Quality Risk Management in Pharmaceutical Dispensing Center

M. Chitmetha, S. Prombanpong, and T. Somboonwiwat

***Abstract*—This paper describes quality risk analysis in the dispensing center where all required medical substances of each formula are weighted, checked, and verified before transferring to the production line. Like any working station, risk in terms of both information and operations can take place here. Thus, all of these risk opportunities must be identified and evaluated and the possible prevention and protection measures must be devised to avoid these risks. Based on the analysis in the case study in this paper, there are a number of potential risks and four of them are shortlisted with recommended alleviation actions.**

***Index Terms*—FMEA in pharmaceutical, FMECA, pharmaceutical dispensing center, quality risk management.**

I. Introduction

Nowadays almost all of the pharmaceutical manufacturers utilize the dispensing center as a single unit to prepare all starting chemical substances for each production batch in clean room environment. The main tasks of this dispensing unit are to acquire starting materials from store or warehouse, to weigh and transfer to the production line. A typical function of the dispensing center in the pharmaceutical factory can be illustrated in Fig.1. The flowchart begins with a receiving of starting materials from the warehouse and they are divided into two separated bundles i.e. bulk and loose packs. The unopened bulk packs will then be weighted and sorted in the control area. The loose packs will be transferred to the classified area and then to the dispensing booths. Once the weigh activity is completed, the weighed materials will then be carefully labeled, transferred, and sorted with the corresponding bulk packs located on the pallet in the waiting area. Once all of the starting materials are well-processed and documented, the pallet will be plastic wrapped, labeled and ready for transfer to production line on demand. Note that risk marked in the flowchart is deemed potential quality risk. However, one can imagine that there will be several steps within the main process that needed to be done. Each of steps may use equipment and require human to operate. Thus, failure modes due to equipment malfunction or human error can occur and effect(s) will be ensued. As a result, counterfeit products may be inadvertently produced. Based on Malid et al. there are five different types of counterfeit mechanism i.e. no active ingredient (43%), low levels of active ingredient (21%), poor quality drugs (24%), wrong ingredients (2%), and wrong packaging or source (7%) [1]. Potential risks must be managed and how to manage them is also the main topic of this paper which will be described later.

It is very crucial that all of the possible risks must be identified, evaluated, and prioritized so that appropriate actions for alleviation adverse effects will be set. Number of international standards i.e. ISO 9000, ISO/TS16949, ICH Q9 established guidelines and procedures for risk assessment and management. The International Electrotechnical Commission (IEC) also established the standard IEC 60812 provided guidelines on analysis techniques for system reliability procedure [2]. One of the systematic procedures for the analysis of a system is the Failure Modes and Effect Analysis (FMEA). The purpose of this system is to identify failure modes and effects on hardware, software, and/or process performance. According to BS5760: Part 5 FMEA is a method of reliability analysis intended to identify failures [3]. MIL-STD-1629A is another standard which is also widely used in automobile industry for failure modes and effect analysis [4]. FMEA is therefore used to determine the severity of potential failure modes and subsequently to provide the mitigating measures to reduce risk. FMEA basically requires the identification of the following basic eight pieces of information [5]. It is composed of item(s), function(s), failure(s), effect(s) of failure, cause(s) of failure, current control (s), recommended action (s), and other relevant details. In addition, a method to evaluate the risk which is pertaining to the issues identified and to prioritize corrective actions must be performed. Basically, there are two main types of FMEA which are design (DFMEA) and process (PFMEA).

The fundamental steps of FMEA include an assembly of the team, setting the ground rules, collecting information. It is important to select the component(s) or process(s) to be analyzed and identified failure modes of the selected one. The immediate effects and final effect of the failure mode together with the severity of the final effect must be identified. Then the potential causes of that failure mode as well as the probability of occurrence will be determined.

