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Review Article

Scanner for Pharmaceutical Packaging

Design and Implementation of a Track n trace 2D Multi Scanner Bulk Code Reader for Pharmaceutical Packaging

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Abstract: With various compliance initiatives surrounding the traceability of medical drugs coming into prominence and with federal regulations becoming more stringent, there is a need to efficiently manage the supply chain process involving drug packaging. To enable traceability of the drugs being packaged, many manufacturers are implementing barcoding of product labels which contains a minimum of the attributes namely GTIN, lot number, serial numbers, expiry date, manufacturing dates, etc., to enable traceability of the packaged item. Currently, manufacturers are looking for ways to keep their supply chain moving at an efficient and optimal process. One of the challenges was to build automated equipment providing a well-defined and properly structured framework for functioning, designing, and implementing of Track N Trace Counterfeit Risk Management (CRM) application to increase the speed of the aggregation with the child-to-parent aggregation and generation of online case labels after the required child's Quantity in Multi carton aggregation station. Track N Trace Counterfeit Risk Management (CRM) allows the manufacturers to establish the parent-child relationship during packaging their drugs. Also, various guidelines US Drug Supply Chain Security Act (DSCSA), EU regulation (Falsified Medicines Directive-FMD), Brazilian Health Regulatory Agency (ANVISA), Indonesia's National Agency of Drug and Food Control (NADFC), India's Directorate General of Foreign Trade - DGFT, and Australia TGA will need to be integrated into one single source of equipment that can meet with their barcoding regulation for tracking of drugs packed. Machine Vision systems are finding themselves in use in the pharma machinery and the "multi-carton" equipment that has been built for implementation for pharmaceutical packaging uses the vision systems architecture. We aimed to build a counterfeit risk management software solution that ensures_compliance with various regulatory agencies by building a common framework that can be extensible for any further changes to the guidelines and/or additional regulatory guidelines from other countries. Lots of design architecture work has been refined through continuous process improvement practices and we developed a software tool that improves efficiency and requires minimal changes to the current manufacturing/packaging supply chain lines.

Keywords: Drug Traceability, Federal Guidelines, Barcoding, Bulk Code Reader, FDA, FMD, ANVISA, NADFC, DGFT, and TGA

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1. INTRODUCTION

Healthcare organizations consistently seek strategies to reduce costs and improve safety while maintaining or enhancing quality. These strategies entail identifying and refining existing methods, as well as adopting innovative technologies. The primary goal of research being undertaken is to prevent and reduce counterfeit[1] and spurious drugs, which have become a menace as the credibility of a true drug manufacturer is affected as the spurious[2] drug firms are trying to manufacture and sell placebo drugs with the same look and feel as the original drugs. Through this research, I intend to close the gap by introducing real-time monitoring techniques. The second major impact has been to stop the smuggling and illegal sale of drugs. Many drug manufacturers have to take a cost over burn due to the misrepresentation of drugs in their inventory, referred to as loan-licensing agreements between the drug manufacturer and licensee. In such contracts, there is always a social impact that ensures that drug manufacturers provide grants to low-income countries and meet their demands for medical drugs to save their citizens from harmful diseases. But many firms are taking advantage of these shipments and diverting the freight to the open market by smuggling drugs. Unique identification of packaged drugs[3] will be an excellent enabler for running advanced analytics programs to gather deep insights into consumption patterns, geographical penetration, sales and marketing spend effectiveness, etc. Based on the purchase of drugs by consumers, a mechanism can be developed to instantly verify if the drug being purchased is a legitimate drug, i.e., it has been manufactured using the required compliance policies. To aid in innovation marketing schema, improved inventory monitoring at various supply chain nodes can assist in forecasting demand more accurately, thereby avoiding revenue loss due to stock-outs. It is important to understand the guidelines that have been released by various compliance authorities from the leading manufacturing countries and it is worth noting some basic understanding of the barcoding procedures that need to be a prerequisite for "unique identification" models. National Drug Code (NDC[4]) is utilized for patient identification throughout the U.S. healthcare industry. It is a ten-digit number utilized in the United States for the establishment of product identity, item traceability, and theft control. The Drug Supply Chain Security Act (DSCSA[5]) is intended to enhance drug safety by requiring drug manufacturers to put identifiers on certain drugs and packaging. The European Union Parliament passed the Falsified Medicines Directive[6], a law with the goals of protecting patients, enhancing the security of the production and transportation of medicines throughout Europe, and preventing the entry of falsified medications into the supply chain. Integrated Validation of Exports of Drugs from India and its Authentication (Iveda[7]) was established primarily as a repository database for serialized batch data. It was created to make it simpler, more effective, and more efficient for exporters and manufacturers to use secondary and tertiary-level coded data. An establishment of the multi-scanner and pallet equipment line in the Track N Trace Counterfeit Risk Management (CRM) application will be used to increase the speed of the aggregation along with online case label printing from the case label printer after required child packs are aggregated to the parent pack. The aggregation will be done in the local client server and after completion of the aggregation process and review and approval of In-process and production review, aggregated data will be moved to the central server. This may lead to the speed of the aggregation process. Overall to improve the speed of aggregation of drug packs, it was determined to introduce automated equipment that would fulfill the requirement without compromising on the supply chain's speed of packaged products. Multi-Carton Line which would enable the set of multiple packs to be scanned in a Single instance thereby increasing the speed of aggregation. Pallet line which would enable aggregate of the packs in the bonded store where the pallet packing is administered. These packs are locally aggregated on the packaging line to isolate the dependency on the manufacturer's computer network and then need to connect to the server for optimal performance. General Approval activity would be managed on the server instance of TrackNTrace. In the present study, we have evaluated the aggregation speed with automated bulk code reading in the combinations namely, 'Child pack' to 'Parent pack' and 'Parent pack' to 'Child pack'. In both combinations illustrated, we found faster completion of the aggregation of packs and met our pilot customers' expectations.

2. MATERIALS AND METHODS

2.1 Aggregation Process

Track N Trace Counterfeit Risk Management (CRM) solution will be running on an Independent Desktop Computer or Laptop and will be connected to a Scanner. The user can manage the US Drug Supply Chain Security Act (DSCSA), Falsified Medicines Directive (FMD), and Directorate General of Foreign Trade - DGFT regulatory agencies in one unique URL. The solution is developed as a web portal that has a very simple and dynamic interface. As a part of security measures, the portal gives certain access rights to the user, not all features can be accessed by all the users. The system takes into the two types of users the administrator and normal users. The role of the administrator is to configure the user functionalities. A scanner has to be attached to the USB Port of the desktop or laptop as the input for capturing the scanned serial number. The scanner can be a 1D, 2D[8] scanner depending upon the type of barcode[9] printed on the package. The line-wise aggregation will be done and each Line/Module can have an URL

2.2 Application Functional Requirements

The Application Functional Requirements consist of the following activities:

2.2.1 Aggregation Requirements

The primary aspect to establish traceability is to record the unique serial barcodes of the parent pack and its child pack. This establishes a relationship that would be used to trace the movement of the child pack from its parent consignment. Using Vision systems[10] technology, the speed of aggregation activities has been improved.

2.2.2 System Output

While the packaging and aggregation are occurring, there are a lot of background validations that need to be automatically addressed like checks on duplication in the serial barcodes, the serial number length as specified in the batch packaging record (BPR), the lot/batch numbers, grading of the barcode, etc. Each of these checks needs to be monitored[11] in real-time to ensure the process is progressing smoothly. At times, the validations will trigger the rejection of pack aggregation. In such cases, the procedures defined in the BPR are followed by the floor

supervisor, and they are solely responsible for the smooth functioning of the activity. Any deviation should be monitored and reported.

