**Business Development from Start to Scale**
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**Week - 12**
**Business Development Case Studies**
**Lecture - 59**
**Creating Value**

Hi friends, welcome to the NPTEL course Business Development from Start to Scale. We are in week 12 with the theme of Business Development Case Studies. In this lecture, the 59th in the series, we consider the topic of Creating Value.

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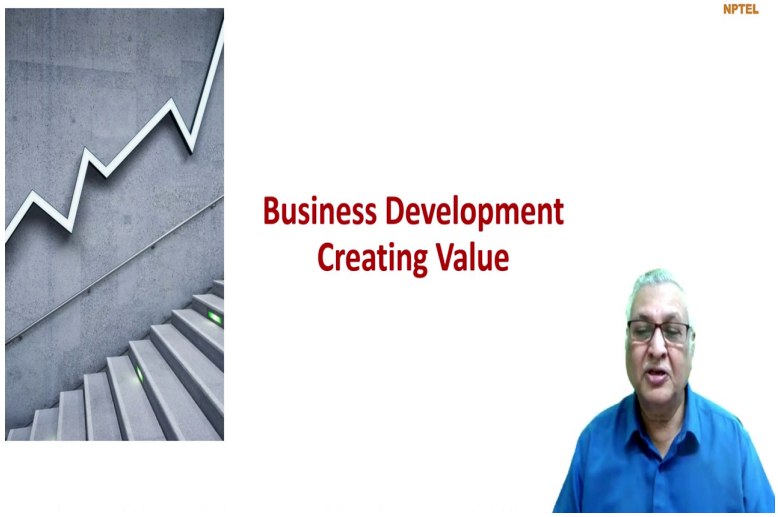


This is a case study of business development for a quality consulting company.

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Generally, we believe that sales, marketing, strategic marketing and business development are concepts that are related to product-based companies. However, these concepts are relevant for service-based companies as well as consulting companies. Sales is the practice of selling a product or service to a customer based on predefined or pre-researched customer needs, promoting the product or service throughout the distribution value chain.

So, salesperson has a task that is defined in terms of closing the transaction of sale. Marketing is the gamut of planning and execution to identify and satisfy customer needs by offering the company's products and services to the customers for a price, influencing customer perception positively through a variety of entities and media.

So, marketing is not only selling a product or service, but identifying the need for a product or service and also creating a perception in the mind of the customer to acquire the product or

service. And for that different marketing toolkits are available, which the marketing person is expected to deploy. Strategic marketing is the discipline of anticipating customer needs and enabling the company to offer new products and services for the customer, co-creating new experiences and value for the company.

Business development is the integrative discipline of guiding the development of long-term business infrastructure and value for the company with or without partnerships, integrating insights from business strategy, strategic marketing, technology management and various other disciplines. We have gone through these definitions as part of this course. We have had several case examples that illustrated the applicability of these definitions and also the importance of each of these practices.

I also demonstrated how these practices are interrelated to each other and how we need to have an integrative approach to the entire domain of business development. Even a consulting company as I said at the beginning of this lecture would require all these, but business development is the key factor for a consulting company, given that consulting business is relationship driven, especially B2B.

In respect of a product such as an automobile or a service such as a telecommunication service, the product or service respectively is quite tangible for the customer. Whereas in respect of consulting, the kind of service that would be rendered by the company is a bit intangible. Therefore, there is so much importance that is laid on successful business development as the prerequisite for undertaking any of the other activities in the quality consulting value chain.

I am talking about quality consulting because this entire case study is about a consulting company which is dedicated to the domain of quality.

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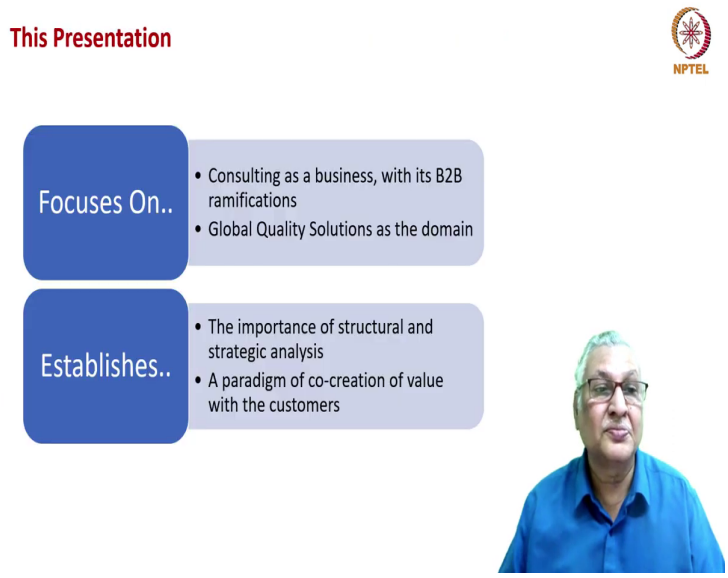


This presentation focuses on consulting as a business with its B2B ramifications, that is business to business ramifications. Most management consulting or technical consulting takes place as business-to-business operation. And the domain of this presentation is global quality solutions with focus on pharmaceutical industry.

This case study establishes the importance of structural and strategic analysis even for a consulting company and how the paradigm of co-creation of value with the customers can be demonstrated.

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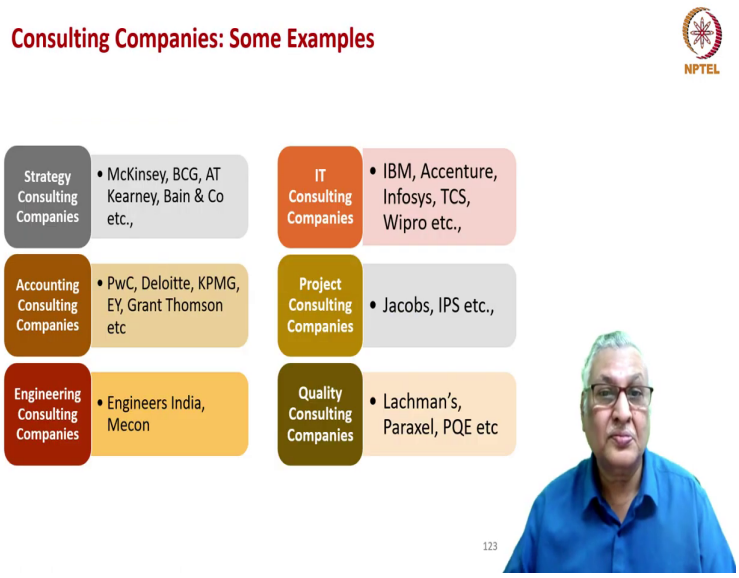


As we know, there are different types of consulting companies. I will give you some examples. There are strategy consulting companies such as McKinsey, BCG, AT Kearney, Bain and Co, etcetera. These kinds of companies typically work with the chief executive officers, the boards and senior leadership team members of a company and guide the company in terms of futuristic growth strategies and also high-level functional strategies.

There are accounting consulting companies such as Price Waterhouse Cooper, Deloitte, KPMG, Einstein, Yang, Grant Thomson, etcetera. They look at accounting-based work. Apart from that, they also have their own management consulting divisions which are quite operationally oriented or quite oriented towards individual disciplines.

For example, if you want to compare the distribution capabilities of different companies, probably the accounting consulting companies with their own management consulting are the best bet for you.

Then there are engineering consulting companies, which design projects which understand what a facility means and selects the right kind of facility along with the right kind of process and helps the company establish the manufacturing value chain. Engineers India, Mecon are examples of such engineering consulting companies. Then we have IT consulting companies such as IBM, Accenture, Infosys, TCS, Wipro, etcetera.

They not only provide software services, but also provide the IT architecture for several companies on an end-to-end BASIS. Project consulting companies are also there, Jacobs, IPS, etcetera. Who undertake turnkey planning and execution of projects, particularly complex projects. Then we have quality consulting companies like Lachmans, Paraxel, PQE, etcetera.

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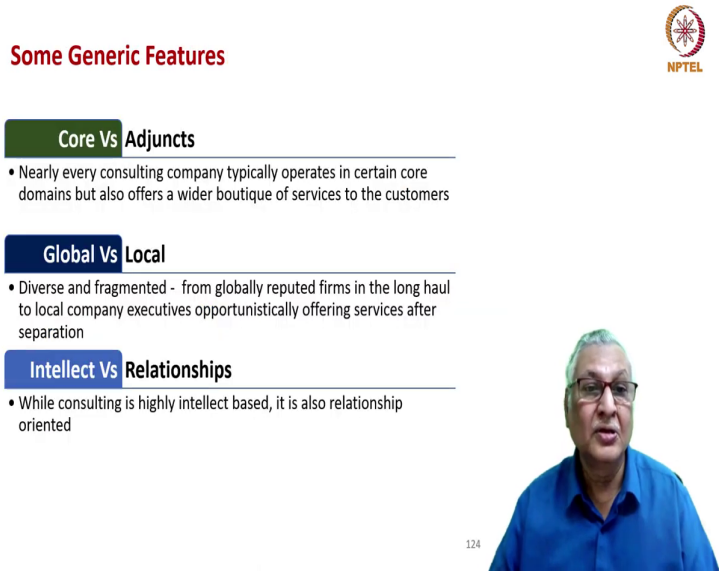


There are some generic features of any consulting company. The first feature is the distinction as well as adjacency of core versus adjuncts. Nearly every consulting company typically operates in certain core domains, but also offers a wider boutique of services to the customers. Whenever you think of strategy consulting, McKinsey comes up as the foremost name. That is because it is the core of the company.

However, McKinsey offers services in a wide spectrum of management activities including supply chain, manufacturing, operations and in recent times environmental, social and governance activities as well as in circular economy as an example. Global versus local, diverse and fragmented from globally reputed firms in the long haul to local company executives, opportunistically offering services after separation. The spectrum of companies offering consulting services is indeed huge.

That is because the entry barriers to set up a consulting company are very low. Intellect versus relationships. While consulting is highly intellect based, it is also relationship oriented. It is not unusual that people get into consulting with a relationship available to back you up.

Similarly, even big companies are now deploying retired executives or highly qualified people as experts or subject matter experts who not only bring in a fresh perspective in terms of the domain, but also make relationships happen. These are the three generic features of a consulting company.

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Another specific features of quality consulting are as follows. Consulting is highly technical. It is industry specific. It has to meet regulatory standards and it also must help the company meet regulatory standards. Some projects which the consulting companies undertake could be

make or break for the survival and future growth of the company. Consulting cannot stay static in terms of intellectual capability.

Consulting business is competency development driven and a consultant must continuously strive for perfection. These are the aspects of quality consulting.

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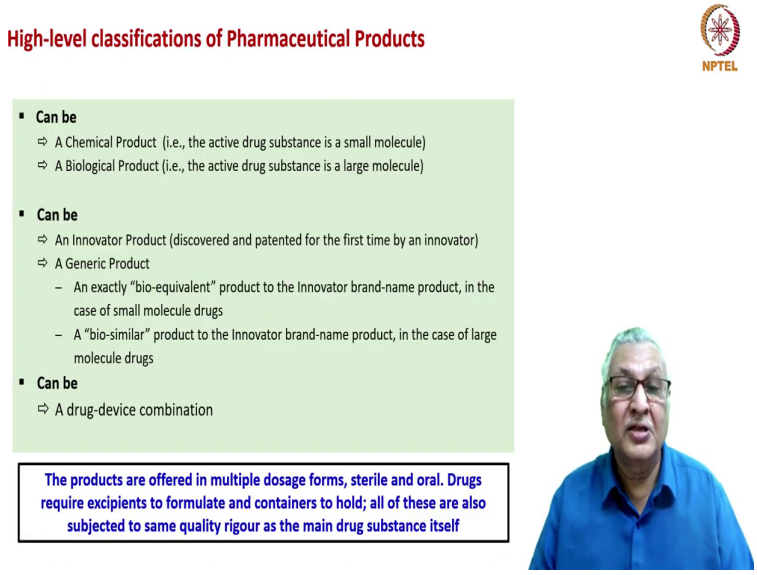


Let us look at the pharmaceutical products as an example. I want to illustrate how the company grew to what it has been and what it could be with the background of the quality domain. The quality domain in the pharmaceutical industry is very special and a very specific domain.

Before we appreciate the case, it is also important that we appreciate the domain of pharmaceutical industry and the domain of quality. A pharmaceutical product can be a

chemical product that is the active drug substance is a small molecule or a biological product that is the active drug substance is a large molecule.

It can be an innovator product that is discovered and patented for the first time by an innovator or it could be a generic product and exactly bio equivalent product to the innovator brand name product in the case of small molecule drugs.

A biosimilar product to the innovator brand name product in the case of large molecule drugs. It can be a combination of a drug and device. The products typically are offered in multiple dosage forms sterile and oral. As part of the orchid case study, we have considered the kind of classifications that are available in terms of therapeutical application as well as in terms of the dosage form. So, I will not repeat it.

Drugs require excipients to formulate and containers to hold that is as an example. If you want to formulate a product as a tablet, you cannot just punch the active substance into a tablet. The powder may not hold itself together. You need a binding agent or you need an excipient or both for the powder to bind itself as a tablet and stay like that over the period of the shelf life.

So, you require excipients and the finally, made tablet must be put in a container. It could be a bottle; it could be a plastic bottle or it could be in a blister pack. Similarly, if you are talking about a sterile product, it could be in a vial or it could be in an ampoule. And if it is a drug device combination, it could be in a prefilled syringe. All of these things are also subjected to the same quality rigor as the main drug substance itself. That is the beauty and the rigor of a pharmaceutical product.

