

ASTUDYONHANDLINGPHARMACEUTICALINCOLDCHA IN SUPPLY LOGISTICS WITH REFERENCE TOFLYTONXPRESS

Submittedinpartialfulfillmentoftherequirementsfortheawardof

MASTEROFBUSINESS ADMINISTRATION

by

NEETHU.V.R
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SCHOOLOFMANAGEMENTSTUDIES

SATHYABAMA

**INSTITUTE OF SCIENCE AND TECHNOLOGY
(DEEMED TO BE UNIVERSITY)**

**Accredited with Grade "A" by NAAC 12B Status by UGC Approved by AICTE
JEPPIAARNAGAR, RAJIV GANDHI SALAI, CHENNAI-600119**

APRIL 2022



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SCHOOL OF MANAGEMENT STUDIES

BONAFIDE CERTIFICATE

This is to certify that this Project Report is the bonafide work of **NEETHU.V.R 40410112** who carried out the project entitled "**A Study On Handling Pharmaceutical in cold chain supply logistics with reference to flytonxpress**" under my supervision from January 2022 to March 2022.

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I wish to express my thanks to all Teaching and Non-teaching staff members of the **School of Management Studies** who were helpful in many ways for the completion of the project.

NEETHU.VR

ABSTRACT

Cold chains are common in the food and pharmaceutical industries and also in some chemical shipments. One common temperature range for a cold chain in pharmaceutical industries is 2 to 8 °C. but the specific temperature (and time at temperature) tolerances depend on the actual product being shipped. Unique to fresh produce cargoes, the cold chain requires to additionally maintain product specific environment parameters which include air quality levels (carbon dioxide, oxygen, humidity and others), which makes this the most complicated cold chain to operate.

Through this study, the researcher tries to identify the key areas to be enhanced to improve the overall efficiency of the cold chain logistics for pharmaceutical products like vaccines.

The general objective of this study was to establish the influence of cold chain supply logistics on safety of vaccines in pharmaceutical distributors. The other objectives are to determine how storage conditions in pharmaceutical distributors influence safety of vaccines, evaluate the influence of packaging in pharmaceutical distributors on the safety of vaccines and to establish the extent to which technical capacity in pharmaceutical distributors influences safety of Vaccines.

Convenience sampling method has been used in the research work. Multiple choice questions have been chosen to collect the responses from 100 members involved in cold chain logistics of pharmaceutical products. The data collected has been analyzed through various statistical tools like Karl Pearson's Correlation, Chi-square test and One-way Anova test. Numerous new findings have been derived from this research has helped to provide few suggestions to improve the efficiency of the cold chain logistics for pharmaceutical products like vaccines of Flyton Xpress.

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CHAPTER 1

1.1 INTRODUCTION

A cold chain is a monitored temperature-controlled supply chain. The goal of the cold chain is to keep a sample or material within a certain temperature range during all stages of delivery, processing and storage. Cold chains are widely used to ensure the viability of products in the pharmaceutical and agricultural sectors, and are critical components of vaccination programs and bio-medical surveillance activities. Many biological samples deteriorate when exposed to heat, sunlight, or fluorescent light. When transporting and storing such biological substances, it is imperative that field and laboratory teams control environmental conditions, ensuring that exposure to potentially damaging environmental factors is minimized.

The cold storage, handling, and distribution of temperature-sensitive drugs represent an increasingly important component of the global pharmaceutical supply chain. Clinical trial material (CTM) or investigational medicinal products (IMP) are an important part of the earliest stages of the life sciences supply chain. Given the increased number of global regulatory and standards-based guidance documents issued over the past two years, members of the pharmaceutical supply chain are taking notice and making changes to ensure product quality and protect patient safety. The purpose of this paper is to review the various factors affecting Good Cold Chain Management Practices for Clinical Trial Materials/Investigational Medicinal Products.

Cold Chain is a system of storing and transporting vaccine at the recommended temperature range from the point of manufacture to point of use. In order to provide potent and effective vaccine to the beneficiaries a vast cold chain infrastructure is required, which should have a network of Vaccine Stores, Walk-in-coolers (WIC), Walk-in-freezers (WIF), Deep Freezers (DF), Ice-lined Refrigerators (ILR), Refrigerated trucks, Vaccine vans, Cold boxes, Vaccine carriers and ice packs from national level to states up to the outreach sessions. The cold chain system and vaccine flow in the country:- The vaccines are transported from the manufacturer through air transport under the temperature range of 2-8°C to the primary vaccine stores (GMSDs/State head quarter).

1.2 Company Profile

Flyton Xpress is a pioneer in Logistics and Supply Chain Solutions in India. We, at FlytonXpress, offer comprehensive customdesigned logistics projects and supply chain management services to our customers. Ourhighly experienced professional satvarious locations in India ensure sustainable growth and development to enhance customer value andquality. Wehave set benchmarks incustomer satisfactionandservice.

Within Flyton Xpress we take a consistent and systematic approach to Health and Safetymanagementwithinouroperations,thusgiving customers theconfidence tochoose ourservicesaboveall others.

Flyton Xpress has an established Global Health and Safety Team comprising regional representation with direct accountability to the Regional and Global Leadership Teams. Thisaffords timely and effective reporting and management support for HSE initiatives. The teamis empowered to oversee and support company-wide compliance to a growing list of industry,customerand legislativerequirements.

Within Flyton Xpress we promote an open reporting culture involving collaboration andactive dialogue between all stakeholders to effectively manage Health and Safety risks. We seek to encourage an environment of awareness, participation and continuous improvement in all aspects of Health &Safety, which we call -Constant Carell.

A primary Health and Safety function within Flyton Xpress which sets us apart is that welisten to the clientto ensure Health andSafety initiativesbring added value toboth partiesand further protect our mutual business interests. In achieving this we prioritize Health &Safety as a corepillar within our business and decision making processes.

At Flyton Xpress we place a great emphasis towards safety of all persons working for or with us including our customers by using a Lost Time Incident(LTI) reporting structure augmented by adevelopinga wareness to Near Miss reporting

Flyton Xpress treats the handling of Dangerous goods very seriously. To keep abreast ofdeveloping world markets, particularly those within mining, oil and gas exploration we areconstantlydevelopingourrobustdangerousgoodscompetencieswithinrelevantcorefunctionsto meet customer needs.

Flyton Xpress encourages active participation with our customers to promote Health and Safety guidance, and knowledge sharing.

SERVICES

1. SUSTAINABLE LOGISTICS

Our extensive supply chain expertise and industry leadership in sustainable logistics allows Flyton Xpress to develop practical solutions that enable our customers to simultaneously remove waste, reduce cost, and minimise environmental impacts in their supply chains.

.

At Flyton Xpress, our global Supply Chain Development team are ready to help you understand how logistics impacts your sustainability goals and give you the tools to integrate sustainability into logistics decision making – all while improving supply chain performance and reducing cost. On average, we find that cost and carbon have a 1:1 ratio: if we can reduce your carbon by 1%, we can reduce your costs by 1%.

Measure and manage carbon emissions in your supply chain To enable you to work strategically with your logistics carbon footprint, we have developed a portfolio of services, including the Supply Chain Carbon Check and the Supply Chain Carbon Dashboard, to enable you measure and manage your logistics carbon footprint.

- End-to-end carbon visibility and management tools – understand the specific activities contributing to your CO₂ emissions
- Logistics efficiency improvements – identification of tangible carbon and cost reduction potentials
- Strategy and KPI development – let our experts work with you to create and achieve your logistics sustainability goals

- Internal awareness and capacity building – we can help you integrate sustainability with your supply chain needs
- Packaging optimisation – choices in packaging design influence logistics cost and carbon.

Our proven solutions demonstrate that green supply chains are lean supply chains – good for both business and the environment.

2. OCEAN FREIGHT

Ocean transportation is the backbone of most global freight forwarding and key in optimising your supply chain. With Flyton Xpress you are in safe hands.

Our hands-on services and strategic solutions are extensive and customised to meet your every need; whether assisting with expediting an urgent shipment or a strategic partner who can provide competitive terms, identify and create short-term efficiencies and build up long-term competitiveness.

Extensive portfolio of carriers We are not ship owners, but transport managers who work closely with an extensive portfolio of global and regional carriers; providing you with the best solutions.

Many of the world's best known companies use us as their logistics partner of choice when delivering overseas.

Flyton Xpress' ocean freight

- Local expertise and superior customer service from our knowledgeable employees in our 280 own offices around the world
- Access to services from first class global carriers and regional niche carriers
- Centralise ocean procurement ensuring competitive rates and terms
- Multiple carrier solutions departing daily
- Available capacity and space protection with multiple carriers
- Cargo visibility through our ocean tracking system
- Documentation management
- Customs clearance/brokerage services
- Cargo insurance services

- Pick-up, delivery and distribution.

3. SUPPLY CHAIN DEVELOPMENT

Optimising your supply chain is a never ending task. Flyton Xpress can help you identify key areas of improvement, thus reducing your logistics costs.

Short-term efficiency for long-term competitiveness Our supply chain development team is made up by more than 60 experts located in our regional offices around the world. Backed by extensive experience in supply chain and project management, we use proven methods and analytical tools to implement solutions that help you maximise the value of your supply chain.

In 2011, our Supply Chain Development team delivered more than 300 customer projects within multiple industries; more than USD 130 million in potential savings were identified.

Our services include:

- Flyton Xpress' unique Supply Chain Healthcheck™
- Business process management and re-engineering
- End-to-end supply chain modelling and inventory optimisation
- Distribution network modelling and strategic recommendations
- Warehouse and distribution design and operation principles
- Green logistics analysis and sustainable recommendations.

4. AIRFREIGHT

Reliable, global air freight used for the right reasons.

If there is one thing we can all agree on, it's that air cargo should only be used for the right reasons. Often, there is no better option. But in many cases, the options just are not easily comparable or actionable. As the manager of the world's most extensive supply chains, we have developed new ways to optimise the use of air cargo to reduce cost and carbon. Give us your air cargo and we're likely to reduce it. What other global air cargo provider can credibly say that?

International coverage

Through our extensive network of hubs, we handle international air shipment of over 110,000 tonnes annually. Our non-asset based operating style means that we don't have our own aircrafts; instead we work with a wide range of different airline carriers, getting the best available deal. Due to this operational scale we can plan according to your production schedules in order to improve inventory flow whilst still securing favourable rates.

FlytonXpress provides

- Cost-effective services-competitive rates and transit times
- Greater capacity-on main lanes even during peak seasons
- Adequate lead times -for improved inventory flow.

1.3 INDUSTRY PROFILE

The 2015 Biopharma Cold Chain Landscape

Although dealing with rising cost pressures from payers around the world, the biopharma industry is enjoying strong growth, especially in the US. The long-sought promise of using genomic information to develop drugs and diagnostics is starting to come home. Monoclonal antibodies (mAbs) have been premier products in oncology (a strong growth area by itself) for several years; now, with new mAbs such as the so-called PSCK9s to treat cholesterol-related conditions, their application is broadening.

These high-value products put an added emphasis on proper storage, transportation and dispensing. Maintaining a secure -cold chain through the storage, handling and transportation of temperature-sensitive drugs, vaccines and blood products assures product quality and integrity for the benefit of the patient, and keeps the manufacturer, hospital, pharmacist, physician and nurse in compliance with various laws, regulations, guidelines and codes.

In clinical trials, where following protocols is so essential to obtaining meaningful results, maintaining the cold chain also preserves the validity of the tests.

It costs more to keep products at 2–8 °C or at frozen temperatures than it does to keep them at uncontrolled ambient conditions, more to pack and transport them cold, and more to be able to demonstrate by process qualification or by measurement of each shipment that they stayed cold. But industry and society benefit enormously when temperature-sensitive drugs and biological products can be made in efficient large batches, shipped around the world, and delivered as needed to the point of purchase or use.

In the 6th annual forecast from Pharmaceutical Commerce, we extend our market-trend predictions for cold-chain and clinical-trial logistics to 2019, and provide insights on the forces that are driving or slowing growth across these essential global industries, and in particular segments and regions.