2.2.3 Module User Roles

In a typical packaging session, various user activities are recorded namely the line supervisor, packaging analyst, in-process quality assurance analyst, production coordinator, lab analyst, other assistants, approval authorities, etc. This is required as each stakeholder is equally accountable for their role[12] in the entire process. To ensure and follow the various compliance guidelines of regulatory agencies, everyone's responsibilities are clearly defined by their access roles, and they would be restricted to that specific functionality.

2.2.4 Security Privileges

In this section, the privileges[13] assigned to each user is managed by granting them relevant access based on access settings. The demonstrated TrackNTrace solution has various preferences to deal with specific barcoding requirements that need to be enabled for automatic barcoding verification and checking.

2.2.5 Configure XT

Considering the security aspects requirements for the system, the functionality has extended to manage the barcode profiles, customer's federal regulation compliance, the application identifiers, package configurations limits, etc. By introducing individually controlled preference settings[14], the functionality becomes flexible to handle various compliance guidelines. CFR Part 11 requirement for electronic signatures has been incorporated across the software application. The mandatory requirements of approvals at each level are configured in this segment, and the system automatically creates a consolidated report at the end of the batch/lot packaging activity.

2.2.6 Packaging CRM

The main process module establishes the aggregation process[15] of various levels of packaging and samples management which is a part of the quality control review requirement. In addition, once the pack has been aggregated, there would be a need to break open an aggregated pack. Such incidents would require a disintegration of an aggregated pack. To record such activity, we have provided the option to delink/disaggregate packs by recording packs as orphans if the child pack is delinked. At each activity child and parent, pack relationship is established to ensure that the required quantity is shipped out. In some scenarios, usually, the last packed item can be a loose shipment because the required quantity of child packs isn't available; there is a need to take the total weight of the loose shipper and record the same to inform the end customer.

2.2.7 Batch Management

In a pharma manufacturing practice, the key unique activity is identified by its batch/lot number. A batch number is assigned a batch manufacturing protocol which is administered by the production teams within the organization. All activities are usually traced back to their batch/lot number, and hence it is very important to ensure and follow all compliance guidelines related to the naming and usage of the batch. In our software system design, we paid special emphasis to the aspect of batch management and enabled the functionality to perform batch consolidations, and trace back to incidents within the batch manufacturing process.

2.2.8 Business Intelligence Reporting

A follow-up process is to allow the management of the organizations to make informed decisions[16] regarding all aspects of their manufacturing process. This includes keeping track of work activities performed by the stakeholders or implementors in their respective areas. We provided numerous reporting activities that streamline the review process, enable automatic incident reporting, and manage the SOP process with evidence reporting like audit trails, usage, user efficiency, training enhancements required, etc.

2.2.9 Safety and Other Requirements

Critical success factors for establishing a Safe Pharmaceutical Supply Chain[17] can be attributed to the influence and gradual reduction in drug counterfeits. We have built a process for the end consumers to trace down the drugs to their original manufacturers. If the drug is found to be counterfeit or falsified, an automatic notification would be sent to the manufacturer of the drug indicating that an infraction has occurred and at the same time notify the consumer that their drug is counterfeit.

2.2.10 Serial Numbers

To establish unique traceability over various packaged items, there was a need to ensure that all the packs are identified by a unique serial number that is validated against the manufacturer's GTIN (Global Trade Identification Number). During the grading and offline printing of serial numbers of the pack cartons, there are chances that some of the rejected pack serial numbers printed are deregistered. We provide all the functions to make the activities seamless.

2.3 *Checklist of Functional Modules*

2.3.1 Customer Registration which enables customization of their internal process SOPs on packaging/labeling.

2.3.2 Facility Setup will be required to track the Global Location of the manufacturing facility.

2.3.3 Prerequisites Details

- FNC1 character setup
- Pack level setup
- Application identifier setup
- Customer engagement with GCP

2.3.4 Operational Setup

- Product registration: Regulatory agency[18], Customer Name, Manufacturer code, item reference code, Product Name, Pack Code, Country Code, Human Readable expiry format, and Product status.
- Pack level configuration: Defined as per the level of packing configuration.
- Serialization number preference: Define the selection for the usage of Internal or External serial numbers

- Batch Planning: Regulatory [19]agency, Customer name, Product name, Batch number, Batch size, Mfg. Date, Expiry. Date, Human readable expiry format, Status of the batch, Installation line, and Module Serial Hub.
- Import of Serials: Define import of serial numbers (External) for US, EU and Brazil but not limited to. The request of Serials: Define the request of serial numbers from TrackNTrace (Internal) with numeric/Alpha-Numeric with preferred length. Serial number control: Define to control the duplication of serials.

2.3.5 Specimen Verification

- Define the verification of the 2D barcode data for correctness.
- Define the record of Specimen label management.

2.3.6 Aggregation (Multiscanners[20])

- Define the Child- Parent aggregation with the specified line mentioned in the batch planning for full case and partial case with the level of packing.
- Define the case label printing in auto and verification[21] after the required child's aggregation.
- Define the Multi scanner camera user credentials.

2.3.7 Disaggregation

- Define the disaggregation by Pack wise, and Level wise.
- Define the Disaggregation report with user details.
- Define the Replace of pack items after aggregation.

2.3.8 Batch Workflow

- Define batch workflow status and approval of the batch to forward to the next stage for further verification and approvals.
- Define batch workflow with batch statistics as product name, batch aggregated statistics, samples, and serials data. Revert of batch serials

2.4 Aggregation Requirements

The System is capable of verifying the FNC1 character based on the regulatory agency. Whether it is printed or aligned in a valid position while verifying the specimen. If the FNC1 character is not printed or not aligned in a valid position, the specimen verification will fail and the TrackNTrace Counterfeit Risk Management (CRM) will not allow the user to start Packaging. The Packaging dropdown will not be enabled. If all the required package levels specimen verification is passed, then the Packaging level dropdown will enable the packaging to start. The Specimen Label verification is only for multi-carton online printing only else the user can scan at least one valid FNC1 alignment label for each level in the Provided Serial pack verification checkpoint option to enable the packaging level dropdown to start the packaging. A detailed design explanation will be available in the design specification. Start Packaging - Aggregation of the label's activity is performed in this step and the outcome would be an establishment of the parent-child relationship during the scanning activity. And also, the system will support multi-child pack aggregation in multi-Carton equipment. And at the Line server, the aggregation of packs shall follow the child-to-parent and parent-to-child pattern with different terminals manually. Loose Packaging - Loose package aggregation is done in this step for partial packages that need to be scanned. Delinking Package - Disassociating an existing aggregated package by removing the link of the Parent-Child Relationship.

3. RESULTS

3.1 Optimization Aggregation

The Pack Configuration setup indicated 12 multi-pack cartons (refer to Figure 1, 2, 3,4) in a 'bundle wrap' which when placed in the Field of View (FOV) facing the high-resolution camera. In a manual practice, it required 12 individual cartons to be manually scanned using a barcode device and the time for each pack was recorded at 44 secs approximately (dependent on the network connectivity to the web server). With the multi-carton equipment, all 12 packs were processed within 2.5 sec.