Normally, the quantitative determination of risk austerity is risk priority number (RPN) as in (1)

$$RPN = O \times S \times D \tag{1}$$

where

O: Denotes probability of occurrence of a failure mode

S: Denotes severity

D: Denotes detection which is the chance to detect and

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eliminate the failure before the system is affected

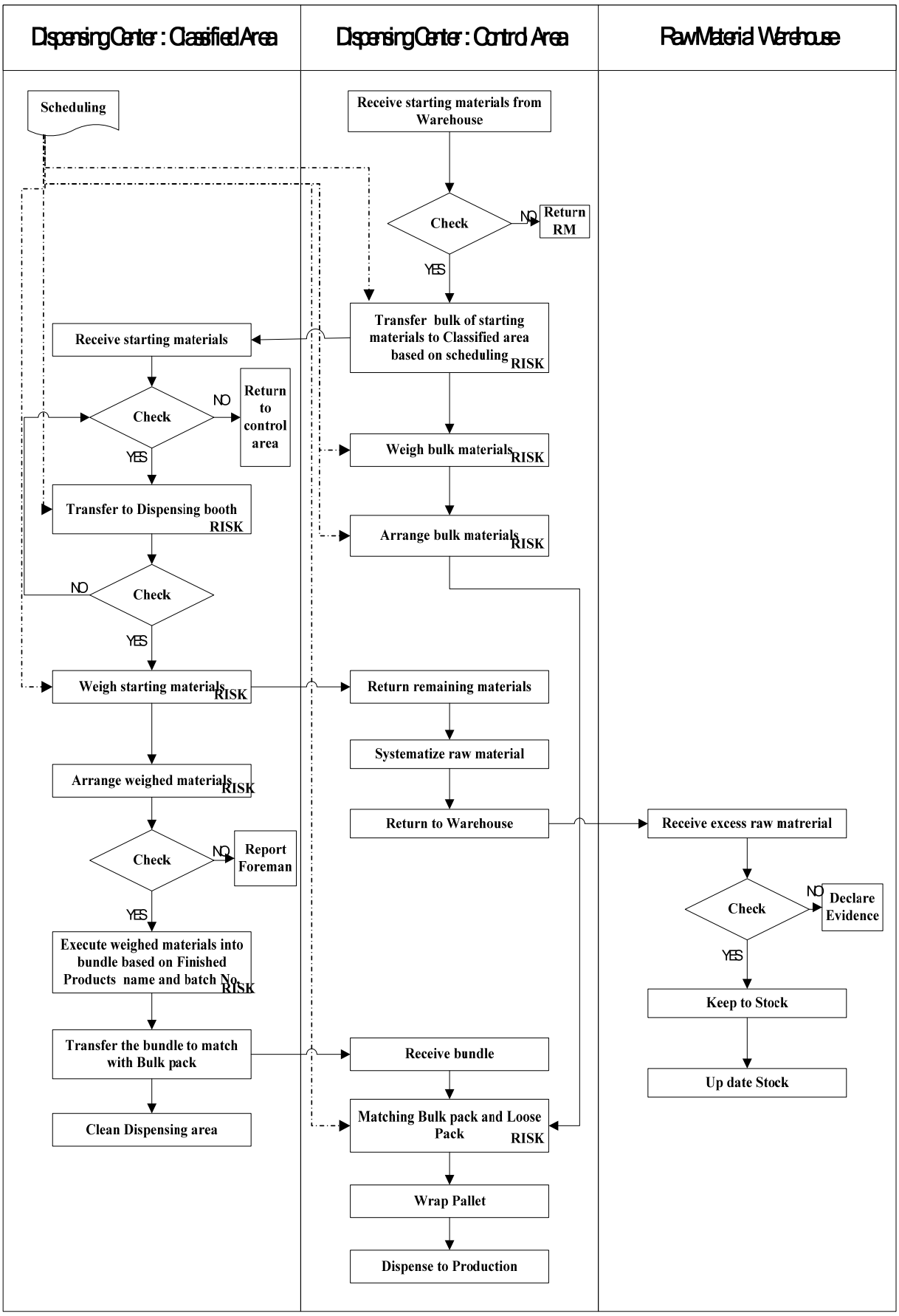

Fig. 1. Functional flow of dispensing center.

