# An EAI Technology - Track and Trace Solution for Production Industries

**[1]Mr Dubbudu Rama Krishna Reddy, [2]Prof P. Premchand**
[1] *Research Scholar, Rayalaseema University, Kurnool. Reg. Id: PP. COMP.SCI. 0264*
[2] *Professor & Dean, Faculty of Informatics, Dept. of CSE, UCE, Osmania University.*

***Abstract:*** Globally, the incidence of fraudulent trade in pharmaceutical products is on the increase (reimbursement, counterfeiting, tampering, expired product). A number of European countries have responded to this threat and have put mass-serialisation based counter-measures in place. Others are working towards similar approaches, not least of which being the FDA (Food and Drug Administration) and a number of individual states in the US, which are pushing for RFID, based product tracking through electronic pedigrees. The proposed solution helps all major drug manufacture companies to prevent counterfeit drugs, effective supply chain management and to find better marketing strategies to project the products and also to help the end consumers to get the right drugs for right diseases. The solution not only feasible in economically but also helpful socially to protect the patients to get proper medicine to cure the problems and prevent anti social elements. The research goal is to provide a solution to uniquely identify a drug in supply chain management and to prevent counterfeit drugs that prevents consumer from taking fake drugs. The proposed solution provides how to identify uniquely a drug across the supply chain with serial number generation, assignment and implement Track and Trace (T&T) solution as per the norms with electronic product code (EPC)/GS1 standards (http://www.epcglobalinc.org/home/).

***Keywords****: Track and Trace, Serialization, FDA, RFID, Anti counterfeiting, Pharmaceutical Industry*

## I. Introduction

The World wide anti-counterfeit packaging market is approximately at USD 107.26 Billion in 2016 and is anticipated to reach USD 206.57 Billion by 2021, at a CAGR of 14.0%.

Counterfeit drugs getting into the supply chain is a major problem around the globe. Consumer and patient safety is crucially important within the healthcare and pharmaceutical industries.
The **pedigree** is a documentation in electronic form containing information regarding each transaction resulting in a change of ownership of the given prescription drug, including returns. Automatic identification technologies such as bar-coding and RFID have been shown to be dependable and effective and in fact, RFID technology has been identified and recommended by the FDA as a reliable option for carrying electronic pedigree information.
According to the California Department of Consumer Affairs Board of Pharmacy,
"Counterfeit prescription drugs is a global problem, reaching as high as 30 percent of the supply chain in some countries. The World Health Organization estimates that in developed countries, counterfeit drugs are less than 1 percent of the market." In other words, "3.4 billion prescriptions were dispensed in the US in 2006. If 1 percent of the supply is counterfeit, means perhaps 35 million of these US prescriptions were filled with fake medicine.

From raw materials to processing, from the wholesaler to the pharmacy, track/trace systems provide visibility and support the company's validation of their procedures and protocols.
**SOME ASPECTS OF A TRACK/TRACE SOLUTION WOULD INCLUDE:**

- Tracking import and export elements of raw materials

- Integrating with FDA safety and other processing systems
- Effectively tracking and tracing products both internally and externally
- Documenting product history from manufacturing to the customer
- Providing a supported chain of custody for finished goods

**PRODUCT EFFICIENCIES OF TRACK/TRACE SOLUTIONS WOULD INCLUDE:**

- Accurately accounting for raw material processes
- Authenticating product at the item/dose level
- Accurately tracing processed products
- Accurately managing recalls
- Accurately managing returns
- Accurately managing distribution of sample products
- Speeding up receiving time
- Speeding up processing time
- Speeding up replenishment time
- Reducing infiltration of counterfeit pharmaceuticals into the supply chain
- Reducing errors
- Providing accurate auditing and inventory forecasting

**PRODUCT LOGISTIC AND WAREHOUSING SUPPORT VALUES WOULD:**

- Reduce inventory management expenses
- Reduce stock levels
- Reduce manual checks
- Reduce product recall costs

It is followed by the marketing and sales of the finished products, which is only possible if an efficient distribution channel is developed. Finally, the end products are distributed to the consumers.

**Target Audience**

- Producers of anti-counterfeit packaging
- Exporters and Importers of anti-counterfeit packaging
- Traders, distributors, and suppliers of anti-counterfeit packaging
- End users (food & beverage, pharmaceuticals & healthcare, and industrial & automotive industries)

## II. Scope and Importance of this Solution :

**The scope of** the anti-counterfeit packaging market can be categorized based on technology, usage feature, end-use sector, and region.