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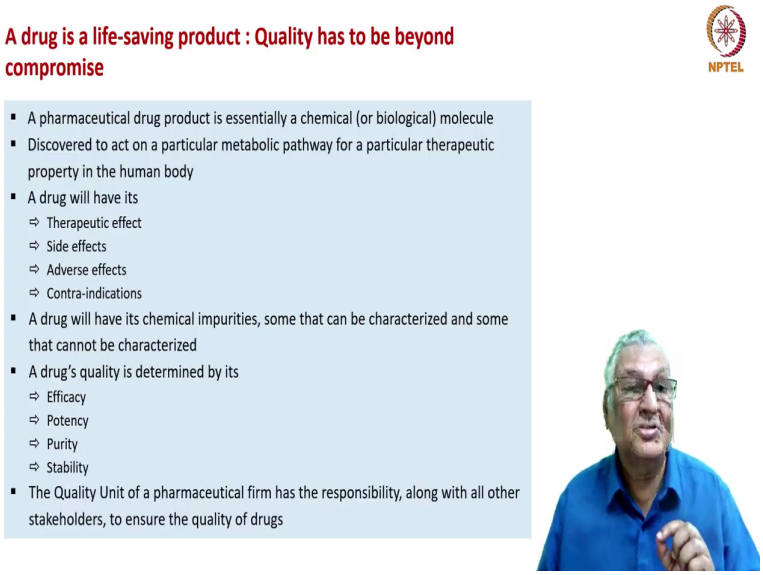


A drug is a life saving product. Therefore, quality has to be beyond compromise. A pharmaceutical product which is essentially a chemical or biological molecule is designed to save a life or improve life. It is discovered to act on a particular metabolic pathway of the human body for a particular therapeutic property in the human body. Therefore, a drug will have its therapeutic effect that is its curative effect, its side effects, its adverse effects and its contra indications. Why do these occur?

These side effects, adverse effects and contra indications because the science of relating the chemistry of a molecule to the exact pathway is not yet completely perfected. We know that a chemical molecule works on a particular pathway. For example, a CNS drug can work to inhibit the serotonin uptake. And because of that, there could be a better mood elevation.

That is how a Prozac has been discovered and brought into the market. However, nobody knows completely the other pathways on which the product will work. Therefore, it may have other therapeutic effects or non-therapeutic effects which are not completely understood.

There was a successor to fluoxetine called duloxetine. And surprisingly, it was discovered to not only act on the mood elevation or social affability, but also on the diabetic neuropathy.

It is an unknown therapeutic effect which came into being after it was tested in the human beings. Similarly, there are many drugs which have unknown therapeutic effects and doctors who have observed that use them for off-label applications. Again, such one or two unknown therapeutic effects that are discovered. They are tend to be many side effects, adverse effects and contraindications that need to be carefully looked at. And that happens because of the impurities impart.

Because the drug is a chemical product, it is bound to have impurities. The way it is manufactured from the basic raw material stage, combining intermediates, converting intermediates into the final starting material and converting that final starting material into the final drug. A whole number of chemical process are involved including use of solvents and then extracting of all those solvents.

So, chemical impurities are bound to be there. Some can be characterized and some cannot be characterized. So, the level of impurities is prescribed to be at the lowest level possible individually and collectively at one level as far as the regulatory requirements are concerned.

So, a drug's quality is determined by its efficacy, potency, purity and stability. Because the drug has to stay for whatever is the prescription life without any deterioration in its therapeutic characteristics or without any potentiation of unnecessary side effects, adverse effect and contra indications. The quality unit of a pharmaceutical firm has the responsibility along with all other stakeholders to ensure the quality of drugs. That is the importance of quality.

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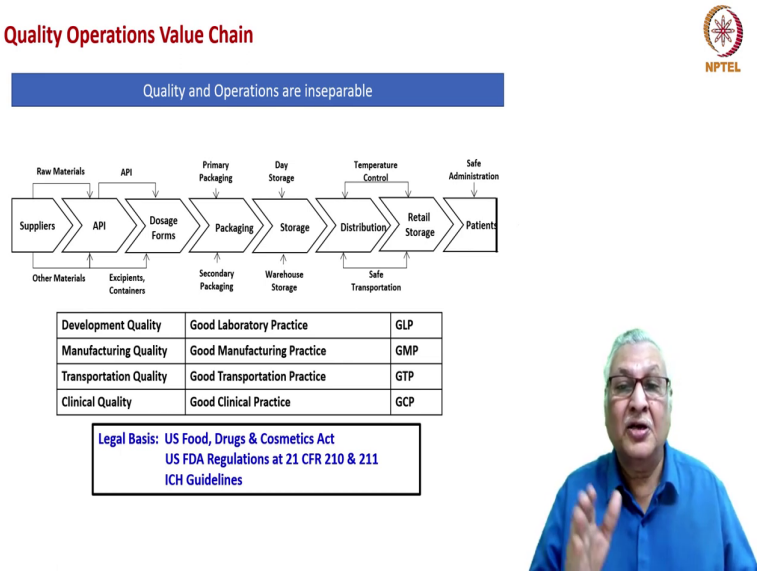


Quality and operations are inseparable. Drug manufacturer is not something where you can produce endlessly and then start inspecting. You got to ensure that quality is ingrained in the operations. When you look at the value chain of a pharmaceutical operation, it starts with the raw material supplies, other material supplies and all of that will help the company make active pharmaceutical ingredients.

API and excipients and containers help manufacture of dosage forms. They are put into the primer packaging which is the blister or the vial as an example. Then secondary packaging takes place in terms of putting it in the (Refer Time: 15:19) and then day storage happens within the shop and then warehouse storage happens. And finally, it is distributed through certain temperature controlled methodologies to the warehouses and the retail storage areas. Safe transportation is also extremely important.

The responsibility of pharmaceutical firm does not stop with the manufacture of a pharmaceutical product. It extends all the way till the product is reached to the retail shelves and then the safe administration to the patients. In order to govern all of these things as per certain internationally recognized and standardized procedures, agents such as US Food and Drug Administration as well as the UK, MHRA and other agencies of the European Union brought up certain quality standards.

If it is development quality that is quality at the and D level, you have what is called Good Laboratory Practice which is GLP. If you are manufacturing a product and you are trying to assure the manufacturing quality, it is a Good Manufacturing Practice are GMP. If you are trying to transport as per the quality standards, is called Good Transportation Practice GTP and if you are conducting clinical trials as per Good Clinical Practice, then it is GCP.

So, for every activity you undertake in a particular pharmaceutical operation on an end-to-end basis, you have either GLP, GMP, GTP or GCP and the responsibility of the quality unit of a company is to make the company compliant with all these standards.

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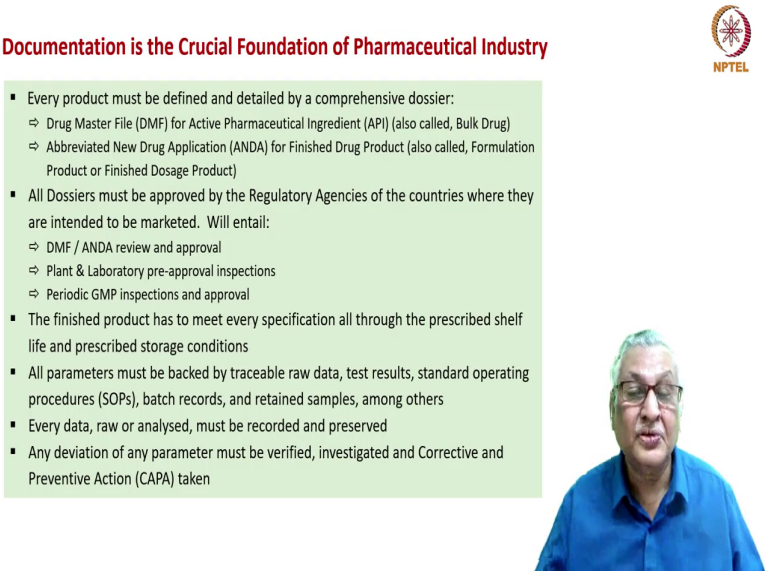


For the pharmaceutical industry, documentation is the critical formulation. Every product must be defined and detailed by a comprehensive dossier, drug master file or DMF for active pharmaceutical ingredient that is the API or the bulk drug and abbreviated new drug application ANDA for the finished drug product also called formulation product or finished dosage form. And this ANDA is applicable, the product is already generic or is going to be generic.

On the other hand, if the product is brought out for the first time, it is called the new drug application or NDA. All dossier must be approved by the regulatory agencies of the countries where they are intended to be manufactured. This will intake DMF, ANDA, review and approval, plant and laboratory pre-approval inspections, periodic GMP inspections and

approvals. The finished product has to meet every specification all through the prescribed shelf life and the prescribed storage conditions.

All parameters must be backed by traceable raw data, test results, standard operating procedures, batch records and retained samples among others. Each of these terms has a meaning in the quality domain and the operations domain of a pharmaceutical company. Every data raw or analysed must be recorded and preserved. Any deviation of any parameter must be verified, investigated and Corrective and Preventive Action CAPA taken.

Not only that, if you make any change to any of your processes, facilities or the formula of the product, you must have a change control mechanism, which is approved by all the divisions or the stakeholders after ascertaining the impact of the change on the quality of the product.

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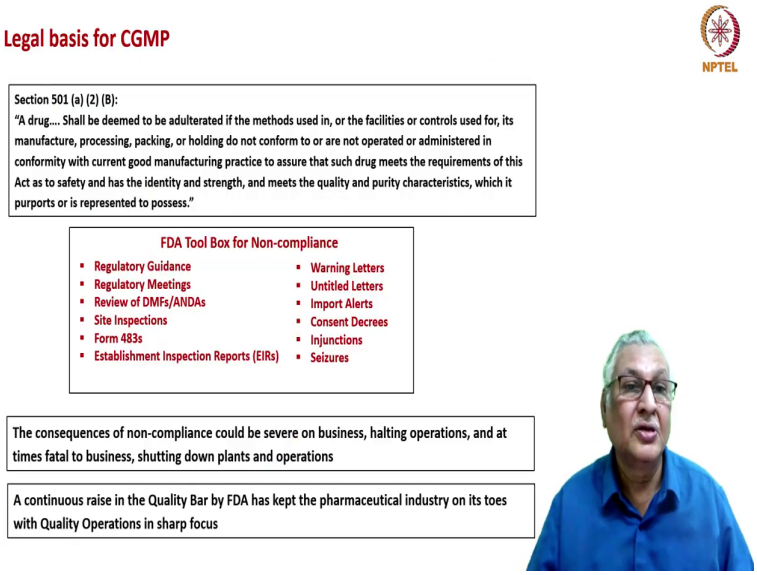

What is the legal basis for this GMP or CGMP? That is current good manufacturing practice. According to Section 501 a 2 B of the FDA legal regulations, a drug shall be deemed to be adulterated if the methods used in or the facilities or controls used for its manufacture, processing, packing or holding do not confrom to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this act as to safety and has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess.

See the complexity of the definition. And for making companies follow this, FDA has a strong toolbox and the toolbox is for compliance as well as for non-compliance. Regulatory guidance is available on development and manufacture for guidance. You can have regulatory meetings with the regulatory authorities to understand whether your processes are appropriate or not.

You can have review of DMFs and ANDAs and the FDA comes back to you saying that these are my observations and what do you feel about them and how do you correct. Then site inspections happen to make sure that this site meets the GLP and GMP standards. At the end of the inspection, the FDA issues what is called Form 483 which lays down all the observations under different heads.

When the inspection is closed after all appropriate answers are provided, the FDA issues establishment inspection reports. And those reports could be issued even when the inspection has failed to approve. Then based on the responses of the companies there could be warning letters, untitled letters, import alerts, consent decrees, injunctions and even seizures. So, all of this means that there is a legal basis for CGMP and pharmaceutical quality cannot be taken lightly.

The consequences of non-compliance could be very severe on business, halting operations and at times even fatal to the business shutting down plants and operations. A continuous increase or raising of the quality bar by FDA has kept the pharmaceutical industry on its toes with quality operations coming into sharp focus.

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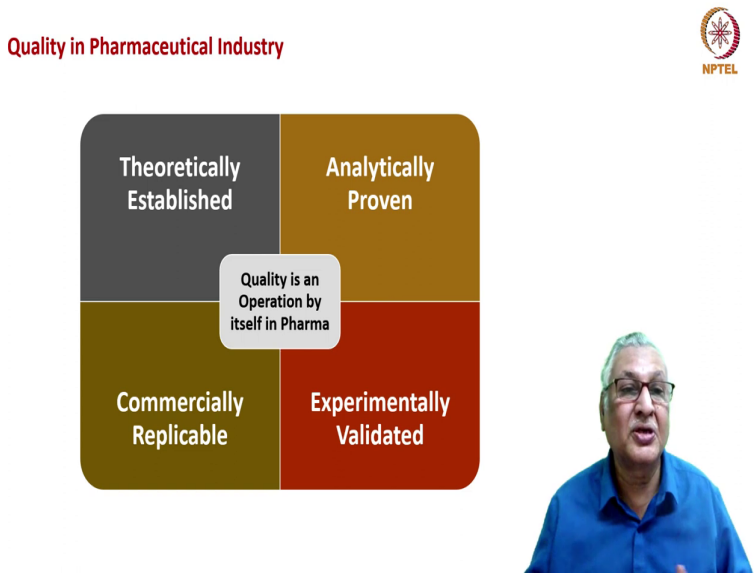


I will try to illustrate this importance in respect of certain frameworks. First quality in pharmaceutical industry has to be theoretically established that is we have the science; we have the technology.

