Innovation Affect China's Pharmaceutical Smart Manufacturing Industrial Upgrading. *Journal of Healthcare Engineering*, 2021, 1–10. https://doi.org/10.1155/2021/3342153

Written Team of Intelligent Manufacturing Exploration and Practice (WTEPIM). (2020a). *Intelligent manufacturing exploration and practice: a compilation of pilot demonstration projects. III. Consumer Goods Industry Volume* [E-book]. Publishing House of Electronics Industry. (In Chinese)

Written Team of Intelligent Manufacturing Exploration and Practice (WTEPIM). (2020b). *Intelligent manufacturing exploration and practice: a compilation of pilot demonstration projects. II. Consumer Goods Industry Volume* [E-book]. Publishing House of Electronics Industry. (In Chinese)

Xu, L. D., Xu, E. L., & Li, L. (2018). Industry 4.0: state of the art and future trends. *International Journal of Production Research*, 56(8), 2941–2962. https://doi.org/10.1080/00207543.2018.1444806

Yi, J., Zhang, H., Zhao, C., Che, A., & Wang, Y. (2021). Key technologies and progress of pharmaceutical intelligent manufacturing production line. *Journal of Central South University (Science and Technology)*, 52(2), 421–433. https://doi.org/10.11817/j.issn.1672-7207.2021.02.010

Zheng, Z., Xie, S., Dai, H., Chen, X., & Wang, H. (2017). *An Overview of Blockchain Technology: Architecture, Consensus, and Future Trends. 2017 IEEE International Congress on Big Data (BigData Congress),* 557–564. https://doi.org/10.1109/bigdatacongress.2017.85

Appendix A

Sinopharm Tongji Tang (Guizhou) Pharmaceutical

TJT, a subsidiary of Sinopharm Group, was founded in 1888 and is located in Guiyang. It has its own herbal planting base, and its products cover capsule, tablet, granule, ingot, syrup, tincture, oral solution, cream, and other dosage forms.

TJT built the hardware technology base from key technology equipment, robots, and IoT, and the software technology base from the internet, cloud platform, artificial intelligence, and big data. Relying on these two bases, TJT realized the visualization of the manufacturing process, predictable optimization of the manufacturing process, the collaboration between the MES system and ERP system, and integration of multi-source data. In addition, intelligent equipment was introduced in key manufacturing processes, manufacturing support processes, and production line failure analysis. Moreover, TJT established an intelligent warehouse, which enabled digitalized warehouse management, three-dimensional storage units, and networked information transmission. This warehouse management system also enabled data sharing with the manufacturing management system and the regulatory code management system, and arranged the delivery schedule based on the analysis of data from hospitals, pharmacies, or distribution centers. TJT reached the leading level of big data intelligence analysis in China and became the first intelligent manufacturing project of Sinopharm Group. The experience derived from TJT could be used by other subsidiaries of Sinopharm or other pharmaceutical companies that produce Traditional Chinese Medicines. By mentoring these companies, TJT also gained a new revenue stream (MIIT, 2020).

During the transformation process, Chongqing University and Guizhou University cooperated in the overall design of the intelligent manufacturing plant, data recording, integration, etc. Chengdu Sefon Software., Ltd developed a customized software and integration system (MIIT, 2020).

To summarize, TJT's transformation is mainly focused on manufacturing and subsequent warehousing. These transformations are based on robots, IoT, the Internet, cloud platform, artificial intelligence, big data, and the collaboration of department level MES and the operations management level ERP systems.

TJT's intelligent transformation improved quality control, productivity, reduced energy consumption, and guaranteed the stability of product supply (MIIT, 2020).

In the process, TJT has made new investments, introduced new equipment, and equipped the corresponding software and human resources for the smooth use of these equipment. Through data sharing, TJT has achieved synergy with the downstream chain in terms of data traceability. In addition, TJT's efforts are exemplary, and TJT can gain new customers and revenue streams by helping other companies develop customized transformation solutions based on Industry 4.0.

