

THE INDIAN PHARMACEUTICAL INDUSTRIAL PROGRESS AND THE ROLE OF SOFTWARE IN IMPLEMENTING SCHEDULE M IN SME OF INDIAN PHARMACEUTICAL SECTOR

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Abstract- The rapid changes in pharmaceutical industries and its growth along with long run advantages. The unprecedented challenges facing by the MSE of this sector regarding Schedule M implementation .The critical role of ERP in developing A SME unit to over come the difficulties in Schedule M implementation A module to implement and Data administration on line with Regulatory requirements.

Key:-*Schedule M-Good manufacturing practices involving premises and plants, SME- Small and medium enterprises*

Introduction

It was very interesting to reflect on the fact that the Indian pharmaceutical sector is merging as one of the major sector. It is one of the worlds largest and most developed we are ranking 4th in volume terms and 13th in value terms. The country accounted for 8 percent of global production and 2 percent of world markets in pharmaceuticals.The Indian pharmaceutical industry meets approximately95% of countries pharmaceutical needs.¹ The export earnings rising from a negligible amount in 1990s to Rs.29,139.57 crores (US\$7.24bn) in 2007-08. The exports of Drugs, pharmaceuticals & fine chemicals of India have grown at a compounded annual growth rate (CAGR) of 17.8% during the five-year period 2003 to 2008.² The Indian domestic pharmaceutical market size is estimated at US\$10.76bn in the year 2008 The economical experts predicting that the trend was continue to grow at a high CAGR of 9.9% percent till 2010 and thereafter at a CAGR of 9.5% till 2015.However, this is still minuscule in comparison to the opportunity existing in the global market or with the exports cornered by major pharmaceutical exporting countries. India is undisputedly a pioneering position in the global pharmaceutical industry (other than drug discovery) measured by any yardstick say number of facilities filing DMFs or facilities inspected by US FDA or number of patent challenges or volume of APIs & formulations exported, etc. In spite of considerable achievements, several untapped business segments and markets exist and the room to enhance the country's pharmaceutical exports is vast. The sophisticated chemistry capabilities, lateral thinking abilities in developing non-infringing processes, disciplined approach to adhere to any stringent guidelines, dedication for manufacturing excellence, etc., make India as a most favorite destination to source or outsource various components of value chain. In addition all the above achievements and efforts we are still at the periphery of this vast opportunity. A number of leading drugs go off patent every year and the generic pharmaceuticals penetration is increasing in all the countries of the world further raising the opportunity for exports in this segment. Approximately US\$123 billion worth of generic products are at risk of loosing patents by 2012.India has the requisite capabilities. Hitherto most opportunities emanated from synthetic chemistry.

Role of Indian government Regulatory Authorities & pharmaceutical sector

The enhanced regulatory requirements are changing the rules of the game making production migrate to east. It was very essential for the Indian pharmaceutical players to take appropriate measures to reach our estimated export goals. This is possible only by understand and proper implementation of the regulatory requirements along with the support of government policy's to win in this developed countries game. The government should provide training for the new regulation and GMP implementation. Along with this should explore the new export marketing opportunities by providing technical and financial Support to participate in trade fairs of different countries

Present Indian contribution for the global pharmaceutical sector

India accounts for over one third of drug master files (DMFs) in USA. (Refer Tables & Charts-1, 2, 3 & 4 and Appendix I for list of Indian companies having active type II DMFs with US FDA). Thirty percent of all approved NDAs in the US are from India, ranking the country number 2 next only to USA. Needless to mention scores of approvals by UK MHRA and various other agencies are also being filed from India.³

Even in patent challenges, India ranks only next to USA with a share of 21 percent of patent challenges. Undeniably India is an emerging leader in pharmaceuticals

FINAL ANDA APPROVALS 2007 BY Countries Figures

Country	Numbers
USA	169
India	132
Israel	40
Germany	25
Canada	24
Switzerland	19
Iceland	14
Jordan	11
Other	25

Number of patents challenged by country wise

Country	Numbers
USA	200
India	113
Israel	89
Canada	43
Switzerland	34
Iceland	17
Germany	10
Other	32

Number of DMF (Type II) Submitted by India ,China and world 1998 to 2007

Year	India	China	World wide Total
1998	32	27	316
1999	26	6	199
2000	33	9	201
2001	47	6	238
2002	55	20	264
2003	115	19	360
2004	160	25	435
2005	233	70	615
2006	267	78	627
2007	274	90	656

The existing Status of SME (small and medium enterprises) sector

On the other hand it is very important to focus on the fact that the India's pharmaceutical sector especially small and medium enterprises this sector currently undergoing unprecedented change. Much of this is due to the country's introduction, on January 1, 2005, of a system of product patents; and amendments in Schedule M have put severe financial strain on the domestic pharma industry.³