Based on that the quality has to be theoretically established that is Quality by Design or QBD. And what you do and what you intend to do must be analytically proven. That is based on the analytical experiments you do or from based on the sophisticated equipment through which you measure the specifications it has to be analytically proven.

Then whatever you are doing must be experimentally validated. Therefore, before you have commercial production you must have an exhibit batch which is probably one tenth or one hundredth of the scale of the intended production. And that must be fully reviewed fully

captured in terms of its data and then reviewed by the company as well as by the regulatory authority.

And the production and the product must be commercially replicable. It must be exactly of the same quality all through it the life of the product. These are the four important parameters of quality.

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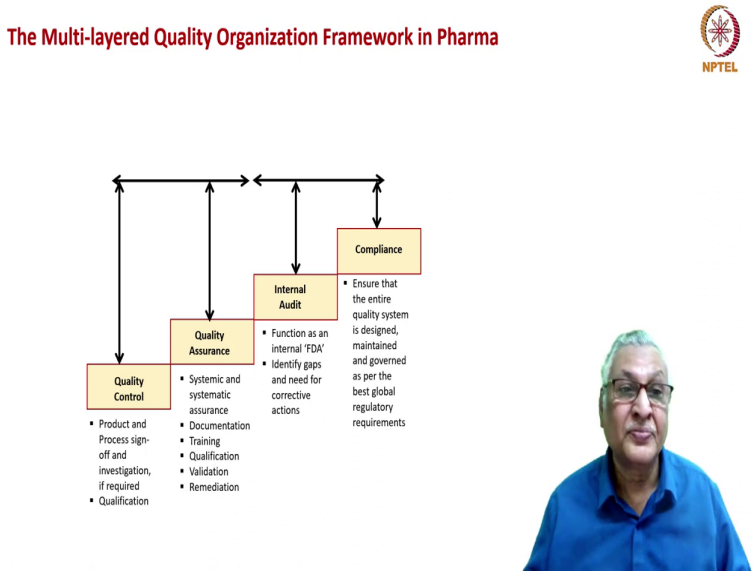


And to be able to do that pharmaceutical industry probably it is the only industry that has a multi-layered quality organization. It starts with quality control. It does product and process sign off and investigation and it also undertakes the qualification. There is a second wing of the quality unit or the quality organization which looks at quality assurance. It does not look at the day-to-day batches.

It looks at the systemic and systematic assurance procedures and controls in an organization. It looks at the documentation. It considers the training of people, qualification of facilities and people, validation of the facilities and processes and remediation where it is required. So, it takes care of the systems. If you have a strong quality assurance department you gain the confidence that this facility is likely to produce standardized high-quality production as per these specifications.

Then there will be internal audit that functions as an internal FDA or a regulatory agents. It identifies gaps from time to time and suggests the need for corrective actions and of course, monitors the implementation of those corrective actions. Then there is a fourth wing of the quality organization. It ensures that the entire quality system is designed, maintained and governed as per the best regulatory requirements of the world.

Not just one, even if you are exporting to the US, it is apt for the company to be compliant with the European regulation as well. That is the way in which quality gets seen by reputed pharmaceutical companies. There is the multi-layered quality organization framework.

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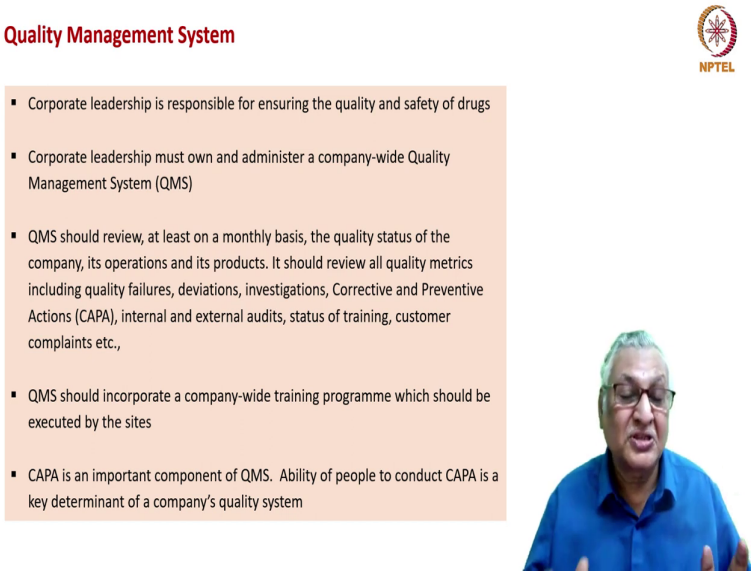


You also must have a quality management system in the company. Corporate leadership is responsible for ensuring the quality and safety of drugs. Corporate leadership must own and administer a company-wide Quality Management System, QMS. QMS should review at least on a monthly basis the quality status of the company, its operations and its products.

It should review all quality metrics including quality failures, deviations, investigations, corrective and preventive actions, internal and external audits, status of training, customer complaints etcetera. It should have volumes of data on whatever is going through the factory or the r and d laboratory. QMS should incorporate a company-wide training program which should be executed by the sites.

CAPA, as I said earlier also, is an important component of the quality management system. Ability of people to conduct CAPA is a key determinant of a company's quality system.

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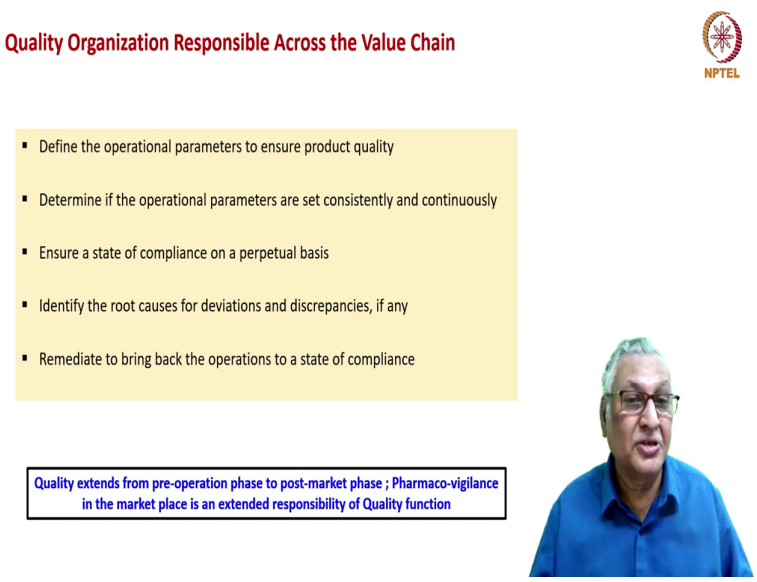


Quality organization is responsible all across the value chain. It has to define the operational parameters to ensure product quality. It has to determine if the operational parameters are set consistently and continuously. It has to ensure a state of compliance on a perpetual basis.

It has to identify the root causes for deviations and discrepancies if any and it has to remediate to bring back the operations to a state of compliance. A quality organization's role in an organization is simply not just inspection. It has to also suggest remediation and make sure that the remediation gets implemented. Quality extends from the pre-operation phase to

post-market phase. Pharmaco-vigilance in the marketplace is an extended responsibility of quality function.

That is how the medicine is performing in the actual usage setting by the clinicians and the patients is a matter of importance for the quality organization. And companies have a pharmaco-vigilance database. The regulatory agencies have a pharmaco-vigilance database and all the effects related to the side effects or contraindications or adverse effects are posted on to the site.

And one of the reasons why suddenly you get black box warnings or change in the usage patterns as stipulated by the regulatory agencies is related to the pharmaco-vigilance outcomes.

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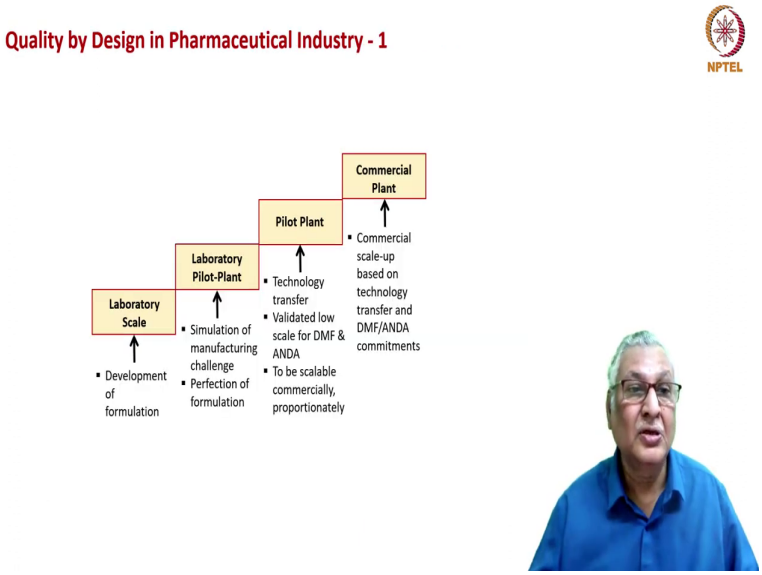

Let us look at quality by design. There are four aspects (Refer Time: 27:14) There is one laboratory-scale quality by design. That is you develop a formulation. You have a prototype formulation, you test it out, then you take it to a pilot plant. You simulate the manufacturing challenge and perfect the formulation.

Then you tech transfer or transfer it through technology to the pilot plant in the manufacturing location. And you validate on a low scale for drug master file and ANDA. And that process should be scalable commercially and technically in a proportionate manner.

And then you have the commercial plant where you do the commercial scale-up based on technology transfer and DMF, ANDA commitments. And approvals, this is the overall framework of quality by design in the pharmaceutical industry.

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Let us look at the other aspect of quality by design. Safety is of paramount importance given the chemical or biological nature of products and the tight controls on facilities and buildings. Therefore, by design, you should have the highest possible environmental controls in and around facilities.

You must have optimized personnel and material flow in a pharmaceutical company you can never have people and materials cross each other. You should have barriers between so-called bad materials and so-called good materials. Finished goods must be treated separately. There must be class conditions for different types of rooms that exist in a pharmaceutical shop or factory.

You must have ergonomics that support sterility in human operations. That is, when you have sterility in a room, if you keep moving too many times in a too risk fashion, the sterility will be affected because sterility is all about airflow. You have high efficiency, high performance filters which provide sterile air into the room. And you cannot have vigorous movements or violent movements within the room.

Therefore, there is need for ergonomics that support sterility in human operations. You must have minimal number of equipment and people so that human contamination on a medicinal product is minimized. You should have minimal and dedicated entries and exits for men and materials. Transfers into critical areas to be minimized. Whenever you move from a less critical area to a critical area, there is always the possibility of air ingress. So, you got to minimize those transfers.

You should have similar principles for adjacent critical areas. You should avoid drains in critical areas because drains are a cause of contamination. Transport and loading procedures to be under class 100. That is the highest level of movement under sterility. All equipment and buildings to be designed to facilitate ease of sterilization. Deviations are change control systems should address atypical conditions. Treatment of effluents that is zero discharge systems constitute another critical aspect of facility design.

And all of these things need to be monitored on a daily continuous basis. Whenever human intervention is more, whenever a campaign gets started or when you are periodically assessing the overall environment burden in a particular sterile facility or oral facility. You also simulate through smoke studies, media studies and various other studies, which of course, is a completely different technical matter.

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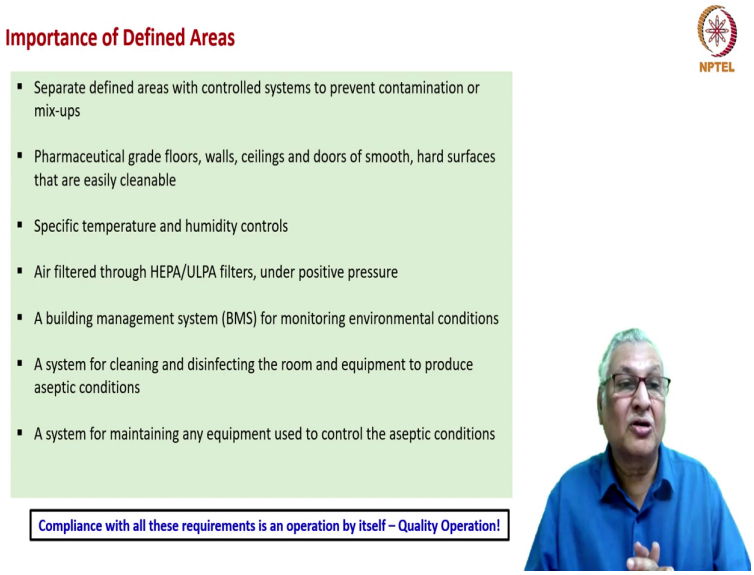


I would also talk about the importance of defined areas because defined areas are those areas which are separate with dedicated control systems to prevent contamination or mix-ups. Pharmaceutical grade walls, floors, ceilings and doors of smooth hard surfaces that are easily cleanable. Specific temperature and humidity controls air filtered through HEPA, ULPA filters under positive pressure.

A building management system for monitoring environmental conditions. A system for cleaning and disinfecting. The room and equipment to produce aseptic conditions and a system for maintaining any equipment used to control the aseptic conditions. Compliance with all these requirements is an operation by itself. Therefore, quality itself is an operation.

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For handling all of these things, a quality organization requires multiple capabilities, air classifications, environmental monitoring, qualification and validation, process simulations, sterility testing, process controls, personal competencies, warehousing controls, auto specification, CAPA and QMS studies, vendor and channel qualifications, data integrity and regulatory compliance.

