Impact of Flexibility on Risk Management in an Indian Pharmaceutical Manufacturer – A system dynamics approach

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Abstract:

Flexibility is a multi dimensional perspective built over the concept of dynamic interplay between thesis and anti-thesis, which facilitates options, freedom of choice and change management mechanism. The freedom of choice is leveraged best when it is backed up with the continuous learning environment. Flexibility is about dealing with diametrically opposite business situations with processes and actors who have the options, change management mechanism and freedom of choice backed up with knowledge, synthesizes and comes up with Learning, Action and Performance (SAPLAP, Sushil 2000). The challenge of today's business world is to transform traditional organizations and their systems so that they can become more flexible. Development of dualistic behavior of business environment has created immense tensions. The environment can be best described by Flowing Stream Strategy (Sushil, 2012) by managing change with continuity. The monolithic either/ or concept has paved ways for multidimensional inclusiveness. It's about dealing with Centralization with decentralization, Continuity with change and Integrity with diversity. The concept of value for money has become a cliché. Customer wants more value with lesser cost. Flexibility, Controllability and Risk sensitivity is gaining increasing importance as organizations strive for competitiveness through enhancing capabilities in three paradigms – people, process and technology.

Keywords: flexibility, risk management, system dynamics model, case study, pharmaceutical manufacturer, bi-modal organization

1.0 Introduction

To understand the impact of Flexibility on Risk a study was conducted on an Indian Pharmaceutical manufacturer major. The challenge identified was aligned to their Research and Development with respect to the biggest risk on working capital – the cost of R&D. The objective was to maximize the success rate of R&D output, which is the key survival for any Pharma-manufacturing organization. The top management of the organization was interviewed and a very interesting view point came out while discussing the risk parameters. The situation was analyzed depicting the causal effect of the process elements. The dynamism of the situation was explained using the help of system dynamics models. The risk parameters related to Research and development were identified and the flexibility parameters were identified. The causal behavior was identified. And a model was created

and situation was simulated. It's imperative that the study was conducted from the process perspective. Intelligence quotient along with the intricacies of motivation factors of the researchers were kept outside the scope of the project. This study was an introspection from systemic perspective.

2.0 Literature Survey

2.1 Flexibility

The interest on organizational flexibility has been growing in the last decades and different approaches have emerged with focus on dimensions of organizational flexibility (e.g. Eppink (1978); Volberda (1996); Sanchez (2004); Verdú-Jover et al. (2005); Hatum and Pettigrew (2006)), on the interaction between firm size and organizational flexibility (e.g. Kraatz and Zajac (2001), Ebben and Johnson (2005)), on context specificity of flexible capabilities (e.g. Eppink (1978); Volberda (1996);; Verdú-Jover et al. (2005), Nadkarni and Narayanan (2007)).

External Flexibility is best described by the maxim of not putting all of one's eggs in a single basket (Ansoff, 1965) Flexibility can be defined as 'the ability to change or react with little penalty in time, effort, cost or performance' (Sushil, 2000 and 2000a). Flexibility is a multi-faceted concept with different connotations, paradigms, foundations and dimensions. Strategic, Organizational, Financial, Information Systems and Manufacturing flexibility have been identified as cornerstones of enterprise flexibility (Sushil, 2000). Flexibility is not shifting to extremes, but to dynamically balance them. There are many connotations of flexibility like agility, adaptiveness, responsiveness, versatility, etc. One popular view of flexibility can emerge by mapping it on to functional structure (Sushil ed., 2000) - Strategic Flexibility, Manufacturing Flexibility, Human Resources Flexibility, Financial Flexibility, Technology Management Flexibility, Marketing Flexibility, Organizational Flexibility, IT/ IS Flexibility. It is widely accepted that, organizations today are facing the issue of responding continually to an environment, which is increasingly dynamic, complex and uncertain as a consequence of demographic changes, a more global economy, the "hypercompetition", or knowledge-based competition (Daft and Lewin, 1993). A company's competitivity will depend not only on being efficient in their organisational routines but also on their innovative ability at the same time (Abernathy, 1978; Hayes and Abernathy, 1980) which represents the notion of balance between exploration (be innovative – radical change) and exploitation (be efficient in organizational routines – incremental change). This is a common topic in literature related to organizational adaptation (Benner and Tushman, 2001). Such balance allows the firm to obtain and sustain its competitive advantage which, according to Sommer has to be redefined in terms of organizational speed and flexibility (Sommer, 2003). This characteristic is related to develop new dynamic processes that enable for instance, a fast reconfiguration of the resource base (Helfat et al., 2007,

Eisenhardt and Martin 2000, Teece et al. 1997), changing the nature of activities (Aaker and Mascarenhas, 1984), or dismantling of current strategies (Harrigan, 1985). The interest on organizational flexibility has been growing in the last decades and different approaches have emerged with focus on dimensions of organizational flexibility (e.g. Eppink (1978); Volberda (1996); Sanchez (2004); Verdú-Jover et al. (2005); Hatum and Pettigrew (2006)), on the interaction between firm size and organizational flexibility (e.g. Kraatz and Zajac (2001), Ebben and Johnson (2005)), on context specificity of flexible capabilities (e.g. Eppink (1978); Volberda (1996);; Verdú- Jover et al. (2005), Nadkarni and Narayanan (2007)). Literature in organizational flexibility is still lacking of comprehensive modelling which explains the relationships between its key variables and consequent side effects of such iterations. Exploring these interactions and the dynamic adaptation processes towards the desired adjustment is the main motivation of the present research.

We decided to start our analysis with Volberda´s model on organizational flexibility which addresses how the companies should manage their dynamic capabilities and organizational design, in order to achieve the desired fit by being flexible. He studied how the organizations deal with the paradox of flexibility over time, that means, how they continuously adapt to the changes in the environment and balance corporate discipline with entrepreneurial creativity. Exploring the paradoxical nature of flexibility, Volberda (1998) develops a strategic flexibility framework to configure the resources of the firm for effective responses to organizational change providing a comprehensive set of variables and their linear relationships. In addition to this argument, we found that Volberda anticipated the possibility of modelling the adaptation process from a dynamic point of view - "Flexibility is not a static condition, but it is a dynamic process. Time is a very essential factor of organizational flexibility." (Volberda, 1998). However, he didn't focus on such adaptation process as a sequence of stages allowing to understanding key factors of organizational flexibility.

Lot of work has been done to examine Volberda´s theory in detail in order to analyze its consistency and effectiveness, especially in terms of its causal explanation of organizational adaptation to changing environments. The causal argument Volberda presents is very detailed and relatively explicit. Therefore, lots of research use Volberda's theory as foundation for its systematic exploration.