For cold-chain logistics, the top drivers are the greater adoption of cold-chain products in both developed and developing markets, and the continued development of new drugs. The

outlook is for continued expansion through 2019, at an average growth rate of about 6% per year, about the same as the 6% uptrend in the 2012–2018 forecast last year, but with more growth in North America.

For clinical trials logistics, a 2.5% average growth rate through 2019, vs. a 1–2% uptrend in the 2012–2018 forecast last year.

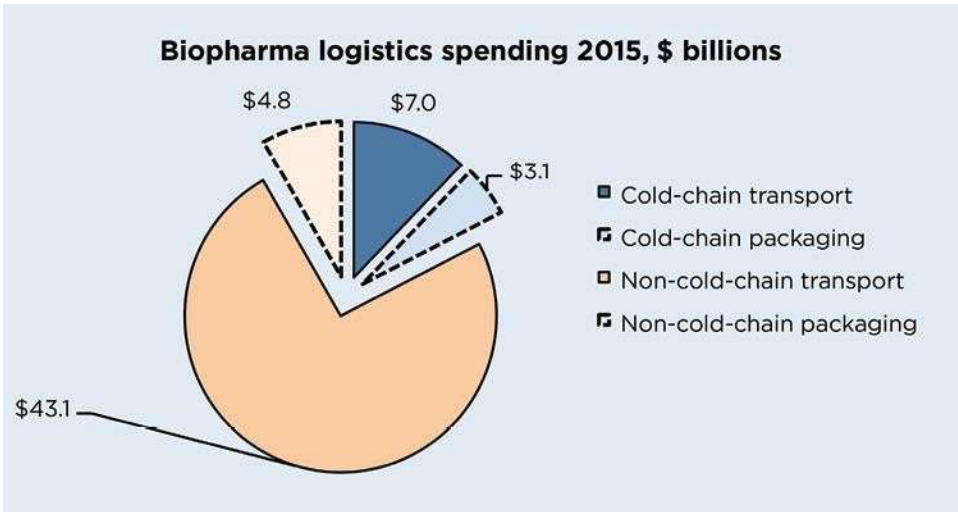


Fig.2. More than \$10 billion will be spent on cold-chain logistics in 2015, in a

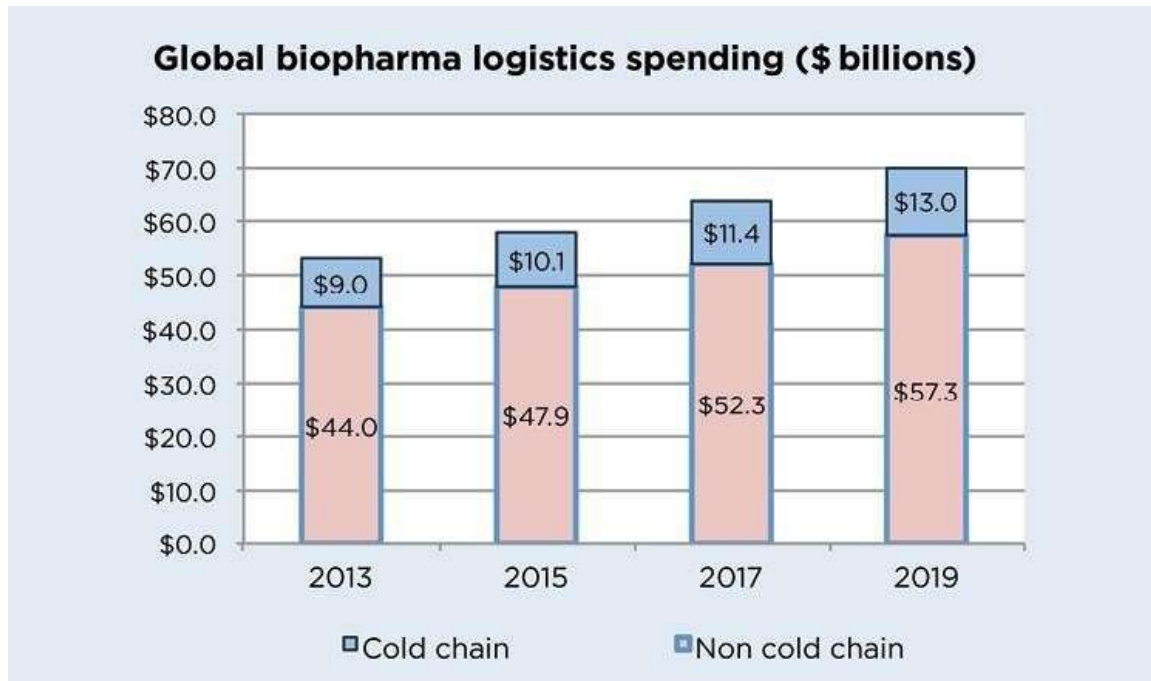
Global bio pharma logistics market of \$58 billion

Marketscale

Projected growth of cold-chain biopharma products will run roughly at twice the rate of the industry over all, according to our analysis (Fig.1),reaching more than \$361billion worldwide in 2019. As of 2015, it exceeds \$250 billion in value, and the special logistics formaintainingthequalityoftemperature-sensitiveproductsastheyareshippedfrommanufacturers to hospitals, clinics, pharmacies and patients around the world account formorethan 15%ofall biopharma logistics spending.

Our forecast for biopharma cold-chain logistics spending (Fig. 2) in 2015 is about \$10 billionworldwide, in a \$58-billion overall pharma logistics market, of which \$7 billion will betransportation and \$3 billion will be specialized tertiary packaging and instrumentation, such as in sulated boxes, blankets, phase-change materials, active-temperature-control shipping containers, and various temperature sensors and recorders (Fig.3). By 2019,cold-chain bio pharma logistics spending will expand to \$13 billion.

Clinical trial logistics is an adjacent and very substantial market for temperature-assured transportation and packaging. It involves shipment of products to be used in trials to study sites that may be dispersed around the globe, and return of unused medicines, as well as shipment of medical samples to centralized analytical laboratories. Because of a recent uptick in number of new trials and enrollment, and a speedup in industry R&D spending overall, our forecast now is for a continued expansion of clinical trials logistics spending at an average 2.5% per year rate.



Growth drivers

Products requiring cold-chain handling are mainly bioengineered drugs, or biologics, derived from living cells, delivered in liquid form by injection or infusion, and packaged in vials or syringes or pens. Most of the drugs are brand-name proprietary products, with only a few considered biosimilars or generics, while many biologics, such as blood products and vaccines, have several or many suppliers of very similar products, whether branded or not.

Some refrigerated products, such as various insulin products, are labeled to allow them to be held at room temperature for some time. USP also defines controlled room temperature as a range around 20–25°C with allowed excursions between 15–30°C, and most tablets and

capsules are labeled for such non-cold-chain storage and handling. In the US, temperature limits for blood, plasma and some vaccines and other specific biological products are written into federal law and, while they overlap with ranges described by USP for drugs, they do not conform; for instance liquid red blood cells and liquid plasma may be stored at 1–10 °C (34–50°F).

The total value of bioengineered drug products is more than \$150 billion worldwide, three times what it was 10 years ago, and vaccines and blood products have expanded as well. Most of these products are made in relatively small volumes and often for small populations with chronic conditions, and sold at high prices, which can add up to \$10,000 or \$100,000 or more per patient per year, with some exceptions, such as insulin products and childhood immunization vaccines, which are used by hundreds of millions of patients per year.

Biotechnology products requiring cold-chain handling make up an increasing fraction of total sales. Of the top 50 global drug products in 2013, 24 required cold-chain handling, accounting for \$104 billion in sales. In 2010, the top 50 drugs included 18 cold-chain drugs, with sales of \$73 billion.

The most widely prescribed of these brand-name cold-chain products are the various forms of insulin, such as Lantus Solostar, which had about 10 million prescriptions in the US last year, according to IMS Health. This is in the same order of magnitude as top non-cold-chain branded products, but much less than the 100+ million annual prescription volume (US) of the top generic (hydrocodone/acetaminophen).

By 2020, 27 of the top 50 sellers will be drugs requiring 2–8°C cold-chain storage and handling. Nine of these are new; the other 18 were on the 2013 Top 50 list (Fig. 4).

Rank in Top 50	Product	Generic Name	Company	Global Sales 2020 (\$millions)	Technology
1	Humira	adalimumab	AbbVie + Eisai	\$12,707	Monoclonal antibody
2	Lantus	insulin glargine recombinant	Sanofi	\$10,252	Recombinant product
3	Enbrel	etanercept	Amgen + Takeda + Pfizer	\$8,572	Recombinant product
4	Remicade	infliximab	Johnson & Johnson + Merck & Co + Mitsubishi	\$8,217	Monoclonal antibody
7	Avastin	bevacizumab	Roche	\$6,613	Monoclonal antibody
9	Nivolumab		Bristol-Myers Squibb + Ono	\$6,361	Monoclonal antibody
12	Prevna 13	pneumococcal vaccine	Pfizer + Daewoong	\$6,078	Bioengineered vaccine
13	Eylea	afibercept	Regeneron + Bayer + Santen	\$5,852	Recombinant product
14	Rituxan	rituximab	Roche + Biogen Idec	\$5,627	Monoclonal antibody
16	Soliris	eculizumab	Alexion Pharmaceuticals	\$5,202	Monoclonal antibody
18	Herceptin	trastuzumab	Roche	\$5,054	Monoclonal antibody
19	Kadcyla	ado-trastuzumab emtansine	Roche + Chugai	\$4,912	Monoclonal antibody
21	Victoza	liraglutide	Novo Nordisk	\$4,443	Recombinant product
22	Perjeta	pertuzumab	Roche + Chugai	\$4,440	Monoclonal antibody
23	NovoRapid	insulin aspart	Novo Nordisk	\$4,438	Recombinant product
24	Botox	onabotulinumtoxinA	Allergan + GSK	\$4,311	Recombinant product
25	Lucentis	ranibizumab	Novartis + Roche	\$4,064	Monoclonal antibody
27	Simponi	golimumab	Johnson & Johnson + Merck & Co	\$3,910	Monoclonal antibody
29	Gammagard Liquid	immune globulin	Baxter International	\$3,533	Protein extract
30	Xgeva/Prolia	denosumab	Amgen	\$3,527	Monoclonal antibody
31	Neulasta	pegfilgrastim	Amgen	\$3,455	Recombinant product
32	Stelara	ustekinumab	Johnson & Johnson	\$3,390	Monoclonal antibody
33	Privigen	immune globulin	CSL	\$3,158	Protein extract
36	RG7446 (in R&D)		Roche + Chugai	\$3,023	Monoclonal antibody
39	Humalog	insulin lispro recombinant	Eli Lilly	\$2,902	Recombinant product
45	Levemir	insulin detemir	Novo Nordisk	\$2,780	Recombinant product
49	Tysabri	natalizumab	Biogen Idec	\$2,573	Monoclonal antibody
Total 2–8 °C				\$139,394	
Total Top 50				\$233,086	

Sources: Evaluate Pharma, World Preview 2014, Outlook to 2020; and FDA label and package insert data. Note, Gammagard and Privigen allow room temp. storage for a shorter period

Fig. 4. By 2020, 27 of the top 50 best-selling global drug products will require 2–8°C cold-chain storage and handling

New drugs and specialty drug trend

In 2014, the FDA Center for Drug Evaluation & Research (CDER) approved 10 biologics, and 30 new molecular entities, of which all the biologics but none of the NMEs require cold-chain handling. This compares with four biologics and 24 NMEs (two cold-chain) in 2013.

One of the new biologics, Opdivo (nivolumab), approved Dec-2014, is projected by 2020 to be a \$6 billion product, #9 on the -top 50 list.

Review of vaccines and blood products at FDA is handled by the Center for Biologics Evaluation and Research (CBER). In 2014, CBER approved an additional 16 biologic products, 13 of which require cold-chain handling.

