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Revolutionizing Pharmaceutical Cold Chain Competency Framework with Reference Process Model and Reference Architecture

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Abstract

The utilization of the reference process model (RPM) and reference architecture (RA) as disruptive information and communication technologies (ICT) in the pharmaceutical cold chain (PCC) industry has enabled the management of tasks through a model-architecture-based approach. This research presents an innovative method for competency development in the cold chain sector, leveraging RPM and RA. By introducing a comprehensive conceptual framework encompassing RPM and RA design and workflow into cold chain competency development, this study outlines the key areas for incorporating RPM and RA into the PCC field. The framework elucidates the functioning of RPM and RA concerning occupational standards (OS) and units of competencies (UOC) within the industry. The study generates a research framework for the PCC industry by systematically implementing RPM and RA using a proposed method. The primary outcomes and empirical evidence are UOC and OS derived from RPM and RA implementation and integration, substantiating the conceptual framework's validity. The research highlights the evolutionary aspects and the significance of the conceptual framework in guiding the research framework and proposes a method for competency development. Furthermore, recommendations are provided for future research endeavors.

Keywords: Pharmaceutical Cold Chain (PCC); Reference Process Model (RPM); Reference Architecture (RA); Research Framework.

1. Introduction

A pharmaceutical cold chain (PCC) is a continually temperature-controlled supply chain. A PCC aims to retain a product's quality and integrity by keeping it within an ideal low-temperature range during its entire life. In order to increase shelf life and ensure items are fresh and safe to use, the cold chain must be closely monitored. The PCC comprises several procedures, disciplines, and processes and has been increasingly used to coordinate competencies in the disruptive Internet of Things (IoT) [1]. The technologies work with monitoring solutions to ensure that items are not damaged due to temperature excursions out of optimal ranges. In addition, the PCC industry's increasing complexity and scale necessitate integrating work processes and interfaces of diverse activities to handle frequent strategy changes. The difficult task of real-time monitoring and information handling in cold chain management necessitates continuous decision-making to update plans with continually renewed competency design [2]. As a result of this circumstance, a variety of information and communication technologies (ICTs) have been brought into the sector to address information management challenges, promote monitoring and real-time tracking, and accomplish advanced practices [3, 4]. It is necessary to prevent wastage of vaccines and pharmaceutical products, and the pharmaceutical industry should consider the importance of cold chains.

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In this study, we address the ongoing need to complete the cold chain due to a shortage of cold chain professionals. Consequently, it becomes crucial for professionals to develop competencies tailored to specific job roles within the cold chain. We advocate for developing a competency framework to effectively evaluate, maintain, and track employee knowledge, abilities, and qualities. This framework enables assessing existing competency levels among staff, ensuring they possess the necessary knowledge to enhance organizational performance. The existing techniques for competency standards development encompass the development of a curriculum method (DACUM), Functional Analysis (FA), work process analysis, and job analysis [5-8]. These methodologies involve defining competency requirements and utilizing structured questions early to achieve expert consensus. Thus, creating a competency framework is essential for continually improving job roles within the cold chain industry [9].

Our research highlights the lack of focus on the cold chain instead of the supply chain in developing occupational standards (OS) [10]. This contributes to the incomplete state of the cold chain and underscores the critical need for proficient cold chain professionals [11]. We propose establishing a more comprehensive and modern competency framework to address these challenges. However, implementing existing frameworks often requires subject matter experts' involvement. For instance, FA aims to identify specific and detailed content for each component of the competence model, drawing from workers' experiences in their respective positions. Nonetheless, challenges arise when future professionals, such as pharmaceutical cold chain professionals, are limited or nonexistent. Therefore, subject matter experts are vital when using conventional methods for competency development. Moreover, these processes can be time-consuming during the development phase.

Given these limitations, we present a novel approach to competency development in the cold chain sector, particularly without subject matter experts [12, 13]. Our conceptual framework introduces a new method for developing competencies, leveraging the Reference Process Model (RPM) and reference architecture (RA) developed in Latha & Samanchuen [9]. We offer a detailed depiction of the cold chain structure through RPM, utilizing object-oriented business process modeling. Simultaneously, RA provides comprehensive information on the digitalized pharma cold chain, employing the Open Group Architecture Framework (TOGAF). The current supply chain competencies may only cover the basics and need specific cold chain procedures or professional positions. As such, the purpose of this study is to propose a conceptual framework that underlies cold chain competence design, drawing upon RPM and RA to foster a more robust and efficient industry.

Packing products information and data [14, 15] integrating cold chain process and information [16, 17] creating a collaborative environment [18, 19] adopting disruptive technology and sustainable packing [20-23]. However, significant obstacles remain in the industry's current adoption of RPM and RA. Integrating application and technology into the managerial processes and procedures of cold chain projects is one of the plans to develop RA implementation into cold chain management practice. Furthermore, the continued deployment of RA necessitates a collaborative approach to fully leverage enterprise architecture's potential. The competency design of cold chain also involves a method that can relate RPM and RA to the entire project process. Besides, regulations and accreditation are still unclear for controlling the cold chain.