Appendix B

Tasly Pharmaceutical Group

TSL was founded in 1994 and its main products cover a wide range of therapeutic areas such as cardiovascular, anti-tumor, digestive and metabolic, fever, and liver disease treatment.

In the process of intelligent manufacturing transformation, TSL applied the concepts from the ICH (The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) guidelines and the quality target product profile to explore the critical quality attributes for extracts or preparations and the critical process parameters for the manufacturing process. Based on these data, TSL digitally described raw material, process, and equipment indicators related to product quality, and realized digital design of quality, digital control of process quality, and digital evaluation of batch consistency according to these indicators. The digital control of manufacturing processes is based on PAT as the core technology, which links the measurement, collection, analysis, modeling, and traceability of manufacturing data. Moreover, TSL was actively involved in the independent development and integrated innovation of pharmaceutical equipment. By using data mining tools to improve the digitalization, quantification, and modeling of the entire manufacturing process, TSL achieved a better level of quality management. This intelligent manufacturing system based on the ICH guidelines could be replicated by other pharmaceutical companies. By guiding these companies, TSL also gained a new revenue stream (MIIT, 2020; WTEPIM, 2020b).

In the process of transformation, Zhejiang University together with TSL jointly developed a Chinese medicine intelligent manufacturing management system. This system integrated MES from Beijing Research Institute of Automation for Machinery Industry, PI System from OSISoft (USA), ERP system from SAP, and multivariate online analysis and monitoring system from Umetrics (Sweden) (MIIT, 2020; WTEPIM, 2020b).

In summary, TSL's transformation mainly covered the manufacturing segment and integrated the manufacturing execution level (control level), the process control level (department level), and the operations management level. IoT and PAT technologies were applied in the transformation process.

TSL significantly improved manufacturing management and quality control during the transformation process, and ultimately achieved an increase in productivity (5x) and a reduction in operating costs (15.4%) (MIIT, 2020; WTEPIM, 2020b).

In the process, TSL has made new investments, introduced new equipment, and equipped corresponding software and human resources for their smooth use. Through data sharing, TSL has achieved synergy with the downstream chain in terms of manufacturing data tracking. In addition, the efforts made by TSL are exemplary and TSL can gain new customers and revenue streams by helping other companies develop customized transformation solutions based on Industry 4.0.

Appendix C

Beijing Tong Ren Tang Technologies

TRT is located in Beijing and its main business includes not only manufacturing but also sales. It has more than 1,800 end-user retail stores and 93 large independent stores nationwide and is involved in online sales activities. The products it sells cover not only pharmaceuticals but also various healthcare products.

In terms of channels, TRT established a C2M (Customer-to-Manufacturer) intelligent manufacturing factory, an OMO (Online-Merge-Offline) integration and interoperability new retail model, and a number of mobile apps related to health. In order to support the new channel, TRT established a lean manufacturing intelligent factory, with PAT applied in the process. Firstly, TRT constructed a bottom-up interconnection network architecture using IoT technology. Secondly, TRT established an automated stereo warehouse. Thirdly, TRT realized the aggregation and storage of heterogeneous data from multiple sources and built its own big data platform. Based on these efforts, TRT established an intelligent factory model covering planning, procurement, manufacturing, quality control, and delivery (MIIT, 2020).

During the renovation process, the China Academy of Machinery Science and Technology was involved in the construction of the automated stereo warehouse. The establishment of the big data platform was built with the participation of Shanghai Jiao Tong University (MIIT, 2020).

To sum up, TRT carried out intelligent transformation mainly focused on manufacturing and subsequent warehousing. These transformations were based on the deep integration of the IoT and the Internet, which realized the interconnection of interdepartmental data and were the operations management level applications.

TRT improved the quality control of its products through intelligent transformation, achieved lean production, increased transparency in the manufacturing process, and improved the execution of manufacturing (MIIT, 2020). However, according to Liu (2021), TRT's paradigm transformation also brought an increase in operating costs and an increase in financial risks arising from the transformation investments.