In global volume, insulin is the largest cold-chain biopharma product. According to Novo Nordisk, one of the original makers of insulin in the 1920s and still a market leader, the unit demand for insulin worldwide grew 6% per year 2009–2014, with much faster growth in emerging markets such as China, which as of 2014 had about one-quarter of the world's diabetic population, but used only 6% of the world's insulin. If every diabetes sufferer in China received the same amount of insulin as a US diabetic, it would more than double the world demand. This trend is translating into very substantial market growth. Since Novo is China's leading insulin supplier, with 60% share, market growth also drives substantial business growth for them. Sanofi and Lilly have most of the remaining market.

The company points to the growth in prevalence of diabetes, and the expansion of treatment, as driving forces for growth of insulin and other therapies. According to the International Diabetes Federation, 382 million adults suffered from diabetes in 2013 (98 million in China), and the prevalence of this disease will grow to 592 million adults—one in ten adults worldwide—by 2035, about a 2% annual growth rate.

Blood and plasma products

In the US particularly, blood and plasma products are produced and handled in high volumes. According to the US National Blood Collection and Utilization Survey, the US has about 16 million blood donations per year; plasma donations were estimated at about 18 million by the Plasma Protein Therapeutics Association. The largest commercial suppliers of plasma-related

products are Baxter International, CSL Behring, Grifols and Octapharma. Baxter had revenues of \$15 billion in 2013, including such plasma-derived products as Advate clotting factor and Gamma Gard immune globulin.

As of 2014, the North American demand for immune globulin, a plasma component which sells for about \$100 per gram, was pegged at about 62,000 kg per year, with a value of about \$6 billion, with growth of about 5% from the prior year.

Overall cold-chain biopharma forecast, and by region

Adding biotech, vaccines, blood, plasma and all other cold-chain products, the overall cold-chain biopharma market is expected to exceed \$250 billion this year, and to top \$350 billion by 2019, driven by innovation in the most-developed markets, as well as by expanded distribution of cold-chain products in Asia and the southern hemisphere.

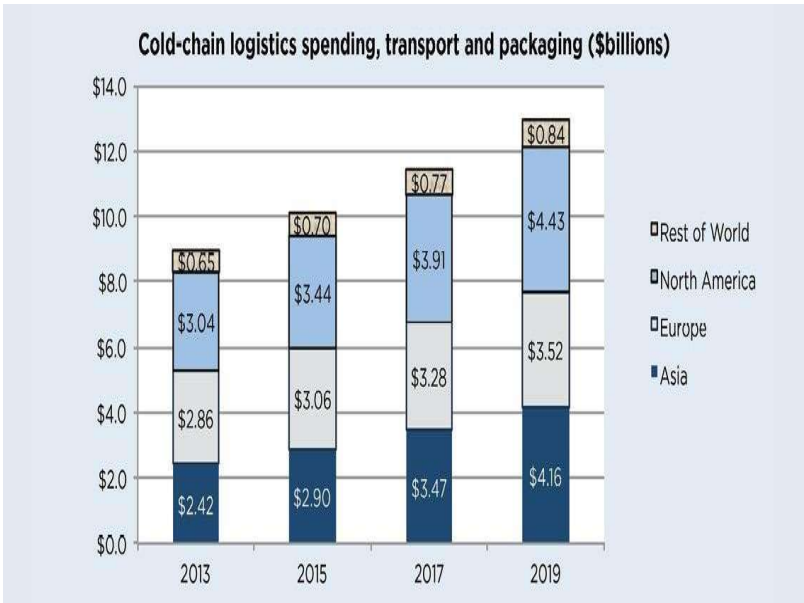
Cold-Chain Logistics Market Sizing and Forecast

We are continuing to predict an expansive future for cold-chain logistics, driven by introductions of new biotech therapies and even more by expanding usage of cold-chain products in developing countries, and shadowed by rapid non-cold-chain growth in those countries, particularly China.

Our estimate of how much is spent per year on transportation and packaging for refrigerated and frozen biopharma products is based on estimates of how many legs the products travel, how far, in what amount, in what kind of protective or -tertiary packaging with what instrumentation or phase change materials if any, and by what mode and speed.

As a starting point for the forecast, logistics for refrigerated and frozen drugs, biologics and blood products are estimated to have cost the global industry about \$9.0 billion in 2013, about 17% of total biopharma logistics spending, which was about \$53 billion. Forward projections are based on volume, and changing patterns of trade and distribution, with prices held constant.

Fig. 5. Growth in cold-chain spending will be faster in Asia and North America than in Europe or the Southern hemisphere



Cold-chain spending is estimated to be about \$10.1 billion in 2015, in a \$58-billion total pharma logistics market, and to grow to about \$13.0 billion by 2019. Asia and the southern hemisphere will account for about the same amount of cold-chain logistics growth as North America and Europe, and more non-cold-chain growth.

With 20% of the world's population, Europe and North America consume more than 60% of its pharmaceutical products in dollar terms; if Asia and the rest of the world used drugs at the same level, the global pharma market would be three times as large. This forecast follows IMS and others in predicting how far that expansion will go by 2019, but it could be faster or slower (Fig. 5).

The proportion of cold-chain products within that mix is based on assumptions about new drugs being approved, and more so on how quickly existing drugs are adopted. In the long term, if biosimilars or other bio-generics dramatically reduce the price of cold-chain drugs, the market could expand much more than three times, but within the scope of this forecast, expectations for biosimilars are minimal, and cold-chain growth is most related to the mid-cost products such as insulin rather than the higher-cost biotech therapies.

There are also assumptions about how cold-chain products are sourced. If developing markets do better than expected at manufacturing cold-chain products locally, that would tend to reduce the logistic spending, but in the probable case that the US, Europe and Japan

maintain a hold on these technologies that tend to continue to drive export trade and air logistics.

Clinical

Trials

Logistics

The economic importance of careful cold-chain handling is extremely high during the development and testing of a drug, because careless handling could spoil an experimental protocol, and prevent or delay approval of some beneficial and profitable new product. While they are being developed, all drugs and also all medical samples generated get special handling, including the highest level of temperature assurance; for instance, having temperatures checked and phase-change materials replenished at transit points between the factory and the study site, and between the study site and the lab.

In 2015, there are more than 60,000 clinical trials in progress around the world, according to the US National Institute of Health's global ClinicalTrials.gov database. Most, if not all, of them take a very high level of care in logistics, whether the drugs or devices involved need refrigeration or not. Phase 3 studies, which precede marketing approval, are the most expensive and account for the greatest fraction of R&D spending, due to per-patient costs that exceed \$40,000, according to research firm Cutting Edge Info in a 2011 survey.

Phase 3 trials also place the most demands for efficiency and speed on logistics providers and the most pressure on the cold chain, not just for outbound shipments of the drugs being tested, but also for sending unused test products back to the maker, and sending medical

samples to a central lab. Challenges include labeling, primary packaging, Customs clearance, barcodes, validated inventory systems, high volumes, temperature controls and associated documentation. For this and other reasons, logistics including packaging, storage and transportation of product and samples can account for several thousand dollars per patient, even as much as 50% of study budgets in an extreme case, according to industry analysts such as the Tufts Center for the Study of Drug Development.

According to the Pharmaceutical Research and Manufacturers of America (PhRMA), the US trade association, there were 5,400 drugs in the global development pipeline as of 2013, and \$51.1 billion was spent by US companies in 2013 on R&D, more than ever before. Spending was up about 3% vs. the prior year, and exceeded the previous peak which was \$50.7 billion in 2010.

European pharma industry R&D was also up in 2013, about 2%, to €30.6 billion, from €30.0 billion in 2012, according to EFPIA, the European Federation of Pharmaceutical Industries Associations.

Clinical-Trials Logistics Forecast

For this year's forecast, we again approached clinical-trials logistics as a single global market (no regional breakdown) and weighed several bottom-up, as well as top-down measures, including:

- Measures and forecasts of clinical-trial activity, such as from the US National Institutes of Health's ClinicalTrials.gov and various forecasters
- Measures of R&D spending
- Revenue estimates for companies dedicated to providing these services
- Documented analyses of trial costs and budgeting norms cited by industry experts.

Since trials are normally completed in 3–4 years, the full impact of the 2009–2010 R&D slowdown was likely realized by 2013. Looking ahead and combining various measures, our estimate for specialized logistics serving drug and biologics trials is \$2.84 billion in 2013, reaching \$3.00 billion in 2015 and increasing to \$3.29 billion by 2019 (Fig. 6).

\$ billions	2013	2015	2017	2019	CAGR %, 2013-2019
Clinical trial logistics spending	\$2.84	\$3.00	\$3.15	\$3.29	2.5%
Change %		6%	5%	4%	
Note: Estimate/forecast for transport and packaging, for phase 1-4, drug and biologic, global clinical trials					

Fig.6 Clinical trials logistics outlook is for an uptrend matching general R&D growth trends

The clinical logistics market could expand faster if companies start seeing greater returns on research, if trials shift again to distant foreign markets, and if biosimilar pathways to approval are adopted and proven to be profitable.

Future

Direction

The top-selling drug through 2020 is expected to be Humira, a monoclonal antibody that requires cold-chain handling. AbbVie—the Abbott Laboratories spinoff—said in late January that Humira sales were up 10.6% in 2014, to almost \$12 billion, from \$10.7 billion in 2013

when growth was 15%. Since its FDA approval in December 2002 for treatment of rheumatoid arthritis, Humira has received additional approvals for treatment of psoriasis, Crohn's disease and several other conditions in the US, Europe and elsewhere.

Thirty years after marketing approval of the very first genetically engineered drug—Genentech's Humulin, a human insulin licensed to Lilly, in 1982—the industry is now in a middle stage of growth. Because of their cost, products like Humira are used more in the US and Europe than elsewhere in the world, and even insulin is much more widely used in the most developed countries. As incomes rise, there is potential for all biotech and cold-chain products to expand in use by a factor of four or six or more, but high cost will limit how fast this can happen. Demand is also rising, as populations in developing countries live longer and become more susceptible to chronic diseases and cancer.

Potential for innovative new treatments also remains strong, as biopharma companies notch successes in developing new bio-engineered treatments for cancers and other diseases. Likewise, potential for biosimilars, whose impact seems to be always beyond the forecast horizon. Though Humira's patent expires in 2016, no generic is expected to replace it in the way Lipitor or other small molecule blockbusters were replaced. A biosimilar from Cadila Healthcare approved in India in Dec-2014 is sold for 1/5 of the price of the

1.4 NEED FOR THE STUDY

common in the food and pharmaceutical industries and also in some chemical shipments. One common temperature range for a cold chain in pharmaceutical industries is 2 to 8 °C. but the specific temperature (and time at temperature) tolerances depend on the actual product being shipped. Unique to fresh produce cargoes, the cold chain requires to additionally maintain product specific environment parameters which include air quality levels (carbon dioxide, oxygen, humidity and others), which makes this the most complicated cold chain to operate.

Through this study, the researcher tries to identify the key areas to be enhanced to improve the overall efficiency of the cold chain logistics for pharmaceutical products like vaccines with special reference to Flyton Xpress

1.5 SCOPE OF THE STUDY

The major scope of the analysis on cold chain logistics in pharmaceuticals are

- a. To increase the longevity of the medical characteristics
- b. Maintain the temperature level for the vaccines
- c. Retain then nutritional value of vaccines
- d. Maintain the chemical substance of vaccines
- e. Reduce wastage and return of expired stock of vaccines

1.6 OBJECTIVES OF THE STUDY

PRIMARY OBJECTIVE

The general objective of this study was to establish the influence of cold chain supply logistics on safety of vaccines with special reference to Flyton Xpress

SECONDARY OBJECTIVES

1. To determine storage conditions in pharmaceutical distributors in fluencies safety of vaccines.
2. To determine the influence of transport systems on the safety of vaccines in pharmaceutical distributors.
3. To evaluate the influence of packaging in pharmaceutical distributors on the safety of vaccines.
4. To establish the extent to which technical capacity in pharmaceutical distributors influences safety of vaccines.