2.2 Enterprise Risk Management

Enterprise Risk Management (ERM) is a data intensive process that measures all of a company's risks. This includes providing managers with an understanding of the full array of a company's risks including financial risks, investment oriented risks, operations based risks, and market risks, as well as legal and regulatory risks for all of the locations in which a company operates or invests (Peterson, 2006). Risk can also be a result of political or social conditions in locations where a

company has operations, suppliers, or customers (Woodard, 2005). Risk to a company's reputation is also an important aspect and element of ERM (Ruquet, 2007).

In each of the risk areas there are two primary types of risks that companies face -

- External Risk
- Manufactured Risk

External risk is the risk of events that may strike organizations or individuals unexpectedly (from the outside) but that happen regularly enough and often enough to be generally predictable.

Manufactured risk is a result of the use of technologies or even business practices that an organization chooses to adopt. A technological risk is caused or created by technologies that can include trains wrecking, bridges falling, and planes crashing (Giddens, 1999). Business practice risk is caused or created by actions which the company takes which could include investing, purchasing, sales, or financing customer purchases.

ERM analytical models should encompass both external and manufactured risks which can be identified through historical analysis as well as reviews of current operations and exposures ("Expect the Unexpected," 2009). Once identified, risks can be validated through discussions with corporate executives, operations managers, production managers, and business unit executives. In addition to gain a better understanding of risks, the overall health of a company (Coccia, 2006; Panning, 2006) was considered.

Investment advisors, institutional investors, and credit rating agencies are adding to the pressure for companies to develop ERM systems and disclose their risks (Karlin, 2007). ERM enables top managers of a company to aggregate, prioritize, and effectively manage risks while enabling business-unit managers to improve decision making in operations and product management (Kocourek & Newfrock, 2006). In managing risks there are several options that corporate executives can take including accepting, preventing, mitigating, transferring, sharing, or avoiding the risks (Woodard, 2005). The ERM process can also support strategic planning activities as well as provide insight into alternative business practices and goals (Millage, 2005). One of the biggest challenges in implementing ERM strategies is to make sure that selected analytical methods are appropriate for the type and size of organization to which they are being applied (Milligan, 2009). ERM strategies and models as well as the utilization of ERM analyses will vary with corporate culture, business goals, and risk management objectives. This means that a one-size-fits-all approach towards ERM is not likely to be successful (Lenckus, 2006). Risk and uncertainty are an inescapable part of investing. Fredman & Wiles (1998) called risk "the possibility of loss, damage, or harm" where risk depends on the individual and the individual's appetite or tolerance for risk. Managing risk is very important for successful long term investing. Investors can use various strategies such as diversification and asset

allocation to reduce risk. Ultimately, the investor must compare financial objectives to the risk and return rates of investments.

3.0 Research Objective and Methodology

3.1 Objective - The research objective is to develop a model to explain impact of flexibility on R&D risk management for a pharmaceutical manufacturing organization in India.

3.2 Methodology – Case Study Method is used to analyze the impact of Flexibility on Risk for a Indian Pharmaceutical Manufacturer major. The methodology followed was in line with the works of many well known researchers such as Robert E Stake, Helen Smons. The case study proposes six steps -

- Determine and define the research questions
- Select the cases and determine data gathering and analysis techniques
- Prepare to collect the data
- Collect data in the field
- Evaluate and analyze the data
- Prepare the report

Step 1. Determine and Define the Research Questions

The researcher investigates the object of the case study in depth using a variety of data gathering methods to produce evidence that leads to understanding of the case and answers the research questions. Case study research generally answers one or more questions which begin with "how" or "why." The questions are targeted to a limited number of events or conditions and their inter-relationships.

Step 2. Select the Cases and Determine Data Gathering and Analysis Techniques

During the design phase of case study research, the researcher determines what approaches to use in selecting single or multiple real-life cases to examine in depth and which instruments and data gathering approaches to use. Each case's conclusions can then be used as information contributing to the whole study, but each case remains a single case. Exemplary case studies carefully select cases and carefully examine the choices available from among many research tools available in order to increase the validity of the study. Careful discrimination at the point of selection also helps erect boundaries around the case. A key strength of the case study method involves using multiple sources and techniques in the data gathering process. The researcher determines in advance what

evidence to gather and what analysis techniques to use with the data to answer the research questions. Data gathered is normally largely qualitative, but it may also be quantitative. Tools to collect data can include surveys, interviews, documentation review, observation, and even the collection of physical artifacts.

Step 3. Prepare to Collect the Data

Because case study research generates a large amount of data from multiple sources, systematic organization of the data is important to prevent the researcher from becoming overwhelmed by the amount of data and to prevent the researcher from losing sight of the original research purpose and questions. Advance preparation assists in handling large amounts of data in a documented and systematic fashion. Researchers prepare databases to assist with categorizing, sorting, storing, and retrieving data for analysis.

4. Collect Data in the Field

The researcher must collect and store multiple sources of evidence comprehensively and systematically, in formats that can be referenced and sorted so that converging lines of inquiry and patterns can be uncovered. Researchers carefully observe the object of the case study and identify causal factors associated with the observed phenomenon. Renegotiation of arrangements with the objects of the study or addition of questions to interviews may be necessary as the study progresses. Case study research is flexible, but when changes are made, they are documented systematically.

Step 5. Evaluate and Analyze the Data

The researcher examines raw data using many interpretations in order to find linkages between the research object and the outcomes with reference to the original research questions. Throughout the evaluation and analysis process, the researcher remains open to new opportunities and insights. The case study method, with its use of multiple data collection methods and analysis techniques, provides researchers with opportunities to triangulate data in order to strengthen the research findings and conclusions.

Step 6. Prepare the report

Exemplary case studies report the data in a way that transforms a complex issue into one that can be understood, allowing the reader to question and examine the study and reach an understanding

independent of the researcher. The goal of the written report is to portray a complex problem in a way that conveys a vicarious experience to the reader.

4.0 Indian Pharmaceutical Manufacturing Major – A Case Analysis

ABC Ltd is a research based health management organization in India involved in research, manufacturing and marketing of branded pharmaceutical formulations, vaccines and natural products. ABC Ltd is the „third largest biotechnology company" (as per ABLE Survey, 2010), as well as among the „top 50 pharmaceutical companies" (as per ORG IMS March 2010) of India. The organization has production facilities at Baddi (Himachal Pradesh), Lalru (Punjab),Mumbai & Delhi for manufacturing tablets, capsules (including soft gelatin), ointments (transgel formulation) liquids, herbal formulations and vaccines. These facilities are WHO cGMP compliant. The organization has also developed four distinguished, ultra modern, state-of-art R&D centers in different locations, having internal capabilities for constant research, with over 300 highly professional and skilled scientists engaged in various aspects of research. Focused research efforts have led to grant of worldwide product patents valid in over 60 countries for ABC Ltd.