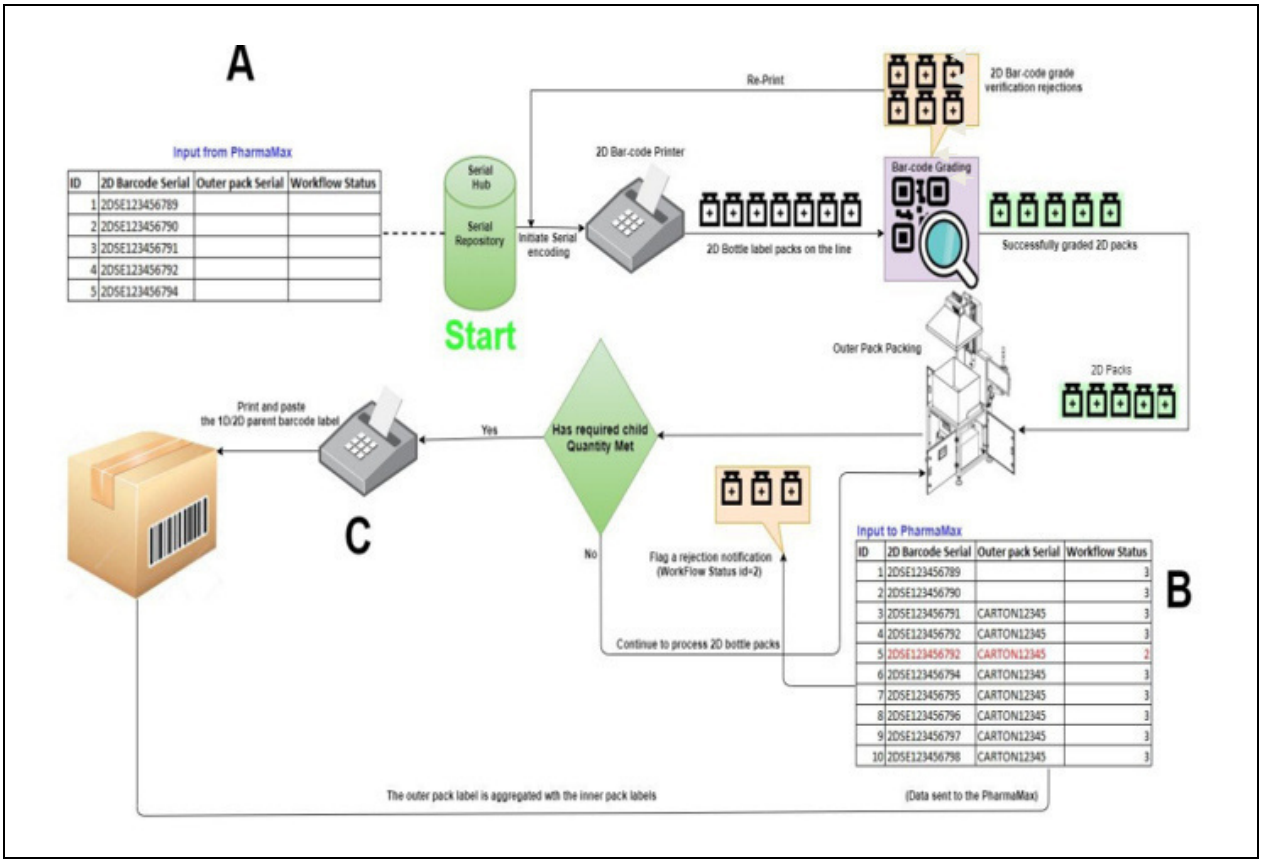


Fig 1: Visual diagram of child-to-parent multi-Carton aggregation. The process ensures that auto-feeding of inputs like serial numbers is fetched from the database based on the registered pack. A typical process involves the child packs being scanned first as a group and then assigning the parent pack serial to the scanned/aggregated child packs.

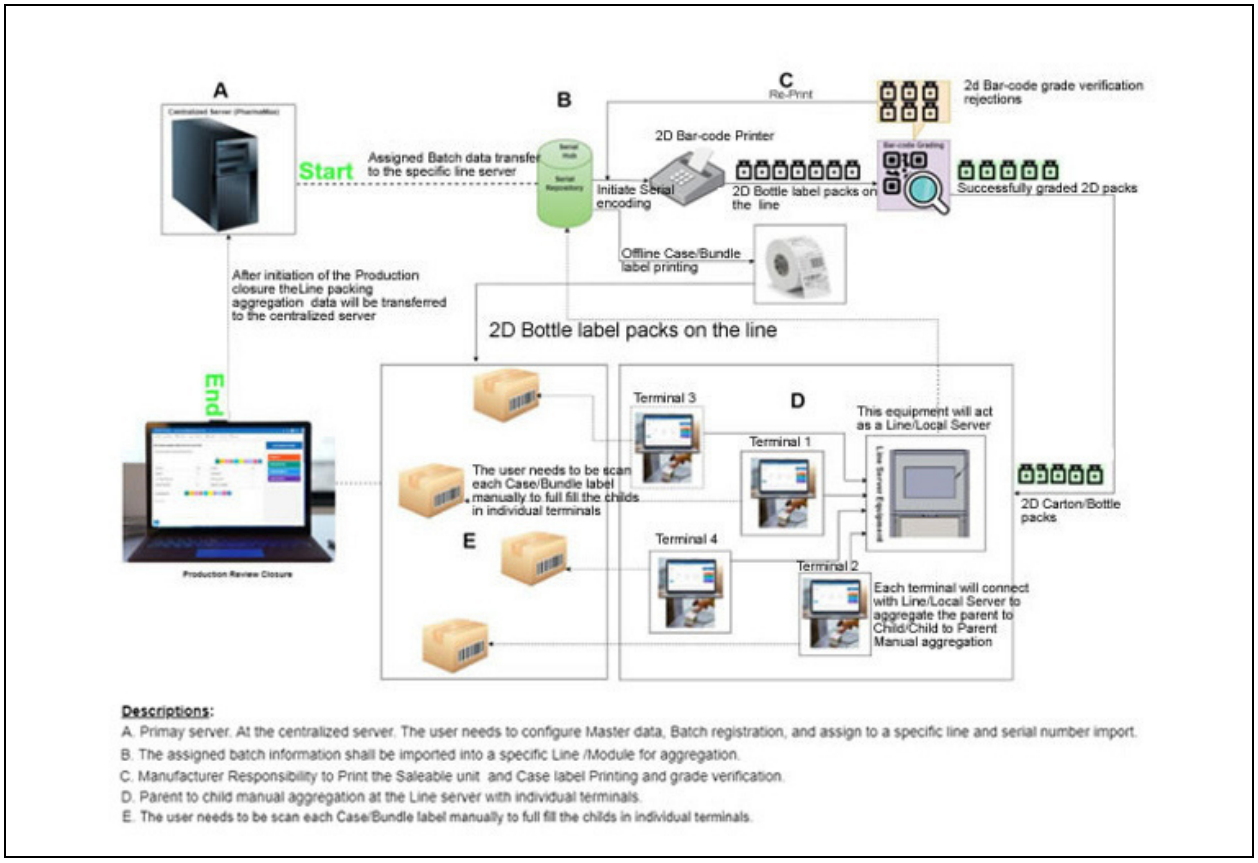


Fig 2: Visual diagram of parent-to-child multi-Carton aggregation. The process ensures that auto-feeding of inputs like serial numbers is fetched from the database based on the registered pack. A typical process involves the parent pack being scanned before scanning the required child pack. The child pack serial numbers are mapped to the parent serial number pack.