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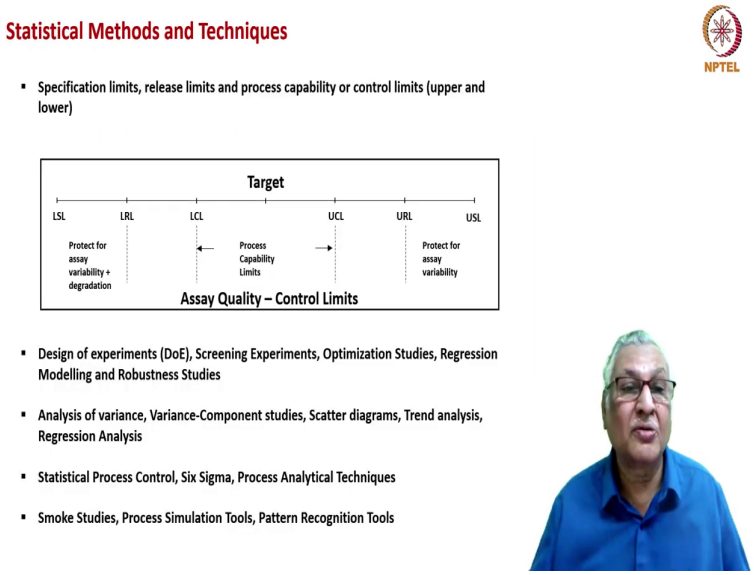


Let me talk about some of these aspects further. You require high level of statistical capability to provide quality consulting or quality service internally. This is how you set the assay quality for a particular product. Within the control limits, process capability limits will be the tightest and then you have protection for assay variability. You have protection for the lower end for the assay variability plus degradation.

So, you set specification limits, release limits and process capability or control limits upper and lower based on experiments, screening experiments, optimization studies, regression modelling and robustness studies. Analysis of variance, variance component studies, scatter diagrams, trend analysis, regression analysis, all statistical tools that are deployed.

In addition, the manufacturing flow requires statistical process control, Six Sigma, process analytical techniques. And before you authorize a room or a facility, you have to have smoke

studies, process simulation tools and pattern recognition tools. So, that is the depth of statistics and technology that is required in signing off any particular product or any particular facility.

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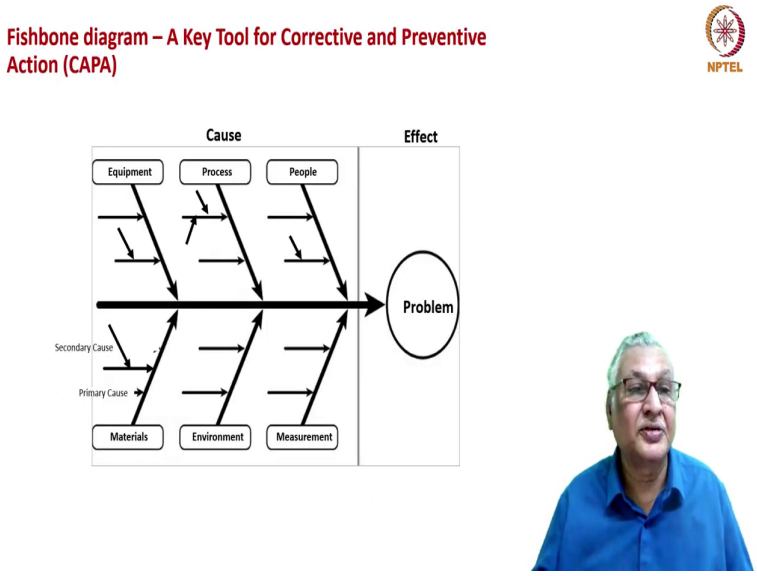


And you have to have very thorough investigation of any action that is required for correction. So, you should study the primary and secondary causes through the filters of materials, environment, equipment, process, people and our own methods of measuring anything. So, there is a cause and there is an effect. Problem is just an effect. We have to find out what is the root cause and address the root cause. That is the idea of investigation in a quality set.

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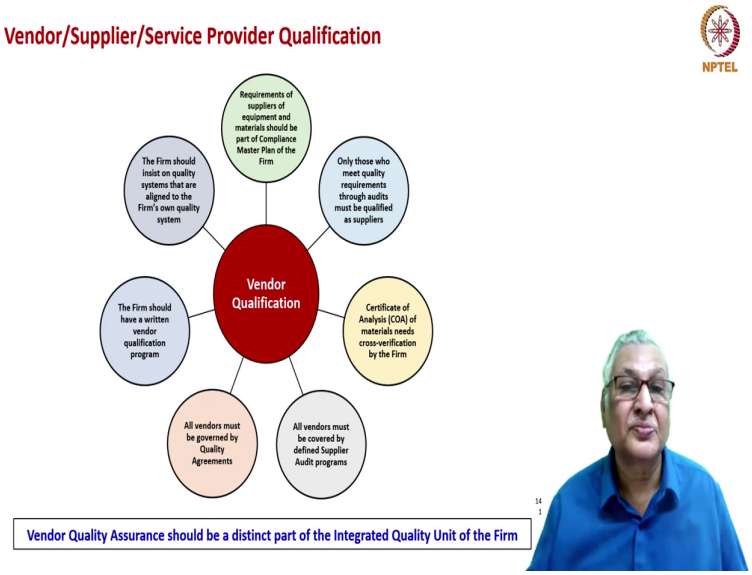


Not only we as a company, but our vendors must also be completely covered by quality systems. Under quality assurance is a very distinct part of the integrated quality unit of the firm. Quality unit does not stop with own quality assurance. It goes all the way up to the vendors. So, the there will be a compliance master plan which integrates the requirements of the suppliers and equipment and materials. Then only those people who qualify get registered as suppliers.

You got to have certificates of analysis for every material and it must be cross verified by the firm. All vendors must be covered by defined supplier audit programs. All vendors must be governed by quality agreements. The firm should have a written vendor qualification program which the vendor itself would implement and that should be open for investigation review by

the parent companies organizational unit. The firm should insist on quality systems that are aligned to the firm's own quality system.

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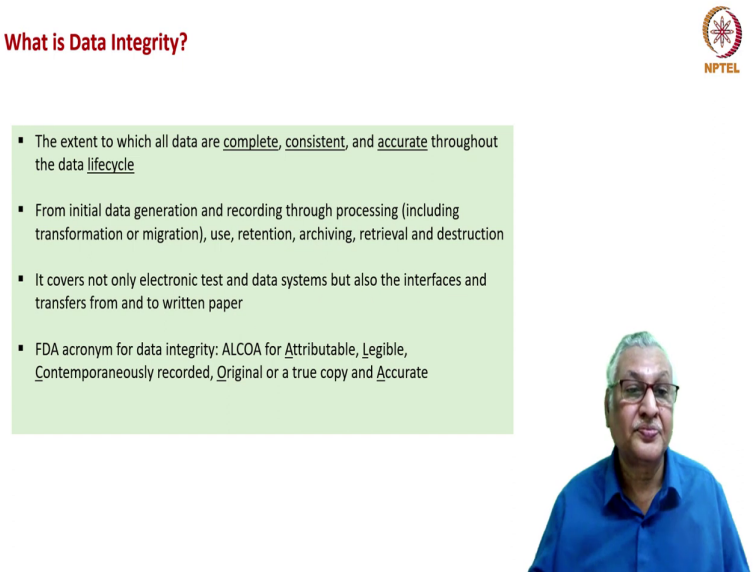


That is the importance of vendor qualification. I talked about data integrity. The extent to which all data are complete, consistent and accurate throughout the data lifecycle is the definition of data integrity. From initial data generation and recording through processing including transformational migration, use, retention, archiving, retrieval and destruction data integrity covers everything. It covers not only electronic test and data systems, but also the interfaces and transfers from and to written paper.

FDA has an acronym for data integrity ALCOA that is Attributable, Legible, Contemporaneously Recorded, Original or a True Copy and Accurate. Every bit of information, every bit of data, every bit of experimental recording or every piece of

information that gets generated in the pharmaceutical industry has to meet the requirements of data integrity as per this ALCOA.

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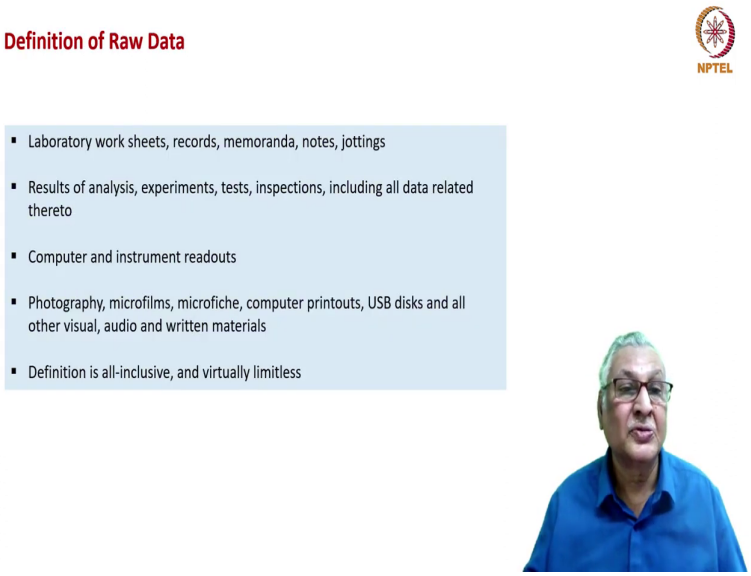


And raw data is what? You cannot say that I concentrate only on the finished data. Raw data is also equally important laboratory worksheets, records, (Refer Time: 36:21) you have, the memoranda, notes, jotting, all of these things are raw data which are subjected to the data integrity test.

Results of analysis, experiments, tests, inspections including all data released there too. Computer and instrument readouts, photography, microfilms, microfiche, computer printouts, USB disks and all other visual audio and written materials. Definition is all inclusive and virtually limitless.

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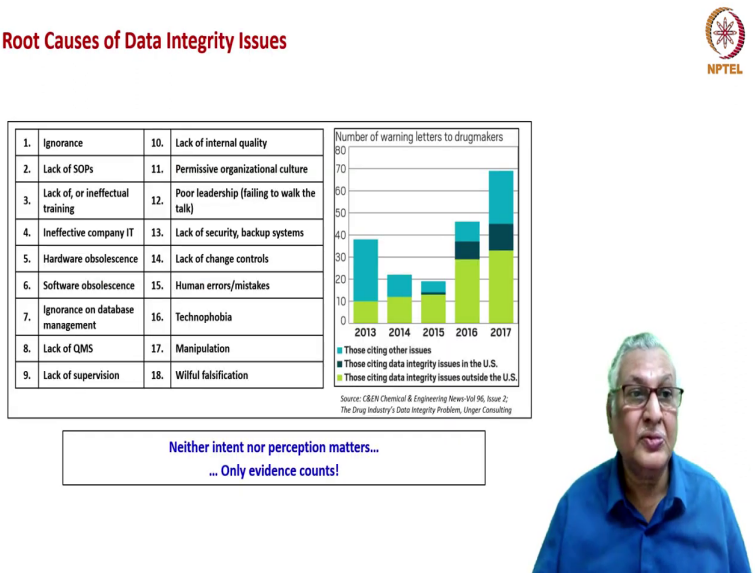


FDA has been issuing warning letters to the drug makers. 2015 was the lowest level at 18 or so. But this has increased to 70 in 2017 and I believe it is at a level of about 100 today. You see three colors in this, but in that the deep blue or the citations on data integrity within the US and the light green or the citations of data integrity issues outside the US.

And data integrity could be as simple as not striking of something when you put another date, you would overwrite that itself is a data integrity issue. And for data integrity there are several causes in general in companies from ignorance to willfull falsification. You have several causes which could be resulting in data integrity perception.

And as far as the FDA is concerned neither intent nor perception matters, only evidence counts. And in that even poor leadership that is failing to walk the talk of quality could be a contributor. IT itself could be a big contributor for data integrity observations. The poor

hardware that is outdated equipment which cannot maintain the process capability could be a contributor.

Lack of QMS could be a contributor, manipulation by people could be a contributor and inability of people to come near technical aspects could be a contributor. All of these things are root causes of data integrity issues in a pharmaceutical company.

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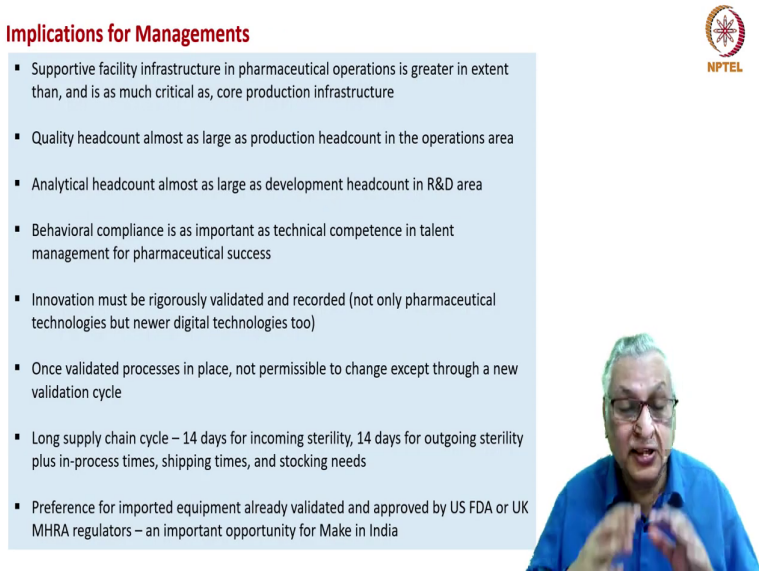


And the implications for managements are the following. Supportive facility infrastructure in pharmaceutical operations is greater in extent than and is as much critical as core production infrastructure. Quality headcount is almost as large as production headcount in the operations area. Analytical equipment or analytical expert headcount is almost as large as development equipment or development headcount in R and D area.