**Based on Technology, the market has been segmented as follows:**

- Coding & printing technology
- RFID
- Hologram
- Security labels
- Packaging design
- Others (digital mass sterilization, digital mass encryption, and surveillance technologies)

**Based on Usage Feature, the market has been segmented as follows:**

- Track & trace technology
- Tamper evidence
- Overt feature
- Covert feature
- Forensic markers

**Based on End-Use Sector, the market has been segmented as follows:**

- Food & beverage
- Pharmaceuticals & healthcare
- Industrial & automotive
- Consumer durables
- Clothing & apparel
- Others (software, entertainment, and toys sector)

**Based on Region, the market has been segmented as follows:**

- North America
- Europe
- Asia-Pacific
- Latin America
- Middle East & Africa

To ensure the integrity of pharmaceutical drugs as they move from manufacturing to the consumer, as well as, to improve the productivity and profitability of all stakeholders, track/ trace solutions including bar-coding and RFID technologies along with EAI tools is the optimal solution.

- A number of governments such as Italy, Belgium, European countries have responded to this threat and have put mass-serialisation based counter-measures in place. Others are working towards similar approaches,
- FDA [1] (Food and Drug Administration) and a number of individual states in the US, which are pushing for RFID, based product tracking through electronic pedigrees.
- Many drug manufacturers are working in close collaboration with national agencies and have implemented tactical solutions where necessary to meet local mandates, to ensure patient safety and to protect the integrity of its business. Through EFPIA, PhRMA and EPCglobal, All manufactures are working in collaboration with other manufacturers, wholesalers and retailers to develop solutions for a safe and secure supply chain.
- The pharmaceuticals industry has struggled to ensure the integrity of its products as they are transferred between the different stops on the value chain from contract manufacturers to wholesalers to dispensers and finally to the patient. This is particularly true as products move across international borders. And the problem has been growing. More money is lost to counterfeiting with each passing year. Product theft is also on the rise – Freight Watch International has released statistics suggesting that drugs account for approximately 15% of the estimated US$8 billion to US$12 billion of annual cargo theft, which amounts to well over US$1 billion annually.
- Preventing theft and counterfeiting have therefore become a key industry focus. Early approaches included tamper-proof packaging and 3-D holograms, but these are now considered too easy to manipulate, so these methods are no longer considered sufficient. Today, regulations include assigning a unique identification number to the smallest unit of sale (for example, a bottle) and tracking that product [5].

## III. Methodology

**1. The proposal is to** provide core functionality for integrating with the drug and providing a simple mechanism for authorization. Facilitating for backend externalisation with 3rd party Manufacturing/packing facilities.

Note: *The solution will be integrating with backend using single interface, drug data can be received in XML, CSV formats with multiple versions supported. The Meta data for Finished Packs will be retrieved from backend systems and will presented in the Life cycle and Authentication views*

**2.** The functionality to provide authorization functionality for internal and external pack authorization. Include internal and external event integration