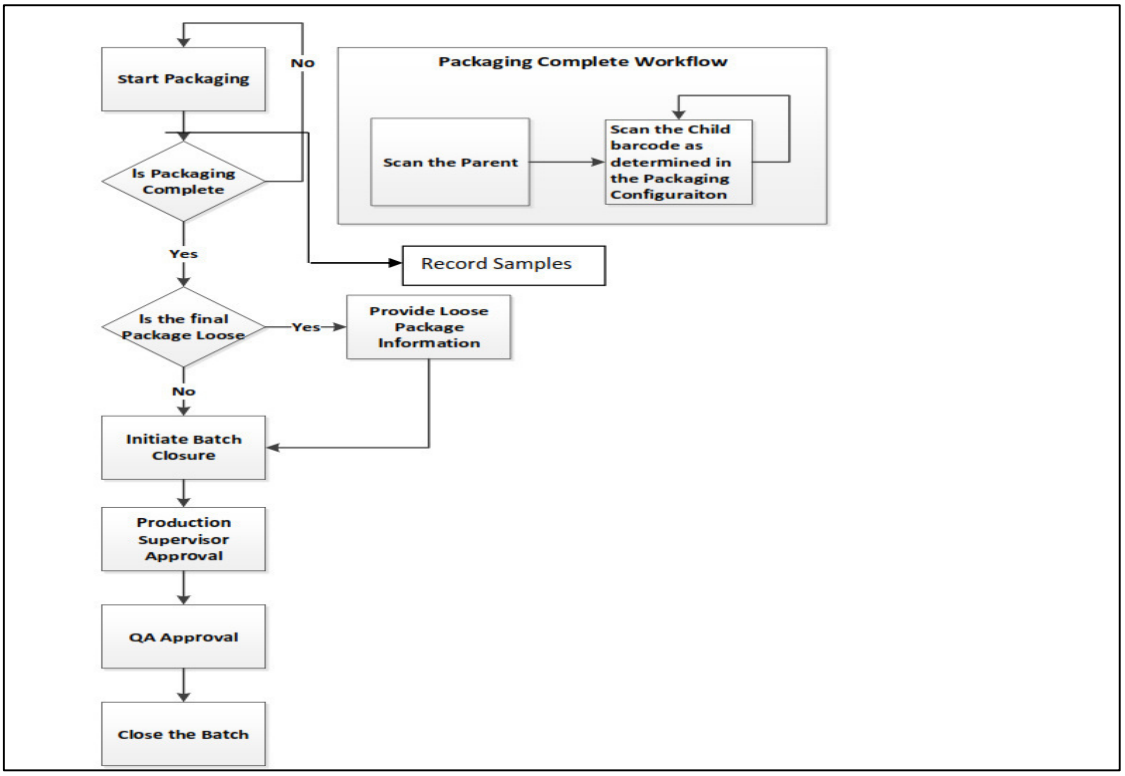


Fig 3: Normal Packaging and Options for Loose Package. Usually, at the end of the packaging session, the required child packs would not be fulfilling the requirements of a full parent pack. In such cases, the required compliance initiatives are in place to record the same as a Loose Pack.

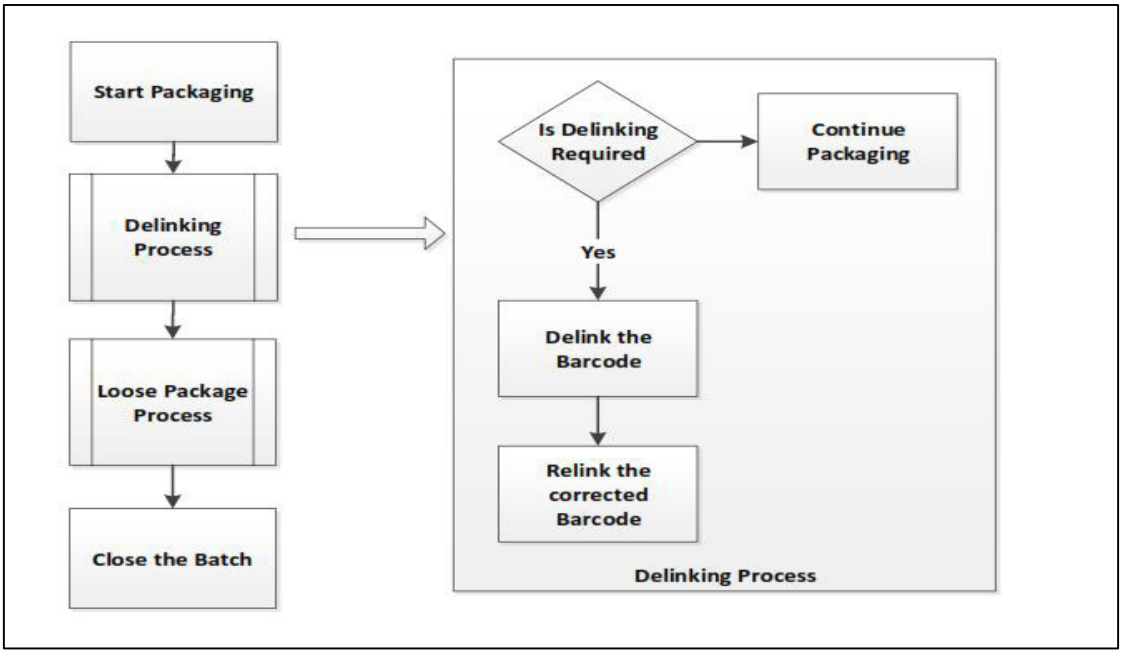


Fig 4: Delink/Disaggregate Packages. During the packaging activities, the standard operating procedure might require some child packs to be picked from an existing parent pack. E.g. for the study of stability, specimen, etc.