Behavioral compliance is as important as technical competency in talent management for pharmaceutical success. Innovation must be rigorously validated and recorded. Not only pharmaceutical technologies, but newer digital technologies too. Once a validated process is in place it is not permissible to change except through a new validation cycle. The supply chain is very long.

14 days for incoming sterility, 14 days for out comings sterility plus in process times, shipping times and stocking needs if it is a sterile product manufacturer and supply. Preference for imported equipment that are already validated and approved by US FDA or UK MHRA regulators. And this is an important opportunity for making India initiative in India.

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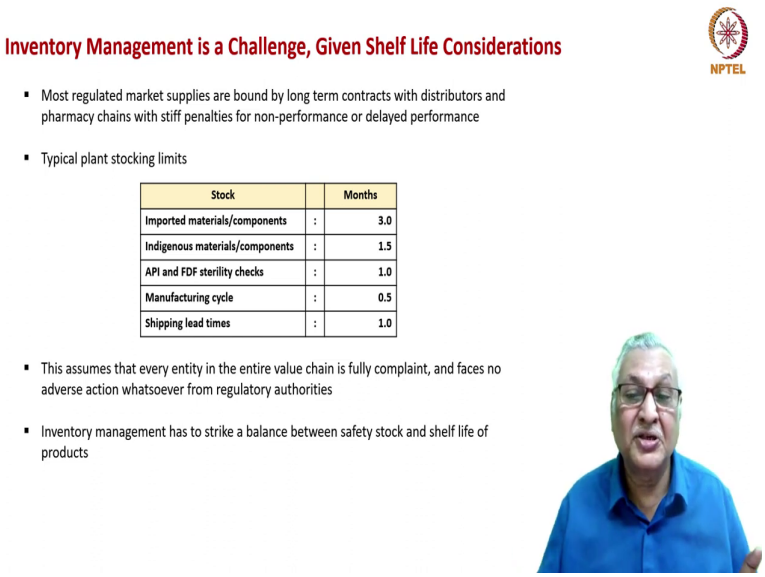

Inventory management is a challenge. I have given you a table here of the stocking limits that are required. For imported materials, 3 months, indigenous materials components 1.5, for bulk drugs and finished dosage forms in terms of sterility checks 1 month, manufacturing cycle half a month, shipping lead times 1 month and these are also disrupted in today's disrupted shipping conditions.

The challenge is that most regulated markets are placed are bound by long term contracts with the distributors and pharmacy chains with stiff penalties for non-performance or delayed performance. When you have this level of months that contribute to stocking as well as processing as well as checking you can understand that the life given for the product is reduced. The effective life that is available for the product is reduced.

Therefore, you have to ensure that there are no hiccups in terms of maintaining the quality value chain. Every entity in the entire value chain has to be fully compliant and it must face no adverse action whatsoever from regulatory authorities. And inventory management has to strike a balance between safety, stock and shelf life of products.

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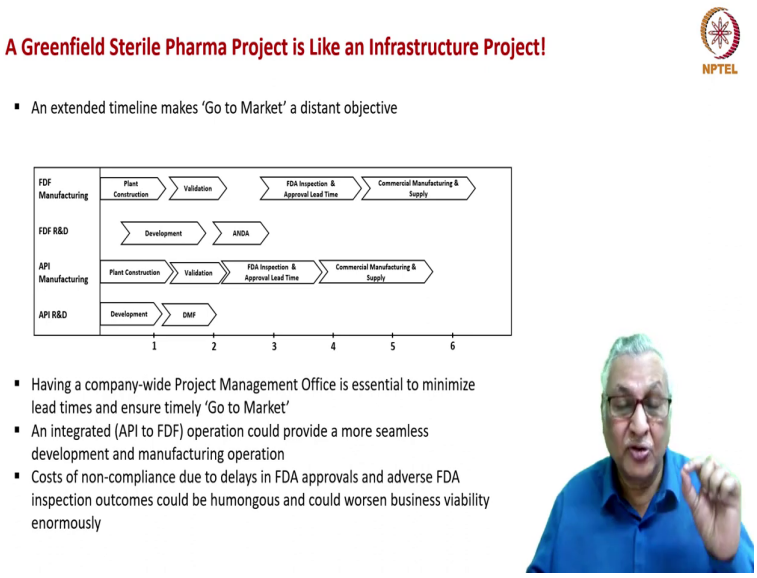


This complexity is reflected in the whole of project planning itself. A greenfield sterile pharma project is like an infrastructure project as we know infrastructure projects are deemed to have very long lead times.

An extended timeline makes go to market a distant objective could be 5 years or 6 years as shown here from API R and D which could take 1 year to 2 years and finally, result in a DMF at the end of 2 years to API manufacturing which requires plant construction, validation, inspection and approval and finally, commercial supply and similar cycle for finished dosage form R and D manufacturing.

Your execution time and final approval time could extend as many as 5 or 6 years. And if you are non-compliant in any of these building blocks of the project execution and project approval then the whole cycle gets set back. If the deviations are too critical then the project

itself can go into a very bad (Refer Time: 42:13), I am aware of companies which could never qualify for US FDA approval even after 2-3 inspections and finally, they had to give up.

So, costly equipment brought in, costly investments made, lot of time spent, but the facility itself is not usable for the intended markets and the intended revenue and profit generation. Therefore, there is a huge cost of bad quality in pharmaceutical industry. So, you got to get the value of good quality by having good quality control systems and the entire good quality domain spectrum as I have discussed here.

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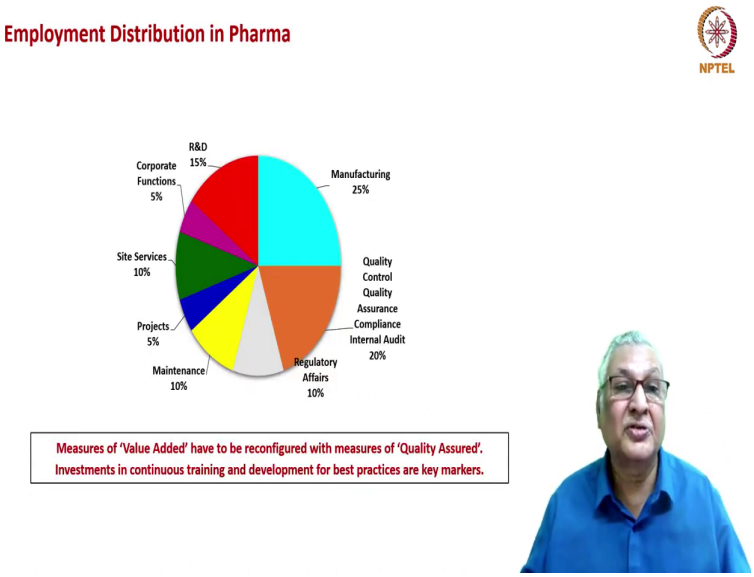


And because of this special nature of the pharmaceutical industry, you will find that if manufacturing employees are 25 percent of the total count quality control, quality assurance, compliance and internal audit are almost at the same level 20 percent. And in addition,

regulatory affairs people who do the dossier in a customized manner for the regulatory agencies constitute 10 percent and then you have all the others related to the other services.

So, the so called value added services are very huge in pharmaceutical industry. So, you got to maybe retune the measures of value added in terms of the measures of quality assured investments in continuous training and development for best practices or the key markers.

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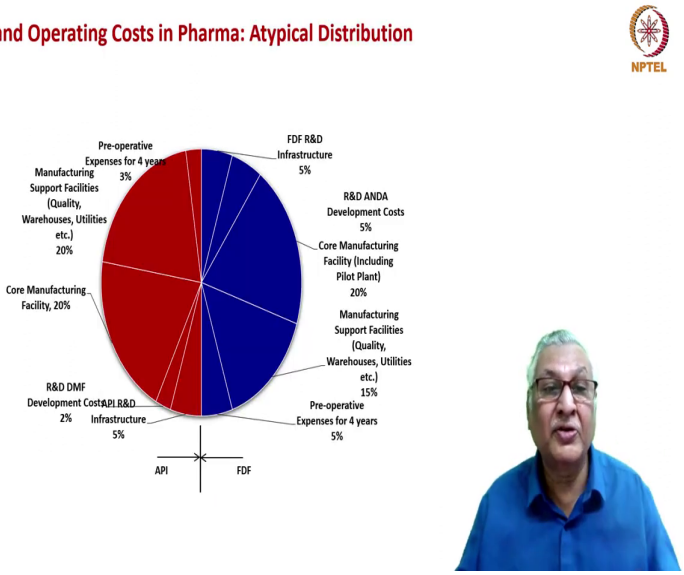


Similarly, when you look at the project and operating costs in pharma the distribution is atypical. Much more investment is made in the utilities and much more investment is made in the manufacturing process controls. This is again another important aspect of quality management.

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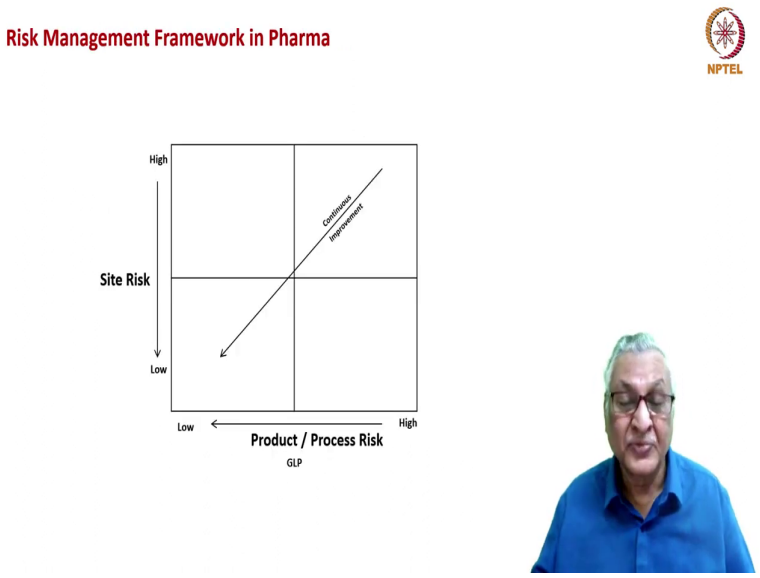


The ultimate objective of pharmaceutical operations and pharmaceutical quality management is to reduce the risk. You should make the risk as close to zero as possible. So, look at this graph which talks about the risk of the site and the risk of the product and process. The objective of the quality unit is to reduce the risk of both product and process together and that of the site by continuous improvement.

So, when you look at this kind of total quality framework for the pharmaceutical industry you will appreciate the importance of quality and quality consulting. Not everyone will have the same level of quality competency that the requirements can be made with. So, quality consulting has a huge business opportunity particularly when we say that India is the pharmaceutical capital of India it is no brainer that quality has to be the most important aspect of development, production and supply.

And for that companies must have strong quality units and there is a huge opportunity for quality consulting companies as well.

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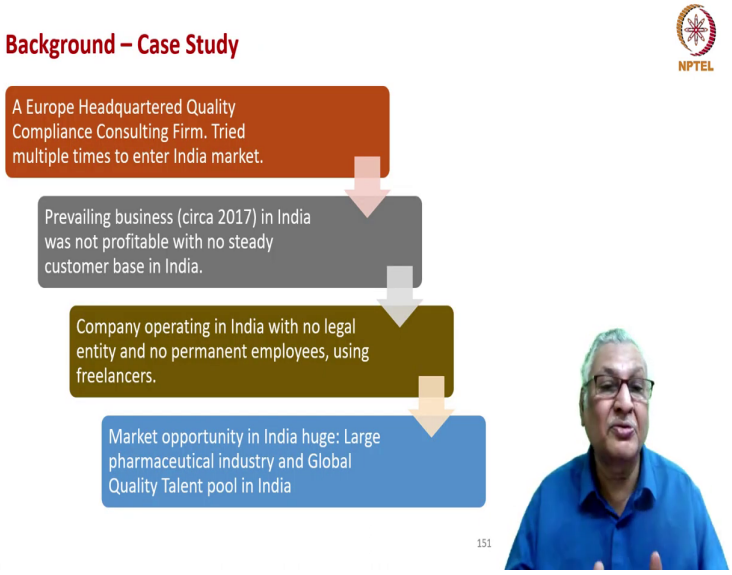


So, let us come to this case study. This case is a (Refer Time: 45:20) company which is headquartered in Europe and it is a quality compliance consulting firm. It tried multiple times to enter the Indian market. Prevailing business approximately around 2017 in India was not profitable as the quality appreciation probably was not at the same level or the FTA stringency was not at the same level or the company itself did not adopt the right strategy. There was no steady customer base in 2017.

Company was operating in India with no legal entity, but as deputation of personnel. There were no permanent employees in the country and the company was using freelancers. But the

company recognized that the marketing opportunity or the market opportunity in India is huge.

We have a large pharmaceutical industry in India and there is a globally competent quality talent pool in India and Indian pharmaceutical industry can meet and is already meeting the global pharmaceutical requirements in a big way. So, there is an opportunity no doubt.

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So, how do you do this structural analysis first? This is an industry as I said with relative low entry barriers. Despite the fact that there is so many technologies, scientific aspects involved. Despite the fact that there is so much of intellect and the behavior pattern that is involved still consulting even in quality is an industry with relatively low entry barriers. Any quality head can move out and set up a quality consulting company.