1.7 LIMITATIONS OF THE STUDY

For any thing there should be some limitations like that my project also have certain limitations. The following are some limitations what I faced:

1. The information provided by majority of the respondent could also be biased or inaccurate. No independent verification of the data was possible.
2. Time is one major constraint, which limits the effective data collection.
3. Non-availability of data collection from all the people involved in cold chain logistics of pharmaceutical products
4. The sample size is only 100 so the sample may not be truly representative of the total population
5. Reliability and accuracy of the analysis depends on the respondents' openness and truthfulness towards each question in the questionnaire.

CHAPTER 2

REVIEW OF LITERATURE

Laboratory Cold Chains:

As medicine developed through the centuries the advances created the basis for diagnostic discoveries. In the latter part of the 19th century the clinical laboratory started to be established. By the turn of the century many specific chemical, haematological and bacteriological tests had been developed due to innovations in basic science (Berger, 1999a) enabling the clinical laboratory to be used for diagnostic purposes. Different types of laboratories started to emerge, including physiological, pharmaceutical, forensic, public health, clinical chemistry and microbiological (Berger, 1999b).

Laboratories developed similarly in Britain and the United States of America (USA) due to the influences of medical faculties in Europe (Petts, 2012; Race, Tillery, & Dysert, 2004). The number of laboratory tests available increased dramatically over the 20th century. The first half of the century was involved in developing individual biochemical methods for the variety of parameters that medical professionals were interested in such as ion concentration of elements in serum (Berger, 1999b). Because the refrigerator was not invented until the late 1910s to early 1920s these methods did not require refrigeration. Today the range of different analyses available is now well over 3000, and still increasing, although not all will be available at each laboratory (Wians, 2009).

Requests for laboratory investigations increased as medical professionals found the data useful in establishing diagnoses. The desire to have this data prior to treatment led to the expectation of faster turnaround times for testing (Seligson, 1966), so more efficient methodologies needed to be introduced. The first convenient and accurate kit-type diagnostic test, Clinitest®, was introduced in 1941 and measured reducing sugars in urine (Chemical

Heritage Foundation, 2010). This was followed by Clinistix® in 1956, the first dipstick which measured glucose in urine (Chemical Heritage Foundation, 2010).

Although Clinitest® has long been discontinued in modern laboratories dipsticks continue today with up to 10 parameters being measured by one dip in the urine. These types of tests did not require refrigeration. Mechanisation followed with the first clinical autoanalyser

being introduced in 1959 (Berger, 1999b) and it was around this time that sub-ambient storage of some reagents became essential. Such analysers could perform multiple tests on much smaller

samples of the patient's blood (Seligson, 1966). In the 1960's culture media became more sophisticated with antibiotics included as selective agents (Smith, 2005) necessitating storage at sub-ambient temperatures. The sixties also saw computers introduced into laboratories in Europe, Britain and the USA but they did not become mainstream until the 1970's-

1980's (Keller, 1982). Miniaturisation of laboratory techniques began in the 1970s with microbiology and immunoassays being the initial beneficiaries' and this has progressed through all disciplines (Fung, 2002; Hansen, Hardesty, & Myers, 1974; McGlennen, 2001).

Thereagents for these kit/reagents needed to be stored at sub-ambient temperatures (Ammann, 2011; Ramanujam, Koelbl, & Ting, 1993). An example of this type of kit is the API® range manufactured by bioMérieux Inc. More recently these techniques have moved onto full automation especially in larger laboratories (Wu, 2006). The molecular era started in 1943 when Oswald Avery (1877-1955) demonstrated that deoxyribonucleic acid (DNA) played a significant role in the carriage of genetic information (Bersch, 2006). Research into DNA moved forward on multiple fronts with James Watson (b. 1928), Francis Crick (1916-2004), Maurice Wilkins (1916-2004) and Rosalind Franklin (1920-1958) all working on defining DNA's structure in the early 1950's (Bersch, 2006).

In 1953 the peer reviewed academic journal Nature published this research and the findings were widely accepted. This along with further discoveries of critical enzymes and manipulation techniques led to the development of new laboratory procedures. However, it was not until the invention of the polymerase chain reaction (PCR) technique by Kary Mullis (b. 1944), in 1983, that molecular methodologies moved from the research laboratory into the clinical laboratory (Tang, Procop, & Persing, 1997) providing enhanced sensitivity and faster turnaround times. Kits that use this technique require sub-ambient temperatures. Kits such as

The primers and probes need to be kept at 4°C and the master mix that contains the enzymes and dinucleotides at -20°C but are provided together in the same kit. Today, the diagnostic industry is starting to move towards "black box" type testing methods (Bersch, 2006) that include the three main phases of PCR, extraction, amplification and detection.

This type of testing often does not

require specialised staff or sub-ambient storage conditions for reagents. An example of this is the Gene Expert® range of cartridges manufactured by Cepheid. To complicate matters the supply chain's national and international regulations are moving towards "controlled room temperature" (CRT) requiring additional monitoring steps for ambient temperature packages, and adding complexity to the transportation process (Healthcare Commerce Media Corporation, April 09, 2010). Ultimately, even the ambient temperature "black box" products being developed by the diagnostic industry will come under the CRT auspices.

There is an abundance of literature and regulations on the development of drugs for human use including stability, experimental design and data analysis for the pharmaceutical industry but for the in vitro device (IVD) manufacturers, who manufacture kits for the clinical laboratory, there are guidance documents but few regulations. However, the need for regulation was reinforced by a study performed in 2011 that showed that devices that had been deemed low risk and were not covered by regulations had resulted in serious health problems or death for some patients (Zuckerman, Brown, & Nissen, 2011). A draft document was issued by the Food and Drug Administration (FDA) that covered companion diagnostic tests, with a deadline of 31 March 2013 but as late as October 2013 the FDA were still talking about regulating but with no definitive action to date (Novales-Li, 2013). Currently, licensed laboratory developed tests (LDTs) and IVDs must be validated and any reagents used, including calibrators, controls, and sample diluents, must undergo stability testing so consumers know the temperature and storage limits of the product. In order to deliver an accurate and precise result each of these components must be functioning properly. Stability studies cover the following: expected shelf life or expiration date, temperature, humidity and photostability, stress testing and storage conditions (Food and Drug Administration, 2003; International Conference on Harmonisation, 2003). Environmental factors such as temperature, humidity and light can affect the quality and shelf life of a product. Stability

testing using the climatic zones helps establish a shelf life and the recommended storage conditions for a product (Markens, 2009).

The shelf life should be based on the long term study at the recommended storage condition. The product should also be subjected to elevated temperatures for an appropriate time period to emulate the effect of short term excursions outside the recommended storage conditions which occurs during shipping (World Health Organisation, 2009). The time-stress excursion hours are cumulative and includes all stages of the product's life from production to storage in the central warehouse, then from the supplier to the distributor, which may mean exporting overseas, customs or border processing, and lastly from the distributor to the customer. At signed acceptance of the delivery the stress period is ended for the distributor company as it has no control over what happens post-delivery.

All products of a temperature-sensitive nature should be labelled appropriately to alert the customer of the package's storage requirements. The expectation is that the customer would have procedures in place to manage the receipt of temperature-sensitive products. However, no products are sold with the cumulative stress hours available making it all the more essential that all parties involved in the transportation of goods monitor and ensure that cold chain products are kept at the recommended temperature.

Knowledge of the stress hours originally available and how many have been used would be useful to the purchaser. For most products the process of bringing a cold chain kit/reagent to ambient temperature is a requirement before the test can be performed. The speed of chemical reactions are altered at different temperatures therefore the prerequisite of bringing a kit to room temperature is necessary because the kit/reagent will have been designed to work in an ambient environment. These excursions should also be considered as time-stress hours outside the recommended storage conditions. Consideration should be given to how many times a kit/reagent is brought to, and left, at ambient temperature in the laboratory environment and if consumption of the kit is slow then it should be discarded prior to finishing or reaching its expiry date.

CHAPTER 3

RESEARCH METHODOLOGY

Fundamental to the success of any formal marketing research project is a sound research design. A good research design has the characteristics of problem definition, specific methods of data collection and analysis, time required for research project and estimate of expenses to be incurred. The function of a research design is to ensure that the required data are collected accurately and economically. A research design is purely and simply the framework or plan for an analysis of data. It is a blue print that is followed in completing a study. It resembles the architect's blue-print (map) for constructing a house. It may be worthwhile to mention here that a research design is nothing more than the framework for the study ensures that the study will be relevant to the problem and the study will employ economical procedures.

Claireseitz et al. defines Research Design as—Research design is a catalogue of the phases and facts relating to the formulation of a research effort. It is the arrangement of collection and analysis of data in a manner that aims to combine relevant to the research purpose with economy in procedure.

Three important about research design are

1. The design of investigation should stem from the problem
2. Whether the designs are productive in a given problem setting depends on how imaginatively they are applied. An understanding of the basic design is needed so that they can be modified to suit specific purpose
3. The three basic design areas as follows
 - i. Exploratory Research design
 - ii. Descriptive Research design
 - iii. Casual Research design

The Research design used in the study is descriptive research design

3.1 RESEARCH DESIGN

Descriptive research design is also called explanatory design. This is the one that simply describes something such as demographic characteristics. The descriptive study is typically concerned with determining frequency with which something occurs or how two variables vary together.

3.2 SAMPLE SIZE

It refers to the number of elements of the population to sample. The sample size chosen for the survey is 153

3.3 DATA SOURCES

After identifying and defining the research problem and determining specific information required to solve the problem, the researcher's task is to look the type and sources of data which may yield the desired results. Data sources are of two types through which data is collected.

Data sources may be classified as

1. Primary data
2. Secondary data

PRIMARY DATA

Primary data is the original data collected by the researcher first hand. It is collected for the first time through field survey. These are those that are gathered specifically, for the problem at hand. The various sources for collecting primary data are questionnaire, observation, interview etc. The primary source used for the study is questionnaire.

SECONDARY DATA

Secondary data is the information which is already available in published or unpublished form. When the needed information is collected from the census of population available in a library means then it is a secondary data. It is also used for collecting historical data. The various sources of secondary data are books, periodicals, journals, directories, magazines, statistical data sources etc. The secondary source used for this study is company profile, scope, need, review of literature.

3.4 RESEARCH INSTRUMENTS

Research instruments are the instruments which are used for gathering or collecting information. The instruments used in the study are

1. Direct questions
2. Close end questions
3. Dichotomous questions
4. Multiple choice questions

DIRECT QUESTIONS

Direct questions are just what their names indicate. They explicitly ask for the desired data. However the directness of the question also relates to the way a response is interpreted.

CLOSE END QUESTIONS

Such questions are also called fixed alternative questions. They refer to those questions in which the respondent is given a limited number of alternative response frames which he/she is to select one that most closely matches his/her opinion or attitude.

DICHOTOMOUS QUESTIONS

A dichotomous question refers to one which offers the respondent a choice between only two alternatives and reduces the issue to its simple terms. The fixed alternatives are of the type, yes/no, agree/disagree, true/false etc.

MULTIPLE CHOICE QUESTIONS

A multiple choice question refers to one which provides several set alternatives for its answers. Thus, it is a middle ground between free answers and dichotomous questions.

3.5 SAMPLING

Collecting data about each and every unit of the population is called census method. The approach, where only a few units of population under study are considered for analysis

Called sampling method. There are two main categories under which various sampling method can be put.

The two categories are

1. Probability sampling
2. Non-probability sampling

The sampling method adopted for the study is convenience sampling under non-probability sampling.

NON-PROBABILITY SAMPLING

In non-probability sampling, the chance of any particular unit in the population being selected is unknown, since randomness is not involved in the selection process. But this does not mean that the findings obtained from non-probability sampling are of questionable value. If properly conducted their findings can be accurate as those obtained from probability sampling. The three frequencies used non-probability designs are

1. Judgmentsampling
2. Conveniencesampling
3. Quotasampling

3.6 CONVENIENCE SAMPLING:

In this method, the sample units are chosen primarily on the basis of the convenience to the investigator. The units selected may be each person who comes across the investigator.

3.7 SAMPLE FRAME:

A Sample frame may be defined as the listing of the general components of the individual units that comprise the defined population.

3.8 SAMPLE DESIGN

Sample design is the theoretical basis and the practice means by generalizing from characteristics of relatively few of the comprising population. It is the method by which the sample is chosen.

