

# Track & Trace Pharmaceuticals

## Do It Before You Must –But Do It Right

### Key Insights:

- Track & trace solutions can help pharmaceutical companies enhance top and bottom line while also ensuring compliance.
- Track & trace solutions can enhance both top and bottom line while helping to ensure regulatory compliance.
- It requires commitment from all stakeholders: pharmaceuticals, governments, etc. to combat the drug counterfeit issues
- To ensure a successful deployment of a track & trace solution we believe it is critical to:
  - Priorities challenges
  - Start small
  - Ensure buy in and involvement from the channel
  - Engage with an experienced partner

## Introduction

*Track & trace solutions –mainly RFID based, are increasingly used in the pharmaceutical space. Major pharmaceutical brands like Pfizer are leading the way with their Viagra RFID track & trace solution per bottle level across the USA. The key reasons for deploying track & trace solutions are linked to the desire to enhance efficiency in the channel; ensure compliance and reduce frequency of theft and counterfeit products.*

*The article will explore the major challenges facing pharmaceutical companies, how track & trace solutions can overcome them, and how to choose an optimal solution by examining some concerns about track & trace solutions.*

## The Three C Challenges of Pharmaceutical Companies - Competition, Compliance and Counterfeit

Western pharmaceutical companies are under immense pressure from what Frost & Sullivan call the three “C Challenge” and are those they must act upon to ensure sustainable growth:

*Competition* from generic lower cost products from emerging markets is squeezing prices at a time when other factors are also depressing prices. The Internet is undermining price differentiation across markets. Many strong revenue generating patents are running out. Finally the economic climate has reduced spending by cash stripped consumers and organisations. Pfizer’s CEO Jeffrey Kindler, for example, predicts that a number of acquisitions will be made across the industry before the economy would start to recover. The increased competition is forcing Western pharmaceutical companies to find ways to compete more effectively.

*Compliance* is a significant element of the pharmaceutical industry. To ensure the safety of drugs, the US and EU regulators have embarked on various legislations. One of the most significant examples in the USA was that of the California Pedigree. Although this legislation has been postponed to 2015, it still poses a huge cost for companies to comply. In Europe, the EU is trialling a track & trace programme in Sweden which is expected to end with a mandatory track & trace legislative compliance requirement in the longer term. As a result, pharmaceutical companies must find cost efficient ways to comply with legislative requirements while still supporting top line goals.

*Counterfeit* drugs are a major problem estimated to cost between 7-10% of global pharmaceutical market revenue. Not only do pharmaceutical companies face low cost competition, they are also seeing counterfeits of their branded and generic products. It is a serious problem for the pharmaceutical brands due to the direct loss of revenue and the indirect loss of brand equity when consumers are adversely affected by fake drugs. The challenge of counterfeit drugs must be addressed to ensure future revenue streams, but the solution is likely to need government support.

## Benefits of Track & Trace Solutions

The challenges for pharmaceutical companies in addressing these three Cs mostly pertain to the lack of information flow through the channel. Ensuring more effective control of the supply and distribution channel is critical. Track & trace solutions can help support pharmaceutical companies compete better by achieving strategic goals in terms of enhancing both top and bottom line.

### Enhance Top and Bottom Line

Track & trace solutions support pharmaceutical companies in competing more effectively. The wealth of business intelligence data accumulated by such solutions can be used to enhance sales and efficiency. This is done through lower costs enabled by visibility of such key parameters as the most efficient sales outlets; better selling product categories; more efficient distribution, production and repackaging (if this occurs) processes. In addition, the solution may also help organisations raise their green credentials due to lower resource usage in production and lower gas miles consumed by the distribution fleet.

### Ensure Regulatory Compliance

Legislators in both the USA and EU have gone beyond serialisation; for example, they advocate the use of RFID based track & trace solutions to authenticate, monitor and control the flow of drugs through the channel.

This is currently voluntary. However, Frost & Sullivan believes this voluntary compliance could become mandatory. Pharmaceutical companies should therefore start considering implementing systems to optimise the investment they will eventually be required to make. We believe this can be done by designing systems and processes to derive data that both satisfy the legislator and enable the companies to compete more efficiently.