This is an industry that requires however, intellectual capability and capital of the highest order for growth and sustainability. It is highly competed with a spectrum of Indian and global competitors; demanding customers want the highest service at their lowest cost. Because not everybody appreciates the importance of the cost of quality.

It is a multi-tiered industry and it has to be continuously sensitive to the regulatory actions on pharma companies. That is if there is a warning letter issued to any particular company, the quality company should be able to assimilate those observations and modify its practice or upgrade its practice that is the requirement.

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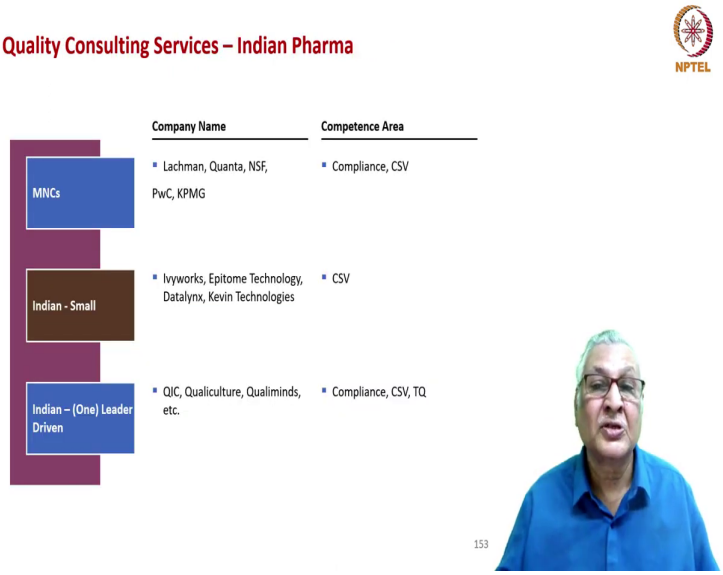

So, when you look at the quality consulting service in Indian pharma, from the viewpoint of the company which creates a value for the customer, you have the MNCs, Lachman, Quanta, NSF, PWC, KPMG, etcetera.

And their competence areas are usually in terms of compliance and computer system validation and of course, data integrity related to that. Then we have small Indian companies such as Ivy Works, Epitome Technology, Datalynx, Kevin Technologies. These are boutique companies focusing more on IT based computer system validation.

Then we have this typical Indian one-leader driven companies that is a quality head moves out as a set and sets up his or her own quality division, QIC, Qualiculture, Qualiminds, etcetera typical examples of that. And their focus area is in terms of audits, compliance, computer system validation and total quality.

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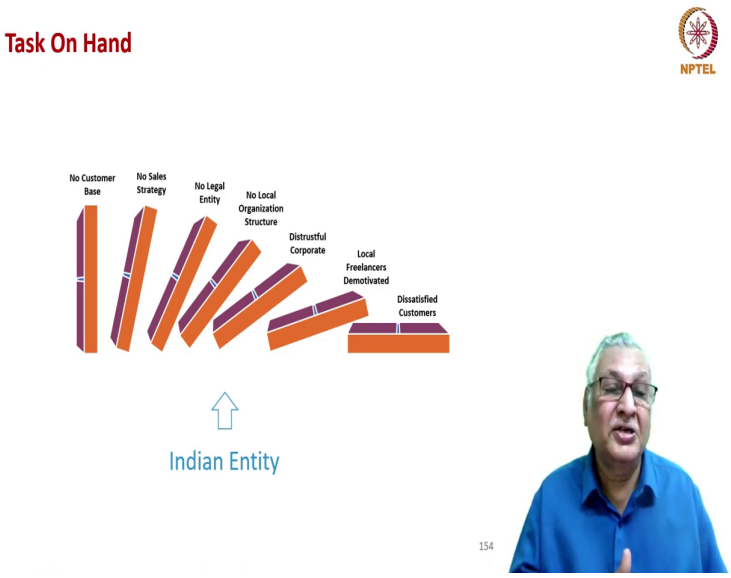


For the Indian entity as the CEO of the Indian entity looked at, the task on hand was daunting. There was no customer base, there was no sales strategy, no legal entity, no local organization structure. Corporate was distrustful because this is the third or fourth attempt at getting into India. Local freelancers were demotivated and the customers were dissatisfied. Not a very healthy fertile ground for establishing a new rejuvenated company.

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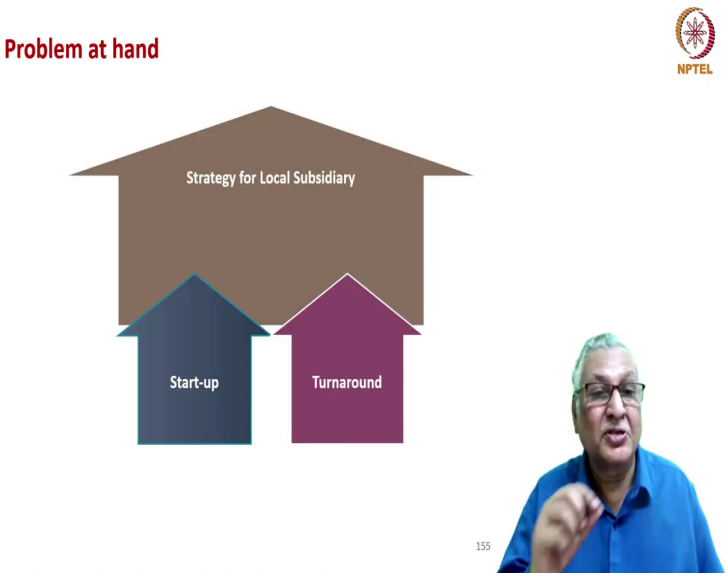


What was the problem at hand? The problem at hand was that the company did not have a real good strategy for the local subsidiary. The strategy had to look at the company as a genuine start-up and also one which is under the turnaround mode. Because the company is not an unknown name.

The company has been experienced by the Indian customers, but the positioning of the company had to be changed which means that you have got to affect a turnaround strategy. But at the same time because the company is starting all over afresh it also has to work nimble, fast and focused as a start-up company and that is the problem at hand.

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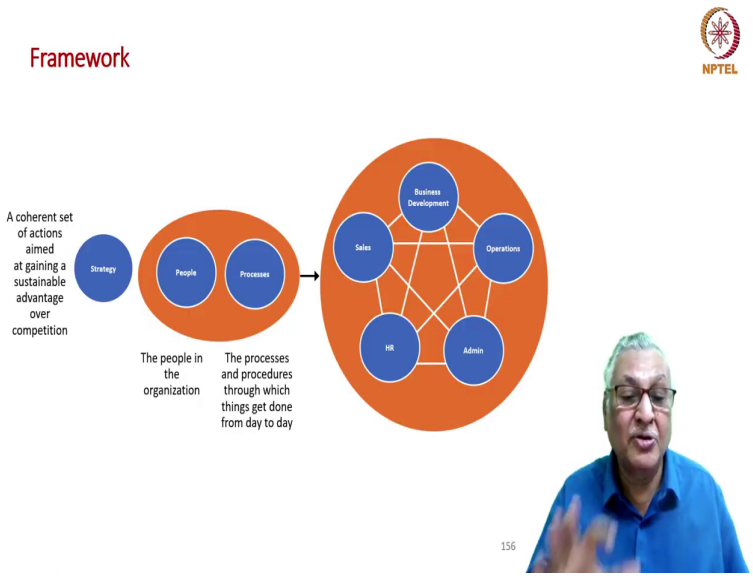


To be able to do that you need a framework. The framework comprises strategy, people, processes and a whole tier organization comprising sales, HR admin, operations and business development. Strategy is a coherent set of actions aimed at gaining a sustainable competitive advantage over competition. We have seen that time and again and that applies here as well.

The people in the consulting organization, the processes and procedures through which things can be get done from day to day or once where the company has to be at the top. And all of these functions have to be kick started to the maximum efficiency with agility, dynamism and customer service that is the framework.

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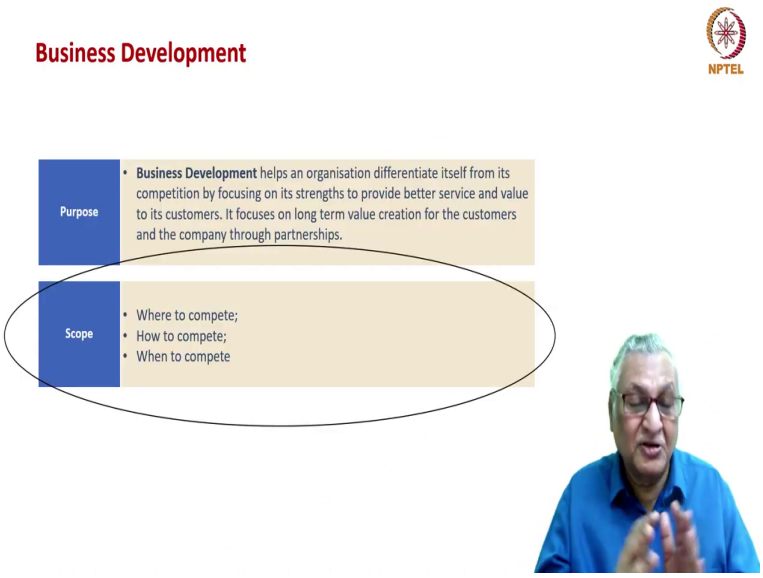


In this case business development was taken as the prime driver for the establishment of the company and for the growth of the company. The CEO thought for himself and laid out clearly for the organization that business development is going to help this company differentiate itself from the competition by focusing on its strengths to provide better service and value to its customers.

The company will focus on long term value creation for the customers and the company through partnerships. This business development purpose was advocated with the corporate headquarters and got approval for. Then the scope of business development was delineated in terms of where to compete, how to compete and when to compete.

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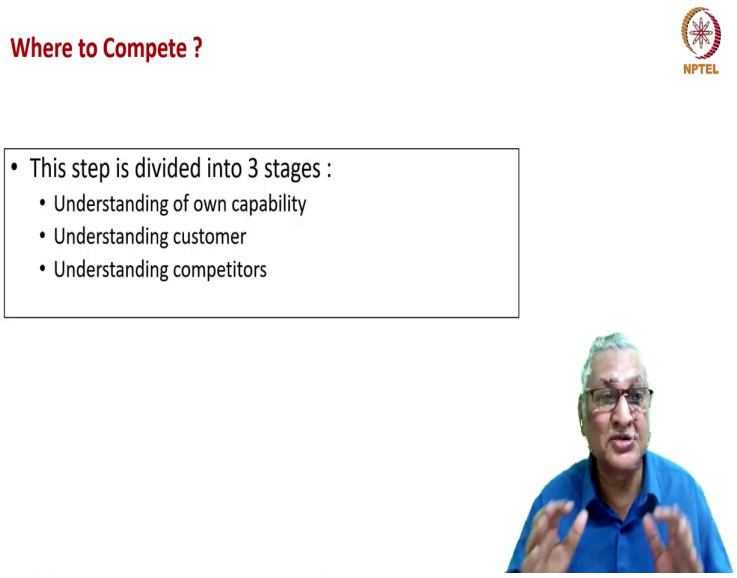


And this has resulted in a series of questions in stage wise manner. Where to compete is analyzed in terms of 3 stages. Understanding the company's own capability, understanding the customer and understanding the competitors.

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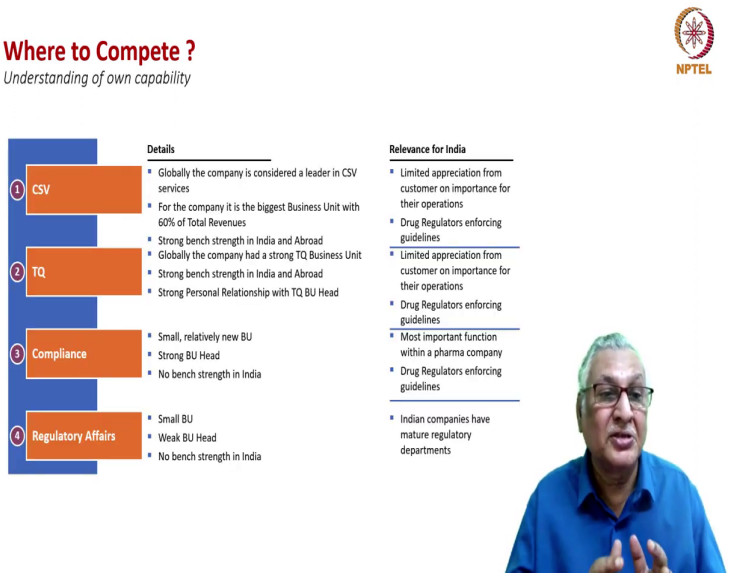


Where do you compete? That is understanding of own capability. There are four areas CSV, TQ, compliance, regulatory affairs. The company which is the subject matter of our case study is considered a leader in CSV services. Therefore, it is an important aspect of the company's entry strategy or reentry strategy.

But the challenge is that there is limited appreciation from the customer on the importance of computer system validation for their operations. And that has to be articulated and the companies had to be educated. And drug regulators enforcing the guidelines is a tailwind for the company.

When it has a strong bench strength in India and abroad, then total quality again limited appreciation from the customer on the entire gamut of the quality operations which I have

discussed. They would like to address things piecemeal. Again, drug regulators actions are a tailwind for the company.

As far as the compliance is concerned, there was no bench strength in India for the company. But it is the most important function within a pharma company. And with drug regulators enforcing guidelines, the company has to get into this space through proper positioning and through proper people support. And regulatory affairs is something which is the conversion of whatever is done correctly into a DMF or an ANDA in a manner that it satisfies the regulatory authorities.