"These (units) have to make definite choices in terms of products, quality standards, prices, production, R&D, marketing and organization. While the market for generic formulations/bulk drugs, loan-licensing could be considered an opportunity by the industry, lack of adequate awareness on the impact of the new patent regime and GMP compliance on the business mode and alternate courses of action would be an inhibitor to industry growth and vibrancy," it said. The MSME said the requirements of international standards of manufacturing practices were increasing day by day. Some of the manufacturers were finding it difficult to comply with the revised norms while majority of units have enforced the norms. "As a result of this, it is reported that some of the small scale units have partially closed or completely closed down their manufacturing activities," the note said. The big players in the market were taking this as an opportunity and building more pressure on these units by their new marketing and purchasing

strategies. This leads to increase the price of the medicines and the complete market will be under the control of big players only so the and investing more techniques. The MSME come forward and take a proper action to support the SME to over come this situation by providing new Schemes and technical support by providing training secessions on GMP and Schedule M If we observe the today's manufacturing companies they are taking a broad view of compliance, using it as an umbrella term for all aspects of governance, risk management, and regulatory compliance. This is particularly evident for process manufacturing companies, which must not only abide by new fiscal regulations but also adhere to strict regulations concerning the manufacture and distribution of their products.

"Compliance pertains wherever there is a defined set of rules and regulations that must be adhered to and where proof of compliance to these rules and regulations is required," The study reflects that there are four distinct types of rules and regulations facing process manufacturing companies:

1. Generic regulations such as International Accounting Standards
 2. Industry regulations that are specific to certain industries, such as the Federal Drug Administration's 21CFR Part 11 EDQM, ICH & WHO
 3. Customer requirements enforced by specific clients, such as how particular products must be manufactured, checked, shipped, or invoiced
 4. Internal rules and procedures, such as standard operating procedures and policies governing external communications
- these are the thing very big challenges

Role of Software for smooth functioning and progress of Pharma SME sector

At this junction it was very important for the government and the SME to adopt proper Measures to safe guard the SME progress. In this scenario the IT industry play a very important role in achieving Pioneering results to achieving the expected export targets.

With the introduction of cGMP compliant ERP solution, the software sector has been armed with highly regulated ERP solution for Pharmaceutical industry. With this technology of ERP it has become easy to manage to perform the pharmaceutical regulatory activities easily with more effectively.4

It is very clear that for any Pharmaceutical ERP, compliance with GMP & Regulatory requirement considered as prime importance. Pharmaceutical Industry has been categorized under Batch Process Manufacturing. ERP makes the process of forecasting simple. It is a powerful end-to-end business integration solution.

The basic advantages at glance

- It improves GMP compliance: SOP adherence, operator skill set qualification, activity dependency, less operator errors, accurate batch documentation

It reduces operational costs and saves time:

- less time is spent on entering, reviewing & approving data
- lower cycle times (less quarantine time)
- less on-hand inventory is needed
- with less inventory, less storage space is needed
- less time is needed to archive & store batch records
- less product waste is generated
- higher yield are obtained.
- it improves asset utilization (return on investment)
- alerting capability helps to fix problems quickly
- It lowers paper archiving requirements: less storage, less people
- It improves product quality: by enabling people to respond more quickly to problems, the process control limits can be tightened; this enables the manufacture of drug ingredients or products more consistently (with less waste & higher yields)
- It enables people to focus on process improvement, not on compliance issues: people now have the opportunity to be empowered with continuous improvement or lean manufacturing initiatives
- It enables better decision-making: managers have visibility to real-time & accurate information (integration of all data into a common framework)
- Extensive reporting, workflow and online real-time capabilities
- Increased Operational Effectiveness & Productivity
- Timely and target information feedback system for decision support
- Improved Customer Support
- Improved batch tracking management

Quality

Quality tops the priority list as far as any pharmaceutical company is concerned. The ERP system has been designed in unique style so that the Quality Control department with its integrated sophisticated Quality Control / Module which not only monitors quality by control plans in purchasing and production but also provides real-time process capability index for quick review.

ERP for SME

If we go by tradition, we see that organizations the world over are divided into the following:

1. Small Enterprises
2. Medium Enterprises
3. Large Scale or Multinational Enterprises

It was very well known that at present scenario the SME's are facing very critical financial crises keeping this in mind we are suggesting that this segment of units can adopt an ERP either for all the departments or for only very specific departments.⁵ Thus, we can say that these organizations would implement an ERP depending on its size and the number of departments that are there in the organization. A large organization can afford to implement an ERP in its entirety only because it would have the money power to do so. However, this would be a dicey situation if we consider any small or medium-sized enterprise. Implementing an ERP for SME would have to be based on a number of factors:

1. The number of departments in the organization
2. The cost-effectiveness of the implementation
3. Whether the investment in ERP would yield a profitable return

The last factor mentioned above is of paramount importance as far as any small or medium scale organization is concerned. A lot of small scale enterprises play the waiting game. What they do is that instead of implementing the ERP in its entirety in the beginning itself, they would implement it for departments where it is felt that the implementation of an ERP is felt to be an absolute necessity.