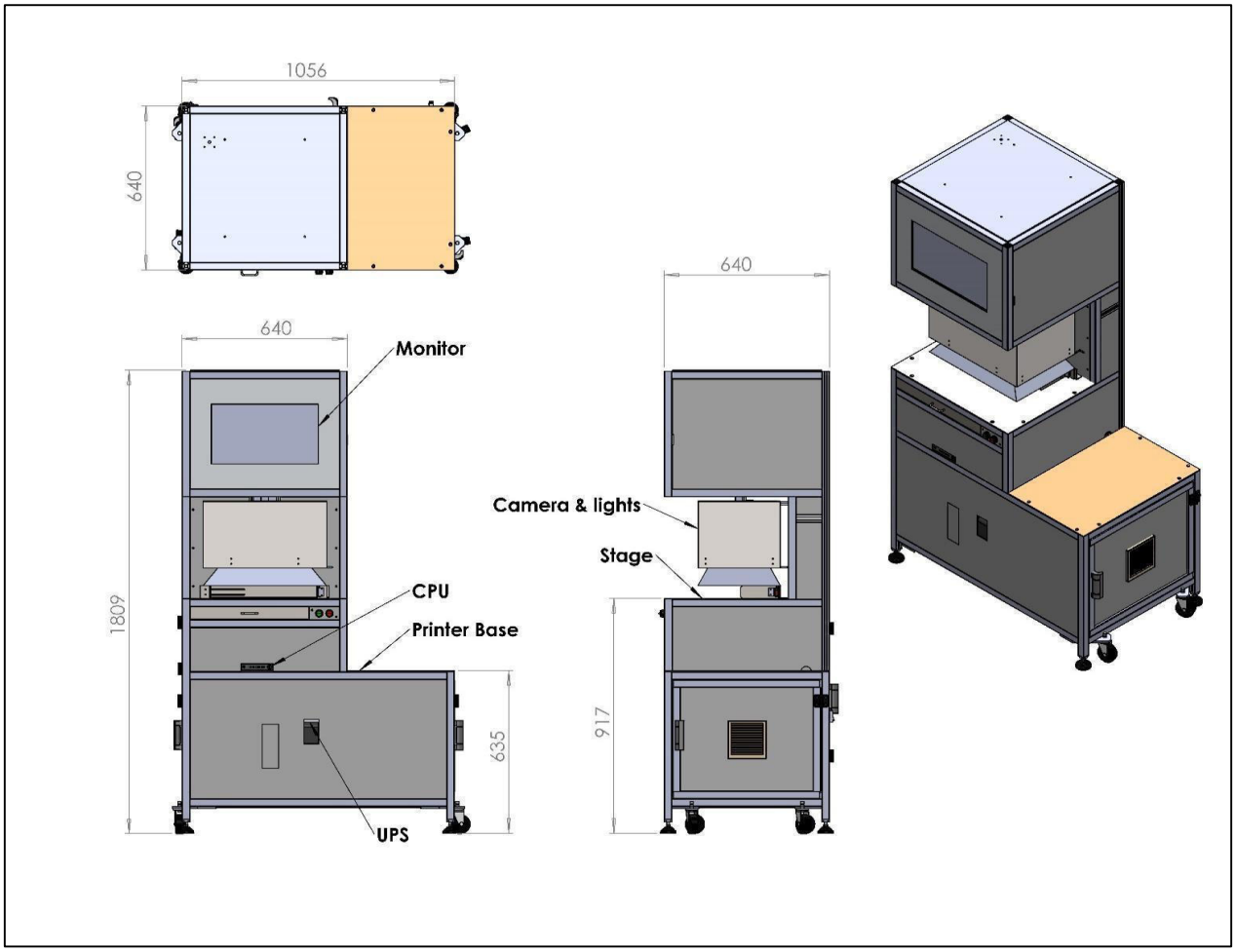


Fig 5: Multi-Carton General arrangement diagram.

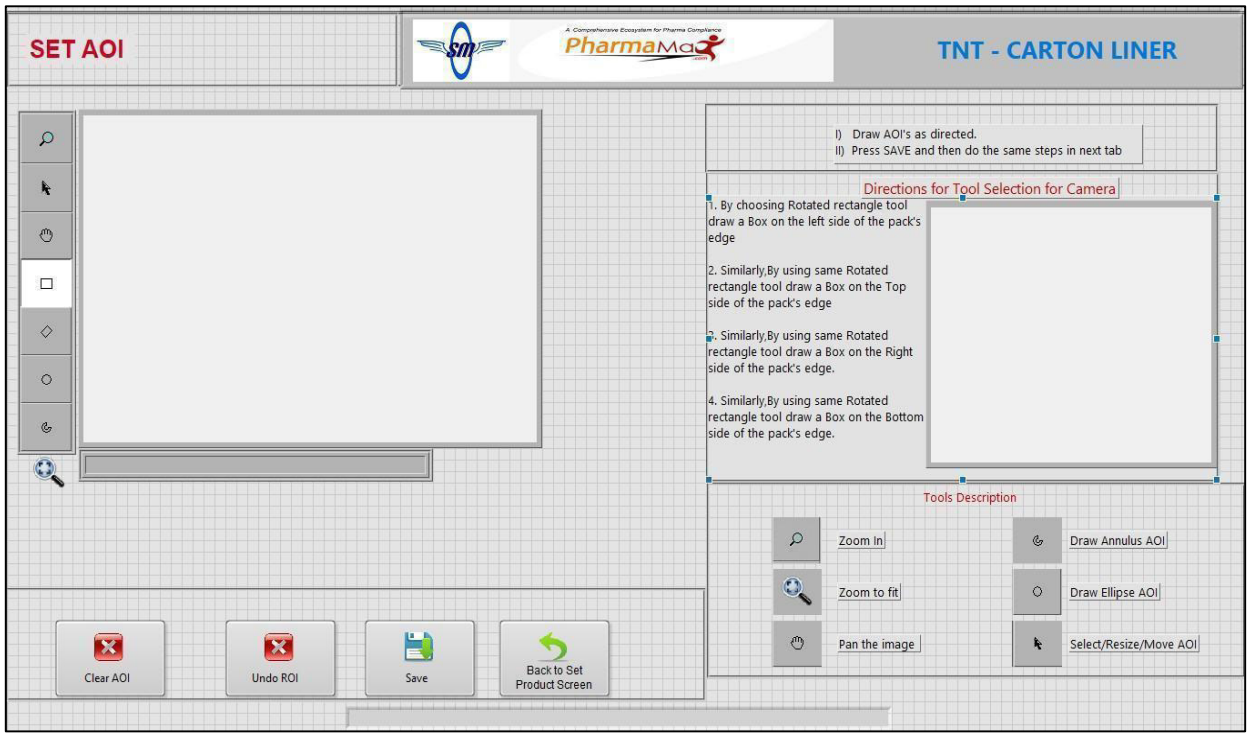


Fig 6: Configuration of Pack dimension by placing it on the Area of Interest (AOI)

The activity for processing each pack involves placement of the pack in the FOV of the barcode scanner/camera, need to ensure that the barcode is visible in the direction of the FOV of the scanner/camera, checking for barcode grading guidelines (a grading of A, B, C is acceptable and anything beyond that is considered a failure), check for the duplicate serial number of the pack, verification of over 42 attributes checks need to be conducted for each pack.

3.2 *Duplicate Pack Verification*

To ensure that every pack is identifiable by a Unique Serial number, all the packs that are aggregated must be checked against the already aggregated source packs for duplication. Our results were that if any attempt was made to rescan an existing pack and/or any pack contained the same serial numbers due to erroneous printing of the barcode labels, the pack was identified as 'Duplicate' and the entire bundle got rejected for further action. (refer to Figure 7)