To tap newer opportunities, ABC Ltd has organized its formulation marketing into Six SBUs - PRO Care, Diacar Alpha, Diacar Delta, GROW Care, Onco Trust, and Critical Care, which enables it to respond to changes in the industry and marketplace. ABC Ltd has identified brand building in exports as its thrust area and it has significant presence in the global markets including the CIS, Africa, the Middle East and Asia. The organization is actively exploring opportunities for launching as well as licensing out some of its patented products for manufacture/marketing in developed countries in Europe & North America. ABC Ltd has established a countrywide sales and marketing network in India through a vibrant sales force of more than 1,500 professionally trained and highly motivated marketing and sales professionals and efficient logistic network of 22 sales depots/carrying and forwarding agents all over India to make its products available at all places and at all times.

4.1 Processes of Indian Pharmaceutical Manufacturing Major (Bi-Modal Approach)

The concept of Bi-Modality was explicitly discussed by Homa Bahrami in his paper The Emerging Flexible organization: Perspectives from Silicon Valley. There are firms who appear to have striked a balance between two completely opposite stimuli. The flowing stream strategy (Sushil, 2012) is an example of firms who deals with Change considering the importance of continuity. These attempts cannot be described in monolithic, unidimensional terms, as simple recipes and "either/or" solutions.(Bahrami, 2010). The control was perceived within the organization by imbibing flexibility –

the dynamic interplay between the thesis anti-thesys, which generates options, freedon of choice and change mechanism. The system needs to be backed by the strong knowledge management framework. In modern management system, the concept of dualities and dichotomies are common phenomenon to deal with. The management teams were not mavericks, yet an entrepreneurial zeal and anti-bureaucratic sentiments were frequently observed. The management team looks forward to look at short term objectives along with long term goals. The resulting organizational systems can be best depicted as "bi-modal"—in that they could accommodate opposing tendencies and yet function as coherent and cohesive concems. Signs of bi-modality were commonly observed in broaching three types of tension: Centralization versus decentralization, stability versus change, and uniformity versus diversity dealing with Continuity and Change (Flowing Stream Strategy, Sushil, 2012). ABC Ltd is an example of Bi-Modal organization looking forward to improve on every opportunities.

4.2 The Process dimensions:

The main R&D areas of ABC Ltd are

- New Chemical Entities (NCE) / Generic API's
- Development of Generic Formulations and Novel Drug Delivery System (NDDS)
- New Biological Entities (NBE)
- Novel peptides & human monoclonal antibodies.
- Vaccine development.

The company has developed three state-of-art R&D centers in different locations, having internal capabilities for constant research, with over 300 highly professional and skilled scientists engaged in various aspects of research.

As on 31st March 2011, the company had filed over 1400 patent applications in various parts of the world including India. Of these, 382 have been granted patent and others are under various stages of examination or publication by the patent authorities.

Each of these three R&D facilities operates independently with its own R&D head and Project Management teams. An anomaly observed by the Exec Mgt in the current structure being the Project Manager reporting into the R&D Head. With a potential of leading to conflict of interest situations such as amendments in project baselines agreed with executive management. The current decentralized structure does not provide the PB executive management with a clear and consolidated view and control of the R&D division as a whole.

4.2.1 Research & Development (R&D)

R & D at ABC Ltd consists of a team of over 300 professionals and a team of highly talented researchers who continuously pursue the quest for innovation and therapeutic advancements. ABC Ltd has R & D centres for the following areas of research: Pharma (New Drug Development), Drug Discovery, Vaccine, Bio Pharma. Each of the R&D centres are responsible for the following: Experimental research & exploration to improve the current product range, Innovation of new products, Production of products similar to competitive products in the markets. All research initiatives are project based and have dedicated project teams that are responsible for performing various experiments to give expected research results.

To accomplish the above listed responsibilities R&D performs the below listed activities:

- Submits Project Initiation Form (PIF) for approval from internal stakeholders
- Estimates the active pharmaceutical ingredient(API‟s) and other ingredients & equipment (if any) requirements
- Performs literature research
- Verifies the country specific compliances
- Imports innovative product, request for import licence to RA
- Requests for Lab Notebook from RA
- Conducts Prototype development activity
- Initiates IPR Process (if applicable)
- Carries out Bio-equivalence study (if required)
- Defines protocols for Clinical test research
- Monitors Clinical test research
- Defines optimized batch
- Prepares Optimization batch report
- Prepares technology transfer document
- Supervises first three commercial batch production

ABC Ltd currently does not outsource any R&D activity nor does it undertake contract based R&D activities for other organizations. The entire R&D team at ABC Ltd is dedicated for developing the products for the organization. The organization also has plans to further strengthen the R&D base to cater to more profitable niches in vaccines and formulations segments, both in domestic as well as international markets.

4.2.2 IPR

ABC Ltd has an in-house Intellectual Property Management team which caters to all the patent, trademark, copyright and design related issues. This team prepares patent applications, files patents, identifies potential new products and markets for its vaccines and pharmaceutical formulations and provides support to its research activities. This team is responsible for the following activities:

- Assessing the eligibility of filing the IPR (Patents, Copyrights & Trademarks) considering the novelty of the innovation
- Filing the applications for IPR‟s with competent authorities Maintaining and renewing patents/trademarks/ copyrights

4.2.3 Clinical research

Before any drug or formulation is available for commercial sale, it must pass an approval process involving clinical research. Clinical Research is divided into 4 broad phases namely: Human pharmacology, Therapeutic Exploratory Trials, Therapeutic confirmatory trials and Post marketing trials. At ABC Ltd, the clinical research team determines the safety and effectiveness of the medications. ABC Ltd and its investigators are responsible for conducting the trials and documenting and reporting the generated data according to the protocol defined by R & D department during the development of the product and the GCP guidelines.

4.3.4 Central Planning & Customer Support (CP&CS)

The prime objective of CP&CS team at ABC Ltd is to ensure that the orders are met and the production targets and schedules are achieved in quantity, quality and cost. The CP&CS team also has to ensure that the resources and the production capacities of ABC Ltd are most optimally utilized. To attain the defined objectives, the team performs the following key activities:

- Analyzing the forecasted product wise sales provided by sales and marketing department
- Analyzing the contract manufacturing productions (in licensing and P2P)

Interpreting the sales forecast to the production cycle considering the resources of the organizations and constraints (if any) Planning as per production capacity of various plants, customer‟s country, batch sizes, and availability of other resources to complete the production as per the timelines Preparing a rolling plant wise plan which is further classified as per the production plan for each product that can be produced at the corresponding plant. On basis of the production rolling plan,

plant SCM teams plan the material procurement and prepare a product wise production plan for respective plants.