Once the enterprise makes a profit and starts to grow, then the ERP can be gradually extended to other departments as well, finally reaching the climactic point where the ERP has been installed in the entire enterprise. Thus, one can say that implementing an ERP for SME is done in stages.

The moot point to be considered here is, "Would an ERP for SME be beneficial in the long run?" The answer here would have to be a "Yes". This is based on a simple and logical assumption that any entrepreneur who sets up an enterprise does it with only one thing in mind, that the enterprise starts growing, makes a decent amount in the initial stages and yields a return on his investment, and finally when the enterprise has really taken off, starts yielding a surplus. i.e. starts yielding a profit for the initial amount invested. Now, investing in an ERP for SME would only serve to augment this fact, as an ERP would not only save a lot of time by integrating all the departments together, but the departments would be able to function effectively and efficiently if they function together in a co-ordinated manner, rather than in an individual fashion. Also, a sense of purpose becomes apparent when there is a collective responsibility shared between various departments, which is exactly what an ERP strives to do.

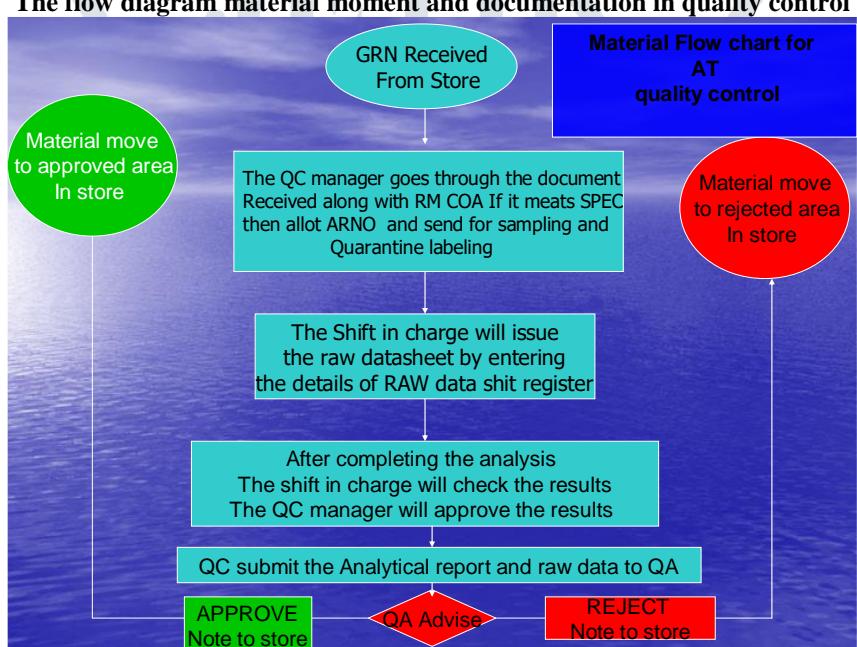
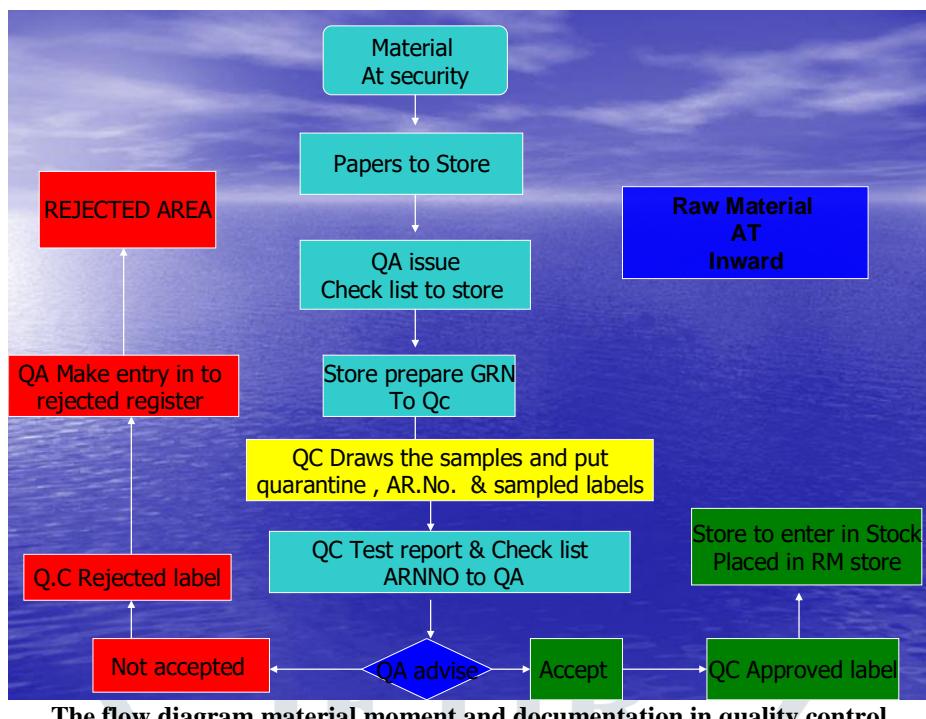
We considered a small scale industry at Nashik and implemented the best possible software implementation in four different phases. Before implementing we provided training to the different department heads and the persons who are expected to handle this system.