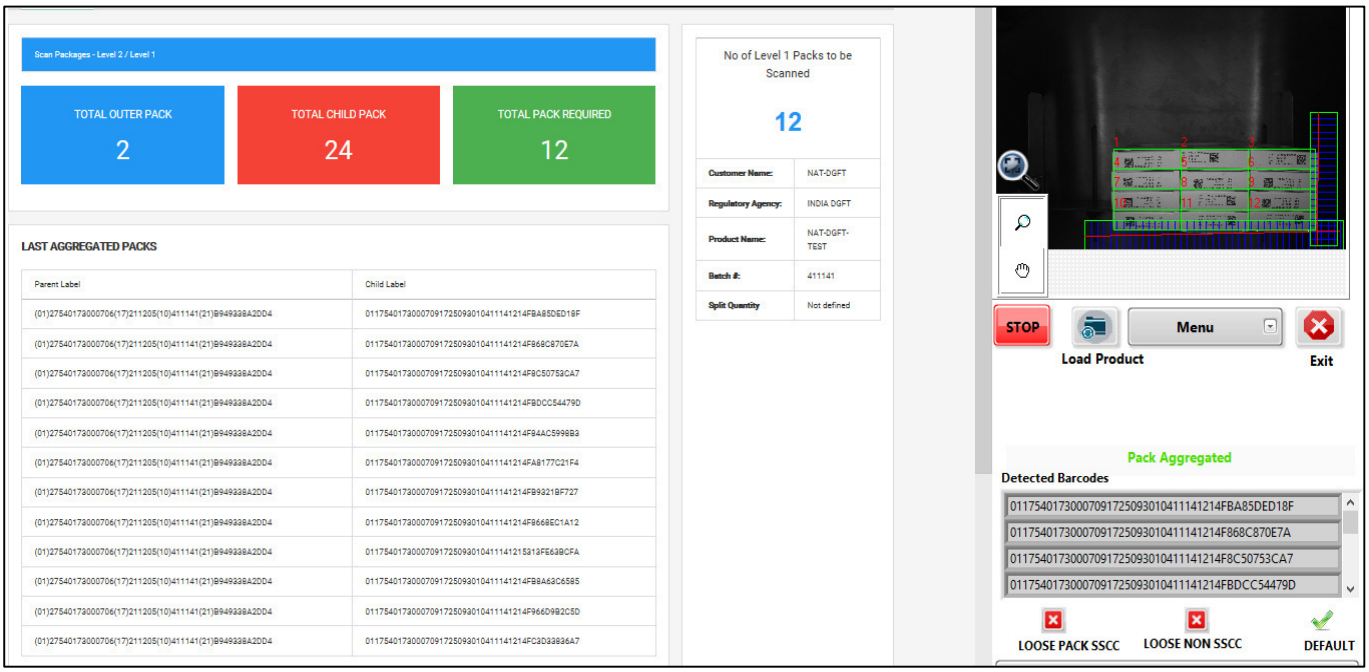


Fig 7: Live Activity of Pack Aggregation in the Field of View (FOV). As the pack pass over the FOV area, the packs are automatically scanned and then aggregated with their parent pack. There are two options namely 'Loose pack SSCC and Loose Non-SSCC which allow the packs to be delinked from them parent pack or the child pack as the case may be.

3.3 *Barcode Grading*[46]

International standards for measuring and grading the printed quality of barcodes have now been developed since the first American and European standards, ANSI X3.182 and EN 1635, were first published in 1990 and 1995 respectively. The latest ISO/IEC standards define the techniques required for both conventional linear barcodes, and two-dimensional barcodes such as Data Matrix, and QR Code. The results of this testing are used to give the barcode an overall grade, which runs from 4.0 down to 0. 4.0 is the best result, 1.5 is the passing grade for most barcodes, 0.5 is allowed for outer case barcodes printed onto brown corrugate, and 0 is a failure. The American ANSI standard was developed using alphabetic grading running from A to D, then F, so a passing grade of 1.5 or C is often required. ANSI grades compare to the ISO/IEC grades

Table 1: Barcode Grading sourced from AXICON[46].

ISO/IEC grade	ANSI grade
3.5 - 4.0	A
2.5 - 3.5	B
1.5 - 2.5	C
0.5 - 1.5	D
0 - 0.5	F

Using the above criteria, those barcode labels that did not fall in the ANSI grade of A, B, and C were rejected.

3.4 *Pack Configuration Limit Check*

Every customer defines their individual batch/lot numbers to cater to a specific product pack with a predefined number of individual packs (child) in a bundle pack (parent). An option is provided in the pack configuration module to define the variable quantities of the child pack to be contained in a parent pack. The result of aggregation ensured that the acceptance of child packs in the FOV will be in iteration mode until the parent pack limit has been met. The system automatically resets itself when the limit is reached to enable a new pack. (Refer to Figure 7)

3.5 *Delink Packages*

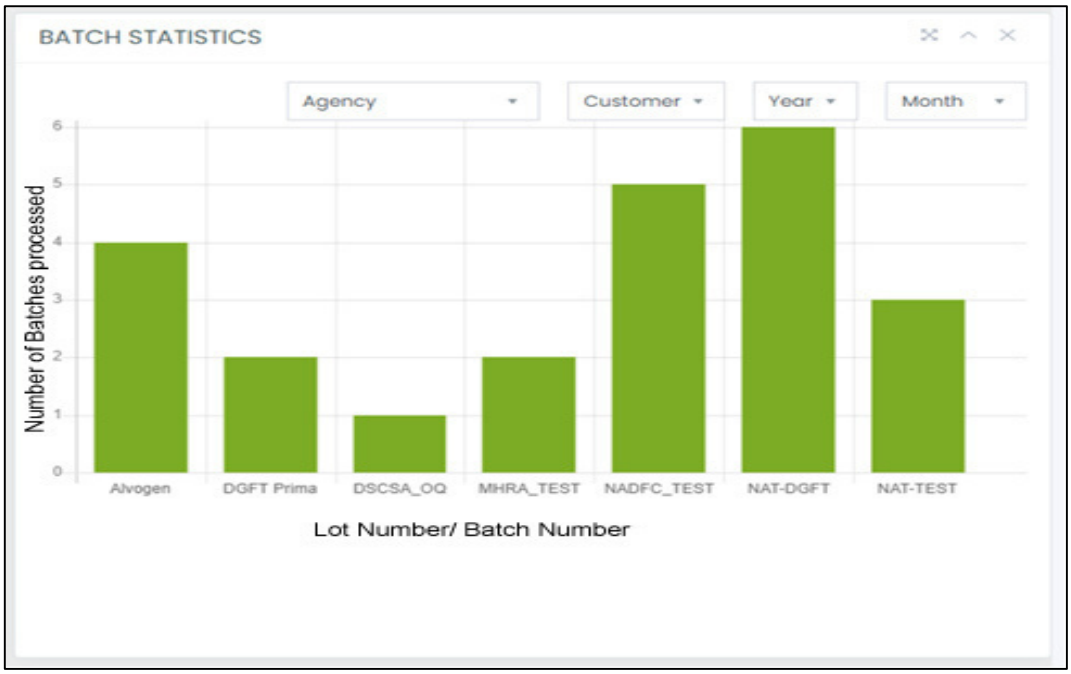
During the packaging activity, there would be situations when individual packs may need to be disaggregated from their parent pack due to reasons like destroyed barcode labels during packaging/after packaging, reconciliation of packs, duplicate barcode labels replicas, etc. The system allowed the delink of individual packs and the package configuration was automatically reset in the aggregated count based on the delink pack activity. (Refer to Figure 7)

3.6 Business Intelligence Compliance Reporting

In the Life science industry, one of the most important aspects is Quality which is managed by strict auditing practices from the quality assurance teams. Most regulatory agencies in the pharma domain have guidelines that ensure accountability for the person who is initiating the activity. The solution that we have designed monitors real-time progress and validation by approving agencies before it moves through the supply chain process. (Refer to Graphs 1 thru 6)

Graph 1: Pack Aggregation by Customer. Ad-hoc progress reporting enables the folks at the packaging activities to monitor and do pack consolidation if ever needed using this real-time tracker report.

At the end of each cycle of pack aggregation, it is very important to follow the Batch Package Record (BPR) which indicates the ratio of the combination of parent-child packs. So at the end of each cycle, the super random checks against the selected batch/lot number. In the above figure, batches 411141,987654 were batches recorded for FDA regulation, while ANVT19 was for Brazil ANVISA, DGFT19, and DGFTP2 are IVEDA customers and DSCSCI was for the EU regulation market.