The risk priority number can be used to prioritize failure modes and to determine which failure modes must receive

attention for mitigation or elimination the effect of these failure modes. Then corrective actions must be performed and risk will be re-evaluated. Finally, the team should review and update the analysis as appropriate [5].

An extension to the FMEA is the failure modes effects and criticality analysis (FMECA) which includes a method of ranking the severity through a criticality metric as shown in (2).

$$R = P \times S \quad (2)$$

where

P: Denotes probability of occurrence

S: Denotes severity

A criticality matrix is typically used to identify magnitude of critical which is a plot between likelihood of occurrence, on the Y-axis and severity classes, on the X-axis. The purpose of criticality analysis is to prioritize failure modes so that appropriate action to mitigate an effect can be established. A criticality matrix used to assess magnitude of failure modes is depicted in Fig. 2. The severity increases in the direction from left to right whereas the probability of occurrence increases in the direction from bottom to top. Thus, any failure mode which locates at the top right area of the criticality matrix will have high effect to the system. It is obvious that the controversial part of FMEA/FMECA is an assessment of risk in the critical matrix since this method is subjective and it depends upon a person who appraises the components. Thus artificial intelligent technique named fuzzy logic has been applied to aid both in calculation and interpretation in FMEA. Some of the literatures will be reviewed and described later.

A number of literatures have been conducted and demonstrated the utilization of FMEA/FMECA. However, a number of published papers in the area of pharmaceutical manufacturing are quite limited. Based on the World Health Organization Public Inspection Report (WHOPIR), Cipla Ltd, Baddi one of the pharmaceutical manufacturers in India has utilized FMECA for risk assessment in quality risk management (QRM) [6]. Hatem studied supply chain in drug store and analyzed failure modes using FMECA technique. The simulation model was then utilized to view proposed scenarios based on risk exposure [7]. Bonnabry, *et al.* utilized FMECA to assess risk and its impact on patient safety of drug prescription process using computerized provider order entry system (CPOE) [8].

Beside the application of FMEA/FMECA in health science, this technique is also widely used in logistic and supply chain as well as in engineering. FMEA technique is also a vital tool for assessing risk in the process of various industries and supply chain business. Adis reported that a risk framework plays a significant role in business process modeling [9]. The risk assessment is based on a probability of the event and its consequence. A risk matrix between probability of occurrence and severity is then used to select the failure modes. Teoh explained modeling and reasoning method for FMEA generation [10]. He showed that function decomposition can be achieved by the flow-based approach including the integrated definition (IDEF) method and a functional diagram approach. Pahl and Beitz suggested a flow-based 'black-box design process which is simple and easy to model [11]. However, Ulrich and Eppinger pointed out that a flow-based approach has some disadvantages in the formation of implicit relationships in a model [12].

The IDEF0 diagram initiated by the National Institute of Standards and Technology is a standard methodology for representing a process [13], [14].

The functional diagram represents function and structure interaction in the system. It presents in a form of activity flow from the beginning to the end. Chou *et al.* analyzed the potential failures of the Holter using FMEA for risk assessment and suggested mitigation actions through protection and alarm system [15]. Nisakorn and Pongpanich applied FMEA technique in defect reduction for the spindle motor assembly process for hard disk drives. The potential risks have been pinpointed and corrective actions have been taken [16]. Pinna et al. used FMEA to study safety-relevant implication arising from possible failures in performing remote handling transfer system [17]. Mill *et al.* proposed risk based maintenance method using FMECA to assess potential risks [18].