In the process, TRT opened up new online and mobile application channels by basing on the Internet. To complete the creation of this new model, TRT has made new investments, introduced new devices, and equipped the corresponding software and human resources for their successful operation. This new model met the potential needs of many customers and created a new source of revenue.

Appendix D

Guangzhou Xiangxue Pharmaceutical

XX was founded in 1986 and is located in Guangzhou City. It has a full industrial chain from the cultivation of Chinese herbs, to the manufacturing of Chinese decoction pieces, to the manufacturing of Chinese patent medicines, to the distribution of medicine. Its main products are modern traditional Chinese medicine and Chinese decoction pieces, and it is also involved in the fields of health care products, medical devices, and precision medicine.

The use of traditional Chinese medicine requires that it be prepared according to a prescription and decocted as required before it can be taken. This process will consume more time and personal energy. Due to the accelerated pace of life, it is becoming more and more common for customers to have no time to decoct Chinese medicines. Furthermore, many pharmacies in the community are unable to provide large-scale decoction services. XX established the Xiangxue Intelligent IoT Chinese Medicine Decoction Center. This center was based on Internet and IoT technology, using self-produced Chinese decoction pieces as raw materials, and under the guidance of the GMP management concept. It realized the whole process from prescription entry, decoction monitoring, data recording, and finally to automatic interface with hospitals, patients, or logistics companies by equipping fully automatic decoction machines, automatic preparation and packing machines, and supporting equipment. Hospitals or patients could learn about the decoction process through the Internet. In addition, XX established an ERP system for the center to manage various modules covering human resources, sales, and manufacturing. This decoction center model could be used as a reference for other companies seeking to provide decoction services (MIIT, 2020; WTEPIM, 2020b).

During the renovation process, Beijing Hollycon Medical Technology Co., Ltd. participated and helped to realize the automatic preparation of more than 400 different Chinese decoction pieces (MIIT, 2020; WTEPIM, 2020b).

In conclusion, the transformation carried out by XX focused on the needs of the customer, covering the entire process from order taking to manufacturing to distribution, and these transformations are mainly based on the IoT and Internet systems, which are department level applications.

XX discovered new customer needs through intelligent transformation, significantly improved customers' previous perceptions of substitute decoction services, and formed new channels. The emergence of intelligent IoT Chinese medicine decoction center improved the quality control level of traditional Chinese medicine decoction process, improved decoction efficiency, achieved traceability of the decoction process, and improved product delivery efficiency (delivery within 24 hours). The discovery of this new demand allowed the intelligent IoT Chinese medicine decoction center to be profitable in the year it was established, with a profit margin of 37%, achieving significant economic benefits (MIIT, 2020; WTEPIM, 2020b).

In the process, XX pioneered a new business model by basing it on the Internet. To complete the establishment of this new model, XX has made new investments, introduced new equipment, and equipped the corresponding software and human resources for their successful operation. This new model met the potential needs of many customers and created a new revenue stream.

Appendix E

China Resources Jiangzhong Pharmaceutical

JZ was founded in 1969 and is mainly engaged in the manufacturing, R&D, and sales of over-the-counter drugs and health care products.

JZ adopted computer simulation and digital reality technology in the overall design and digital modeling process to form a 3D visualization of the whole manufacturing process. Besides, JZ applied intelligent sensing and control equipment in the manufacturing process and quality control process and applied PAT to successfully achieve continuous operation from material feeding to finished product storage. In addition, JZ has established an intelligent storage system and an intelligent energy management system. Finally, JZ has upgraded and improved its ERP system around the synergy and integration among the information systems established at the department level (MIIT, 2020; WTEPIM, 2020b).