5.0 Model Development using System Dynamics

The term system refers to “reality” or some aspects of reality. A system may be defined as a “collection of interrelated elements, forming a meaningful whole.” So, it is common to talk about a financial system, a social system, a political system, a production system, a distribution system, an educational system, or a biological system. Each of these systems consists of many elements interacting in a meaningful way, so that the system can presumably serve its “purpose.” A common scientific tool used in investigating problems and solutions is modeling. A model can be defined as “a representation of selected aspects of a real system with respect to some specific problem(s).” Thus, we do not build “models of systems,” but build models of selected aspects of systems to study specific problems. The crucial motivation, purpose that triggers modeling is a problem.

ABC Ltd’s R&D processes has three sub phases

1. Idea to Product Identification
2. Product Identification to Proof of Concept
3. Proof of Concept to Launch

Ideas can come to anyone in the organization (scientists, medical practitioners or business development managers). The idea need to be vetted by the medical team from felt deprivation perspective, patent team from regulatory perspective, finance team from the perspective of financial viability. The whole initiative needs to be vetted from the effective resource plan perspective as well. The whole evaluation activities were conducted in parallel tracks. The products are identified.

Once the product is identified, the resources need to get allocated. The chemists, Researchers, Toxicologists, Animal House and technologists get involved to create the Proof of Concept.

Once the proof of concept is ready, it gets evaluated by the Clinical Research Panel (toxicologists). The Bill Of Material is identified. The production capability is assessed in terms of go to market strategy. This also gets evaluated by the patent team with the production planning team members. Then the launch platform is identified. And finally the product is launched.

5.1 Risk Identification

Attrition – Scientists leaving the organization. Loss of Tacit and Explicit knowledge

Project Schedule – Continuous failures increases the project time line and impacts cost of R&D

Risk of Competition – Competition launching the product just before the launch of ABC. The entire R&D cost goes down the drain as the market has always prevailed for the first launcher of the new drug.

Technological Risk – the technology used for production may get replaced by the new technology which is much cheaper and less time consuming

5.2 Inbuilt Flexibility / controllability identified within the system

The processes are discussed and analyzed with the CEO of the Indian Pharma manufacturer and the parameters identified after several discussions with the board of directors.

- Reward and recognition – To reward and the acknowledge the effort of the scientist a proper mechanism is created with the system to warrant attrition rate.
- Better market collaboration – better competitive intelligence through proper collaboration with the Market Research Agencies. Information is power, it is extremely important to be aware of competitors' activities in the area of R&D.
- Training and Knowledge Management – to warrant technological risk. The adoption process is imposed from the top to make sure of the adherence of the desired technological innovation standard
- Continuous Monitoring of R&D projects to warrant adherence to the schedule

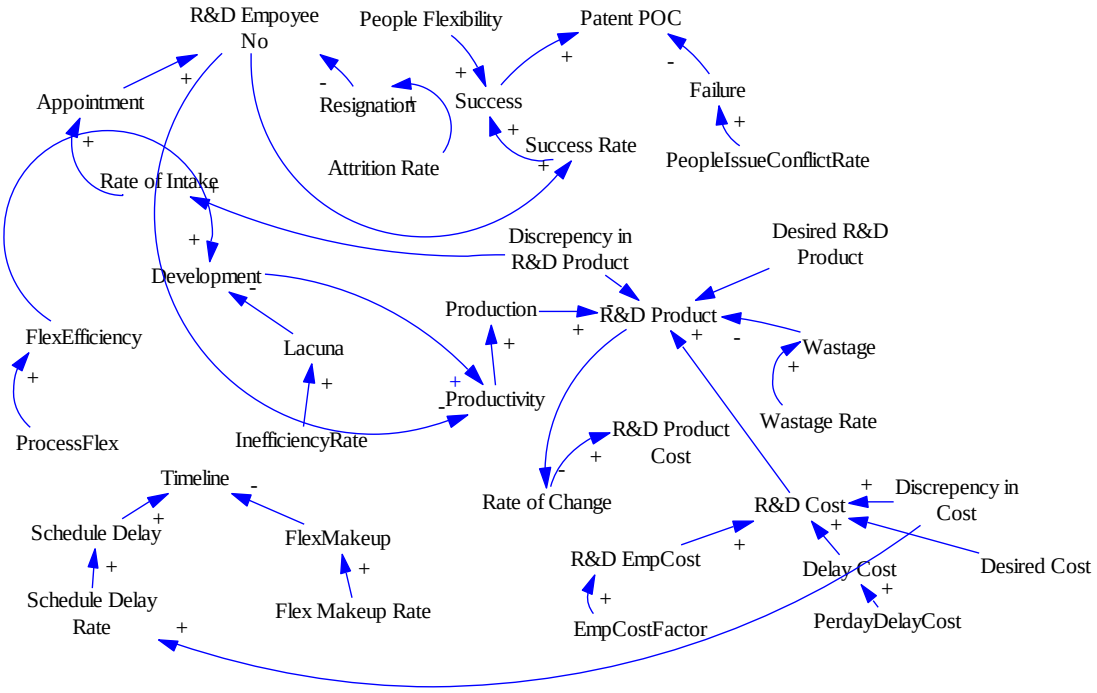
6.0 Causal Loop Diagram

Causal loop diagrams show the cause and effect relationships between the variables of a system. There are two basic feedback loops at the root of all systems behavior -- balancing and reinforcing loops. Balancing loops tend to keep the system in its current stage and reinforcing loops tend to compound change in one direction. These two loops are the building blocks for describing all complex social and economic systems. The power of causal loop diagrams is in their ability to capture the reasons systems behave the way they do and portray this understanding in a power graphic manner. Causal diagrams can be thought of as a language. This language's syntax is built up from causal loops, which are like sentences constructed by linking together variables of importance and showing the causal relationships between them. Multiple loops can then form paragraphs that tell a story with the graphic representation.

Causal loop diagrams concisely capture and communicate cause and effect relationships that can explain dynamic issues in a concise manner. What they do not do is provide a detailed representation of the structure producing the dynamics. That purpose is served by stocks and flows diagrams. The diagram helps to understand the actual workings of the system. It also reveals the interrelationship between the parts of the system, how its outcomes are produced by the circular cause and effect relationships.

The objective is to use this knowledge to make better decisions about how to achieve the desired results from changing a system

Figure 1 Causal Loop diagram depicting R&D product output vis a vis R&D cost



The CLD is staretd with R&D Emplyee number. The number is a function of Appointment and Resignation. Rate of Intake contributes to Appointment whereas Attrition rate determines the Resignation.

Patent POC is impacted deeply influenced by the success and failure of the projects being taken under consideration. Success is determined by the Success Rate whereas Failure is determined by one of its key components PeopleIssueConflictRate. Conflict is the function of some people issues within the work force. PeopleIssueConflictRate is a variable which determines a rate which acts negatively to the cause of organizational effectiveness. People Flexibility is one of the key components which actually contribute to the success of Patent POC. It is needless to say that Success has direct relationship with Competent R&D Employee number.