5	Undesirable	Intolerable	Intolerable	Intolerable
4	Tolerable	Undesirable	Intolerable	Intolerable
3	Tolerable	Undesirable	Undesirable	Intolerable
2	Negligible	Tolerable	Undesirable	Undesirable
1	Negligible	Negligible	Tolerable	Tolerable
	I	II	III	IV

Occurrence Level — Severity Level

5 : Frequent	Pi < 0.2
4 : Probable	0.1 ≤ Pi < 0.2
3 : Occasional	0.01 ≤ Pi < 0.1
2 : Remote	0.001≤ Pi < 0.01
1 : Improper	0.0 ≤ Pi < 0.001

Fig. 2. Criticality and severity matrix.

As previously mentioned such mathematical method as fuzzy logic has been attempted to improve assessment procedure. Monika and Roland applied fuzzy logic in a calculation of RPN [19]. Tay *et al.* improved a fuzzy assessment model to fulfill monotone output property using a derivative approach [20]. Ung *et al.* applied fuzzy rule base method for criticality assessment using FMECA for port security [21]. Hu et al. utilized fuzzy analytic hierarchy process (FAHP) to determine relative weight of consideration factors before the RPN is calculated [22]. Wang et al. proposed fuzzy weighted geometric mean to prioritize failure modes by a calculation of fuzzy risk priority number [23]. Moreover, some other techniques used for assessment improvement can also be found. Chin presented an FMEA using the evidential reasoning approach, a newly approach for multiple attribute decision rule which is

different from fuzzy rule base method [24]. Li proposed the model which Boolean matrix of the polychromatic sets to represent the failure modes in terms of their interrelationships and their relations to the physical system. This method is a structure-based modeling technique [25]. Risk assessment pertaining to the dispensing center in the pharmaceutical manufacturer cannot be found in literatures. Let alone conduct research on risk management in the dispensing center.

It can be seen that FMEA /FMECA is a widely used method for identification of failure modes and effect and has been applied in many fields and applications. Moreover, some researchers attempted to improve assessment technique by applying fuzzy rule base, evidential reasoning, and structure-based technique.

However, application especially Failure Modes Analysis in the System

As mentioned earlier, the dispensing center is considered one of the most important units in the production line since the production begins here. If there is any mistake in this unit, the end products are adversely affected in terms of quality and safety for use. The cross contamination on the starting materials or any error on active pharmaceutical ingredients (APIs) can easily make end products become counterfeit. Thus, it is indispensable to perform quality risk management in this department in order to prevent these adverse effects.

Note that this research employed FMECA and conducted under the standard IEC60812 guidelines. The dispensing unit at government pharmaceutical organization (GPO) in Bangkok is the case study. The main task of the dispensing center can be visualized from IDEF0 which are shown in