This work proposes a conceptual framework for creating competence designs based on RPM and RA. The study aims to demonstrate the new methodology for developing competencies to validate the competency standards. The study focuses on the PCC to develop competency standards for professionals, usually called occupational standards [10, 24]. A conceptual framework that combines cold chain competence and practice can help organize knowledge about the cold chain while guiding the development of competence in the discipline [25, 26].

This study outlines the formulation of conceptual and research frameworks. The foundational literature review is presented in Section 2. Section 3 details the research methodology employed to construct and validate the conceptual framework. Ethnographic action research was conducted, incorporating a validation survey involving professionals from various sectors, including supply chain, logistics, pharmaceuticals, and the cold chain [27, 28]. The outcomes of the conceptual and research frameworks are presented in Section 4. The ensuing sections, Sections 5 and 6, delve into the discussion and conclusion, respectively.

2. Literature Review

Given the fragmented nature of the cold chain business [29, 30], ICT-enabled information management can help to transform traditional practices and improve performance and competitiveness [31]. With the organization of perishable items as a process, the use of ICTs in transportation and storage is inextricably linked to cold chain management techniques, and the use of ICTs to manage information is linked to various parts of the cold chain process. As a result, to maximize the competency framework in cold chain management, an integrated strategy is required [13, 32]. Furthermore, a few studies, such as [25, 33] propose frameworks to examine and enhance cooperation in cold chain projects. In this research sector, competence design is frequently employed in the cold chain.

2.1. Cold Chain Environment

The regulatory structure produced by cold chain-related standards, requirements, and norms to assure RPM and RA implementation within the industry is called the institutional environment, as shown in Table 1. The institutional environment is defined by developing rules and requirements that individual organizations must follow to acquire support and accrediting rightfulness [29, 33]. Regulatory governance, standardization of the body of knowledge and process norms, and establishment of organizational cultures and standards are all examples of institutional activities in the supply chain [30]. The institutional environment acts as a context for competency design adoption in the cold chain business. Cold chain governance also refers to competency models and modeling-related activities for systematically and successfully implementing occupational standards into the cold chain [31]. A green cold chain-based project requires an institutional context to enable cold chain management and assure collaboration among specialists. Several studies have explored the requirements of necessary regulation for cold chain-related industry operations and procedures. Singh et al. [33] used the phrase "cold chain policy" to define the freezing temperatures in which some products must be stored and distributed. Maintaining the cold chain ensures that vaccines are transported and stored according to the manufacturer's recommended temperature range of +2˚C to +8˚C until the point of administration. Moreover, the literature on competency model implementation encompasses standardizations, technical requirements, and organizational requirements and validates these points in their cold chain accreditation. The cold chain institutional environment material is presented in Table 1, along with comprehensive examples.

Table 1. Information of the cold chain institutional environment standards

Contents of Cold Chain Standards	
Contents	**Detailed Examples**
Occupational standards and technical requirements	Industry standards, cold chain accreditation, refrigeration standards, quality, and data specification
Key regulations and requirements	Roles and responsibilities, hierarchy, and work process
Cold chain policy and procedure	Standard legal document, warehouse administration, contractual agreement

2.2. Existing Competency Frameworks

The Cold Chain Association [34] claims that experts offer networking opportunities, thought leadership, and potential answers to challenging business issues. Their goal is to encourage and support vertical and horizontal collaboration, knowledge sharing, and innovation among members and stakeholders to decrease waste and enhance the quality, efficiency, and value of the temperature-sensitive supply chain. They actively participate in educational programs that help the development of competencies to improve cold chain operations and support accomplishing their professional objectives. The Global Cold Chain Alliance Association has released a formal declaration on the critical significance of maintaining cold chain competency for the quality of product outcomes, similar to many other cold chain associations worldwide [35]. A multinational organization that represents all significant industries involved in temperature-controlled warehousing, logistics, and transportation is called the Global Cold Chain Alliance (GCCA) [36]. To be innovative leaders in the global movement of perishable goods, GCCA unifies all partners. Delphi research was carried out to define lifelong learning from a cold chain viewpoint. According to their findings, lifelong learning is a dynamic process affecting personal and professional life.

Being able to transform knowledge into the capacity to provide high-quality cold chain service and maintaining the capacity for lifelong learning depends on keeping the mind engaged. Professionals in the cold chain have also mentioned how important transit, keep-in-process, and shipping processes are. The cold chain occupational standards created a set of occupational skills for cold chain professionals [10, 24]. According to the findings, specialists believe cold chains are crucial to the quality and safety of perishable goods. Additionally, they view the availability of continuing education opportunities as a sign of respect for the cold chain, which supports their motivation and retention.

Nevertheless, when professionals feel obligated to participate in educational activities occasionally in the future, the digital cold chain may be seen more favorably. It was discovered that cold chain professionals' attitudes towards digital pharma activities are influenced by how useful they believe these activities are for their practice and careers, how interested and challenging they find them to be, and how much value their peers and managers place on them. A crucial element of cold chain engagement in the pharmaceutical process is the combination of digital transformation and the cold chain process [35]. While management support is unquestionably beneficial, another deciding aspect is the specialists' level of qualification. A national nursing skills framework was also created for the transportation operation to guide cold chain practice and continue education programs. Currently, the work quality development techniques are FA, work process analysis, and DACUM [27, 28].