Development is deeply impacted by the FlexEfficiency and the prevalent Lacuna in the processes. By FlexEfficiency is the function of people efficiency in multiple areas. ProcessFlex contributes to FlexEfficiency and similarly inefficiency rate contributes to the Lacuna of the processes. ProcessFlex is the function, which is determined by its responsiveness to market opportunities.

R&D Product is deeply impacted by the Production and wastage. Productivity is the function of R&D employee number along with the Development. Productivity has direct relationship with the

Production. Wastage is deeply impacted by the wastage rate. Discrepancy in R&D product is the difference between the Desired R&D Product and the Actual R&D Product. (The assumption is : Desired R&D Product > R&D Product and none of the variables are equal to zero).

The next part of CLD explains the cost part of it. R&D product cost is the function of Rate of change of batch, which has negative relationship with R&D Product. R&D cost has direct relation with R&D product cost, Employee cost and Delay Cost. R&D Employee Cost is deeply impacted by the employee cost factor, whereas delay cost gets calculated on the basis of per day delay cost. Discrepancy in R&D cost is the difference between the R&D cost and the desired cost. (The assumption is: Desired R&D Cost < R&D cost; both the variables are not equal to zero).

Timeline is the function of schedule Delay and FlexMakeup. Schedule delay has direct relationship with the schedule delay rate. FlexMakeup has direct relationship with FlexMakeupRate. Discrepancy in cost has direct relationship with Schedule Delay Rate.

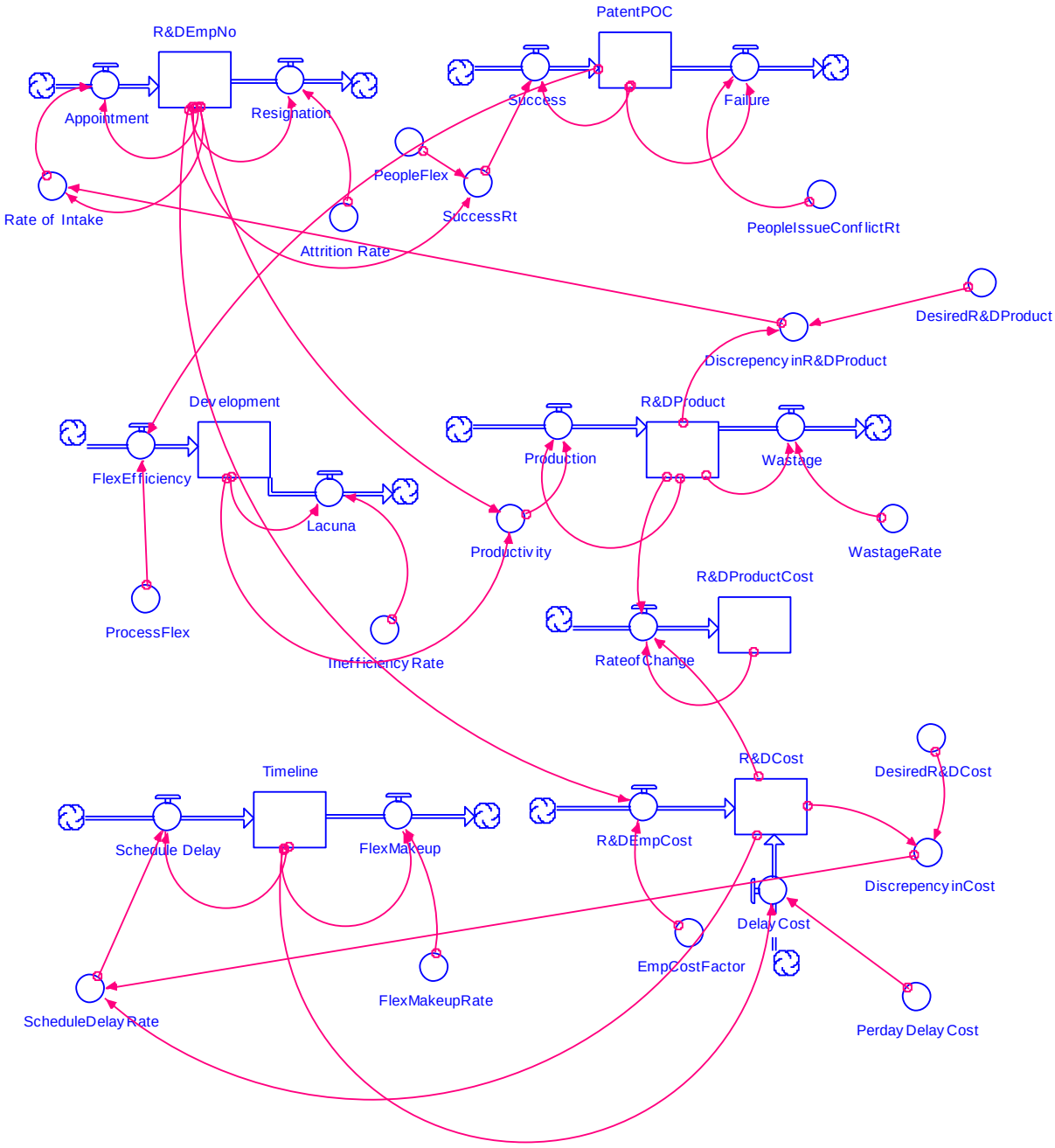
7.0 Following Model depicts effect of Flexibility over R&D Risk

Assumptions:

The model starts with the depiction of R&D Manpower. The actual R&D employee number is derived considering the intake and attrition in the system. Success Rate is calculated by multiplying People Flexibility with R&D Employee number. This is an attempt to capture effectivity of the R&D team. The rate of people flexibility was considered after discussion with the ABC board. As POC generation largely depends on the individual as well as team competency. People Flexibility is a rate attached to the team on the basis of their past accomplishment and training attended in ABC. This assessment was done by the top management of ABC. In ABC Ltd, the R&D process starts with the idea generation. There is an effort to transpire ideas into Patent POC. PatentPOC is calculated on the basis of the difference observed between successful attempts and failures. Development is calculated considering the flexibility in the development process. Flexibility Rate is calculated on the basis of options, change management capability and freedom of choice available in the system. The assessment was done after the discussion with the top management of ABC. Similarly the inefficiency rate is also calculated. Accordingly actual number of POCs converted into development can be identified. Successful POCs are transferred to development process. Process flexibility factor is identified on he basis of options, change management capability and freedom of choice available in the system. The assessment was done after the discussion with the top management of ABC. Successful POCs multiplied by the Process Flexibility Factor generates Flexi-Efficiency which is an input parameter to Development. Similarly Inefficiency Rate (factor) is calculated on the basis of past performance and Lacuna in the process are mapped. R&D Products (output) are calculated considering the Productivity (Development/R&D Employee) and R&D employee. One of the major

concern of R&D projects are delay in schedule and this impacts heavily not only on the development cost but also on the opportunity cost as it creates delay in the Go to market strategy. Initial project time line is one year and delay is calculated on the basis of the flexibility imbibed in the project management system. The fraction is decided after having a discussion with the top management of the ABC. R&D cost is calculated considering the amount of money lost during the delay in schedule. Manpower cost is also calculated. Total R&D cost is calculated on the basis of employee cost and delay cost. Productivity is calculated as Actual Development/ Retailed Employee. Feedback loop is created by mapping Rate of Intake as the ratio between Discrepancy in R&D product output and R&D employee. Similarly Discrepancy in R&D cost is mapped with the Time schedule delay rate.