3.9 ANALYTICAL TOOLS

ANALYSIS USING KARL PEARSON'S CORRELATION:

Correlation analysis is the statistical tool used to measure the degree to which two variables are linearly related to each other. Correlation measures the degree of association between two variables. The Pearson product-moment correlation coefficient is a measure of the strength and direction of association that exists between two variables measured on at least an interval scale. It is denoted by the symbol r .

$$\sqrt{\frac{\sum (x_i - \bar{x})(y_i - \bar{y})}{\sqrt{\sum (x_i - \bar{x})^2 \sum (y_i - \bar{y})^2}}}$$

CHI-SQUARE TEST I- (χ^2)

A chi-square test, also referred to as a chi-square test or χ^2 test, is a statistical hypothesis test in which the sampling distribution of the test statistic is a chi-square distribution when the null hypothesis is true, or any in which this is asymptotically true, meaning that the sampling distribution (if the null hypothesis is true) can be made to approximate a chi-square distribution as closely as desired by making the sample size large enough.

The χ^2 test was first used by Karl Pearson in the year 1900. The quantity χ^2 describes the magnitude of the discrepancy between theory and observation.

It is calculated using:

$$\chi^2 = \sum \left[\frac{(O_i - E_i)^2}{E_i} \right] \text{ with } (n - 1) \text{ degrees of freedom.}$$
Where, O_i refers to the observed frequency & E_i to the expected frequencies. χ^2 was used as a test of independence and goodness of fit.

PERCENTAGES

Percentages refer to a special kind of ratio. Percentages are used in making comparison between two or more series of data. Percentages are used to describe relationships, it is expressed as.

$$\text{Percentage} = \left(\frac{\text{no of employees}}{\text{total no of employees}} \right) 100$$

CHARTS:

Charts are graphic displays of data for easy understanding of relative positions that is not always possible with descriptive words or numbers. Types of charts commonly used in business data presentation are: Bar and pie.

BAR CHARTS:

The bar chart is commonly used for presentation of qualitative data. The data can be continuous or discrete data, which are plotted against discrete data intervals. The vertical bar diagram, also called bar chart where the length or height of bars represent the numerical value of the event or measurement. Width or gap between the bars is of no significance to the bar chart data, but they are uniform in a diagram.

CHAPTER 4

DATA ANALYSIS AND INTERPRETATION

4.1 PERCENTAGE ANALYSIS

TABLE 1 AGE OF THE RESPONDENT

Age(in yrs)	No.of Respondents	% of Respondents
20-30	96	62.7%
30-40	35	22.9%
40-50	22	14.4%
above 50	0	0
Total	153	153%

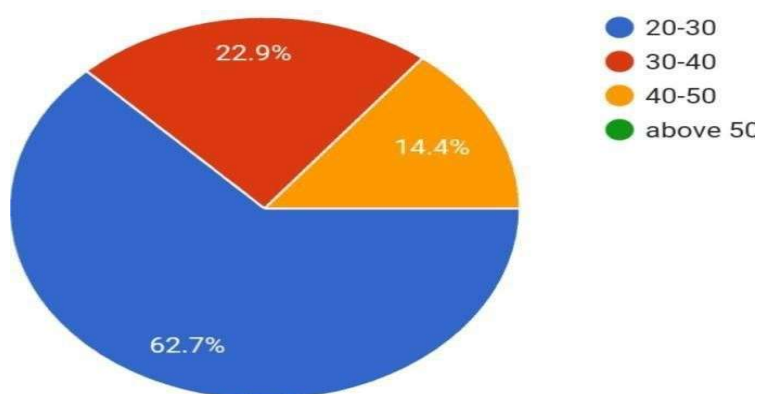


CHART 1 : AGE OF THE RESPONDENT

Source : primary data

INTERPRETATION:

62.7% of the respondents belong to the age group between 20-30 , 22.9% of the respondents belongs to the age group between 30-40, 14.4 % of the respondents belongs to the age group between 40-50 and 0% of the respondents belongs to the age group above 50.

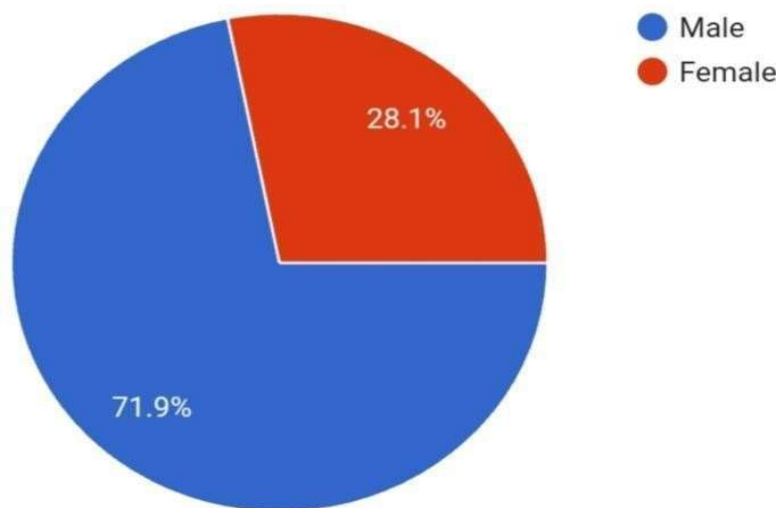
INFERENCE:

Therefore 62.7% of the respondents belong to the age group between 20-30.

TABLE 2 : GENDER OF THE RESPONDENT

Gender	No.ofRespondents	%ofRespondents
Male	110	71.9%
Female	43	28.1%
Total	153	153%

CHART 2 :GENDER OF THE RESPONDENT



Source: primary data

INTERPRETATION :

71.2% of the respondents are male and 28.1% of the respondents are female.

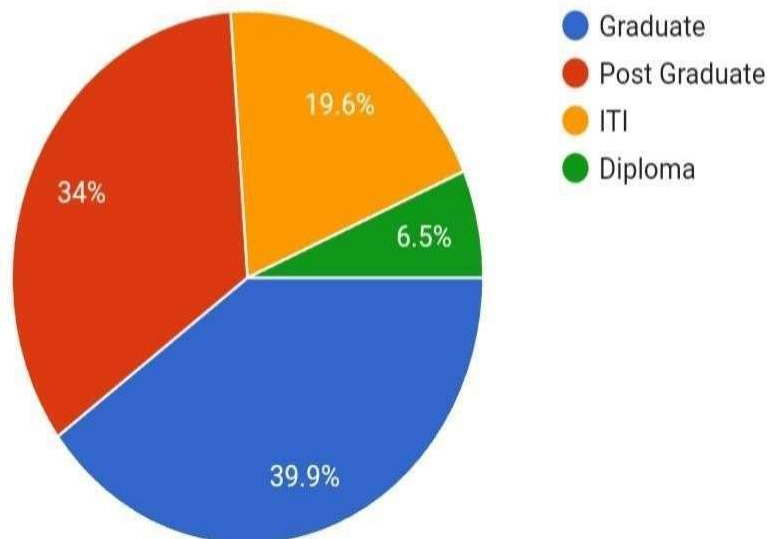
INFERENCE :

Therefore 71.2% of the respondents are male.

TABLE 3 :EDUCATION OF THE RESPONDENT

EducationalQualification	No.ofRespondents	%ofRespondents
Graduate	61	39.9%
PostGraduate	52	34%
ITI	30	19.6%
Diploma	10	6.5%
Total	153	153%

CHART 3: EDUCATION OF THE RESPONDENT



Source: primary data

INTERPRETATION :

39.9% of the respondents are graduate, 34% of the respondent sare ITI, 19.6% of the respondents are post graduate, 6.5 % of the respondents are diploma

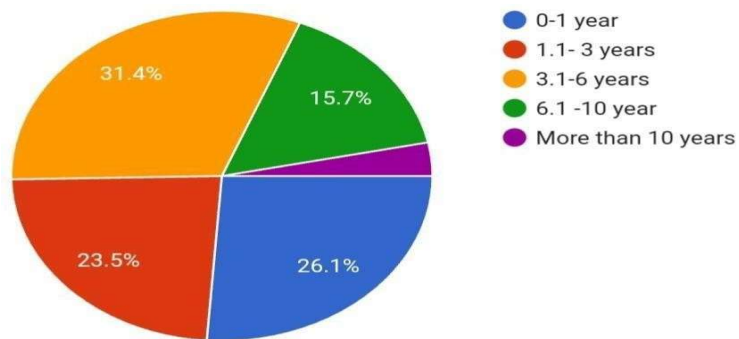
INFERENCE.

Therefore 39.9% of the respondents are graduate.

TABLE 4 :EXPERIENCE OF THE RESPONDENT

Experience	No.ofRespondents	%ofRespondents
0–1year	40	26.1%
1.1–3years	36	23.5%
3.1–6years	48	31.4%
6.1–10years	24	15.7%
Morethan 10 Years	3	3.3%
Total	153	153%

CHART 4 :EXPERIENCE OF THE RESPONDENT



Source: primary data

INTREPRETATION:

26.1% of the respondents have 1.1–3 years of experience ,23.5% of the respondents have 0 – 1 years of experience, 31.4% of the respondents have 3.1 – 6 years of experience, 15.7% ofthe respondents have 6 .1– 10 years of experience & 3.3% of the respondents have more than 10Years of experience.

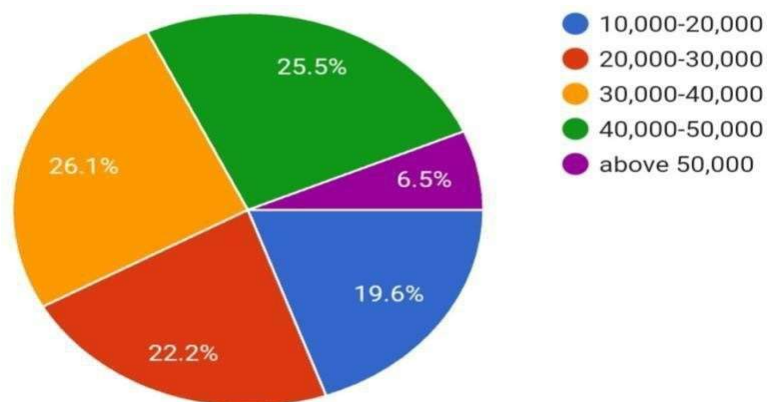
INFERENCE

Therefore 31.4% of the respondents have 3.1– 6years of experience.

TABLE 5: INCOME OF THE RESPONDENT

Income	No.ofRespondents	%ofRespondents
10,000-20,000	30	19.6%
20,000-30,000	34	22.2%
30,000-40,000	40	26.1%
40,000-50,000	39	25.5%
above50,000	10	6.5%
Total	153	153%

CHART 5: INCOME OF THE RESPONDENT



Source: primary data

INTERPRETATION:

22.2% of the respondents income range between Rs.20,000-30,000, 19.6% of the respondents are income range between Rs.10,000-20,000, 26.1% of the respondents income range between Rs.30,000-40,000, 25.5% of the respondents income range between Rs.40,000-50,000, 6.5% of the respondents income are aboveRs.50,000.

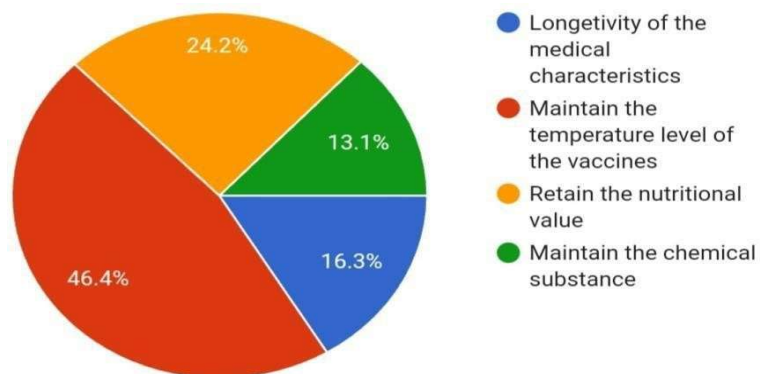
INFERENCE:

Therefore 26.1% of the respondents income range between Rs.30,000-40,000.