2.3. Impact and Benefits of Competence Design for Cold Chain

The work process is viewed as a disruptive technology in constructing IoTs, changing the cold chain [37, 38]. The main goal of competence design is to provide occupational standards to efficient cold chain experts and to improve the cold chain environment with accurate data, tracking, and workflow analysis [9, 39]. Competence design can provide accreditation to rebuild the cold chain environment in addition to cold chain information management [40, 41]. It also concluded that competency design enabled professional teams to manage large amounts of data and information, allowing them to make better decisions in the operations and working process. Ultimately, National Skills Qualifications Framework (NSDC), [24] demonstrated how competence design may be used to foster an integrated cold chain process through cooperative labor [42].

Table 2. Comparison between FA, Work Process Analysis, and DACUM

Components	FA	Work process analysis	DACUM
Uses by	• Training Center, Industries	• Training Center, Industries	• Vocational College, Universities, Training Centers, Industries
Participants	• Researchers, Subject Matter Experts, and experts (the number of people depends on the sector of occupation	• Researchers, Subject Matter Experts, and experts (the number of people depends on the sector of occupation	• DACUM facilitator, and Subject Matter experts (5 to 12 people)
Output	• Competency Focused • Limited Scope	• Level of occupations • Limited Scope	• Duties and Tasks • Limited Scope
Overall process	• Direct observation of the participants • Interviews, and Questionnaires	• Collect Data, create a Process Map, Analyze the Process, • Interviews, workshops, observation studies	• Focus Group Discussion
Time used	• Time-Consuming • No specific time (depend on sector of occupation)	• Time-Consuming • No specific time (depend on sector of occupation)	• Time-Consuming
Advantages	• Comprehensive Analysis, • Can use for all occupation	• Use for shop floor work • Greater Employee Satisfaction	• Comprehensive Analysis, • Can use for all occupation
Disadvantages	• Costly • Limited to Scope • Resistance to Change	• Costly • Limited Applicability • Resistance to Change	• Costly • Requires Skilled Facilitator • Limited Scope
Location of development Process	• Discussion room / workshop. Must have unlimited access to the workshop	• Discussion room / workshop. Must have unlimited access to the workshop	• Implemented in a discussion room, and not necessary to come to the workplace

* Adopt from [43].

Based on Table 2, both curriculum development processes differ in process, time, and results obtained. The following will be compared to the user, participants, output, process, time used, and achievements. From the description and comparison of the above, it can be concluded that the DACUM process is suitable for developing tasks and duties according to the needs of task analysis and curriculum development of vocational education. In addition, FA and work process analysis are appropriate for developing work standards, especially at the workshop level.

2.4. RPM and RA Implementation in Competence Design

This research presents a new approach based on the RPM and RA integration into competency design, which has challenges but is improving future job skills developments. The most common challenges to implementing RA in competence design are the lack of applications, lack of real-time tracking, lack of capturing essential data during transit, resistance to change, poor technical management, and inadequate systematic support [22, 44]. Meanwhile, a few studies have focused on the benefits of using process-oriented design. Johnson et al. [45] proposed a cold chain framework for methodically executing blockchain technology. Chircu & Kern [18] demonstrate a managerial approach that underlined the importance of digital transformation by using the enterprise architecture method.

Furthermore, Chen & Yang [46] analyzed the various perspectives on RPM and RA and proposed that cold chain applications be aligned with processes [47]. Interface techniques and tools, such as business modeling, web services, tracking, and web packaging, are constantly being introduced and adopted in the cold chain to improve practical cooperation toward an integrated information management approach [48, 49]. Integrating RPM and RA into competency design is a methodical effort. Only a few studies have attempted to define the extent of work required to systematically implement the work process in the cold chain industry, particularly from the perspective of transportation and storage [50].

Current competency standards development techniques are DACUM, Work Process Analysis, and FA. According to the literature review, it was realized that these current methods are limited in scope, applicability, and resistance to

change. The main disadvantages of these methods are that they are time-consuming and expensive, especially if subject matter experts have to go to a central location for analysis or bring in outside consultants or experts to conduct the analysis. This research introduced a new approach to developing competency standards based on RPM and RA to overcome the lack of subject matter experts, cost, and time-consuming issues. If using this RPM and RA approach for developing competencies, some initial job/occupational analysis steps can be avoided compared to other current methods. If a detailed work process chart, sub-process, and job roles can be provided through an RPM and RA design, it can develop competencies with the help of subject experts. As a result, this approach can be more helpful if we face a shortage of subject matter experts in a specific field. Therefore, this study proposes a conceptual framework underlying the cold chain competence design based on RPM and RA

3. Research Methodology

This section describes the research methodology, which is shown in Figure 1. The figure illustrates the sequential process of the research undertaken. It comprises several essential stages that collectively lead to formulating research problems, developing a conceptual framework for competence development, and establishing a research framework. The first phase involves an in-depth review of existing literature, which is the foundational step in shaping the research direction. Subsequently, a field survey is conducted, allowing for data collection and insights directly from the field. This empirical data serves as a valuable input for the subsequent phases. An integral part of the research process is using Ethnographic Action Research, a comprehensive approach that combines observation, participation, and reflection. This method gathers holistic and contextually rich information from supply chain, logistics, pharmaceuticals, and cold chain industry professionals. The feedback and insights obtained from this stage are crucial for refining the research direction. The next step involves integrating the outputs from both the field survey and the Ethnographic Action Research. This data synthesis serves as the foundation for multiple crucial outcomes, including articulating research problems, developing a conceptual framework focused on competence development, and establishing a comprehensive research framework.