### Ensure Revenue and Taxes, Together

Pharmaceuticals can not combat the issue of counterfeit alone. They can invest in track & trace solutions to help reduce the extensive amount of counterfeit drugs. Track & trace can help by tracking original products along the channel avoiding theft, substitution, etc. In addition, pharmaceuticals can invest in advanced authentication features on packaging. However, a unilateral effort can be more effective with in a government environment. Governments must take a proactively role to vigorously enforce copyrights and patents; commit police and custom services; make punishment for counterfeit more punitive and support pharmaceutical companies in creating consumer awareness of the dangers of counterfeit drugs. The government benefits from reducing the incidence of counterfeit drugs as it would mean fewer consumers getting hurt from fake drugs. Furthermore, the government gains from tax revenue by recovering the loss in sales tax from consumers buying the fake drugs and protecting the loss of corporate tax revenue from pharmaceutical companies.

In general, counterfeit and theft are more prevalent among expensive life critical drugs such as HIV medicine and cancer drugs. As such, GSK, for example, now trials an RFID based track & trace solution at a per bottle level for their HIV drug, Trizivir, to reduce counterfeit and theft risks. However, the main reason for the deployment is not to reduce stolen goods, but to enhance efficiency in the processes throughout the supply and distribution channel.

In summary, Frost & Sullivan believes that a track & trace solution at a per bottle/package level can support pharmaceutical companies overcome the three Cs:

- *Competition:* A track & trace solution will gather more detailed business intelligence along the channel than pharmaceuticals and their distributors have ever had in the past. This can help them detect areas for further sales generating or product development efforts by identifying such parameters as the best selling product lines. In addition, the pharmaceutical and its distributors will get a tool that can support them in enhancing channel efficiency and fleet management that in turn reduces costs.

- *Compliance:* A track & trace solution in conjunction with the current requirements for serialisation can ensure regulatory compliance. For example, pharmaceutical companies can easily detect batches for recall, or prove a direct and undisturbed route to market.
- *Counterfeit:* A track & trace solution in conjunction with serialisation and an authentication function can help ensure that the drugs reach the destination in time, in its original shape and content. The solution can therefore help pharmaceutical companies to recover lost revenue. Finally, the solution can help governments ensure tax revenue and also ensure that consumers avoid getting hurt from counterfeit drugs.

## Barriers for Track & Trace Solutions

### Lack of Common Standards

The lack of common standards has restricted the growth of especially the RFID based industry because the FDA in the USA allowed the industry to define a common standard. The inertia towards a common standard stems from the fact that some industry players have already implemented solutions and have therefore no incentive to switch to new standards.

In Europe, a trial in Sweden is currently being deployed and it is likely that it will be the foundation for the standards and processes to be recommended by the European Commission (EC).

The lack of common standards poses another problem. Resellers are not interested in having several types of solutions across their facilities.

Frost & Sullivan believes that resellers may hold the key to establishing a common standard. Nearly 80% of pharmaceuticals in the USA are distributed by three major distributors such as McKesson. As a result, their commitment is critical. Distributors will prefer the one that is most widespread across their facility, and that best supports their processes and objectives. It should be noted, that pharmaceutical distribution is more fragmented in Europe.

### Lack Security

Some pharmaceutical companies and security agencies argue that RFID tags are less secure because they can be easily replicated. Frost & Sullivan believes that while the deploying technology has a risk, there is technological progress to enhance both logical and physical security features.

There are also concerns regarding unauthorised access and security of track & trace solutions because they contain sensitive and private information. Frost & Sullivan believes that the risk of unauthorised access can never be completely eliminated. However, we also believe that there are at least three reasons why an integrated track & trace solution will be secure enough to handle the strategy, planning and execution of processes:

- A good track & trace solution is deployed with a strict governance framework. It has a strong hierarchy determining privileges inside and outside the system, in accordance with the chain of command. If an intrusion is suspected in one area, the system is designed such that the central IT function can remotely isolate the component to delete data, for example.
- Current track & trace systems are heavily protected, and security tools are continuously being improved. It is common to have several physical and logical security layers. The logical layer also takes several forms and steps. However, we believe that the specific organisation's IT governance and security policies must also be changed to reflect the new system.

- A well-designed track & trace solution comes with extended disaster recovery capabilities. There will be several locations with real-time data back up. If a threat is detected in one location, data can be drawn from a secondary data centre making the system less vulnerable. Finally, to optimise security, pharmaceutical companies can choose a vendor with strong experience and access to a large variety of best practices in security solutions in other security sensitive sectors such as financial services. By doing so, we believe pharmaceutical companies have the best opportunity to define an optimal system security level.