TABLE 6: THE MAJOR PURPOSE OF COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY

Particulars	No.ofRespondents	%ofRespondents
Longevity of the medical characteristics	25	16.3%
Maintain the temperature level for the vaccines	71	46.4%
Retain the nutritional value	37	24.2%
Maintain the chemical substance	20	13.1%
Total	153	153%

CHART 6 : THE MAJOR PURPOSE OF COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY



Source: primary data

INTERPRETATION:

46.4% of the respondents says Maintaining the temperature level for the vaccine, 16.3% of the respondents says longevity of the medical characteristics, 24.2% of the respondents says retaining the nutritional value, 13.1% of the respondents says maintaining the chemical substance

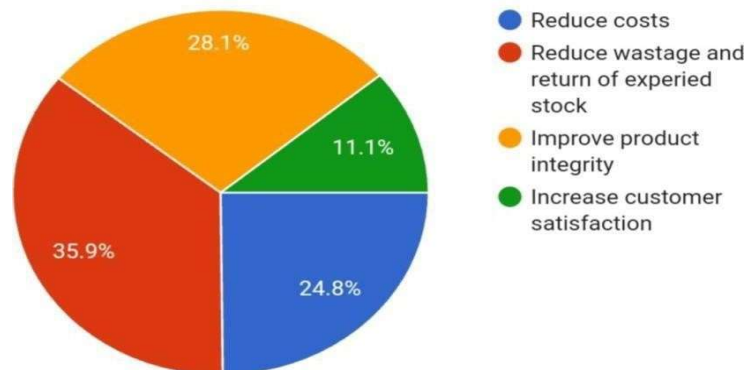
INFERENCE :

Therefore 46.4% of the respondents says maintaining the temperature level of vaccine

TABLE 7: THE MAIN OBJECTIVE OF COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY

Particulars	No. of Respondents	%of Respondents
Reduce costs	38	24.8%
Reduce wastage and return of expired stock	55	35.9%
Improve product integrity	43	28.1%
Increase customer satisfaction	17	11.1%
Total	153	153%

CHART 7: THE MAIN OBJECTIVE OF COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY



Source : primary data

INTERPRETATION:

11.1% of the respondents says that increase the customer satisfaction, 28.1% of the respondents says that to improve the product integrity, 24.8% of the respondents says to reduce the costs, 35.9% of the respondents say to reduce the wastage and return of expired stock.

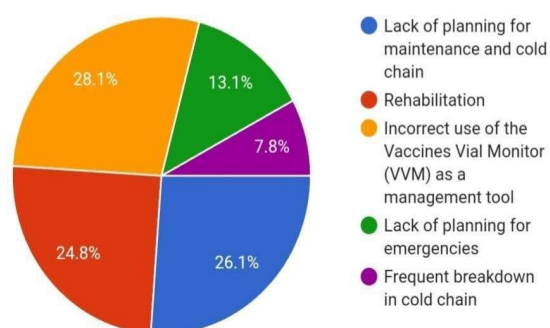
INFERENCE

Therefore 35.9% of the respondents say to reduce the wastage and return of expired stock.

TABLE 8: THE MAJOR ISSUE FOR THE TRANSPORT PROBLEMS IN COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY

Particulars	No.ofRespondents	%ofRespondents
Lack of planning for maintenance and cold chain rehabilitation	40	26.1%
Incorrect use of the Vaccines Vial Monitor (VVM) as a management tool	43	28.1%
Lack of planning for emergencies	20	13.1%
Frequent break downs in cold chain	12	7.8%
Total	153	153%

CHART 8: THE MAJOR ISSUE FOR THE TRANSPORT PROBLEMS IN COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY



Source : primary data

INTERPRETATION:

28.1% of the respondents says incorrect use of the Vaccines Vial Monitor(VVM) as a management tool ,13.1% of the respondents mention that the lack of planning for emergencies causes the 26.1% of the respondents mention that the lack of planning for maintenance and cold chain rehabilitation, 7.8% of the respondents mention that the frequent breakdowns in cold chain.

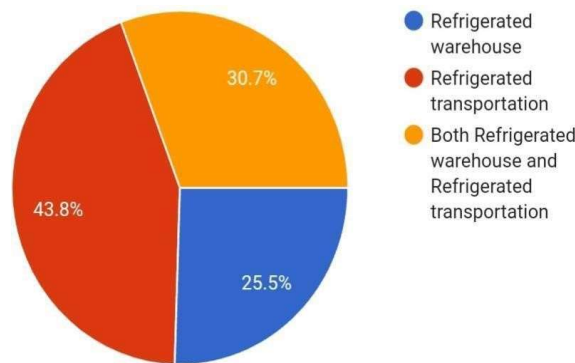
INFERENCE :

28.1% of the respondents says incorrect use of the Vaccines Vial Monitor (VVM) as a management tool

TABLE 9: THE MOST PRELIMINARY REQUIREMENT IN COLD CHAIN SUPPLY LOGISTICS FOR VACCINES

Particulars	No.of Respondents	%of Respondents
Refrigerated warehouse	39	25.5%
Refrigerated transportation	67	43.8%
Both Refrigerated warehouse & Refrigerated transportation	47	30.7%
Total	153	153%

CHART 9: THE MOST PRELIMINARY REQUIREMENT IN COLD CHAIN SUPPLY LOGISTICS FOR VACCINES



Source : primary data

INTERPRETATION

30.7% of the respondent preferred both the refrigerated warehouse & refrigerated transportation, 43.8% of the respondent preferred the refrigerated transportation 25.5% of the respondents preferred the refrigerated warehouse.

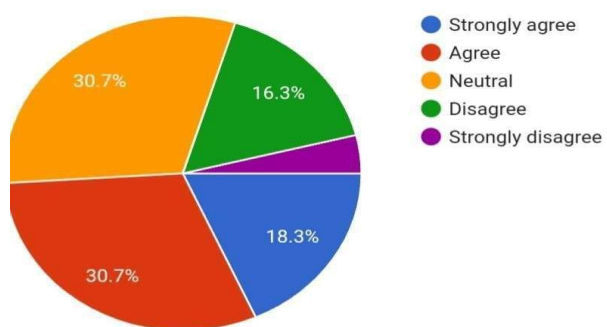
INFERENCE:

Therefore 43.8% of the respondents preferred the refrigerated transportation

TABLE 10: TRANSPORT SYSTEMS INFLUENCE THE SAFETY OF VACCINES IN PHARMACEUTICAL DISTRIBUTORS

Particulars	No.ofRespondents	%ofRespondents
Strongly agree	28	18.3%
Agree	48	32.7%
Neutral	47	31.7%
Disagree	25	16.3%
Strongly Disagree	6	3.9%
Total	153	153%

CHART 10: TRANSPORT SYSTEMS IN FLUENCE THE SAFETY OF VACCINES IN PHARMACEUTICAL DISTRIBUTORS



Source: Primary data

INTERPRETATION :

32.7% of the respondents says agreed 18.3% of the respondents says strongly agree 30.7% of the respondents says neutrally agreed 16.3% of the respondents says Disagreed 3.9% of the respondents says Strongly Disagreed

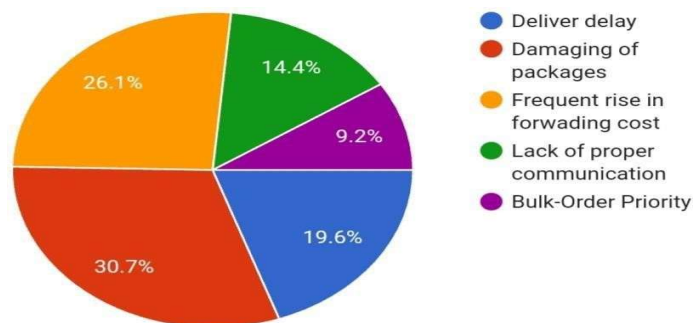
INFERENCE:

Therefore 32.7% of the respondents agreed with the transport systems which influence the safety of vaccines in pharmaceutical distributors.

TABLE 11: RANKS THE PROBLEMS FACED FROM CARRIERS DURING COLD CHAIN SUPPLY LOGISTICS IN MAINTAINING THE SAFETY OF VACCINES

Particulars	No. of Respondents	%of Respondents
Delivery delay	30	19.6%
Damaging of packages	47	30.7%
Frequent rise in forwarding cost	40	26.1%
Lack of proper communication	22	14.4%
Bulk-Order Priority	14	9.2%
Total	153	153%

CHART 11: RANKS THE PROBLEMS FACED FROM CARRIERS DURING COLD CHAIN SUPPLY LOGISTICS IN MAINTAINING THE SAFETY OF VACCINES



Source : primary data

INTERPRETATION :

9.2% of the respondents says Bulk- Order Priority 30.7% of the respondents for damaging of packages ,14.4%of the respondents for lack of proper communication 26.1% of the respondents for frequent rise in forwarding cost 19.6% of the respondents for delivery delay

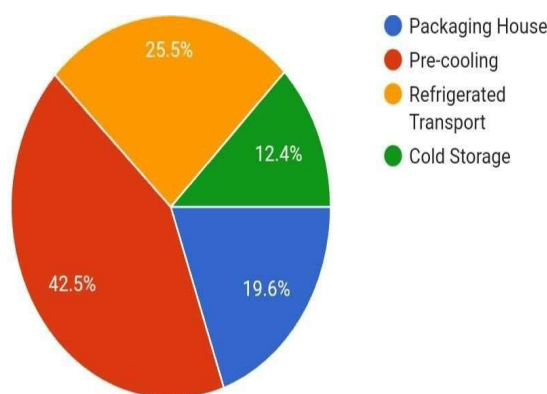
INFERENCE :

Therefore 30.7% of the respondents for damaging of packages which causes the problems faced from carriers during cold chain supply logistics in maintaining the safety of vaccine

**TABLE 12 : THE PROCESS FACES MORE PROBLEMS IN THE COLD CHAIN
SUPPLY LOGISTICS OFVACCINES**

Particulars	No.ofRespondents	%ofRespondents
Packaging House	30	19.6%
Pre-cooling	65	42.5%
Refrigeratedtransport	39	25.5%
ColdStorage	19	12.4%
Total	153	153%

**CHART 12: THE PROCESS FACES MORE PROBLEMS IN THE COLD CHAIN
SUPPLY LOGISTICS IN VACCINES**



Source : primary data

INTERPRETATION:

25.5% of the respondents say that the refrigerated transport , 42.5% of the respondents say that the pre-cooling transport 12.4%of the respondents say that the cold storage transportation 19.6% of the respondents say that the packaging house transport .

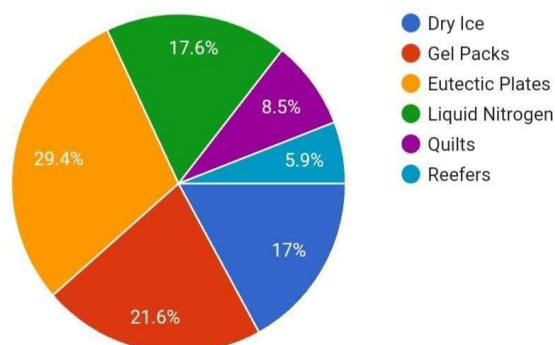
INFERENCE :

Therefore 42.5% of the respondents say that the pre-cooling process faces more problems in the cold chain supply logistics of vaccines.