Figure 2 Systems Dynamics model worked out in Stella



The model starts with R&D employees – the most important ingredient to create a successful Pharmaceutical manufacturing organization. Rate of Intake of employee gets balanced out with the attrition rate to arrive at the desired number of R&D employees.

R&D employee and their quantity and quality contribute to the success rate of Patent POC. Element of people flexibility contributes to success rate as it warrants the aberration of desired R&D resource number.

The success of Patent POC depends on the success rate, which gets by the people conflict issue. Its important to keep people issue conflict rate down. These people issues get transpired to the efficiency of the processes they execute.

The next part of the model tries to explain the process impact to the R&D initiatives. It is quite visible that desired number of Patent POC gets impacted by the flexibility efficiency. Needless to say that Flexibility efficiency along with Flexible process orientation (Process Flexibility) contribute to the overall Development process. Now the desired Development gets impacted negatively by the Lacuna of Processes. The lacuna of process is the function of inefficiency rate.

Model tries to explain and simulate the R&D product development process. Productivity is the function of R&D resources and their competencies. It is also the function of Patent POCs which have been successful through the development phase. So in a way people flexibility and process flexibility are contributing a lot to the context of Production. It's imperative that R&D product output gets negatively impacted by the wastage and wastage rate. It is important to keep the wastage rate down at the desired level in every aspect of production process.

The model tries to explain another important aspect – discrepancy in output of the final R&D product, which is the difference between the desired number of R&D product and the actual outcome. Discrepancy in R&D product has a role to play in determining the rate of resource intake.

The model tries to explain the cost of production as well. R&D product cost gets impacted by the number of R&D product and the rate of change. R&D cost is the function of employee cost and the scheduled time line delay cost. Timeline gets deeply impacted by the schedule delay rate and Flexibility make up rate. It's important to keep the delay rate down as much as possible.

R&D cost is the function of R&D employee cost. It is also function of flexibility delay makeup rate along with the desired number of R&D employee. The discrepancy in cost from the budgeted R&D cost has an impact of schedule delay rate.

Graphical Interpretation

Figure 3: The following diagram is a graphical interpretation of schedule timeline considering flexibility factors and delay