The company noted that Indian companies have mature regulatory departments. Therefore, there is not something where there is a priority for play. So, the company focused on CSV, TQ and compliance to re-establish itself as a value creator for the Indian pharmaceutical industry.

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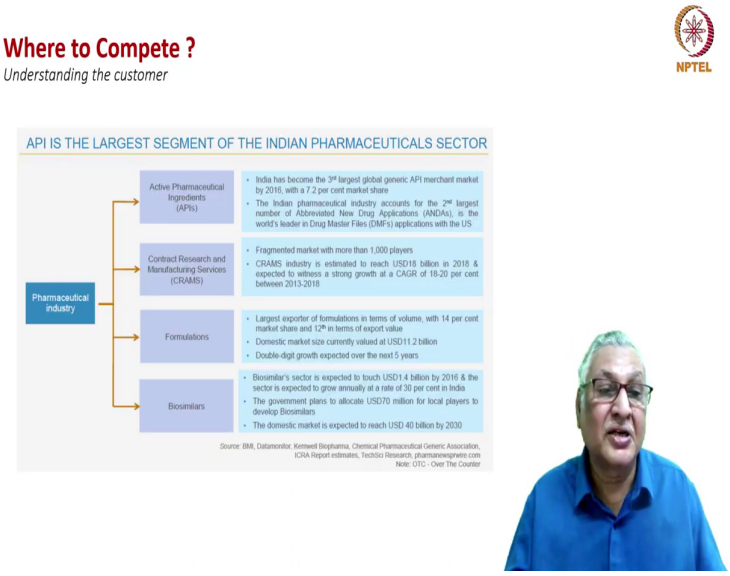


And understanding the customer, which are the most important aspects active pharmaceutical ingredient, customer research and manufacturing services, formulations or biosimilars. A detailed understanding of the whole number of pharmaceutical industry constituents, the number of DMF's filed, the number of ANDAs filed, the number of inspections carried out and the ownership of the various companies was carried out to develop a total matrix of the entire pharmaceutical industry.

Therefore, you understand the customer needs on a total canvas based and they will deliver a strategic approach.

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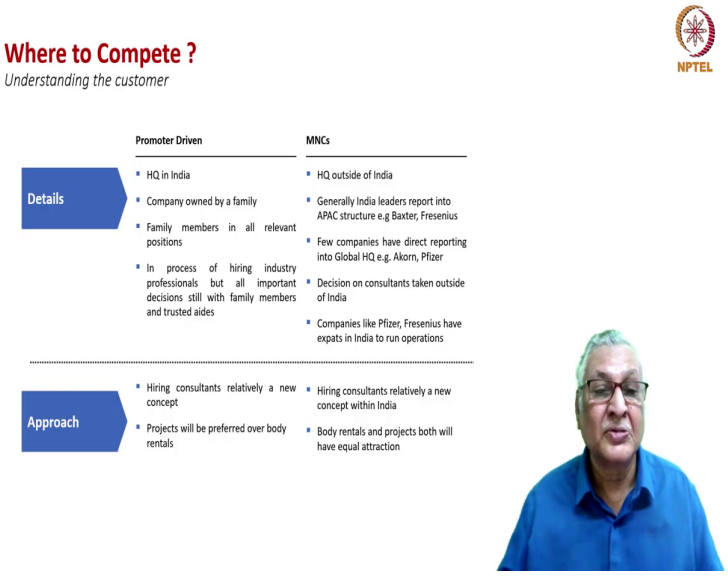


So, the details of the customers could be two ways. One companies are promoted driven that is driven by the Indian promoters. It could be a doctorates or Zydus at the highest level or a mankind or all came at the middle level and efforts are another company such as that at the lowest level or the smallest level. Now, we also have MNCs which I have headquarters outside of India.

Generally, India leaders report to the APAC structure, example, Baxter Fresenius. Some people directly report to the US headquarters, Akorn, Pfizer and decision on consultants taken outside of India in such cases. In respect of promoter driven for family companies, the decision making on engaging in consulting companies is done in house within India whereas, for MNCs it is usually outside of India.

Therefore, look at the approach that could be taken for satisfying the customers. Hiring consultants is relatively a new concept for promoter driven companies. Projects will be preferred over body rentals whereas, for multinational companies. Doing that in India is a relatively new concept although that is an established practice globally. For them body rentals and projects both will have equal attraction. So, that is how the customer mindset is mapped by the.

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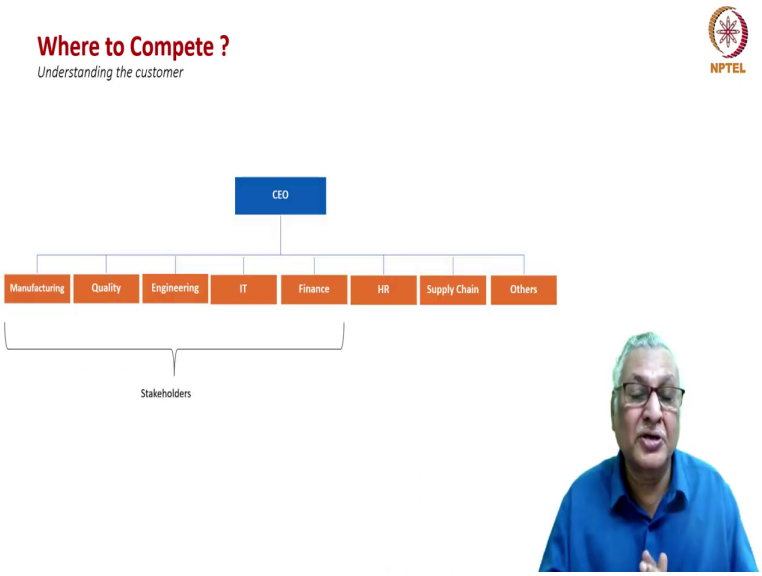


Then who are the stakeholders? Typically, in a pharmaceutical company CEO has all the domains reporting to the person out of these manufacturing, quality, engineering, IT and finance or the essential stakeholders and you must make your pitch as a new consulting company to these stakeholders that has been decided.

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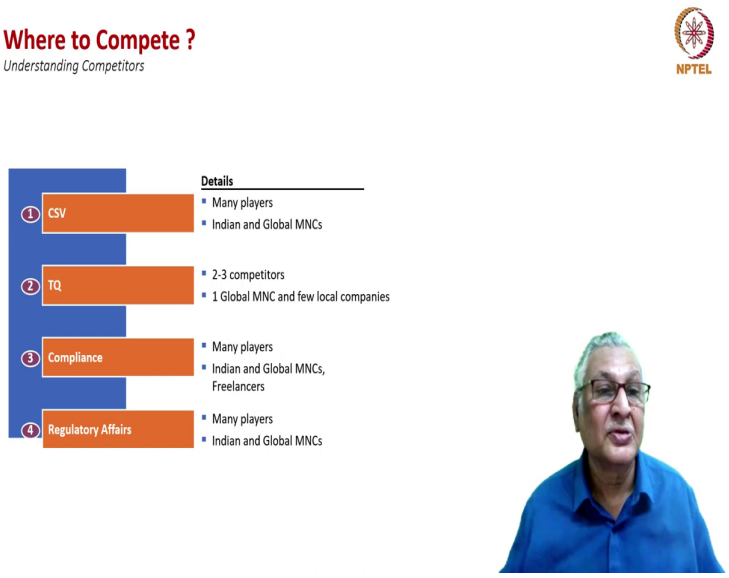


And how do you understand the competitors? On CSV many players Indian and global MNCs for total quality 2 to 3 competitors only. One global MNC and few local companies for compliance many players freelancers for regulatory affairs again many players and Indian and global MNCs. So, competition is strong in certain areas and competition is low in certain other areas.

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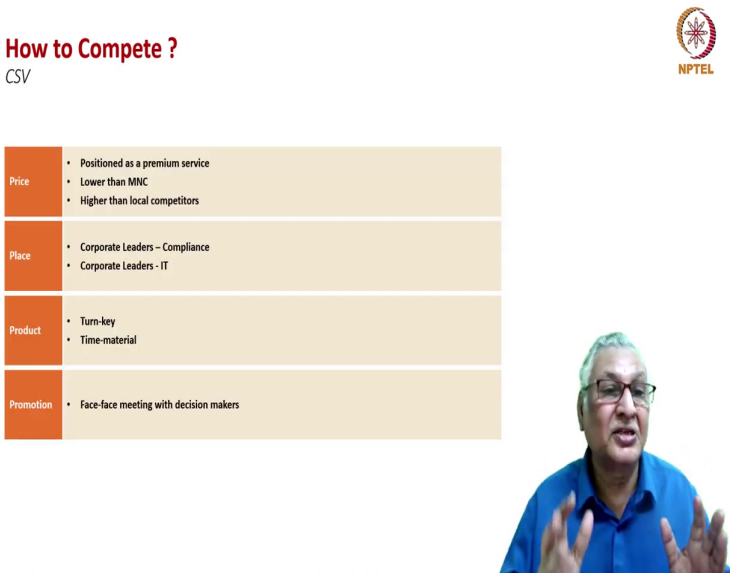


So, in each case how do you compete? If it is computer system validation position yourself as a premium service because you have globally acknowledged capability and you have globally proven templates. However, you are lower than a typical MNC such as latch ones, but higher than local competitors.

In terms of place corporate leaders who deal with compliance, corporate leaders who deal with information technology or the people who are the marketplace constituents. As a product you can offer a turn-key product or a time material product and the promotion happens through face-to-face meeting with decision makers.

No advertising, no sales promotion of any kind is involved. You got to meet people make a pitch based on your science technology and people capabilities. That is how you promote the quality service.

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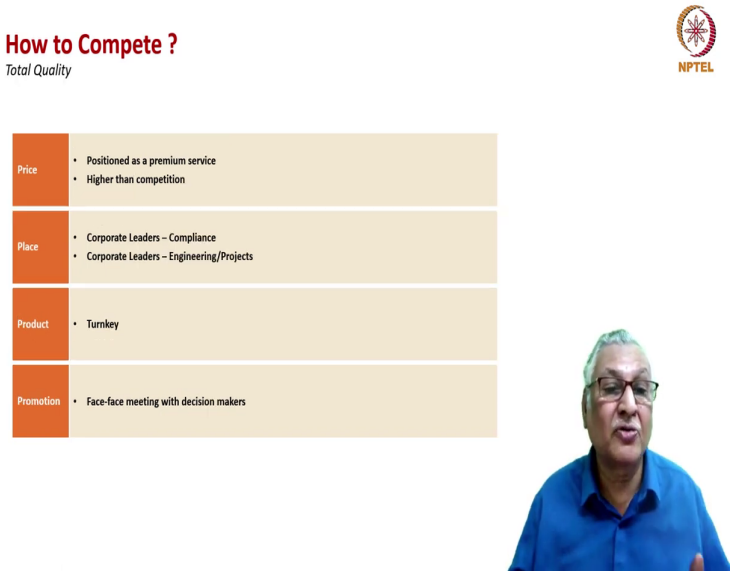


And in total quality how do you do that again? Undertaking total quality is really a challenging task given the kind of points I have mentioned. And mind you I have not talked about the entire spectrum of quality services that need to be positioned I just in a way scratch the surface by providing some examples. And therefore, it has to be positioned as a premium service higher than competition need not necessarily be lower than the MNC 2.

Again, corporate leaders who deal with compliance engineering and projects are the key stakeholders. The product has to be turn-key and the face-to-face meeting with decision makers from the CEO to the CXO's becomes important.

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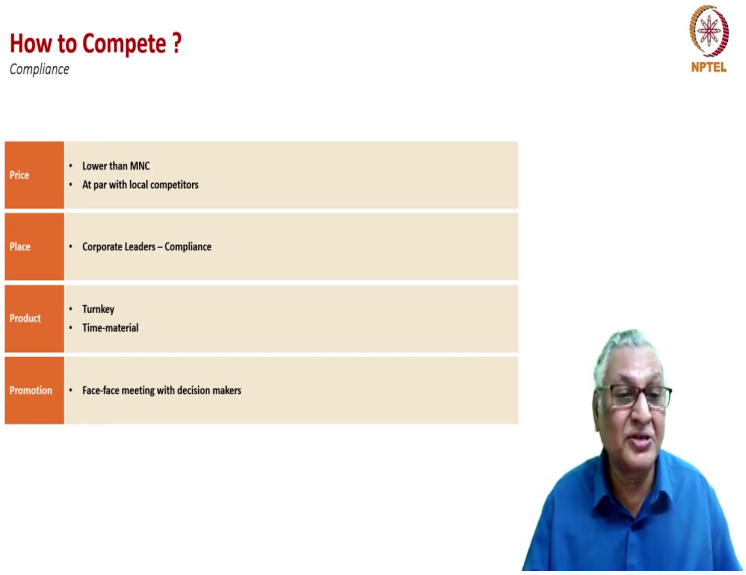


In respect of compliance, you have a different kind of pricing level must be lower than the MNC, at par with local competitors because there are far more number of people who are operating in the system. The place is a corporate leaders with compliance responsibility, product could be again time material or turnkey, promotion here again face to face meeting with decision makers.

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And in respect of regulatory where you do not want to compete there is of course, no discussion. But what comes out of all this is that the promotion has to happen through face to face meetings which means that the business development leader of the company has also the chief executive officer of this company must be technically sound, must be articulate, must be having lot of commitment, passion and dedication for the function of quality which he or she should be able to communicate effectively with all these stakeholders in the customer.