**3.** Providing functionality for supply chain functionality (pedigree and track and trace).

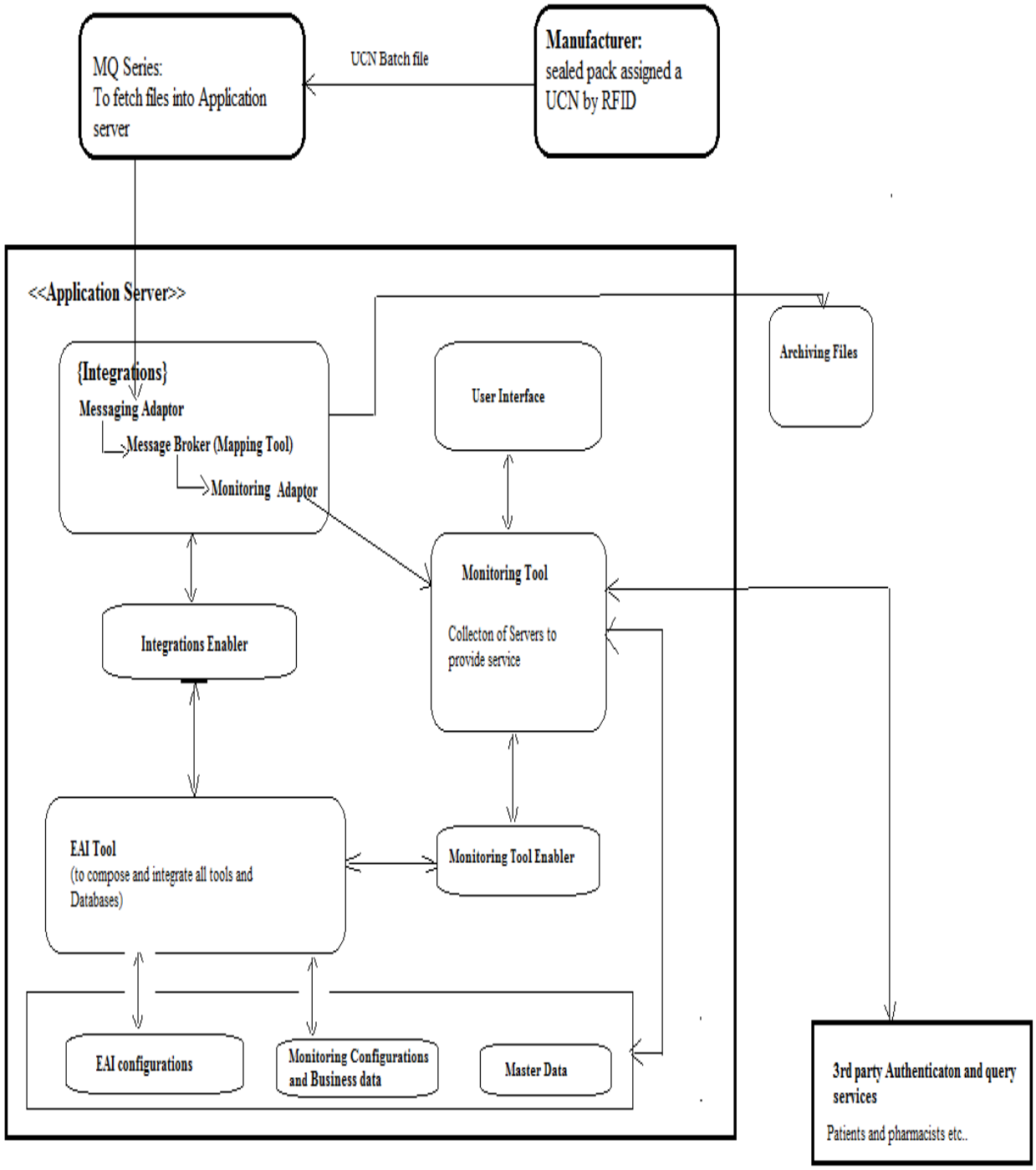
**Track and trace integration in the pharmaceutical production system :**

Track and trace functionality requires the addition of **specific software and application components to the existing IT architecture of a company**.

1. **Serialization solutions** need to be fully integrated with centralized systems (corporate level), to properly allocate and manage serial numbers within the packaging process of each production line.
   These systems also allow the management of data communication and storage in a common corporate database, in order to prevent data duplication.

2. It is necessary to **install adequate interfaces (tools like Integration Brokers, IBM MQ Series, Sentinal, *SAP Exchange Infrastructure, Tibco, BizTalk, Web methods, See Beyond, Mercator, Oracle fusion, Vitria* etc..)** between the existing ERP system (inter-sites) and the new T&T system, in order to allow material master data downstream communication, and serialized production data upstream transfers. At the enterprise resource planning (ERP) level, a company will require specialized software to retrieve and store all the necessary data in the company databases.

3. At a lower architectural level (production site), a dedicated server needs to be connected to the site network, and an additional interface might be necessary to allow communication with the present manufacturing execution system (MES).




**Methodology in Detail**:

1) The Manufacturer creates the sealed packs with UCN (Unique Carton Numbers) 2D Matrix / RFID techniques.

2) The Application Server (Proposed Solution) will accept the UCN data from third party providers of manufacturing and/or packing of drugs who will generate and send the information. It is designed to accept the UCN pack data as in XML or CSV formats through MQ Series.

UCN generation process (phase I)

Authentication process

- Internal Authentication process (phase I)
- External Authentication process (phase II)

UCN data set provider process (phase I, phase II, and phase III)

**UCN generation process (integration process)**

1. Manufacturer generates UCN numbers and sends these to the 2D data matrix printer that prints the UCN on the packs
2. At the packaging end they collects all UCN numbers generated and verified in a batch and the UVN (UV-readable) 2D data matrix from one of the two labels on the packs as well as other optional numbers and produces a file with the UCN records in.
3. The file is picked up by the configured file adapter and put on a remote MQ-queue. When this is done, the file will be deleted from the file share.
4. The file is sent through (MQ transport) that provides a secure transport to Application server
5. The Application Server gets the files, and processes the messages.
6. The file is archived and then kept as the master record.