In the process of transformation, the Beijing Research Institute of Automation for Machinery Industry was responsible for the integration of information systems and equipment, software development, and research of related technology applications. Zhejiang Wenxiong Machine Valve Co., Ltd. and Shenzhen Sunevap Tech. Co., Ltd. was responsible for the design, manufacturing, and installation of the manufacturing systems. The Jiangxi University of Chinese Medicine was responsible for the research on the characteristics and manufacturing process of traditional Chinese medicine. Additionally, JZ developed an automatic cycle extraction system and automatic concentration technology with its own intellectual property rights. These technologies were applied to five other pharmaceutical companies. (MIIT, 2020; WTEPIM, 2020b).

In a nutshell, JZ's transformation mainly covered the manufacturing and subsequent warehousing process and realized the collaboration and integration of the ERP system at the operations management level with MES and WMS. In the process of transformation, technologies such as IoT and sensors were applied. The concept of continuous manufacturing was also realized in this process.

JZ achieved an increase in productivity (159.11%), a reduction in energy consumption in the drying process and concentration process, a reduction in sulfur dioxide emissions (34.18%), a reduction in Non-premium rate (25.08%), a reduction in energy consumption per unit of output value (56.77%), and a reduction in operating costs (34.45%) (MIIT, 2020; WTEPIM, 2020b).

In the process, JZ has made new investments, introduced new equipment, and equipped them with the corresponding software and human resources for their smooth use. Furthermore, JZ developed and patented new technologies in the process. By licensing the patents, JZ gained a new source of revenue. In addition, JZ's efforts are exemplary, and JZ can gain new customers and revenue streams by helping other companies develop customized transformation solutions based on Industry 4.0.

Appendix F

Xinjiang Uygur Pharmaceutical

UP was founded in 2001 and is located in Urumqi, with Uyghur medicine as the core species, manufacturing including granules, capsules, tablets, syrups, etc.

UP's intelligent transformation mainly focused on the integration of ERP, LIMS, and MES systems and the study of extraction automation control technology. MES enhanced the digitalization and automation of the manufacturing process. The extraction automation control technology-enabled centralized monitoring and remote intervention on the manufacturing site through a human-machine interface. UP's intelligent transformation could provide a reference for other companies manufacturing Uyghur medicines (MIIT, 2020; WTEPIM, 2020b).

During the transformation process, a total of seven equipment and software companies were involved in the design of the solution and the manufacturing of the customized equipment (MIIT, 2020; WTEPIM, 2020b).

As shown above, the transformation of UP covered the two main stages from R&D to manufacturing and realized the synergy of MES at the department level with LIMS and ERP systems at the operations management level.

UP increased its own data management capabilities through intelligent transformation, enabling it to support management decisions. Additionally, the intelligent transformation enabled the networking and informatization of laboratories, reduced losses due to human factors, improved the quality of drugs (failure rate reduced from 4% to 2%), productivity (3x), reduced operating costs (more than 21%), and improved energy efficiency (13%) (MIIT, 2020; WTEPIM, 2020b).

In the process, UP has made new investments, introduced new equipment, and equipped them with corresponding software and human resources for their smooth use. Through data sharing, UP has achieved synergy with the downstream chain in terms of data tracing. In addition, the efforts made by UP are exemplary, and UP can gain new customers and revenue streams by helping other companies to develop customized transformation solutions based on

Industry 4.0.

Appendix G

North China Pharmaceutical

NCP is located in Shijiazhuang and its products cover 16 fields and 235 varieties of specifications. The dosage forms mainly cover tablets, hard capsules, soft capsules, oral solutions, granules, powder injections, powder lyophilization, small volume injections, and eye drops.

NCP established the existing operating model of the platform layer (big data analysis) - software layer (MES, WMS, etc.) - equipment layer (field equipment). In the manufacturing segment, NCP firstly laid out the data communication interface and introduced more intelligent equipment and PAT support equipment. In addition, NCP also laid out the monitoring and energy-saving system for manufacturing support systems. At the quality control stage, NCP introduced an automatic light inspection system based on image recognition. Moreover, NCP established a WMS to manage the stereo warehouse. The intelligent transformation of NCP could be a reference for other manufacturers of preparations (MIIT, 2020; WTEPIM, 2020a).