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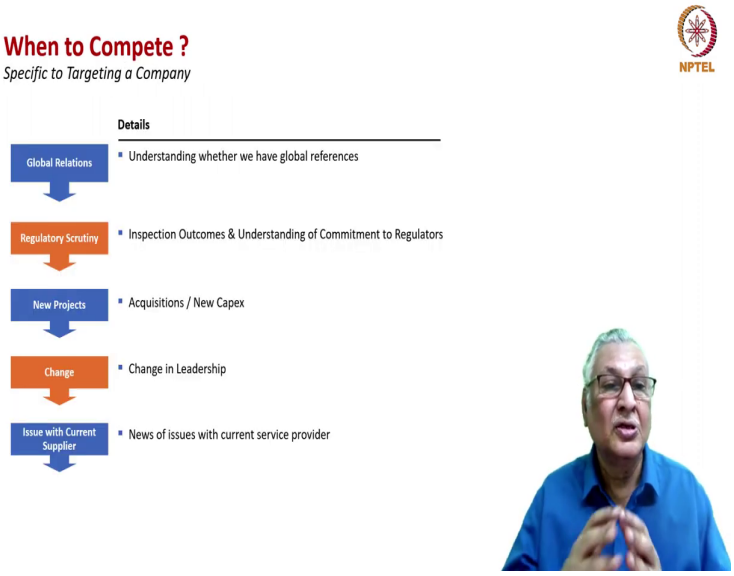


Now, how do you target a company? You can see whether there are global references that are possible. So, if the Indian company has global relations such as let us say Sanofi or GSK and you are a sub-wing company for those kinds of companies there would be a global reference.

Then you can look at the regulatory actions that have been taken on the company inspection outcomes, understanding of commitment to regulators. So, you do a pre-study and tell the company that you seem to be found wanting by the regulators on this and this is where I can help you.

Then new projects that are getting set up and need therefore, to build quality by design from the beginning or you have acquired a company therefore, you need to integrate it to your quality levels or you are setting up new facilities and incurring new capex you have to make sure that is quality compliant and is going to be effective for you. Then there is a change in

leadership in which case again there is a possible exposure and there is a possible need for quality consulting to help the company with.

And there could be issues with the suppliers then you should get into the frame and then help supply. Also, when you are developing a third party you need quality consulting. When you are acquiring a company abroad you need third party audit.

You need to have due diligence studies particularly when private equity investors make acquisitions, they do lot of due diligence study either too it was only in terms of finance and performance, but today everybody appreciates the need for quality due diligence study. So, these are all the opportunities to compete.

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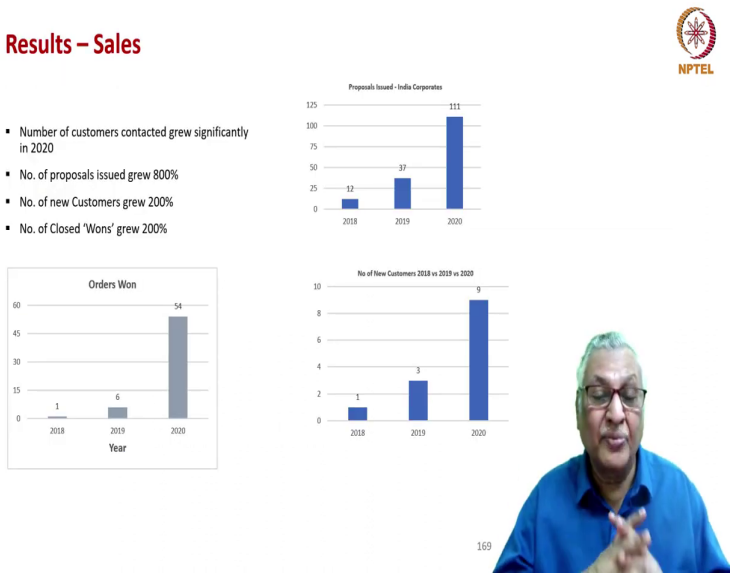

When the company under the new CEO in India had this level of strategic understanding, had this level of first strategic execution capability the reasons for phenomenal. The number of customers contacted grew significantly in 2020 which is a cross section year for our study before the COVID. Even in COVID times the business continued to grow. Number of proposals issued grew 800 percent, number of new customers grew 200 percent and number of closed deals that were won grew 200 percent.

The proposals issued grew 10 times in a period of 2 years and the number of new customers won grew 9 times in this period. That is the effectiveness of business development strategy that was deployed.

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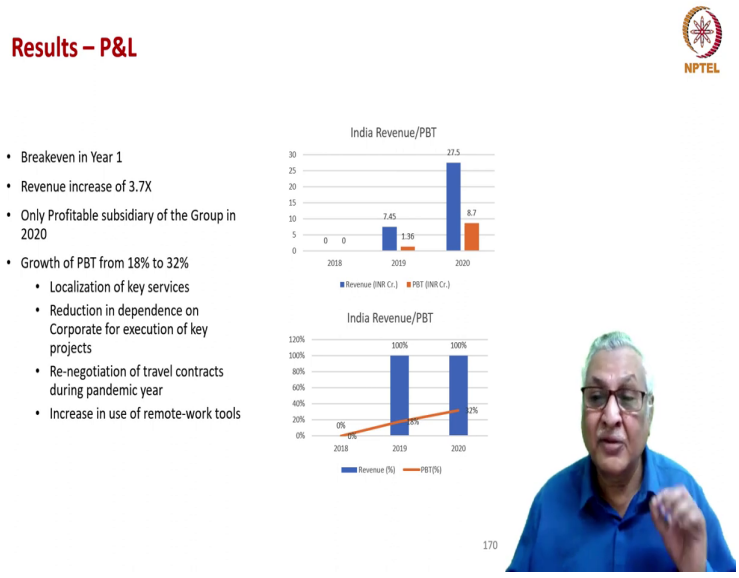


And the P and L also showed similar results within the first year the company broke even. A revenue increase of 4 times was achieved and it became the only profitable subsidiary of the

group in 2020. The PBT grew from 18 percent to 32 percent with localization of key services, reduction in dependence on corporate for execution of key projects, renegotiation of travel contracts during the pandemic year and increase in use of remote tools including smart classes.

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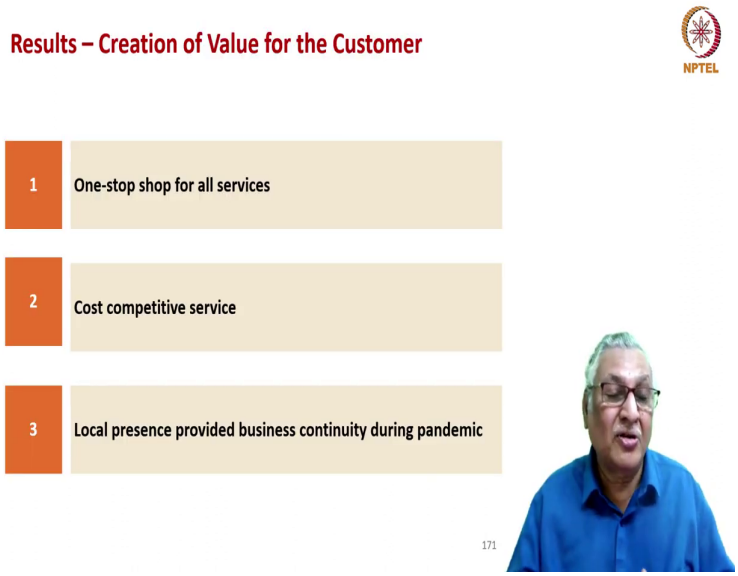


As a result of all these efforts the company not only built value for itself, it actually fundamentally built value for the customer. It became a one-stop shop for all quality services. It offered the services at cost competitive levels. It positioned itself as a global quality provider at locally affordable cost.

And local presence provided business continuity during pandemic when multinational quality companies could not come to India or was apprehensive about coming to India. This company which was based in India with Indian full-time employees has been able to fulfil that service

and it bridged that gap and therefore, became a very preferred partner for the Indian companies.

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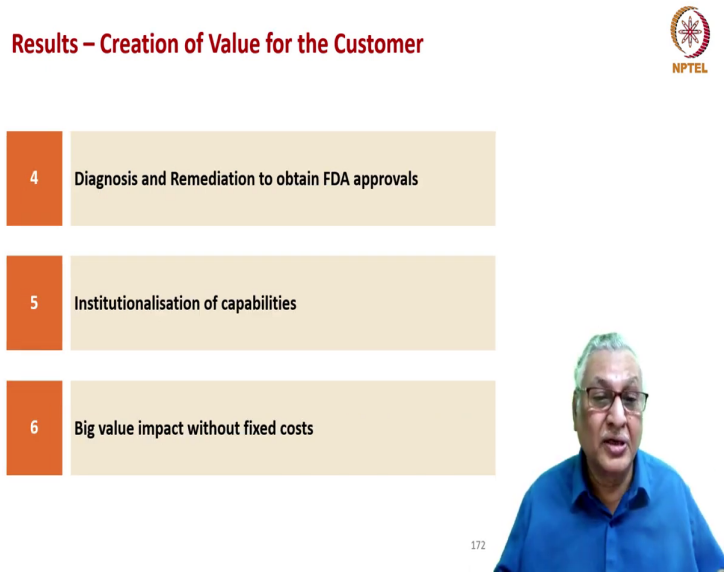


It also applied itself to the diagnosis and remediation to obtain FDA approvals because that was seen to be a very strong pain point for the customers. Institutionalization of capabilities in the clients has been one of the success factors for the company and that was very much appreciated by the clients. And the ability to provide big value impact without fixed costs of the internal quality organization was also something which the customers appreciated.

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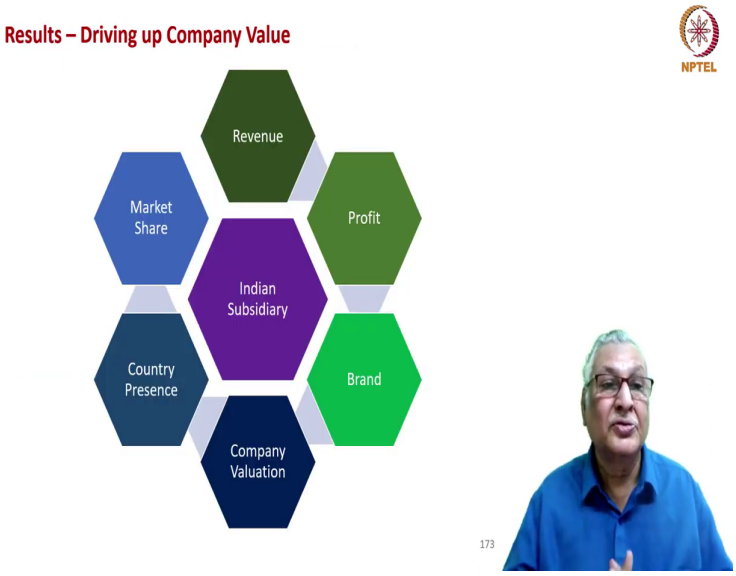


So, the results were in terms of driving up company value through a number of performance metrics revenue, profit, brand value, company valuation, country presence and market share and the Indians subsidiary has taken off as never before.

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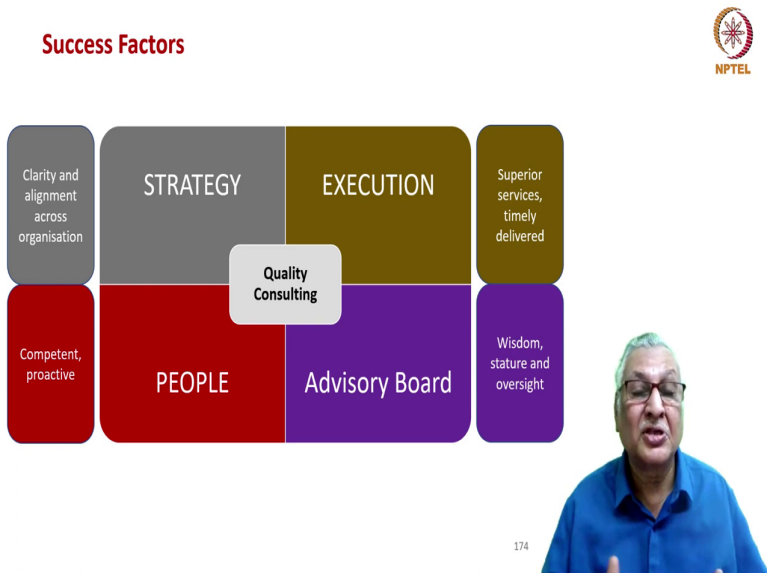


And how was that possible? There was a clear strategy as I have detailed. So, far and that strategy was built on the deep understanding of what a quality function must deliver for the companies in the pharmaceutical industry. And execution was done with full-time employees, fully trained with global capabilities, but with local dynamism.

And the company had people who were getting trained on a regular basis within no time a full-time equivalent strength of 100 in-house experts was built, apart from 50 percent being freelancers. So, a total capability of 150 highly talented quality professionals was built within 1 year and that provided the success factor for companies to take note and provide service deals.

Then most importantly the company also constituted an advisory board of seasoned experts from the industry just 1 or 2 and that advisory board could advise the company on going

forward in a methodical manner, helping in relationships with the chief executive officers after the first contact is made. And then making sure that the right kind of positioning is made based on the understanding of the business strategy and quality positioning of the company.

So, together the wisdom, stature and oversight of the advisory board, clarity and alignment across the organization of the strategy, superior services timely delivered in terms of execution and competent, proactive, talent-based help the company achieve a great level of performance in terms of quality consulting. So, with this we come to the end of this lecture.

Thank you very much for your attention. We will meet in the next lecture.