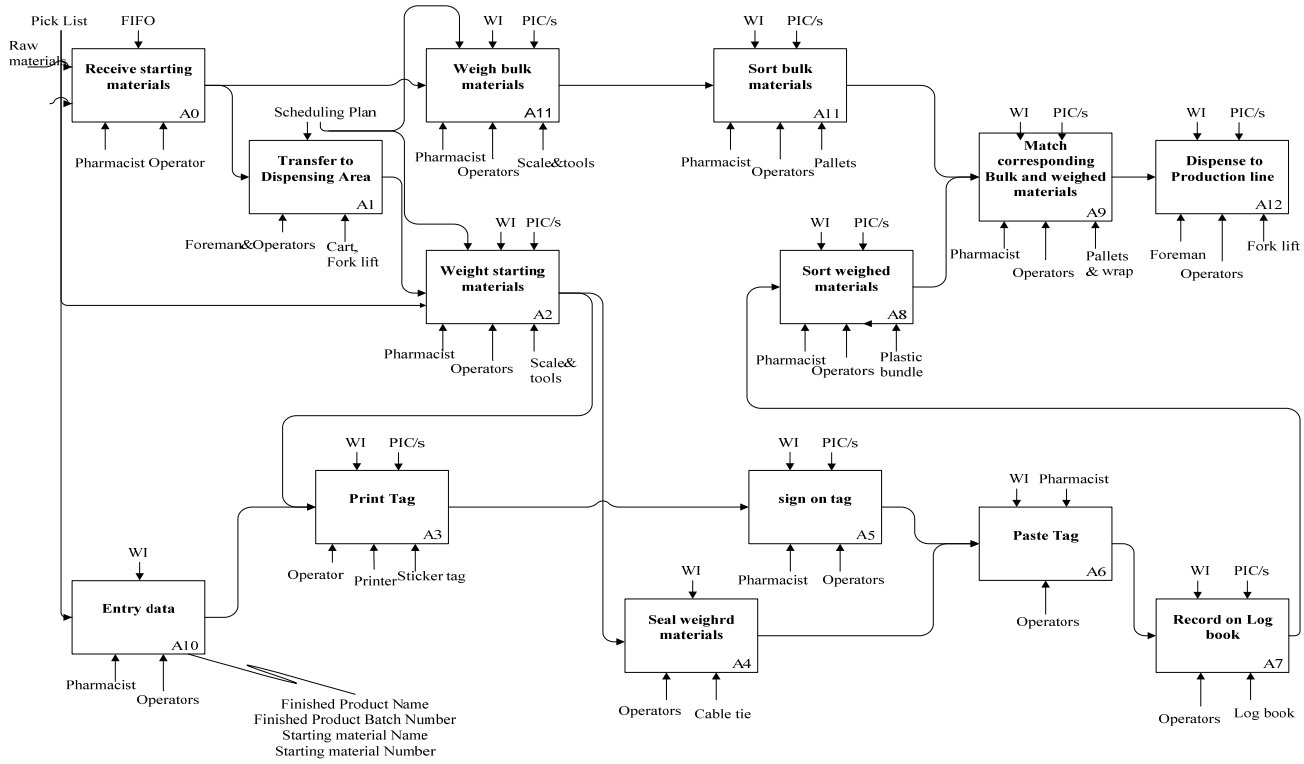

Fig. 3. IDEF0 of dispensing center.

Fig. 3. IDEF0 enhances understanding of a mechanism enabling the function. Moreover, factors that influence function performance can be included in the diagram. The IDEF0 diagram elucidates factors and function of each activity in the dispensing center which make it easy to identify failure modes related to the function. Once IDEF0 diagram is well established, the next step in FMECA is to identify failure modes and effect which will be described next.

A. Failure Modes Analysis of Equipment

The main equipment most affecting quality of starting materials can be identified into two items i.e. weighing scale and HVAC system. The weighing scale is used to weigh starting materials to the right amount based on the said ingredient. The position, accuracy and performance of the scale are very crucial factors attributing to the wrong ingredient which is one of the categories in counterfeit drug. The failure modes in weighing scale are wrong reading in two counts. One is due to scale at incorrect position [26]. The latter is load cell malfunction.

The HVAC system is of crucial in controlled environment. The quality of starting materials also depends upon the performance of HVAC system. As a consequence, the poor quality drugs may produce, if the system is not properly controlled or it is malfunction. Therefore, the HVAC system will be taken into account in failure modes analysis. The analysis of failure modes of weighing scale and HVAC system is tabulated in Table I.

B. Failure Modes Analysis of Processes

Although the main processes in the dispensing center seem simple and straightforward, failure modes can be pointed out in a few steps. In this case there are a total of eight possible

failure modes. They are: (a) wrong delivery of starting materials to dispensing area, (b) wrong delivery of starting materials to dispensing booth (c) entry incorrect data (d) dispense incorrect type, quantity, lot number of raw materials (e) label wrongly on weighed starting materials pack (f) mix up of weighed materials (g) mix up of bundle with bulk pack (h) strain remaining at return grille. The analysis table of failure modes of processes is tabulated in Table II.