During the transformation process, NCP worked primarily with Equipment Companies. NCP worked with Beijing Materials Handling Research Institute Co., Ltd. to build a stereo warehouse and warehouse management software system. In addition, NCP partnered with Hebei Boxline Intelligent Equipment Technology Co., Ltd. to build an automated conveyor line for the shop floor (MIIT, 2020; WTEPIM, 2020a).

As mentioned above, NCP's transformation in the face of Industry 4.0 was mainly concentrated in the field of preparation manufacturing, covering the manufacturing segment and focusing on the control level and below. However, in terms of quality control, the implementation of LIMS reached the department level.

NCP reduced the quality risk due to human factors through intelligent transformation, improved productivity by 116%, reduced the labor cost by 50%, reduced the power cost by 50%, and reduced the total cost by more than 20% (MIIT, 2020; WTEPIM, 2020a).

In the process, NCP made new investments, introduced new equipment, and equipped corresponding software and human resources for their smooth application. Through data sharing, NCP has achieved synergy with the downstream chain in quality data tracking. In addition, the efforts made by NCP are exemplary and NCP can gain new customers and revenue streams by helping other companies to develop customized transformation plans based on Industry 4.0.

Appendix H

Hunan Kelun Pharmaceutical

KL belongs to Sichuan Kelun Pharmaceutical Group and was established in 2001. KL mainly developed, manufactured, and marketed 12 kinds of preparations including injections.

In the process of applying MES, KL realized the integration of the upper ERP management system and the lower execution control system and integrated the application of LIMS to realize the informationization and intelligence of the whole chain covering R&D, manufacturing, quality control, and logistics. The main transformation in the manufacturing segment applied technologies such as IoT, robots, intelligent vision sensing systems, and big data analysis. Among them, the application of computer vision technology became the highlight of the intelligent transformation process. Based on this technology, the intelligent light inspection machine utilizing image processing, analysis, and identification technology achieved automated and high-precision inspection requirements. In the process of intelligent transformation, KL acquired five software intellectual property rights and marketed these results to other branches of the Kelun Group. Moreover, KL's intelligent transformation could serve as a model for other manufacturers of formulations. By guiding these companies, KL also gained a new revenue stream (MIIT, 2020; WTEPIM, 2020a).

During the transformation process, Shinva Medical Instrument Co., Ltd., Chengdu Hongrui Technology Co., Ltd., and Beijing Neotrident Technology Ltd. helped Kelun realize the application of MES in the injection industry by completing The deployment of an intelligent light inspection machine, customized automatic packaging, etc. and the application of intelligent vision technology, information management system and other technologies (MIIT, 2020; WTEPIM, 2020a).

As described above, the transformation at KL covered two major segments, from R&D to manufacturing, and enabled department-level MES to collaborate with LIMS and company-level ERP systems. IoT, robots, big data, and computer vision technologies were applied in the transformation process.

Through intelligent transformation, KL improved product quality control (33% reduction in defective products), productivity (30%), and overall energy efficiency (10%), lowered operating costs (21.3%) and manufacturing period (20%) (MIIT, 2020; WTEPIM, 2020a).

In the process, KL has made new investments, introduced new equipment, and equipped them with the corresponding software and human resources for their successful operations. Moreover, KL developed and patented new technologies in the process. By licensing the patents, KL gained a new source of revenue. Additionally, KL 's efforts are exemplary, and KL can gain new customers and revenue streams by helping other companies develop customized transformation plans based on Industry 4.0.

Appendix I

Northeast Pharmaceutical Group

NEP was founded in 1946 and is located in Shenyang. Its products cover 10 therapeutic areas and more than 400 types of APIs. Besides, the application of Industry 4.0 in Northeast Pharmaceutical Group focuses on the manufacturing of APIs.