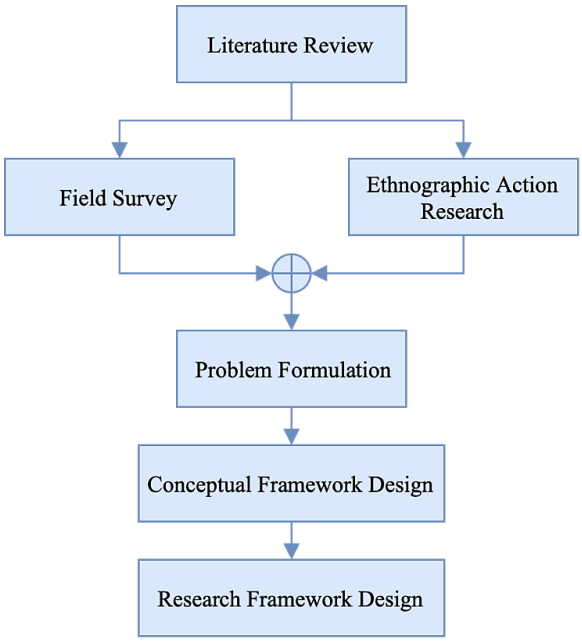

Figure 1. Research process for developing the conceptual and research frameworks

3.1. Field Survey

We conducted the field study in August 2020 at the pharmacy warehouse under the Faculty of Medicine in Siriraj Hospital, Mahidol University, Thailand, to gain practical knowledge in the field of cold chain. Additionally, to monitor how the system works in the cold chain process. As a result, this field study was helpful throughout our research when understanding the existing practices used in the hospital warehouse. Generally, the hospital warehouse keeps the pharma products following the cold chain standards at between 2 to 8 degrees Celsius, and the mentioned system is followed in the hospital. The research topics include the packing process, loading process, unloading process, unpacking process, keeping in the storage process, and inspection process, as shown in Figure 2, divided into subparts a to f. Accordingly, Figure 2-a shows the pack system in the cold chain. Thermocol insulation for cold storage is the most cost-effective and durable core material. Temperature-controlled shipping containers transport temperature-sensitive medical products from one location to another. These containers have insulation and temperature-control systems to maintain a consistent, low temperature during transportation. It has much lower water absorption over time and retains its insulating properties

better over the years [51]. Figure 2-b shows that the indicator is attached to the primary packaging. The indicator has an intuitive display that helps to display quality information briefly. The cold chain completes the process as it is attached to the secondary-level packaging. Figure 2-c shows that the unpacking process, when unpacked, should be immediately moved into storage, which can be either a standard capable of maintaining temperatures ranging from or a medical-grade refrigerator maintaining +2˚C to +8˚C. Figure 2-d shows that keep-in-storage describes cold chain equipment in hospital warehouses, typically including refrigerators, freezers, and temperature-controlled containers. These storage devices are designed to maintain a consistent, low temperature to protect the quality and effectiveness of temperature-sensitive medical products [52].

Figure 2-e shows the existing cold chain system in the hospital warehouse, which includes automated temperature monitoring and alarm systems that can continuously monitor vaccine refrigerator(s) temperatures in real time. An alarm system is a computer-based control system that alerts nominated clinical staff or the vaccine coordinator when a temperature deviation outside the recommended +2°C to +8°C temperature range occurs in a vaccine refrigerator [53]. Figure 2-f shows the hospital warehouse clinical and pharma specialty products. The hospital pharmaceutical warehouse facilities are fully licensed and accredited, maintaining cold chain good manufacturing standards and pharmacy licensing, providing compliant cold chain storage for finished and pharmaceutical products. Most critical to operational success, our dedicated and experienced team stands behind our cold chain logistics service offerings to ensure the utmost product quality and maximum customer satisfaction through supply chain management.

(a) Packing process

(b) Packing process

(c) Unpacking process

(d) Keeping in storage

(e) Cold chain controller system

(f) Keeping products in the warehouse

Figure 2. Field study at hospital warehouse

The goal of fieldwork was to gather relevant practical information in terms of cold chain outside of a research lab, reading room, or working environment setting through questionnaire sessions and inspections in which field notes were

documented, which are an essential part of the ethnographic document. Field study is constructing and recognizing an organization's cultural identity and behaviors. Field notes are created when an investigator engages in regional events and activities and makes findings. Accordingly, our field study collected real-time information about the pharmaceutical cold chain process. Also, we realized that the cold chain process still needs to be completed in another way at the unpacking and transfer stages. If the process encounters any lack of temperature at the stage of transfer and storage, the possibility of reducing the validity of the product is slightly higher.

Consequently, the study concluded that cold chain professionals are essential for this pharmaceutical sector. If trained professionals with knowledge of cold chain standards and information. Better results than the existing cold chain system. As a result, the study concluded that this pharmaceutical sector still needs cold chain professionals in the future.