#### **Negative Impact on Production Process**

For each time production or distribution processes slow down by just a second, pharmaceutical companies incur huge costs. As a result, they have concerns that track & trace systems should not slow down any processes. For example, they ask such questions as how the RFID tags can be attached to the bottles without slowing down the production process; how can RFID tags be read without slowing down the aggregation and disaggregation processes at the distributor; etc.

Frost & Sullivan believes that it is possible to design processes that incorporate track and trace solutions and yet do not slow down production. We believe it is critical to have a solution partner with extensive pharmaceutical experience. The partner can endorse best practice into the design phase by providing expertise on how tags can be attached, and how processes can be developed without any lost time at both the manufacturing and distribution sites.

One solution could for example be to integrate the RFID tags with the label such as Pfizer's Viagra solution provided by IBM, SupplyScape and TAGSYS. This involved close collaboration with the label partner so that the RFID tag can be integrated with the label and thus avoid adding additional time. Having an experienced partner may also be beneficial in dealing with complex processes such as the aggregation and de-aggregation of products along the channel.

#### **Lack of Infrastructure**

The lack of infrastructure along a channel within a region or across a larger country will reduce the efficiency of a track & trace solution as synchronisation with the system will be lost. This is a relatively small issue in such markets as North America and Western Europe, where solutions have been deployed. However, the issue becomes more complex in the case of deploying a solution, for example, in India where infrastructure may be patchy. Infrastructure investment will be significant. It will often entail a government commitment to improve ground infrastructure. Alternatively, a company can choose to use a satellite for its track & trace solutions, like the oil company Shell.

#### **Cost**

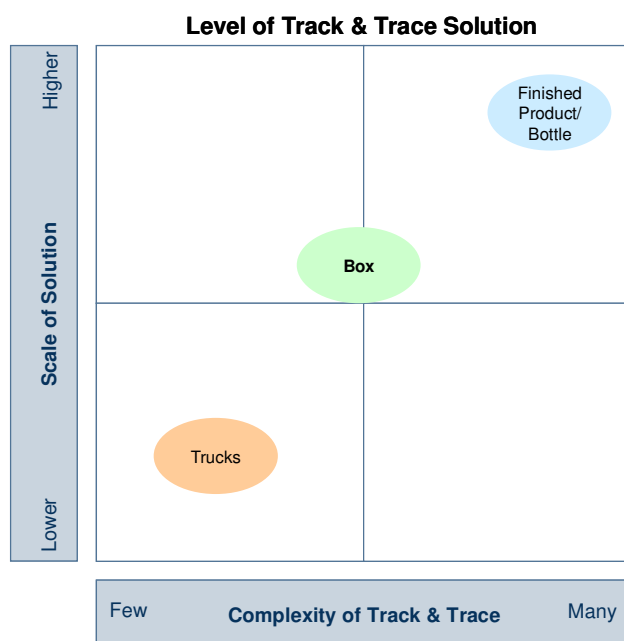
Deployment costs for RFID track & trace solutions are still relatively high. However, as RFID track & trace solutions become more widespread not only in the pharmaceutical space, but also in food, fashion, utilities, chemicals, the cost of solutions decreases as vendors achieve scale. Currently, tags can still be relatively expensive, but prices will likely fall in the short term as they are often regarded as a commodity. Frost & Sullivan believes that the benefits from such solutions are longer term and therefore ROI should be measured over several years as the solution evolves.

## **Choosing an Appropriate Track & Trace Solutions**

There is a range of applications for RFID based track & trace solutions within pharmaceutical companies.

A challenge may be to decide the appropriate level of where to track. Should the solution track at the trucks, per box or per bottle/package level? If the solution, for example, mainly attempts to enhance fleet efficiency, a track & trace solution at a per truck level may be appropriate. An example could be I. D. Systems' track & trace fleet management solutions. The solution for trucks will entail a relatively fixed number of tracking devices but it needs to track along the channel adding to the complexity of the solution.

Generally, the more challenges the solution is meant to overcome, the higher is the scale of solution. If, for example, a company attempts to overcome the three Cs, a bottle/package level solution may be more appropriate. In this situation, tracking needs to occur at a detailed level for each bottle/package to avoid disappearance. The number of tags and the amount of information that has to be retained keeps increasing. In addition, tracking has to occur across the channel. As a result, complexity often increases with scale.