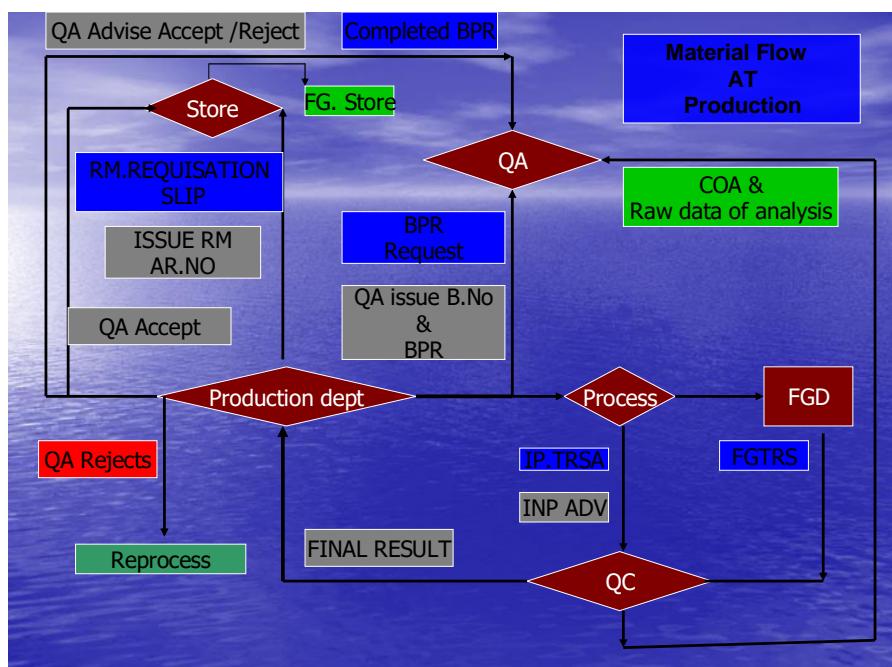
Prepared all the Documents and trained the employees regarding Schedule M and ERP At the present scenario it is difficult for the SME to bear the financial burden so we implemented the ERP in selected departments based on the market experience. The following departments were given priority

1. Ware house
2. Quality control
3. Production
4. Dispatch planning

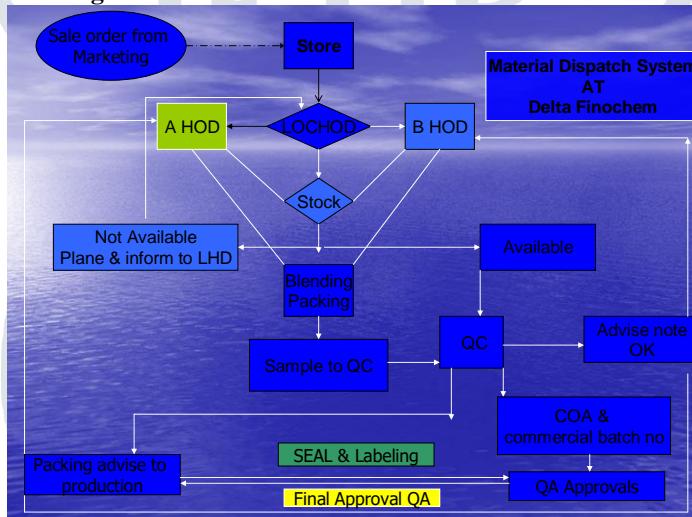
The quality activity begins at the security while receiving the raw material and it ends with the dispatch of finished goods at the gate. The documentation part also begins here only one should not be skip these activities. The following was the implemented moment of documents during the receiving of the goods

The flow diagram for material moment along with documents in warehouse





The flow diagram for material moment and documentation in Dispatch



Conclusion

By taking the above measures the study revels that the organization able achieve

1. Scucefully implemented Schedule M and pioneering to words WHO certification
2. Able to retain your market share in new business environment?
3. Have a strategy for meeting the new challenge of global business competition
4. To improve quality and reduce cost to remain competitive

Thus, we can say that an ERP for SME could only prove to be beneficial for any Small or Medium level enterprise in the long run.

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