3.2. Ethnographic Action Research

The competency management system is developed using this study's ethnographic action research approach [54, 55]. This method entails a thorough literature evaluation to determine the extent and concepts of the conceptual framework, detailed action research in system development, and ethnographic analysis to get a broad picture. As a result, this is qualitative research, as qualitative research is best suited to process analysis and context specification [56]. The ethnographic approach was employed in research competency as part of the qualitative research method to create theories and inductively collect evidence through observation and discussion with experts [57].

Action research allows for discovering new knowledge and propels the cold chain sector forward. According to Mugharbel & Al Wakeel [58], action research aims to handle practical concerns from a theoretical perspective and construct a situation, assessing the pragmatic problem from different perspectives through observation and interference by the researchers. Action research can be used to address practical difficulties and build theories in the field of cold chain management research. Although it is desirable to have two concurrent projects to compare the study's results, this is a rare occurrence. As a result, the ethnographic action research method was chosen since it uses the Delphi approach to immerse participants in the actual situation and create study results [59, 60].

Establishing competence design and occupational standards based on RPM and RA is a primary focus of this research. The research design adheres to [18, 25] to build an ethnographic action research cycle. The research cycle can be shown in Figure 3, which includes four steps as follows.

1. Conduct a literature review of relevant practical and academic background and plan the implementation of RPM and RA approaches to developing occupational standards by the objectives and needs of cold chain management.
2. Code of the primary focal areas and job routines to establish a research framework based on traditional occupational standards development.
3. Integrate the RPM and RA design into the competency development framework and identify key areas for further investigation or improvement based on observations and reflections.
4. With the existing literature review, restart the research cycle.

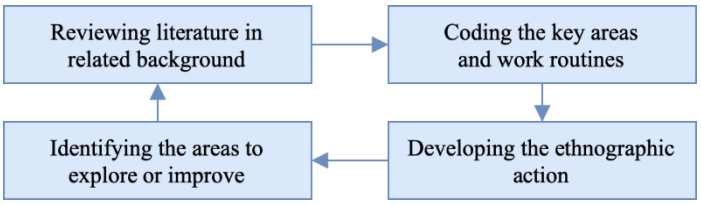

Figure 3. The ethnographic action research cycle for the current study adopts from Ma et al. [54]

The procedures above have helped to construct the conceptual framework. We iterated the study cycle by researching relevant papers to gain renewed perspectives, examining data from the competency development project, and connecting the concepts with the decoded focused areas. As a result, the processes were intertwined and impacted one another. This article offers the conceptual framework before formulating the RPM and RA design to preserve a straightforward logical flow in this study. The conceptual framework establishes the work area for competency-related concerns by implementing the research framework.

The conceptual framework has been developed through the above steps. We repeated the research cycle by reviewing related studies to gain new insights, analyzing evidence from field studies, and identifying concepts with focus areas. As a result, the procedures became highly interdependent and influenced each other. This paper presents the conceptual framework before developing work criteria for cold chain system development to maintain a simple logical flow in this study. The conceptual framework defines the scope of work to develop issues related to labor standards by implementing RPM and RA. Furthermore, the process provides implications and additional evidence.

4. Research Finding

The field survey and ethnographic action research have revealed several critical concerns about formulating occupational standards. Challenges have arisen in establishing cold chain standards and ensuring compliance with complex cold chain processes. To solve this problem, we found that developing an RPM design would be helpful in the future. It can provide a detailed description of the existing cold chain process. Accordingly, subject matter expertise can develop relevant competencies for professionals. Second, there is a specific investigation into the effective use of related data and information in cold chain logistics. It covers aspects like packaging, transporting, loading and unloading, scheduling, and quality control, all of which are demand information management. The study is facing a lack of technologies in the cold chain sector. This problem can be overcome by integrating RA design into the research framework. The RA will describe existing technologies that help provide accurate data of real-time monitoring of temperature parameters and related environmental information.

Additionally, digital transformation is a must in today's world. Finally, a key concern surrounds the integration of cold chain professionals and processes within the framework of occupational standards. This research framework aims to provide a formal definition for developing competence design for the cold chain, which can be linked to current knowledge in future research. RPM and RA are integrated into competency design and contribute to achieving this goal. In conclusion, the cold chain industry can use these findings to set the basis for work analysis and draw broad conclusions for future competency development.

4.1. Conceptual Framework for OS Development

The modeling method generally takes knowledge as input and produces a functional application of competency design as output. The substance of competency design is based on several studies. Wang, S., Tao, F., & Shi, Y presented a process of occupational standards to correlate the cold chain process with the requirements of different phases, such as transportation of referring to models, goods, and activities to manage the cold chain process in the target [35, 50]. A functional analysis method and a focus group were used to demonstrate traditional competence development [6, 8] with the abundance of detailed industry information, describing how the traditional competency design concept in the industries has changed.