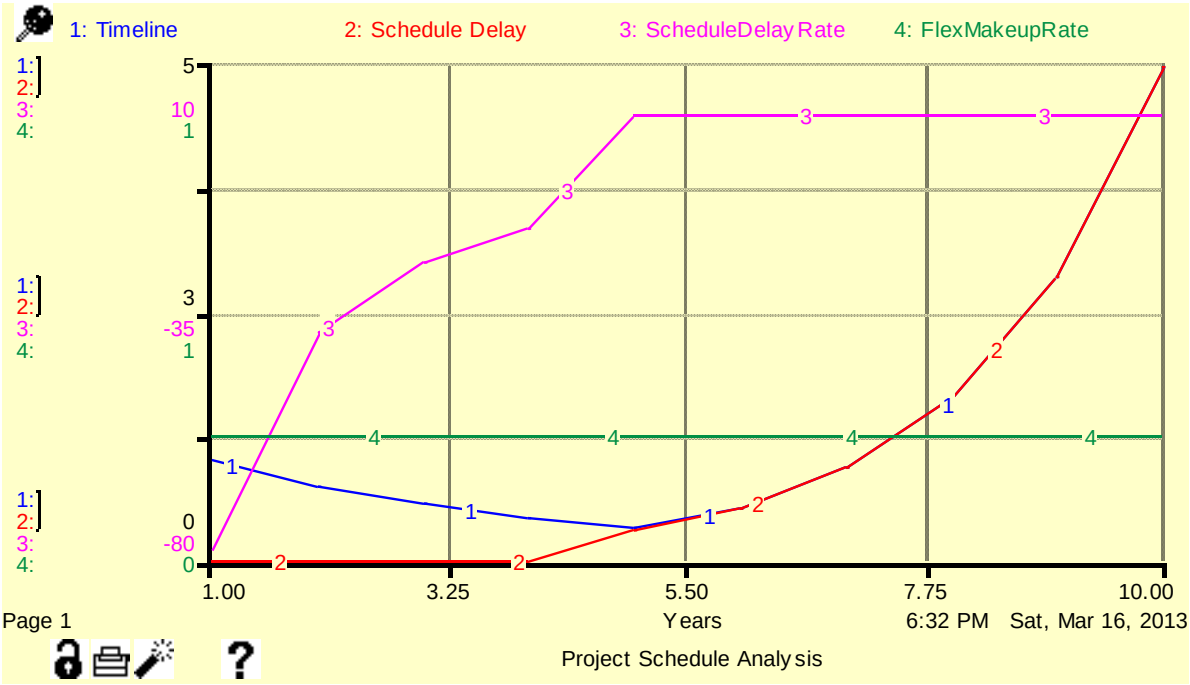


Fig 4 – Following diagram depicts Productivity vis a vis R&D Cost

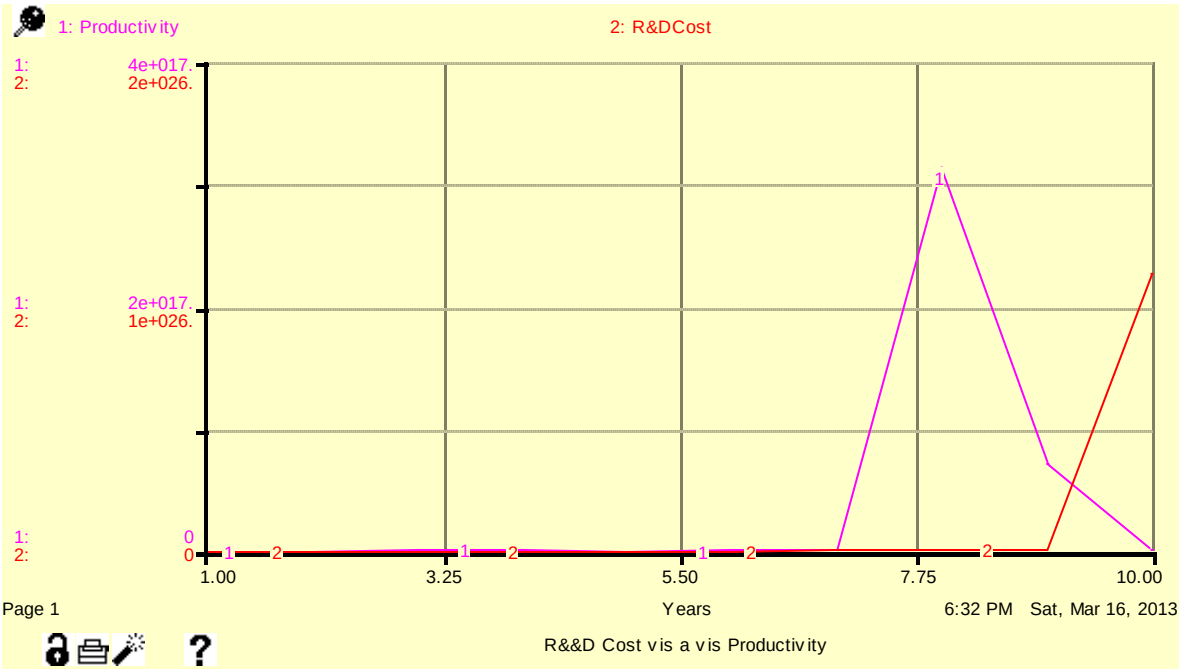


Fig 5 – Following diagram depicts the impact of Flexibility on Risk and expressed in terms of Actual R&D output and Actual cost of R&D

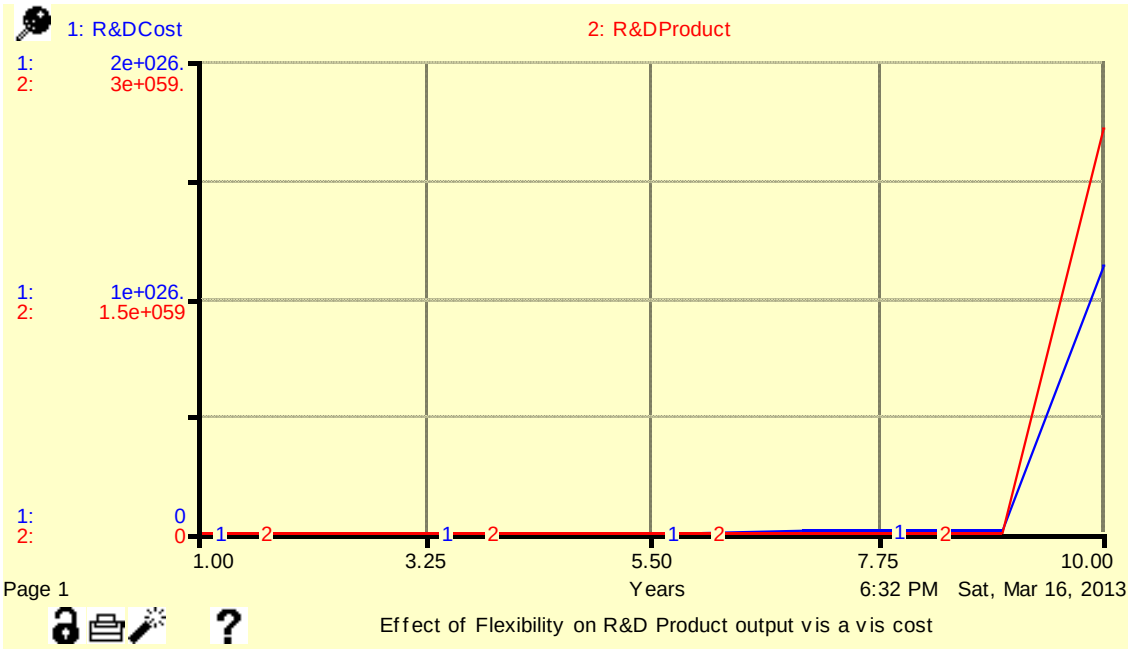
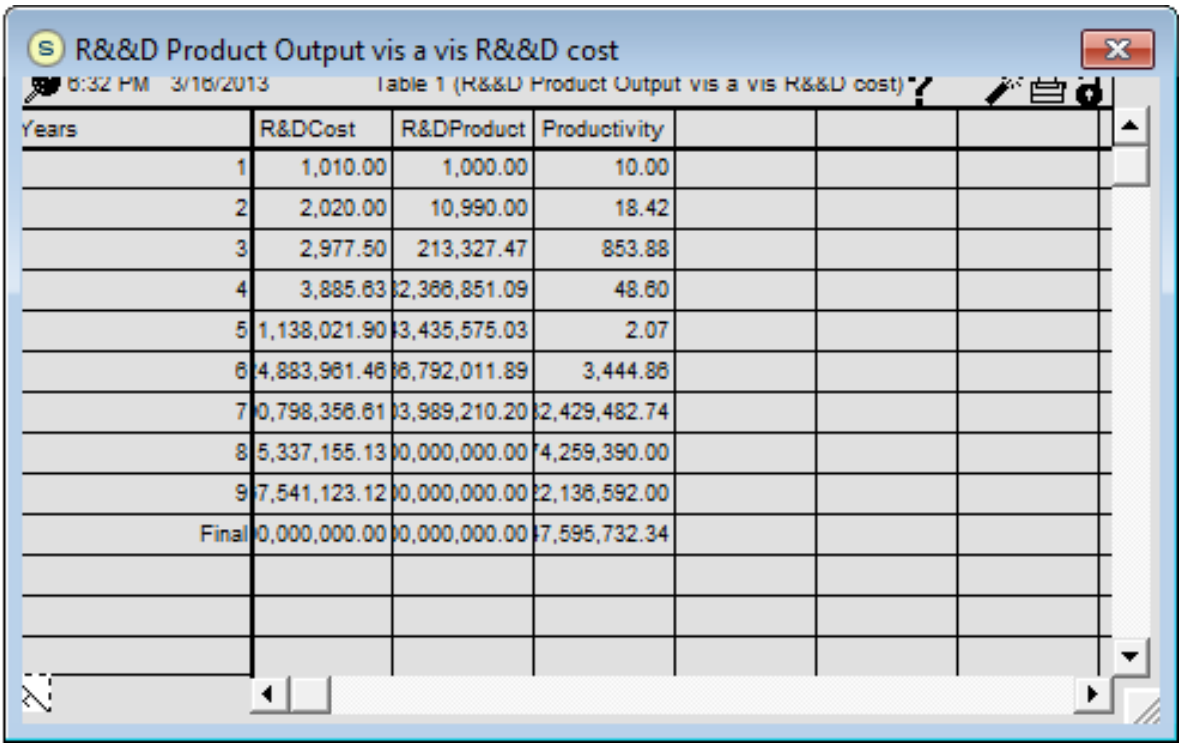


Table 1

The table simulates the effect of flexibility over R&D Cost, Productivity, R&D Product output, Development, Patent POC and R&D Employee



R&&D Product Output vis a vis R&&D cost

6:32 PM 3/16/2013 Table 1 (R&&D Product Output vis a vis R&&D cost)

Years	R&DCost	R&DProduct	Productivity
1	1,010.00	1,000.00	10.00
2	2,020.00	10,990.00	18.42
3	2,977.50	213,327.47	853.88
4	3,885.63	2,366,851.09	48.60
5	1,138,021.90	3,435,575.03	2.07
6	4,883,961.46	6,792,011.89	3,444.86
7	0,798,356.61	3,989,210.20	2,429,482.74
8	5,337,155.13	0,000,000.00	4,259,390.00
9	7,541,123.12	0,000,000.00	2,136,592.00
Final	0,000,000.00	0,000,000.00	7,595,732.34

Disclaimer – we used dummy data to simulate the situation.