**Authentication process (Business process)**

The Application Server will be providing two Major services, "Authentication" and "Life Cycle Views" in Phase1

**Authentication:**

**Standard Internal users, Power users & PSDM Admin Users**

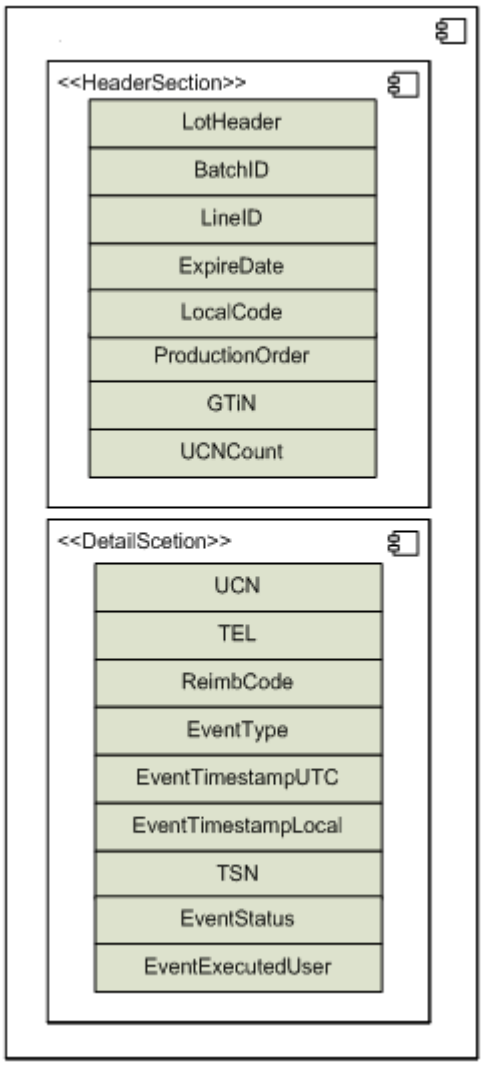
1. An internal user obtains a pack UCN that needs authorization.
2. The user logs in to the UI and submit a request containing the UCN
3. The Monitoring Tool will Query the repository and provide a response as defined for the user profile. The Tool responses will be "Authentication Success" or "Authentication Failure".

**Life cycle views:**

1. Power users, Admin Users will obtain a pack UCN that needs to be investigated.
2. Power users log in to the UI and submit a request containing the UCN
3. Power users will be able to see the life cycle view and detailed information about the UCN.

The solution can be extended by implementing additional Services in later Phases, for 3rd Party Authentications, Track and Trace.

**UCN BATCH FILE INFORMATION:**




The figure above shows the data entities and their relationship

LotHeader – 7 Digit LotHeader
BatchID – 10 digit Lot Number
Version – 3 digit
LineID – 3 Digit Line
LocalCode – 20 digit Local Market Code
ExpireDate– the Pack expire date in MM/YYYY format
ProductionOrder – 20 digit Unique for Site
GTiN – 14 digit code will be used after 2 years
UCNCount – 7 digit, Count of UCNs in detail section

UCN – 20 digit
TEL – 20 digit
ReimbCode – 10 digit
EventTimestampUTC
EventTimestampLocal
TSN - ??
EventStatus: Active | Blocked | Dispensed | Archived
EventExecutedUser

## III. Conclusion

The research will identify the potential problems in identifying a drug uniquely and the objective is to provide a solution with serial number generation and assignment using UCN. The solution not only discusses individually about a drug but also identifies all manufacturers across industry with unique number by its site and location with unique number and the solution is as per norms with EPCIS. The dataset will be taken from drug manufacturing company; the XML/CSV files will be created based on data collected; the XML files will be taken as input to test this research proposal through MQ Series and then into EAI Integration and Monitoring tools to File Archives and Databases for further Tracking and Trace purpose.

**References**

[1]. "FDA 2006 Compliance Policy Guide for the Prescription Drug Marketing Act". http://www.fda.gov/OHRMS/DOCKETS/98fr/06-9211.htm.

[2]. IDC Home: The Premier Global Market Intelligence Firm. 11 February 2009. <http://idc.com/>.

[3]. "Counterfeit Drugs and Travel." 10 February 2009. <http://wwwn.cdc.gov/travel/contentCounterfeitDrugs.aspx >.

[4]. Linthicum, David S, (2000). Enterprise Application Integration, Addison-Wesley.

[5]. "Counterfeit Drug." Wikipedia 10 February 2009. <http://en.wikipedia.org/wiki/Counterfeit_drug >.

[6]. "Epedigree." Wikipedia 10 February 2009. <http://en.wikipedia.org/wiki/Electronic_pedigree>.

[7]. "IBM—A Smarter Planet." 10 February 2009. <www.ibm.com/ibm/ideasfromibm/us/smartplanet/20081106/index2.shtml

[8]. Wiehler, Gerhard, (2004). Mobility, security and Web services: technologies and service-oriented architectures for a new era of IT solutions, Erlangen:Publics.

[9]. (2002) *The benefits of EAI*, SeeBeyond.
http://h71028.www7.hp.com/enterprise/downloads/Benefits_of_eAI_Whitepaper.pdf