Based on the development concept of compliance and safety, NEP established the MES, intelligent logistics, and warehousing system based on intelligent sensing and automation control equipment through the interconnection of multiple heterogeneous systems. In addition, it established a big data platform to optimize warehouse and logistics design and reduce inventory costs. Through the above efforts, NEP established a manufacturing scheduling command center responsible for integrated supervision. The automation base platform, three-dimensional supervision platform for safety and environmental protection, and flexible manufacturing execution management platform to achieve a real record of information, integration, and interconnection with ERP system. Furthermore, in the process, NEP developed industrial software with independent intellectual property rights, providing a complete set of solutions to data integrity in the pharmaceutical industry. Other pharmaceutical companies could obtain a license for this software to improve their information management (MIIT, 2020).

Furthermore, NEP formed a consortium to create the intelligent factory and developed industrial software with full intellectual property based on the consortium. In addition to NEP, this consortium includes two main types of partners (MIIT, 2020):

(1) Equipment Companies: Zhejiang Supcon Technology Co., Ltd., Shenyang Northeast Pharmaceutical Design Co., Ltd., SIASUN Robot & Automation Co., Ltd.
(2) Software Organization: Zhejiang Supcon Technology Co., Ltd., Shanghai Jiao Tong University.

Above all, NEP's transformation in the face of Industry 4.0 is mainly focused on API manufacturing, covering manufacturing and subsequent warehousing. These transformations focused on the department level and below, and eventually achieved data interoperability with the operations management level.

Based on the views from Huang (2021), NEP improved productivity by 10%, reduced the number of production operators by 40%, improved risk control in the production process, eliminated information silos, and improved the outcomes of management decisions through intelligent transformation.

In the process, NEP has made new investments, introduced new equipment, and equipped them with the corresponding software and human resources for their successful operations. Through data sharing, NCP has achieved synergy with the downstream chain in manufacturing data tracking. Moreover, NEP patented new technologies in the process. By licensing the patents, NEP gained a new revenue stream. Additionally, NEP 's efforts are exemplary, and NEP can gain new customers and revenue streams by helping other companies develop customized transformation plans based on Industry 4.0.

Appendix J

Jinyu Bio-technology

JY was founded in 1958 and is located in Hohhot, with its main product being vaccine.

JY introduced automatic feeding and unloading system for freeze-drying of biological products and an automatic detection system for cytopathic effect, which reduced the risk introduced by humans and improved the level of quality control during the manufacturing process, continuity of manufacturing process, the accuracy of operation, and safety of manufacturing workers. Furthermore, JY implemented ERP, MES, LIMS, and LES (Laboratory Execution System) for each department based on IoT, mobile internet, and RFID. On the basis of LIMS and LES, JY has established a cloud platform and a big data analysis platform for manufacturing, quality, and supply chain management. JY's intelligent transformation integrated its own software and hardware systems to build a new model of intelligent manufacturing at a lower cost, which could serve as a reference for other biologics manufacturers (MIIT, 2020).

Yonyou Network Technology Co., Ltd. was the system integrator and software developer in the transformation process. Truking Technology Limited and Shinva Medical Instrument Co., Ltd. were the core equipment providers. The Fourth Construction Co., Ltd. of China Electronics System Engineering was responsible for the implementation of the intelligent factory decontamination system and biosafety system (MIIT, 2020).

Overall, JY's transformation mainly covered manufacturing and quality control and achieved the integration of department level MES, LIMS, LES, and the operations management level ERP systems. These transformations are based on a cloud platform, IoT, mobile internet, big data, RFID, and other technologies.

JY improved the quality control of its products through intelligent transformation, which also reduced the quality risks caused by human factors while safeguarding the production safety of employees, improved productivity, and enhanced management efficiency (MIIT, 2020).

In the process, JY has made new investments, introduced new equipment, and equipped corresponding software and human resources for the satisfactory utilization of the equipment. Through data sharing, JY has achieved synergy with the downstream chain in data tracking. Besides, the efforts made by JY are exemplary and JY can gain new customers and revenue sources by helping other companies to develop customized transformation plans based on Industry 4.0.