8.0 Synthesis and suggestion

It's imperative from the above dynamic model that flexibility element increases output and reduces risk considerably. The objective is to bring in more flexibility in the R&D process. It could be argued that companies should shift focus to the areas promising more profit/ opportunity. But given the concentration of completion in such areas are much higher, it is advisable to devote more careful management attention to reducing costs, accelerating time to launch, and deciding when to remove poorly performing drugs from the portfolio and which compounds to invest in. This calls for Rebalancing of R&D with focus on the followings:

1. Common path of development needs to be identified
2. Options should be available at the output of every sub processes
3. Development should be equipped with changed options at the last phase with Finance and competency (Man power)
4. This should be backed by strong Change Management Process
5. Knowledge Management frame work should support the competition Information system by collaborating with the external agencies
6. Freedom of Choice should be there with the development team

It is important for the pharmaceutical and biotech companies to look beyond conventional way, which targets the specific population group in a particular geography. The segmentation was done on the basis of disease categories – the objective is to identify the patent groups to focus on for drug discovery and development. The objective is to build a capacity for mass customization. The focus is to reduce the average cost of goods sold.

To sustain growth it is imperative that organizations need to increase productivity by bringing in the element of flexibility in three paradigms of business – people, process and technology.

The objective is to make Drug manufacturing process more agile and responsive. The production lines should be equipped to respond quickly as opportunities arise. Control System of production batches should support this initiative. It is important to imbibe Integrated sensors for continuous monitoring of the quality parameters on a real-time basis.

Over a period of time patient treatments have become individualized. To address the felt deprivation flexibility in the design and size of the batch is the need of the hour. Flexibility calls for modular customizable strategies for manufacturing plants. This approach offers significant cost savings and reduced startup timeframes for new facilities.

This will also reduce financial risks due to seamless flow of product subcomponents across production lines with multiple options.

Considering the above following recommendations can be made for ABC Ltd.

i) ABC should focus on consistently overpower clinical trials, for example, could reduce the number of patients per trial. It is observed that R&D costs could fall by 5 to 10 percent through more aggressive outsourcing of selected noncore activities to bring in operational flexibility.

2. The cost of failure can also be lessened by sharing risk—say, with another pharmaceutical company, a contract research organization, or investors. This is a strategic call that ABC needs to take considering the severity of impact on schedule by the failed POCs. It is observed that this strategic intent if well executed can reduce the overall cost of R&D by 15 percent or more (Mackenzie Study 2010).

3. Focus should be given in bringing in more flexibility in the development process. For example Merck accelerated the launch of the diabetes drug sitagliptin (Januvia) by three to four years through novel parallel-development techniques. But gains in speed cannot come from shortcuts: the key to capturing value by accelerating programs is choosing the right programs to accelerate.

9.0 Conclusion

ABC Ltd case study is an attempt to understand the intricacies of the relations exists between the processes. This is an academic attempt to explain certain business behavior where Flexibility plays a major role. Flexibility impact analysis was done considering the local propagation of process outputs. The Case clearly establishes the impact of flexibility on the Risk parameters. The study is an attempt to explain the behavior of Flexibility parameters in certain business scenarios using system dynamics.

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Appendix A

Stella Equations

Development(t) = Development(t - dt) + (FlexEfficiency - Lacuna) * dt

INIT Development = 1000

INFLOWS:

FlexEfficiency = PatentPOC*ProcessFlex

OUTFLOWS:

Lacuna = Development*InefficiencyRate

PatentPOC(t) = PatentPOC(t - dt) + (Success - Failure) * dt

INIT PatentPOC = 1000

INFLOWS:

Success = PatentPOC*SuccessRt

OUTFLOWS:

Failure = PatentPOC*PeopleIssueConflictRt

R&DCost(t) = R&DCost(t - dt) + (R&DEmpCost + DelayCost) * dt

INIT R&DCost = R&DEmpCost+DelayCost

INFLOWS:

R&DEmpCost = R&DEmpNo*EmpCostFactor

DelayCost = Timeline*PerdayDelayCost

R&DEmpNo(t) = R&DEmpNo(t - dt) + (Appointment - Resignation) * dt

INIT R&DEmpNo = 100

INFLOWS:

Appointment = R&DEmpNo*Rate_of_Intake

OUTFLOWS:

Resignation = R&DEmpNo*Attrition_Rate

R&DProduct(t) = R&DProduct(t - dt) + (Production - Wastage) * dt

INIT R&DProduct = 1000

INFLOWS:

Production = R&DProduct*Productivity

OUTFLOWS:

Wastage = R&DProduct*WastageRate

R&DProductCost(t) = R&DProductCost(t - dt) + (RateofChange) * dt

INIT R&DProductCost = 500000

INFLOWS:

RateofChange = (R&DProduct/R&DCost)*R&DProductCost

Timeline(t) = Timeline(t - dt) + (Schedule_Delay - FlexMakeup) * dt

INIT Timeline = 1

INFLOWS:

Schedule_Delay = Timeline*ScheduleDelayRate

OUTFLOWS:

FlexMakeup = Timeline*FlexMakeupRate

Attrition_Rate = .05

DesiredR&DCost = 80000

DesiredR&DProduct = 100000

DiscrepencyinCost = R&DCost-DesiredR&DCost

DiscrepencyinR&DProduct = R&DProduct-DesiredR&DProduct

EmpCostFactor = 10

FlexMakeupRate = .25

InefficiencyRate = .25

PeopleFlex = .75

PeopleIssueConflictRt = .25

PerdayDelayCost = 10

ProcessFlex = 1

Productivity = Development/R&DEmpNo

Rate_of_Intake = DiscrepencyinR&DProduct/R&DEmpNo

ScheduleDelayRate = DiscrepencyinCost/R&DCost

SuccessRt = R&DEmpNo*PeopleFlex

WastageRate = .01