**Figure 1: Track & Trace Solution Types**

Frost & Sullivan has established 4 factors that pharmaceutical companies should consider when planning to deploy a track & trace solution.

### **1) Prioritise**

Frost & Sullivan believes it is important to prioritise the challenges to define clear and specific objectives. This makes it easier to choose a solution that matches the objective. Furthermore, choosing a vendor with strong service capabilities can be helpful as they have experience in helping customers meet their objectives within specific time frames.

### **2) Start Small**

It has been our experience that successful projects start small. When the smaller specific project is working, it can be more readily expanded. These projects are also manageable and it is easier to measure if the established objectives are being achieved.

Starting small often means starting with a specific product in one country. For example, GSK's trial with Trizivir in the USA samples for one research project or trucks at one distribution hub.

### **3) Ensure Buy In from the Channel**

Track & trace solutions in the pharmaceutical sector are generally deployed along the channel. In the USA, the distribution of drugs is highly concentrated. Three major players account for nearly 85% of the total drug distribution market so their bargaining power is very high and little will happen without their buy in. As a result, it is critical to gain their buy in.

In Europe, distribution is more fragmented and bargaining power from distributors is therefore lower. However, gaining distributors buy in is still important to be able to track & trace all the way to the retail outlet, whether that is a hospital or a pharmacy.

### **4) Experience Matters**

As discussed earlier, Frost & Sullivan believes that choosing an experienced vendor may help reduce concerns and ensure that the solution is well designed for the particular pharmaceutical company. This is especially so when looking at high scale solutions such as tracking at a per bottle/package level. Experience in both pharmaceutical industry and a strong EPC compliant solution including best of breed technology and strong service experience is critical to provide a solution that supports the customer's business processes.

We believe pharmaceutical companies following these guidelines can use RFID based track & trace solutions to help them overcome their three main challenges.

## **Future View**

Frost & Sullivan believes that the EPC standard RFID based track & trace solutions market in Europe and the USA will continue to grow as pharmaceutical companies will eventually be forced to comply with legislation. As compliance becomes mandatory, many will invest more money to be able to benefit from the compliance solution they have to pay. In addition, with competition becoming fiercer, differentiation and more efficient processes are critical for companies to compete. As a result, track & trace solutions that enhance efficiency will become key tools for companies establishing a competitive advantage.

The main barrier for this market is still the lack of common RFID standards. We believe the government has a strong role in establishing one to overcome industry inertia.

We believe that the following three trends will become important.

First, solutions are likely to become more advanced in regards to further integration between the tags and the packaging such as the drug labels. This development is driven by the desire to ensure integration with the production process by reducing time to attach RFID tags. Therefore, the consortium approach among vendors may change to include a labelling or packaging company such as De La Rue.

As a result, new competitors from the packaging space and the labelling space may enter. For the pharmaceutical company, it may mean close collaboration with packaging and labeling companies.

Second, differentiation amongst vendors according to the type of solution within one vertical will become more prevalent. Looking at it from the top of the complexity scale, the following types of solutions are likely to evolve further within each vertical such as pharmaceuticals:

- Large scale bottle/package, unlimited number of tags and focussed along the entire channel.
- Tracking a relatively fixed number of trucks across the channel.
- Tracking a limited number of critical equipment within one plant.

This makes the definition of objectives even more important to be able to choose the optimal solution for a specific pharmaceutical company.

Third, many RFID track & trace solutions are still at the trial stage. We believe that pharmaceutical companies can start to benefit from systems that provide them with increased amount of business intelligence. The pharmaceutical companies that manage to use such information in the smartest way will have a significant competitive advantage. This may be dependent on existing legacy systems. However, technologies and tools such as cloud based solutions can help making the data accessible to the wider organisation. Naturally these tools cannot stand alone. Further training and support for employees to start making use of the enhanced data will be necessary.

## Conclusion

We have illustrated through the paper how RFID based track & trace solutions can support pharmaceutical companies to overcome their main challenges and achieve strategic business goals by enhancing both top and bottom line. While there are still issues around lack of standards, higher initial deployment costs in RFID solutions, Frost & Sullivan believes that the business case for deploying RFID based track & trace is robust. Even without the compliance requirements, there are business benefits when RFID solutions are deployed appropriately.