TABLE I: FMECA ANALYSIS OF EQUIPMENTS

Description	Failure Mode	Possible causes	Local Effect	Final Effect	Compensating action	Severity Level	Occurrence Level
Scale and Weight	Incorrect reading	Scale not in the correct position	Wrong weight of starting materials	Counterfeit Drug	Daily Check and Self-check before use	4	2
Scale and Weight	Incorrect reading	Load cell error	Incorrect weight of starting materials	Counterfeit Drug	Calibration every 3 month and Daily Check	4	2
HVAC system	Humidity uncontrolled	Dehumidifier malfunction	Too much moisture in materials	Quality of Product	Calibration and MDB, Main Distribution Board, control	3	3
HVAC system	Temperature uncontrolled	Compressor/ electronics breakdown	Materials spoiled	Quality of Product	Annual preventive maintenance	3	1
HVAC system	Pressure uncontrolled	AHU breakdown or door problem	Unclean room	Contamination	Annual calibration	4	3

TABLE II: FMECA ANALYSIS OF OPERATIONS

Description	Failure Mode	Possible causes	Local Effect	Final Effect	Compensating action	Severity Level	Occurrence Level
Transfer starting material from unclassified area to classified /dispensing area	Wrong delivery starting material to classified /dispensing area	Human Error	Delay the schedule	Rework	Double check by operator in dispensing area	2	3
Transfer starting material from classified area to dispensing booth	Wrong delivery starting material to dispensing booth / Receive wrong Lot No. of starting materials	Human Error	Weigh wrong starting materials/starting materials mixing Lot No.	Counterfeit Drug/Impact to FIFO and Traceability system	N/A	4	3
Data logging	Entry incorrect data	Human Error	Non traceability problem and incorrect data being use	Counterfeit Drug	Double check by Foreman or Pharmacist	4	4
Dispense bulk pack of starting materials	Dispense incorrect type, quantity, Lot No. of starting materials	Human Error	Wrong ingredients/ starting materials mixing Lot No.	Impact to FIFO and Traceability system	N/A	4	2
Labeling	Wrong label on weighed starting materials pack	Human Error	Wrong ingredients	Counterfeit Drug	Double check by Foreman or Pharmacist	4	3
Sortation	Mix up of weighed materials	Human Error	Wrong ingredients	Mix up	Double check before execute to bundle	3	3
Placing of bundle	Mix up of bundle with bulk pack	Human Error	Wrong ingredients	Mix up	N/A	3	3
Cleaning return Grille	Strain remaining at return grille	Improper cleaning	Poor quality	Cross-contamination	SOP and Training	4	2

II. Criticality Assessment of Failure Modes Effect

Once the failure modes analysis is completed, the criticality assessment of the effects of these modes is followed. The assessment is based on the function of probability of occurrence and severity. The summary of high risk failures is shown in Table III. There are four failure modes needed attention to establish mitigation actions. Each of them can be described as follows:

1) HVAC (heating, ventilation, air-conditioned) system: This system is for ambient control such as temperature, humidity, and pressure in the clean room where pharmaceutical materials or product are stored and processed. Typically, these materials or products require controlled conditioned for quality purpose. Regarding HVAC system, pressure leak is crucial and difficult to recognize by operators. The only way to realize this discrepancy is from pressure gauge reading and the most common error is due to pressure leak at the air lock door. Thus, in line monitoring should be used to detect and recover when there is any problem.
2) Error during transfer of materials to dispensing booth: These problems can occur and become one of the potential failure modes. For example, wrong delivery of starting materials, receive wrong lot number or type of material are the most possible common error and end result is quite severe.
3) Incorrect data entry: This is due to human error during operation. New data obtained from different operations are created and must be stored for traceability and identification purpose. If entry mode is done by human, error is most likely occurred. It is considered one of the potential risks that can cause counterfeit product.
4) Labeling: After the starting materials are weighted, each pack must be labeled. If labeling procedure is not well organized, the weighed material pack can be wrongly labeled. This eventually leads to a production of counterfeit drug.