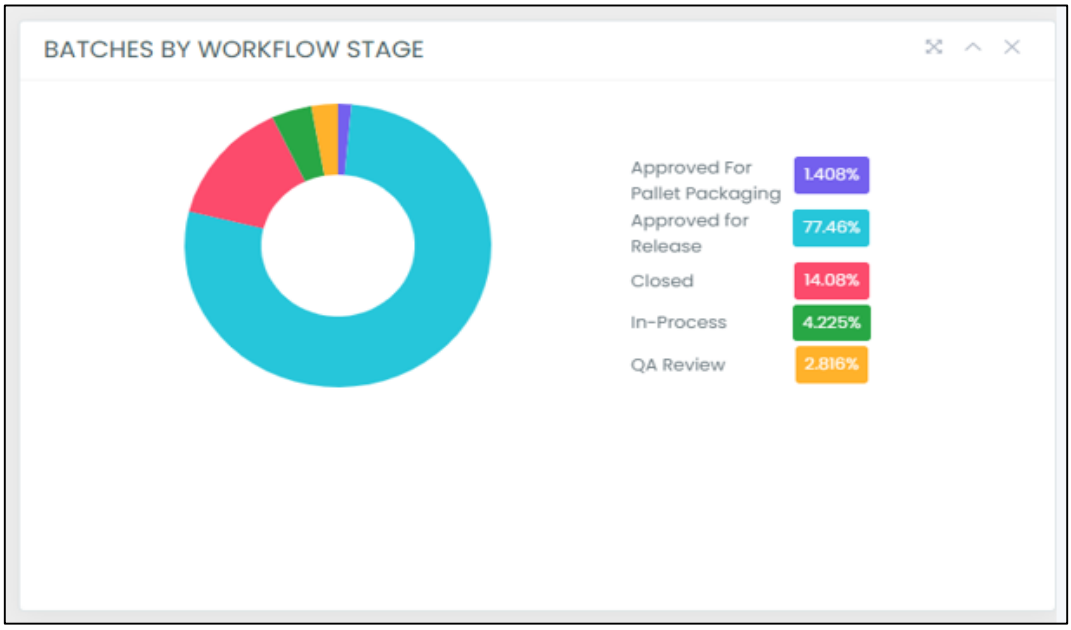


Graph 2: Lot Number/Batch Number Statistics. The plant supervisor is provided with the real-time progress of how a batch/lot number as there would be many batches being executed in multiple lines.

The efficiency of batch/lots processed for given regulatory agencies is reported to analyze further reporting of the batch consolidation requirements by the Quality Assurance department. A Report will be generated for the specific customer with their product's expiry date(year/month) and provided to the primary manufacturer or CMO.

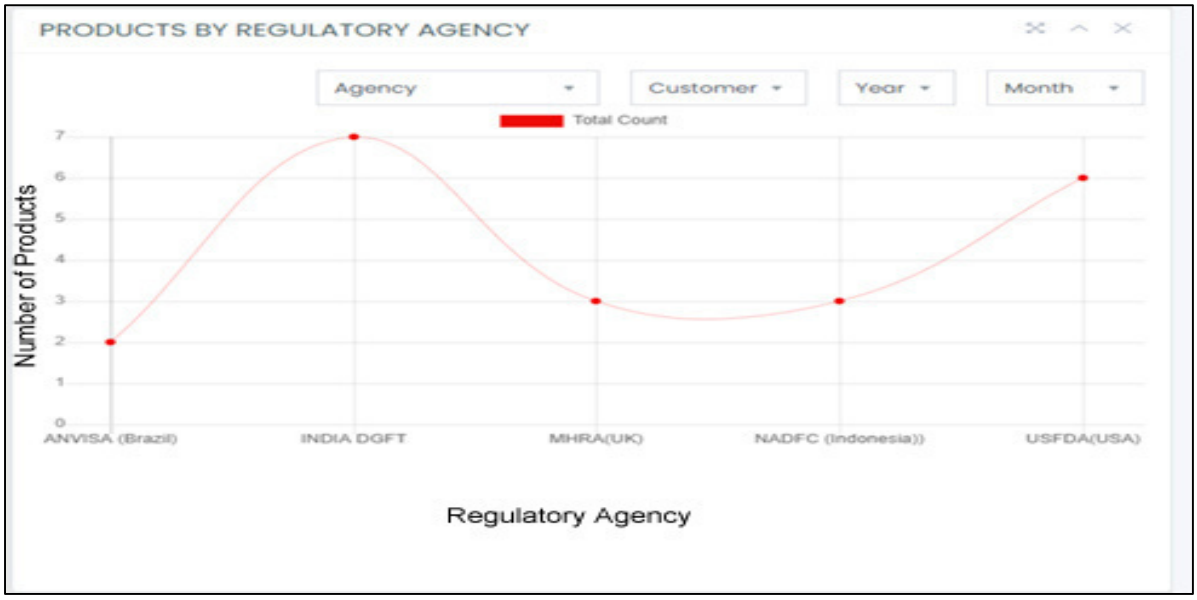
Graph 3: Samples Management Activity. As part of the compliance initiatives, the standard operating procedure would require various packs to be taken off while the pack aggregation is in progress. Before a batch consolidation is complete; the required packs must be pulled out for various sampling studies.

Various sample packs are picked from aggregated packs as per the specification mentioned in the BMR (Batch Manufacturing record) document. These are very critical since various types of quality controls test are conducted to ensure that the medicines meet the customer's manufacturing specification and that any anomalies will or may require product recalls or short termination of the drugs. The types of samples collected are Control Samples, Stability Samples, Validation Samples, Analytical Samples, Specimen Samples, Terminal Samples, Reserve samples, QP Samples, Testing Samples, Retention Samples, Trial Samples, and Pool Samples.



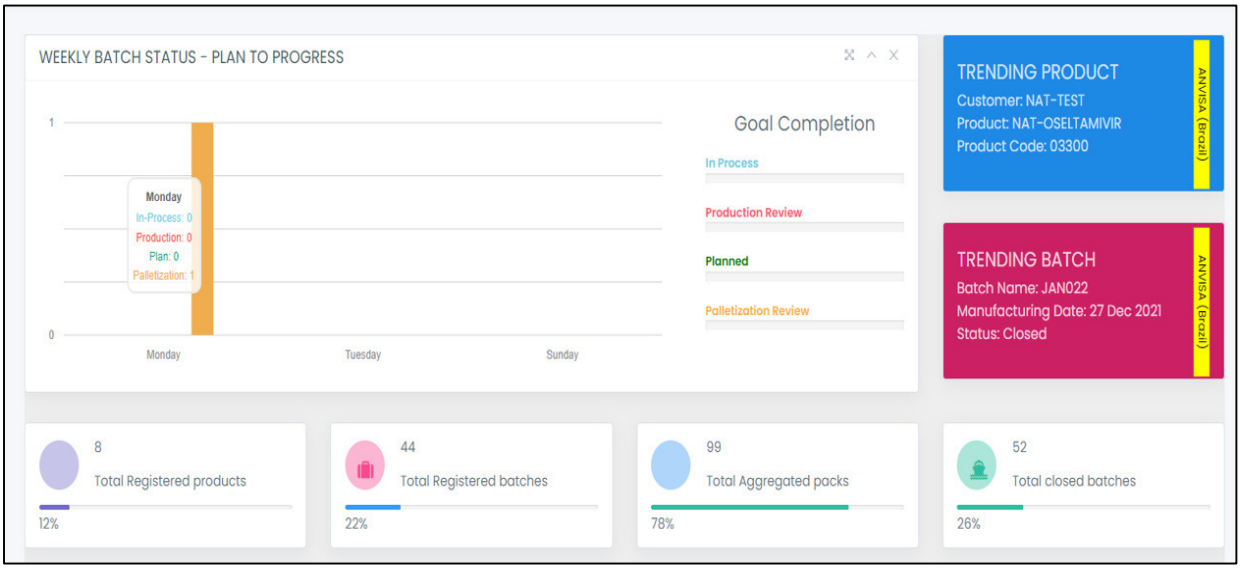
Graph 4: Batches by Workflow Stage. The TrackNTrace solution that we built would enable the stakeholders to review the progress of each stage of the batch workflow process (BWP). As in the life science industry, patient safety takes the highest priority, and various checks and approvals are required. If batch progress is stalled, this graph would help to identify the stage where they could investigate.