Cold chain occupational standards based on competency design are a framework information system enabled by information technologies to support the cold chain labor process and associate RA with cold chain management practices. Occupational standards for the cold chain should be allowed to continue to serve their purpose in promoting cold chain competence design. Cold chain work process, reference architecture [18, 40], and cold chain network technology have all been used to build competence design-based occupational standards [28]. Incorporating innovative techniques for competency design, critical for cold chain logistics, is made possible by coupling RPM with RA. Implementing competency design interface schemes, on the other hand, raises technological, administrative, and accreditation concerns [14].

The RPM reflects a thorough process of sequential cold chain advancements via several phases and disciplines in the competence design process. As a project progresses, the global supply chain model becomes increasingly complex. A cold chain model, for example, can be created by incorporating IoT-related application and technology data into a design cold chain model. The RPM allows the cold chain process to be shared among different job responsibilities at various phases, resulting in more integrated information and data management. Work process modeling information and data can be information and data in various formats that can be processed with cold chain or simply a specific product cold chain model that encompasses the information and data of a cold chain discipline or a part of a perishable product, such as an operational model or a foundation model, in this study. The cold chain process and RA are linked via the information flow, which connects the data and information clusters. The competence design of the interaction between CC accreditation and occupational standards is built around this concept. As a source of cold chain process knowledge and data, the competence design organizes information flow across the pack to inspect the process [39]. The competency model encourages CC in the workplace; however, the CC process necessitates accreditation with specific product features and information [61, 62]. The cold chain implementation competency design should also meet the individual requirements of each cold chain and present a process for developing cold chain OS [63, 64]. The conceptual framework presents three concepts to accommodate occupational norms in the cold chain: RPM, RA, and the development of competence design.

The conceptual framework introduces three key concepts to incorporate occupational standards within the context of the cold chain: RPM, RA, and UOC Development, as illustrated in Figure 4. The initial step involves the simultaneous development of the RPM and RA. These developments provide essential foundational information. Subsequently, this acquired information is utilized to construct the UOCs. In the final phase, these UOCs are systematically grouped to formulate job roles that serve the requirements of the cold chain industry. Table 3 highlights the main objectives and meanings of the key concepts in the conceptual framework.

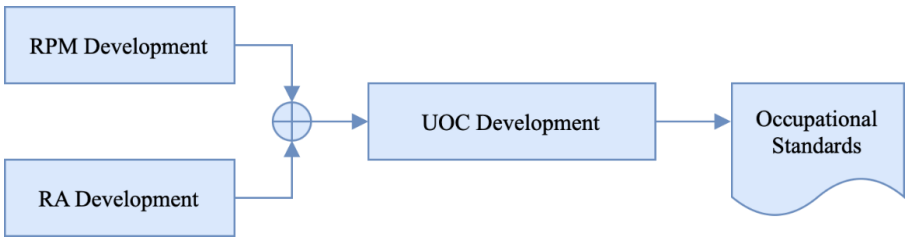

Figure 4. Conceptual framework for OS Development

Table 3. Summary of the conceptual framework

Concept summary of the conceptual framework		
Key concepts	**Major elements**	**Main purposes**
Reference Process Model	Cold chain process, Job role, Information, Data	Describing RPM model throughout the cold chain process
Reference Architecture	Technology, Applications, Data, Business	Incorporating RA into the information system
Competence design	Occupational standards, Elements of competencies, Performance criteria	Developing occupational standards for cold chain professionals

4.2. Research Framework for OS Development

The conceptual framework serves as a foundation for extending the research framework. This expanded framework integrates the details of each component by incorporating a critical evaluation process. Consequently, the final research framework is illustrated in Figure 5. Elements can be identified within this research framework: The research work starts with a literature review, field study, and TOGAF. From this study, we realized that cold chain needs more attention regarding professionals and services. Accordingly, we introduced a new approach combining RPM and RA design to develop occupational standards for PCC. RPM and RA design can describe the cold chain process and related information based on applications and technologies. After that, we will use the functional analysis method to develop the UOC with the help of subject matter expertise. In addition to RPM and RA design, which will share a common subprocess structure, while the development processes of RPM, RA, UOC, and OS show variations, the evaluation processes based on applying the Delphi technique remain consistent throughout the research.