TABLE 13 TECHNOLOGIES IS WIDELY USED FOR PACKAGING OF VACCINES IN COLD CHAIN SUPPLY LOGISTICS

Particulars	No.ofRespondents	%ofRespondents
DryIce	26	17%
GelPacks	33	21.6%
EutecticPlates	45	29.4%
LiquidNitrogen	27	17.6%
Quilts	13	8.5%
Reefers	9	5.9%
Total	153	153%

CHART 13: TECHNOLOGIES IS WIDELY USED FOR PACKAGING OF VACCINES IN COLD CHAIN SUPPLY LOGISTICS



Source: primary data

INTREPRETATION:

5.9% of the respondents say that Reefers, 29.4% of the respondents say that Eutectic plates, 17% of the respondents say that DryIce, 21.6% of the respondents say that Gel Packs, 8.5% of the respondents say that Quilts , 17.60% of the respondents say that Liquid Nitrogen

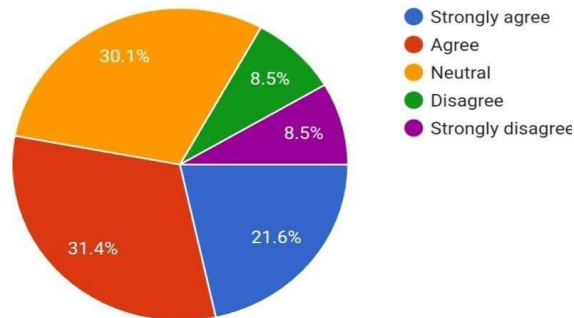
INFERENCE :

Therefore 29.4% of the respondents say that Eutectic Plates is widely used for packaging of vaccines in cold chain supply logistics.

TABLE 14 : THE PACKAGING HAS A BIG INFLUENCE IN PHARMACEUTICAL DISTRIBUTORS ON THE SAFETY OFVACCINES

Particulars	No.ofRespondents	%ofRespondents
Stronglyagree	33	21.6%
Agree	48	31.4%
Neutral	46	30.1%
Disagree	12	7.9%
StronglyDisagree	13	8.5%
Total	153	153%

CHART 14 : THE PACKAGING HAS A BIG INFLUENCE IN PHARMACEUTICAL DISTRIBUTORS ON THE SAFETY OF VACCINES



Source: primary data

INTERPRETATION:

21.6%of the respondents strongly agreed,31.4% of the respondents agreed 30.1%of the respondents neutrally agreed, 7.9%of the respondents strongly disagreed, 8.5% of the respondents says disagreed

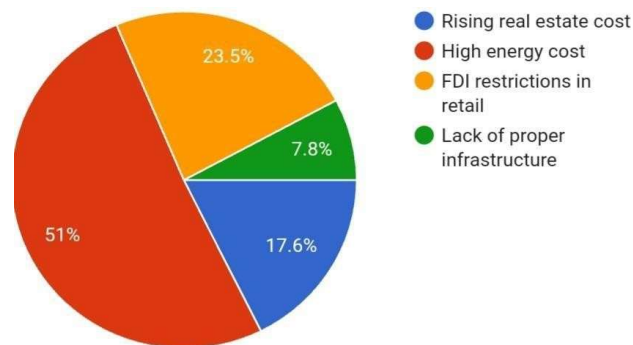
INFERENCE:

Therefore 31.4% of the respondents are agreed with the packaging has a big influence in pharmaceutical distributors on the safety of vaccines

TABLE 15 : THE MAJOR CHALLENGES IN THE COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY

Particulars	No.ofRespondents	%ofRespondents
RisingrealEstatecost	27	17.6%
Highenergycost	78	51%
FDIrestrictions inretail	36	23.5%%
Lack of proper infrastructure	12	7.8%
Total	153	153%

CHART 15: THE MAJOR CHALLENGES IN THE COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY



Source: Primary data

INTERPRETATION:

23.5% of the respondents say that FDI restrictions in retail, 51% of the respondents say that high energy cost, 7.8% of the respondents say that lack of proper infrastructure, 17.6% of the respondents say that rising real estate cost

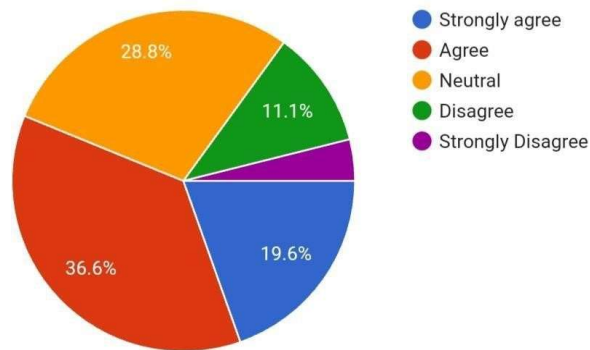
INFERENCE:

Therefore 51% of the respondents say that high energy cost is the major challenges in the cold chain supply logistics in pharmaceutical industry.

TABLE 16: THE COMMON TEMPERATURE RANGE FOR A COLD CHAIN IN PHARMACEUTICAL INDUSTRIES IS 2 TO 8°C

Particulars	No.ofRespondents	%ofRespondents
Stronglyagree	30	19.6%
Agree	56	36.6
Neutral	44	28.8%
Disagree	17	11.1%
StronglyDisagree	6	3.9%
Total	153	153%

CHART 16 : THE COMMON TEMPERATURE RANGE FOR A COLD CHAIN IN PHARMACEUTICAL INDUSTRIES IS 2 TO 8°C



Source : primary data

INTERPRETATION :

19.6% of the respondents strongly agree, 36.6% of the respondents agree, 28.8% of the respondents neutrally agree 11.1% of the respondents disagree 3.9% of the respondents strongly disagree

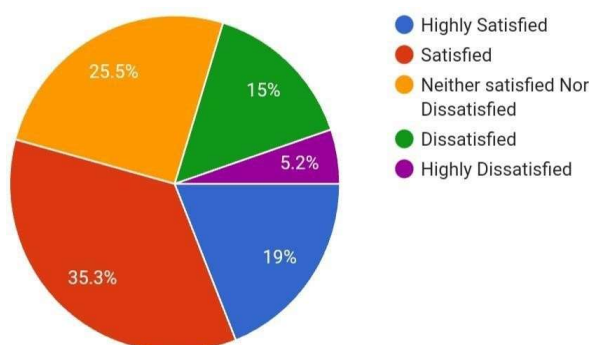
INFERENCE:

Therefore 36.6% of the respondents agree with the common temperature range for a cold chain in pharmaceutical industries is 2 to 8°C.

TABLE 17 SATISFACTION LEVEL WITH THE OVERALL QUALITY SYSTEM (NON CONFORMANCES AND CAPA'S) IN THE COLD CHAIN SUPPLY LOGISTICS FOR VACCINES

Particulars	No.ofRespondents	%ofRespondents
HighlySatisfied	29	19%
Satisfied	54	35.5%
NeitherSatisfied Nor Dissatisfied	39	25.5%
Dissatisfied	23	15%
Highly Dissatisfied	8	5.2%
Total	153	153%

CHART 17: SATISFACTION LEVEL WITH THE OVERALL QUALITY SYSTEM (NON CONFORMANCES AND CAPA'S) IN THE COLD CHAIN SUPPLY LOGISTICS FOR VACCINES



Source : primary data

INTERPRETYATION:

19% of the respondents are Highly Satisfied, 35.3% of the respondents are Satisfied
25.5% of the respondents are Neither Satisfied Nor Dissatisfied 15% of the respondents are
Dissatisfied 5.2% of the respondents are Highly Dissatisfied.

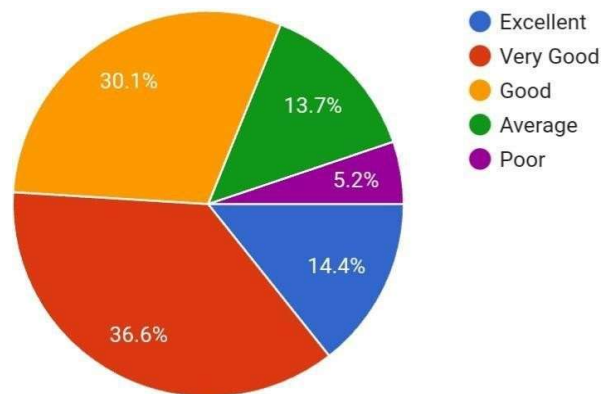
INFERENCE:

Therefore 35.3% of the respondents are Satisfied with the overall quality system (non conformances and capa's) in the cold chain supply logistics for vaccines

TABLE 18 OPINION ABOUT THE TECHNICAL CAPACITY IN PHARMACEUTICAL DISTRIBUTORS

Particulars	No.ofRespondents	%ofRespondents
Excellent	22	14.4%
VeryGood	56	36.6%
Good	46	30.1%
Average	21	13.7%
Poor	8	5.2%
Total	153	153%

CHART 18: OPINION ABOUT THE TECHNICAL CAPACITY IN PHARMACEUTICALDISTRIBUTORS



Source: primary data

INTERPRETATION:

14.4% of the respondents have an excellent opinion 36.6% of the respondents have a very good opinion30.1% of the respondents have good opinion13.7% of the respondents have an average 5.2% of the respondents have a poor opinion

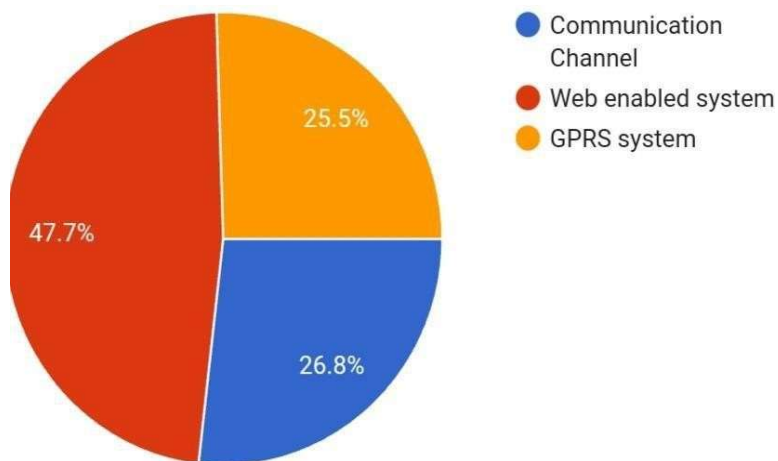
INFERENCE:

therefore 36.6% of the respondents have an very good opinion about the technical capacity inpharmaceutical distributors.

TABLE19 :TRACKING OF VACCINES IN COLD CHAIN SUPPLY LOGISTICS

Particulars	No.ofRespondents	%ofRespondents
Communicationchannel	41	26.8%
Webenabledsystem	73	47.7%
GPRSsystem	39	25.5%
Total	153	153%

CHART19: TRACKING OF VACCINESIN COLD CHAIN SUPPL YLOGISTICS



INTERPRETATION:

25.5% of the respondents prefer the communication channel for tracking of vaccines in coldchain supply logistics, 47.7% of the respondentsprefer the web enabled system for trackingof vaccines in cold chain supply logistics, 25.5% of the respondents prefer the GPRS systemfortrackingof vaccines in cold chainsupplylogistics.

INFERENCE:

Therefore 47.7% of the respondents prefer the web enabled sytem for tracking of vaccines incoldchain supplylogistics.

4.2 CHI-SQUARE

CHI-SQUARE TEST I- (χ^2)

Chi-square is the sum of the squared difference observed(o)and the expected (e)data (or the deviation, d), divided by the expected data in all possible categories.

Null hypothesis(Ho):

There is a relationship between the Experience and Income.

Alternate hypothesis(H1):

There is no relationship between the Experience andIncome.