III. Mitigation Actions

TABLE III: Summary of High Risk Failure Modes

Description	Final Effect	Compensating action	Severity level	Occurrence level
HVAC system	Contamination	Annual calibration	4	3
Materials transfer	Counterfeit drug	N/A	4	3
Data logging	Counterfeit drug	Double check	4	4
Labeling	Counterfeit drug	Double check	4	3

The actions to alleviate the adverse effect must be established and implemented. In this case the summary of mitigation actions is tabulated in Table IV. Each of the high criticality failure modes will be described as follows:

1) The first failure mode is related to HVAC system. The problem of uncontrolled pressure receives high magnitude in criticality matrix. This problem jeopardizes the cleanness of the classified area and it is very crucial. Thus, mitigation actions must be established. One of the main reasons that this failure mode deserved attention is that the door at air lock room is the only entrance of starting materials to dispensing area. These facilities tend to malfunction and can cause problems. Likewise the hinges of the door at air lock room tend to dislocate and are not able to position the door at the right angle. Thus, the door is uneven due to heavy use. The recommendation is to request dispensing personal constantly observe the pressure gauge. The preventive maintenance of air lock door must be included in CAPA (corrective and preventive actions) of the factory. Moreover, a warning system when pressure drops is highly recommended.
2) A number of risks occurring during transferring of starting materials from receiving area to dispensing room, the controlled clean room may be due to congestion of starting materials, unsystematic procedure, and/or human blunder.Although, checking stations are designed along the processes, no mistake is still better than detecting it.

TABLE IV: Actions to Mitigate Risks

Description	Final Effect	Proposed mitigation action
HVAC system	Pressure uncontrolled	- Door redesign - Preventive maintenance for AHU with warning system - Pressure gauge daily check
Materials transfer	Wrong delivery and receive wrong materials	- Design queue for starting materials based on weighing schedule plan - Visual check
Data logging	Entry incorrect data	- Encoder and decoder equipment i.e. RFID, Barcode
Labeling	Wrong label on weighed material pack	- Barcode system for data entry - Combination of new business model and barcode system

These types of problems can be easily prevented by many ways. FIFO organization of the items will impede lot number mix-up. Color tags for visual check can hinder materials mix-up and expedite sorting and grouping of materials onto

the pallet. With the advent of technology such as RFID (Radio Frequency Identification) ample of information can be stored and retrieved [27].

1) Data logging error due to human is deemed one of the potential risks and must be prevented. Although data is just information not exactly involved to the physical product, confusion and traceability is of momentous to the quality assurance. This influences recall procedure, CAPA activity, QMS (quality management system), and so on.

Reduction or elimination of manual task is strongly recommended for error prevention and perpetual competitiveness. RFID together with bar code system seem to be indispensable and a must.

2) Incorrect labeling after weighing starting materials in weighing booth is considered serious. This leads to misuse of weight materials and engenders counterfeit drug.

Continuous improvement using ECRS (Eliminate, Combine, Rearrange, Simplify) technique should be implemented to prevent this risk. For example, weighed materials must immediately label consecutively to prevent wrong labeled. Standard operation procedure (SOP) should revise to attain best practice.

IV. Discussion

Dispensing center is a prime requisite in the pharmaceutical production line. Failure mode occurring in this unit causes ensued production lines become futile. Thus, FMEA /FMECA technique must be implemented to identify, assess risk and mitigation actions must be established.

V. Conclusion

The potential risk in dispensing center can be concluded into four categories i.e. HVAC system, materials transfer, data logging, and labeling. It is due to the fact that these aforementioned failure modes attribute contamination and counterfeit drug. Thus, much attention to these causes is strongly recommended especially structure of HVAC system which is normally overlooked during normal operation.

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