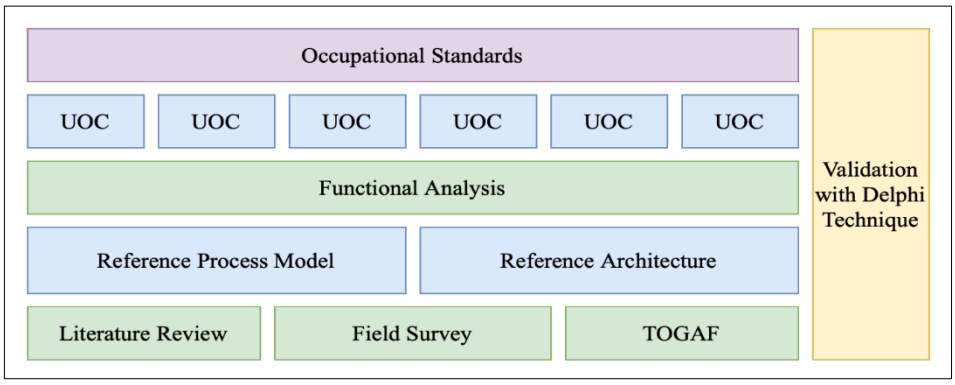

Figure 5. Research framework for OS Development

The initial model's RPM came from the object-oriented business modeling process, which offered the basic cold chain process information, such as transportation and storage information. After the action, researchers built a basic RPM with the experts, and the model was extended with process knowledge from several disciplines to enable job roles. As a result, the cold chain's RPM functioned as the first cold chain logistics model. The labor method became increasingly intricate as the research advanced, allowing technical applications of cold chains to achieve research objectives. As shown in Figure 5, the evolution of competence design at various phases forms a chain that runs through the RPM and RA. The image depicts the research processes in several phases, from left to right. Information Flow is represented by the arrow. The cold chain's alternations are identified throughout the research as a model chain. The framework was ensured by incorporating research workflows into the qualitative design and introducing technical standards and organizational rules. Another requirement from the research was for the RPM and RA-based teamwork to be integrated and interfaced, which became remarkable with the research framework identified.

The main purpose of the research was to develop UOC based on RPM and RA design developed with the help of professionals. According to the field study, we noticed the lack of professionals in the cold chain sector, and we realized

that this will significantly affect the pharmaceutical sector in the coming years. Through the functional analysis method, UOC will be developed in the future. Therefore, if more research is done in the field of cold chain to develop occupational standards, it will be reflected in the future. Accordingly, professionals will develop OS for PCC based on the developing UOC. Finally, UOC and OS will be validated using the Delphi technique.

During ethnographic action research, several supply chain industry specialists encountered administrative, organizational, and technical challenges related to pharma cold chains. Based on action research, this can assess the scope, cost, time, and quality of the work early in future implementation. Existing competency development methods require subject matter experts and a time-consuming process. However, implementing RPM and RA-based approaches will be reliable for future competency development. Finally, RPM and RA implementation was linked to research goals to ensure the development of competency design for cold chain. Therefore, the ethnographic action is very applicable to this work development. As a result, the authors discuss that this approach is well-suited to future skills development alongside existing job roles in PCC. Before completion, the author's main option for using a framework in cold chain management was to create functional applications for cold chain processes. The framework also addressed the need to connect collaborative activities at a later level as an RPM and RA-based competency design.

A research framework can achieve risk management and respond to the change in the research context by adopting a competency design. The conceptual framework was created by a set of competence and related concepts, such as RPM, RA, and cold chain standards. It laid the theoretical groundwork for systematically integrating competency design with cold chain management. Furthermore, an RPM and RA-based competency design were implemented to facilitate communication, integration, and association. The major actions done in the research, as well as the conclusions of the action research and the evidence, were in line with the core principles, as shown in Table 4.

Table 4. Identifying and verifying the research framework for cold chain logistics with the ethnographic action research

Key Concepts	Major Findings	Evidence
RPM Development	Need to manage the work process throughout the cold chain	The major effort on the transport, inspection, and audit process for cold chain
RA Development	Demand for digitalization-based collaboration, in which cold chain can be modified	Introduction of the cold chain platform to enable digitalization
UOC Development	Need to govern the systematic implementation of the cold chain process	Proposed model development and modification for cold chain UOC.
Occupational Standards	Identifying the demand for occupational standards for cold chain professionals	Occupational standards for cold chain accreditation requirement as a response to the change in the cold chain industry

5. Discussion

Even though cold chain management has a wide range of research applications, the best practice of cold chain management, particularly competence design, requires further investigation due to the advent of IoT systems. Our work establishes a conceptual framework for integrating RPM and RA into cold chain management to achieve a competency design-based cold chain approach. The conceptual framework provides a set of associated ideas to incorporate occupational norms into the cold chain. The research workflow links the various components of the competency system. The model Chain is a virtual vehicle that allows the cold chain to operate throughout the investigation. The path in which a competency system can work for cold chain management is known as the research workflow. Cold chain accreditation provides a setting for organizations to implement and utilize a UOC. Thanks to competency-based occupational norms, cold chain applications can collaborate for work linked to information management. However, some aspects of the conceptual framework have been used in previous studies; the concepts synthesize the elements and apply them to workflow, enterprise architecture, risk management, organizational behavior, and information management in the context of cold chain study. As a result, the conceptual framework accommodates all these factors, making it easier to integrate competence design into cold chain management and enabling the process management method.

Meanwhile, it is tough to distinguish between the various aspects of this study, such as framework conceptualization, system development, and system implementation. The conceptual framework is essential for developing the cold chain research framework. Further measures and ongoing improvement are also required to implement the framework to adopt specific research. The methods are iterative and interdependent, and they operate together as a whole to achieve cold chain management.

Furthermore, this research connects competence design to cold chain management, which might help with the comprehension and execution of occupational standards in cold chain initiatives. Competence design is an advanced method for developing skills and knowledge for cold chain staff information in the current study. Information processing against cold chain task uncertainty and risk, according to several classic works on organization design [60, 65, 66], can alter the structure of an organization. Because competence refers to a person's aptitude or talents in each profession, incorporating cold-chain occupational standards into a study necessitates an effort to counteract indiscipline.

Competence design is a transfer between risk management effort and cold chain uncertainty when it is implemented. This is one theoretical result of competence design's application disrupting the cold chain business, and the conceptual framework illustrates how competence design reshapes professionals and their associated organizational structure with occupational standards [67].