CaseProcessingSummary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
EXPERIENCE	153	153.0%	0	.0%	153	153.0%
INCOME						

EXPERIENCE*INCOMECrosstabulation

			INCOME					Total
			10,000-20,000	20,000-30,000	30,000-40,000	40,000-50,000	above 50,000	
EXPERIENCE	0–1year	Count	25	0	0	0	0	25
		% within EXPERIENCE	153.0%	.0%	.0%	.0%	.0%	153.0%
		% within INCOME	96.2%	.0%	.0%	.0%	.0%	25.0%
		%ofTotal	25.0%	.0%	.0%	.0%	.0%	25.0%
1.1–3years		Count	1	41	1	0	0	43
		% within EXPERIENCE	2.3%	95.3%	2.3%	.0%	.0%	153.0%
		% within INCOME	3.8%	153.0%	5.9%	.0%	.0%	43.0%
		%of Total	1.0%	41.0%	1.0%	.0%	.0%	43.0%
3.1–6years		Count	0	0	15	0	0	15
		% within EXPERIENCE	.0%	.0%	153.0%	.0%	.0%	153.0%
		% within INCOME	.0%	.0%	88.2%	.0%	.0%	15.0%
		%of Total	.0%	.0%	15.0%	.0%	.0%	15.0%
6 .1– 10 Count			0	0	1	9	0	10

years	% within	.0%	.0%	10.0%	90.0%	.0%	153.0%
	EXPERIENCE						
	% within	.0%	.0%	5.9%	90.0%	.0%	10.0%
	INCOME						
	%ofTotal	.0%	.0%	1.0%	9.0%	.0%	10.0%
More	Count	0	0	0	1	6	7
than	% within	.0%	.0%	.0%	14.3%	85.7%	153.0%
10Years	EXPERIENCE						
	% within	.0%	.0%	.0%	10.0%	153.0%	7.0%
	INCOME						
	%ofTotal	.0%	.0%	.0%	1.0%	6.0%	7.0%
Total	Count	26	41	17	10	6	153
	% within	26.0%	41.0%	17.0%	10.0%	6.0%	100.0%
	EXPERIENCE						
	% within	153.0%	153.0%	153.0%	153.0%	153.0%	153.0%
	INCOME						
	%of Total	26.0%	41.0%	17.0%	10.0%	6.0%	153.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	348.695 ^a	16	.000
Likelihood Ratio	252.024	16	.000
Linear-by-Linear Association	96.062	1	.000
N of Valid Cases	153		

a. 19 cells (76.0%) have expected count less than 5. The minimum expected count is .42.

Degree of Freedom = $(r-1) * (c-1)$

$$= 4 * 4 = 16$$

Calculated value =

348.695 Tabulated value =

26.296 $Z = Z_{cal} > Z_{tab}$

$$Z = 348.695 > 26.296$$

Hence, the Alternate hypothesis [H₁] is accepted

INFERENCE:

Since the calculated value is greater than the tabulated value, we accept the alternate hypothesis and hence there is a relationship between the Experience and Income.

4.3 ANOVA

ONE-WAY ANOVA CLASSIFICATION

Null hypothesis(Ho):

There is a significance difference between the Transport systems influence the safety of vaccines in pharmaceutical distributors and the packaging has a big influence in pharmaceutical distributors on the safety of vaccines.

Alternate hypothesis(H1):

There is no significance difference between the Transport systems influence the safety of vaccines in pharmaceutical distributors and the packaging has a big influence in pharmaceutical distributors on the safety of vaccines.

Descriptives

Transport systems influence the safety of vaccines in pharmaceutical distributors

	N	Mean	Std.Devia tion	Std.E rror	95% Confidence IntervalforMean		Minim um	Maxim um
					Lower Bound	Upper Bound		
Strongly agree	42	1.36	.485	.075	1.21	1.51	1	2
Agree	22	2.36	.492	.105	2.15	2.58	2	3
Neutral	15	3.00	.000	.000	3.00	3.00	3	3
Disagree	10	3.80	.422	.133	3.50	4.10	3	4
Strongly Disagree	11	4.82	.405	.122	4.55	5.09	4	5
Total	153	2.45	1.242	.124	2.20	2.70	1	5

Test of Homogeneity of Variances

Transport systems influence the safety of vaccines in pharmaceutical distributors

Levene Statistic	df1	df2	Sig.
26.161	4	95	.000

ANOVA

Transport systems influence the safety of vaccines in pharmaceutical distributors

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	134.780	4	33.695	178.130	.000
Within Groups	17.970	95	.189		
Total	152.750	99			

Calculated value =

178.130

Tabulated value=2.47

$F = F_{cal} > F_{tab}$ $F = 178.130 > 2.47$

Hence, the Alternate hypothesis [H_1] is accepted.

4.4 CORRELATION

ANALYSIS USING KARL PEARSON'S CORRELATION

Correlation analysis is the statistical tool used to measure the degree to which two variables are linearly related to each other. Correlation measures the degree of association between two variables.

Null hypothesis (H₀):

There is positive relationship between the major purpose of cold chain supply logistics in pharmaceutical industry and the main objective of cold chain supply logistics in pharmaceutical industry.

Alternate hypothesis (H₁):

There is negative relationship between the major purpose of cold chain supply logistics in pharmaceutical industry and the main objective of cold chain supply logistics in pharmaceutical industry.

Correlations

	THE MAJOR PURPOSE OF COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY		THE MAIN OBJECTIVE OF COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY
THE MAJOR PURPOSE OF COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY	Pearson Correlation Sig.(2-tailed) N	1 153	.913** .000 153
THE MAIN OBJECTIVE OF COLD CHAIN SUPPLY LOGISTICS IN PHARMACEUTICAL INDUSTRY	Pearson Correlation Sig.(2-tailed) N	.913** .000 153	1 153

** .Correlation is significant at the 0.01 level (2-tailed).

$$r = \frac{N \sum XY - \sum X \sum Y}{\sqrt{N \sum X^2 - (\sum X)^2} \sqrt{N \sum Y^2 - (\sum Y)^2}}$$

r=.913

INFERENCE:

Since r is positive, there is positive relationship between the major purpose of coldchain supply logistics in pharmaceutical industry and the main objective of cold chain supplylogisticsin pharmaceutical industry.

CHAPTER5

FINDINGS,SUGGESTIONS,CONCLUSION

5.1 FINDINGS:

- Majority of the respondents belong to age group 20-30 (62.7%)
- Majority of the respondents are male(71.9%)
- Majority of the respondents are graduate (39.9%)
- Majority of the respondents have 3.1 –6years experience (31.4%)
- Majority of the respondents are earning30,000-40,000 (26.1%)
- Majority of the respondents say that maintain the temperature level for the vaccines (46.4%)
- Majority of the respondents are reduce wastageand return of expired stock (35.9%)
- Majority of the respondent are in correct use of the Vaccines Vial Monitor(VVM) as a management tool (28.1%)
- Majority of the respondents are Refrigerated transportation(43.8%)
- Majority of the respondents are Agree with Transport systems influence the safety of vaccines in pharmaceutical distributors (30.7%)
- Majority of the respondents are damaging of packages (30.7%)
- Majority of the respondents are Pre-cooling(42.5%)
- Majority of the respondents are Eutectic Plates (29.4%)
- Majority of the respondents are agree with the packaging has a big influence in pharmaceutical distributors on the safety of vaccines (31.4%)
- Majority of the respondents are High energy cost(51%)
- Majority of the respondents are agree with the common temperature range for a cold chain in pharmaceutical industries is 2 to 8°C(36.6%)
- Majority of the respondents are Satisfied with the overall quality system (non conformances and capa's) in the cold chain supply logistics for vaccines(35.3%)
- Majority of the respondents having very good opinion about the technical capacity in pharmaceutical distributors (36.6%)
- Majority of the respondents are Web enabled system(47.7%)

5.2 SUGGESTIONS

1. Flyton Xpress has to improve their planning for emergencies
2. Necessary measures need to be taken for maintenance and cold chain rehabilitation
3. Frequent breakdowns in cold chain has be avoided to improve the overall efficiency of cold chain logistics in handling pharmaceutical products
4. Frequent rise in forwarding cost can be avoided by owning the cold chain transportation and the cold storage.
5. Government can take suitable actions to reduce the high energy cost. This will help FlytonXpress involved in cold chain logistics to reduce their cost. When both the cost reductions happen, the end customers can avail the pharmaceutical products for a lesser price
6. Incorrect use of the Vaccines Vial Monitor (VVM) as a management tool has be avoided. Proper process has to be followed during the overall cold chain logistics for vaccines.

5.3 CONCLUSION

Cold chains are common in the food and pharmaceutical industries and also in some chemical shipments. There have been numerous events where vaccines have been shipped to third world countries with little to no cold chain infrastructure (Sub-Saharan Africa) where the vaccines were inactivated due to excess exposure to heat.

This study has been undertaken to assess the feasibility in handling the pharmaceutical products like vaccines in cold chain logistics with special reference to FlytonXpress. For this purpose, responses from the members involved in cold chain logistics have been collected and analyzed. Based upon the findings out of the research, few valuable suggestions like proper use of Vaccines Vial Monitor (VVM) as a management tool, improve the planning for emergencies etc have been suggested to Flyton Xpress. These suggestions will pave way for improving the overall efficiency of the cold chain logistics for pharmaceutical products like vaccines.

ANNEXURE

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QUESTIONNAIRE

DEMOGRAPHIC:

1. Age: a) 20-30 b) 30-40 c) 40-50 d) above 50

2. Gender A) Male B) Female

3. Educational Qualification: a) Graduate b) Post Graduate c) ITI d) Diploma

4. Experience

a) 0-1 year b) 1.1 – 3 years c) 3.1 – 6 years d) 6.1 – 10 years e) More than 10 Years
5. Income: a) 10,000-20,000 b) 20,000-30,000 c) 30,000-40,000 d) 40,000-50,000 e) above 50,000

6. What is the major purpose of cold chain supply logistics in pharmaceutical industry?

- f. Longevity of the medical characteristics
- g. Maintain the temperature level for the vaccines
- h. Retain the nutritional value
- i. Maintain the chemical substance

7. What is the main objective of cold chain supply logistics in pharmaceutical industry?

- a. Reduce costs
- b. Reduce wastage and return of expired stock
- c. Improve product integrity
- d. Increase customer satisfaction

8. What is the major issue for the transport problems in cold chain supply logistics in pharmaceutical industry?

- a. Lack of planning for maintenance and cold chain rehabilitation
- b. Incorrect use of the Vaccines Vial Monitor (VVM) as a management tool
- c. Lack of planning for emergencies
- d. Frequent break downs in cold chain

9. Which is the most preliminary requirement in cold chain supply logistics for vaccines?

- a. Refrigerated warehouse

- b. Refrigerated transportation
- c. Both Refrigerated warehouse & Refrigerated transportation

10. Transport systems influence the safety of vaccines in pharmaceutical distributors?

- i. Strongly agree
- ii. Agree
- iii. Neutral
- iv. Disagree
- v. Strongly Disagree

11. Rank the problems faced from carriers during cold chain supply logistics in maintaining the safety of vaccines?

S.No	Variables	Rank
1	Delivery delay	
2	Damaging of packages	
3	Frequent rise in forwarding cost	
4	Lack of proper communication	
5	Bulk-Order Priority	

12. Which process faces more problems in the cold chain supply logistics of vaccines?

- a. Packaging House
- b. Pre-cooling
- c. Refrigerated transport
- d. Cold Storage

13. Which technology is most widely used for packaging of vaccines in cold chain supply logistics?

- a. Dry Ice
- b. Gel Packs
- c. Eutectic Plates
- d. Liquid Nitrogen

- e. Quilts
- f. Reefers

14. Packaging has a big influence in pharmaceutical distributors on the safety of vaccines?

- i. Stronglyagree
- ii. Agree
- iii. Neutral
- iv. Disagree
- v. StronglyDisagree

15. What are the major challenges In the cold chain supply logistics in pharmaceutical industry?

- a. RisingrealEstatecost
- b. Highenergycost
- c. FDIrestrictionsinretail
- d. Lackofproperinfrastructure

16. One common temperature range for a cold chain in pharmaceutical industriesis 2 to 8°C

- i. Stronglyagree
- ii. Agree
- iii. Neutral
- iv. Disagree
- v. StronglyDisagree

17. What is overall satisfaction level with the overall Quality System(Non Conformances and CAPA's) in the cold chain supply logistics for vaccines?

HighlySatisfied	Satisfied	NeitherSatisfied NorDissatisfied	Dissatisfied	HighlyDissatisfied
1	2	3	4	5

18. What is your opinion about the technical capacity in pharmaceutical distributors in fluence safety of Vaccines?

- a. Excellent
- b. VeryGood

- c. Good
- d. Average
- e. Poor

19. Tracking of vaccines in cold chain supply logistics is done by

- a) Communication channel b) Web enabled system c) GPRS system