In the above chart, the current status of all batches for the particular customer's site can be reviewed based on the specific stage of the process namely- Approved for Pallet, approved for release, Closed batches, work in process(in-process) batches, and QA review



Graph 5: Product classification by Regulatory Agency. This report provides the management to make informed decisions on the various Key Performance Indicator (KPIs) and ensure how many packaging lines are dedicated to a specific regulatory agency.

In order to plan the manufacturing schedules, various statistical information is required for the business development teams to make their informed decisions. All the information is classified by the regulatory agency as the required product/packaging line needs to be approved by the respective regulatory agencies. In this graph, a number of products associated with the various regulatory agencies namely ANVISA, DGFT, MHRA, NADFC, and USFDA are recorded in real-time.



Graph 6: Tracking Weekly Batch Activity stages. The dashboard provided various metrics to manage and review the progression of work activities, anomalies that occur, employee activity trackers etc.

Various business teams within the customer organization have access to the specific functional areas and the required KPIs relevant to their review are reported to the customer dashboard in real time which ensures a faster and more efficient way to track the progress and record any anomalies. This was an enhancement feature that we focused to bring to the end customer.

4. DISCUSSION

Machine Vision Technology was used to implement the auto-processing of multiple packs in each instance to optimize the efficiency of the packaging line. The packaging line assembly[26]includes a high-resolution vision camera and sensors to enable quicker processing of the packages in the field of view (FOV). As part of the defect analysis of the barcode labels, A visual inspection system[30] was used to identify the packaging defects. The primary purpose to implement such a robust system was to reduce the counterfeit in drugs[25] being consumed by patients which required the study of all perspectives both micro and macro levels in the pharma supply chain[24]. Global Standards One (GS1) has been pioneering the use of barcoding technology[37] to enable traceability[28] of all drugs shipped out of the warehouse to enable accountability. More innovation has been incorporated to ensure compliance at all levels of the activity, namely the serialization of the barcode labels which required strict conformance to the drug's pack artworks. Integration of the

serial numbers' validation would be taken up during the next phase of refinement. Use of Barcoding[13] as a tool for automatic identification and data capture has found to be a big value to establishing the parent -child relationship that ensures that each shipment can be tracked to its minute detail. Another challenge that was mitigated was the part-shipments or the loose packs that needed to be identified. As a part of the quality regime in various life science industries, there is a practice of taking random samples from within the existing pack to test for stability, Analytical review, Specimen, Validation, Retention, etc. While these samples are being taken, a process of disaggregation of the pack is required so that the lot/batch consolidation can be managed effectively. Reduction in the distribution of counterfeit drugs was the primary reason for enabling barcoding of the labels with unique serialization so that the product item can be traced back to their source of manufacturing thus ensuring patient safety[38] of nonuse of spurious drugs. In the current practice which has a lot of manual processes involved, the decision to use high-speed inspection system[31] equipment to meet the delivery timelines; required us to develop a 'multi-carton' bulk code reader which takes a photographic image of all the barcodes together and then use machine algorithms to parse individual barcode[42] information to execute some validations like unique serial numbers, pack configuration limits, defects, etc. All the validation is performed in real-time[9] to ensure the packaging process progresses with any delays in quality assurance activities that are required to be performed as per the standard operating practice (SOP). The design as shared in figure 5, has to be going through various iteration[33] to finally converge at the final design. Many concerns like how to control the printing of the 'parent' labels when the required 'child' pack limit is fulfilled required us to control the practice by only allowing the 'parent' barcode label to be printed in real-time when the required 'child' packs are met. Through the implementation, the traceability software[34] was refined to meet the new scope of activities that were learned over time based on the actual implementation on the shop floor. Numerous dummy batches/lots with a lot size of over 5,00,000 each; were executed on these systems as a pilot and the required reporting EPICS[41] formatted files were generated by the software[44] in real-time. The success factors were shared across the organization that used the information as Key Performance Indicators (KPIs). The management tasked us to accommodate the medical devices as well; alongside the formulation drugs. It was learned that the opportunities[39] are immense by adopting the 2D Multi scanner. From formulation to medical devices, the 2D bulk code reader has brought immense[16] ROI but it does have limitations. The discussion moved onto the new challenge[40] that arose from the bottle packs like ampules and other drugs packed in bottles. For we are designing a 360 carton line which would be our next research work. The software will need to be enhanced to capture the drug movements[36] from distributor to consumers. With the learning, the attempt to design a multi-carton barcode reader equipment yielded the anticipated results based on the outcomes that we set.

5. CONCLUSION

The system design was demonstrated by executing batches/lots as per the customer's SOPs, and the average size of each batch/lot was over 1,50,000 packs. The attributes like speed and efficiency were recorded. By tracking the usage footprints of each scan, the station enabled the provision of feedback to the Supervisors and the HR department for further skill training advice for their staff. The process was repeated for a different classification of end customers, regulatory agencies, and products which ensures various combinations of functionality are evaluated. For instance, the dimension of the pack, classification of barcodes between 1D/2D, and position of the barcodes at a different location within the cartons as per the artwork guidelines of the end customer. In addition, the required various regulatory agencies were adhered to, and the required compliance reports were generated. One of the key improvements that were tracked was the improved efficiency of the line. A typical line in the past at this customer location was restricted to about 180 packs/min, and now the efficiency has improved to over 110 packs/second. In addition, more controls on the compliance requirements were put in place due to the auto rejection and accountability built into the software, thus ensuring that the changes in human errors have been reduced. Critical success factors of a drug traceability system were analyzed and documented for further refinements to the current design. Additional recommended workflow practices have been suggested based on the continuous improvement cycles of review. The implementation of the TrackNTrace for multi-carton pack lines has enabled faster traceability of fake counterfeit medication which has become a menace to the safety and health of people living in society. The development of a conceptual design framework that incorporates federal guidelines of regulatory agencies; to demonstrate the influence of traceability technologies. We would like to recommend that the Field of View (FOV) concerns might vary based on the pack's dimensions and this area might require additional improvements. Some of the suggestions that were recorded from our customers were to capture any product visible to the mounted camera without teaching it to read a specific dimension. We live it to the researcher to further improve this aspect based on the pros and cons without comprising the compliance guidelines.

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7. AUTHORS CONTRIBUTION STATEMENT

Mr K.Vidyasagar has been involved in the conceptualization and design of the study on automation of the supply chain to reduce counterfeit medical drugs. Various prototype design components were reviewed during the proof-of-concept phase under the guidance of Dr Vanitha Kakollu who reviewed the data analytics and provided valuable inputs. All the authors discussed the methodology and the results and contributed to the final manuscript.

8. CONFLICT OF INTEREST

Conflict of interest declared none.

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