There are now three methods for developing occupational standards, including DACUM, Work Process Analysis, and FA. The studies that have been done on the techniques above have shown that they have limitations in terms of their applicability, scope, and resistance to change. This research suggested a method for developing competency standards based on RPM and RA to address the need for subject matter experts, high costs, and lengthy development processes. While creating competencies utilizing this RPM and RA approach, experts should first perform a job analysis. Compared to other current methodologies, several early occupational analysis processes can be skipped when employing the RPM and RA strategy for establishing competencies. These workshops to determine roles and responsibilities can be avoided if a reference model and reference RPM and RA can be used to offer a complete work process model, business function process, and job roles. As a result, if we are experiencing a need for more subject matter specialists in a particular industry, this technique may be more advantageous and helpful.

This study's contribution, however, goes beyond cold chain management to include labor processes and RA adoption and integration. The conceptual framework highlights the key areas for systematically implementing competence design in research. It provides a theoretical foundation for scaling competence design implementation from discipline modeling to integrated collaboration [68]. By incorporating RPM and RA into cold chain procedures and distributions, the implementation of cold chain helps foster collaborative working and boost communication across different disciplines and teams. In addition, the conceptual framework rationalizes competence design adoption from the standpoint of cold chain management. It presents new concepts for understanding and planning cold chain applications and execution in research [69, 70]. All these achievements can motivate effective cold chain management, and only a few studies have detailed the systematic competency model implementation method with a focus on the research's cold chain practice.

Ultimately, this research was carried out as a field and ethnographic action research. Additionally, current works were reviewed to assess the framework's contribution to cold chain research and practice. In addition, we identified the impact of the cold chain process on the RPM and procedural components of the project in the cold chain design setting, represented in our research framework. Furthermore, the importance of the RA design is consistent with digital transformation for the cold chain [44], which emphasizes the importance of digitalization in the cold chain in conjunction with organizational and technical measures for developing the conceptual framework for integrating RPM and RA into cold chain competence design. Furthermore, the research framework technique used in this study reveals that the competence design helps improve the cold chain industry and strengthen the cold chain logistics system, guaranteeing a workforce that is up to the job fit for purpose now and for the future. CC professionals should be encouraged to evaluate their immediate circumstances, resolve problems, and negotiate the middle ground between centralization and decentralization in a manner that increases chances for mission success. Furthermore, there is a mutually reinforcing effect between the competencies, a synergy. A deep understanding of the cold chain process, particularly its relation to technology, matters greatly as professionals help that company through the turbulent flow of the future.

6. Conclusion

According to the proposed method, RPM and RA will be provided practical applications to advance pharmaceutical cold chain practices. Thus, linking RPM and RA to PCC is crucial to developing UOC. Among the various occupations and advantages of the cold chain, managing information, facilitating technology, and developing competencies are necessary for implementing effective cold chain management. Through ethnographic action research and field study, RPM and RA integration into the competence design establishes and tests a conceptual framework. The conceptual framework that underlies the research has theoretical and real implications based on field studies and action research. The research framework analyzes how RPM and RA design work in competency development and discusses a new approach to developing UOC and OS in cold chain practice, introducing the four related concepts: RPM, RA, UOC, and OS. The conceptual framework can also be applied to identify the significant scope of work while developing UOC and OS. Additionally, the research can diagnose problems for cold chain professionals. In implementing the conceptual framework in this research, RPM and RA design integrate the information of different disciplines, further enhancing competence design.

This study examines the integration of RPM and RA into the cold chain with few limitations. First, the research conducted a field study and ethnographic action research, and then problems were formulated. Then, we introduced a new approach to developing the UOC by integrating the RPM and RA design work, which provides detailed information on the operational process of the cold chain at RPM and technical analysis for RA. Second, to overcome the problem by developing a conceptual framework for developing PCC. Third, the specific application of the research framework for integrating RPM and RA into competency design. However, it establishes a new approach to developing capabilities in PCC. Therefore, the authors consider this research as a pilot project for PCC. Finally, this research mainly focuses on

the research framework that introduces a new approach to UOC and OS development and establishes a theoretical foundation for competency design in the future. As this research is conceptual, RPM and RA design implementation from other peer research will generate further developments that advance the exploration of competency development. Future research can also focus on the standards of the pharma cold chain with other aspects of UOC and OS development.

7. Declarations

7.1. Author Contributions

Conceptualization: T.S. and D.S.L.; Data Curation: D.S.L. and T.S.; Formal Analysis: T.S. and D.S.L.; Investigation: T.S.; Methodology: D.S.L. and T.S.; Project administration: D.S.L. and T.S.; Visualization: T.S. and D.S.L.; Writing—original draft: D.S.L.; Writing—review and editing: T.S. All authors have read and agreed to the published version of the manuscript.

7.2. Data Availability Statement

Data sharing is not applicable to this article.

7.3. Funding

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7.5. Institutional Review Board Statement

This study was approved by the MU-CIRB Research Ethics Committee (approval no. MU-CIRB 2020/ 114.0909).

7.6. Informed Consent Statement

Not applicable.

7.7. Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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