From: Colleen McGinn
To: Michael Edwards; Patrick D Shields; Jason Gardner; Joseph Tomkiewicz; Jenny Gallo
Sent: 8/19/2015 2:50:13 PM
Subject: FW: Global Internal Audit: DEA - Final Report
Attachments: DEA - Final Report.pdf

Attached is Itai's final report. I'll be setting up a meeting with each of you to discuss the response.

From: Itai Rigbi
Sent: Wednesday, August 19, 2015 6:22 AM
To: Carlo De Notaristefani
Cc: Karin Shanahan; Colleen McGinn; Nir Baron; Sandy Sher
Subject: Global Internal Audit: DEA - Final Report

Dear all,

Attached please find the Final Audit report of the Teva's DEA (Drug Enforcement Administration) Department.

We have rated the overall report as *Effective with Opportunities for Enhancement.*

I would like to thank all for their full cooperation.

Best Regards,

Itai Rigbi, Senior Director
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PLAINTIFFS TRIAL EXHIBIT
P-03646_00001

Global Internal Audit

GLOBAL INTERNAL AUDIT
AUDIT: OP 2015-04

DEA
DRUG ENFORCEMENT ADMINISTRATION
- HANDLING CONTROLLED SUBSTANCES IN US -

CONFIDENTIAL

AUGUST 19TH, 2015

SIGNIFICANCE: ***Effective With Opportunities for Enhancement***

EXECUTIVE SUMMARY

EFFECTIVE WITH OPPORTUNITIES FOR ENHANCEMENT

- Overall control environment and business practices for the areas reviewed are in line with company standards are in most cases effective and provide reasonable assurance regarding the compliance with laws, regulations and company policies.
- Isolated control and process deficiencies were identified which neither individually nor collectively compromises the goals and deliverables of the audited function / process; however remediation is necessary to better align with company expectations, requirements and standards.

Preface

The Operational and R&D Audit group of Global Internal Audit (hereafter referred to as "GIA") conducted during July 2015 an audit of the Drug Enforcement Administration Department (hereafter referred to as "DEA department").

The audit was conducted in accordance with the 2015 GIA Plan as approved by the Audit Committee of Teva's Board of Directors.

Teva's GIA has rated the report as "***Effective with Opportunities for Enhancement***".

Objectives, Scope and Method

The aims of the audit were to review the overall way in which the DEA activities are handled in US by the DEA department, to assess the various internal processes and to ensure that the risks associated with this activities are properly managed.

A review of a range of working documents, regulatory requirements, guidelines, SOPs, datasheets, inspection reports, emails and presentations was conducted.

Meetings with DEA members, as well as with other TGO members who are also involved in day to day interactions with the DEA dept., were held in order to get their perspective.

Visits to the DEA department offices in North Wales and to the two main US manufacturing sites that handled Controlled Substances (Salt Lake City UT and Forest VA) also took place during July 6-14, 2015.

Definitions used in this report

Controlled Substance (CSs): A drug or chemical, including schedule I–V, whose manufacture, possession or use is regulated by the US government.

Schedules: CSs are classified into one of five schedules, mainly according to their abuse potential: I - highest risk, V - lowest risk.
The classification applies, for example, the requirement to notify export shipments of schedule I- II from US, or to the special security requirements and warehousing methods that apply for the CS of these schedules.

Drug Enforcement Administration (DEA): The agency within the DOJ (Department of Justice) that grants legal permission to handle CS in the United States and enforce the CS laws and regulations.

Quota: A portion, in grams, provided by the DEA agency to pharmaceutical companies, for legitimate procurement and manufacturing for commercial and development of CS.
The Quota application provided by the Pharma's company is to obtain a Quota approval from the DEA agency. The calculation of the needed Quota is based on several variables like the confirmed sales plan, Inventory, safety stock, production plan, yields, etc. Quota controls the purchasing of CSs by Teva.

Suspicious Order Monitoring (SOM): A processes designed to review and report to the DEA agency on excessive quantities, unusual size of frequency, and deviation from normal sales pattern.

Diversion: A disappearance or defacement of CS product with the intent to commit fraud.

Import / Export: DEA is obliged to monitor movement of CSs across US borders and issue import/export permits for those movements.
During 2014 and the first half of 2015, the import/export volumes of CS handled by the DEA dept. for all Teva sites were as follows:

	Number of Applications	
	2014	2015 - first half
Import	316	311
Export	862	399

The focus of DEA dept. is to ensure that these processes are complied with the DEA agency requirements.

Registrations: Certificates issued by the DEA (renewed on an annual base) allowing the registrant company to conduct specific business activities with CSs.

222 form: A multiple (three) copy order form required by the DEA for each distribution of CSs listed in schedules I and II.

ARCOS: Automation of Reports and Consolidated Orders System. Quarterly and year-end ARCOS reports are required by the DEA agency from Teva.

The DEA Department

- The DEA dept. is responsible for handling all CSs across US pharma and R&D sites, compliance with DEA agency regulations and for traceability of CSs to ensure no diversions. In total 412 CS products are registered in all US sites (it should be noted that multiple sites are registered for the same products).
- The dept. has 17 members who oversee the DEA compliance functions and processes for Teva's registered facilities and maintain the relationship with the DEA agency. The majority of the DEA team members have a background in criminal justice.
- It should be noted that forming a full global function within Teva to oversee all CS activity is not feasible because of the various regulatory requirements in each country.
- The DEA dept. head reports to the SVP, Head of Regional Manufacturing Operations, who reports to the President and CEO of TGO.
- The organizational structure of the team is highly decentralized. The 17 team members are based in seven different locations.
- The team is responsible for DEA activities in 11 Pharma and R&D sites in the US.

- Every of the 11 sites has a dedicated DEA manager who belongs to the DEA dept. and is responsible for daily DEA activities at the sites (some are responsible for several small sites).
  Daily tasks include: maintaining daily interaction with the plant's functions, import/export related activities, DEA reporting and form submissions, SOP updates, destruction management, training sessions of other plants departments, maintenance of DEA files, maintenance of the relationship with local DEA agency offices, etc.

  There are also several support function members who are responsible for specific support function activities such as: Quota, Import/Export, Audits, Training, etc.

  The day to day management at the sites and the support function activities, were carefully observed during the Audit.

- Each of the 11 operational and R&D sites hold at least one the following registrations, granted by the DEA agency: Manufacturer, Distributor, Analytical, Importer, Exporter and Researcher.

- The DEA dept. maintains close external working interactions with DEA agency.
  Internal interactions are maintained with various Teva functions: Production, R&D, Supply Chain, Warehouses, QA/QC Security and Sales.

- During the years 2013-2015, the DEA agency has conducted 18 unannounced inspections at the Teva US sites. In 17 of them, there were no findings/observations.
  It should be noted that the DEA agency has the authority to act against non-complying sites in any action from issuing a "letter of admonition" up to withdrawal of the sites' registrations.

- The regulatory environment in which the DEA operates derives from the "Title 21 - Code of Federal Regulations, Part 1300 - End," which is adapted to Teva's guidelines. The guidelines cover the following aspects:
  - Purchases, Sales, and Transfers
  - Inspections
  - Import & Export
  - Security
  - Storage and Systems Maintenance
  - Receiving and Processing CS Samples
  - Receiving Pharmaceutical Product
  - Registrations, Records, and Reports
  - Storage of Records
  - Training
  - Destruction
  - Diversion Investigations
  - Access to CS Storage Areas and Facilities
  - Auditing
  - Suspicious Order Monitoring

- Each of the registries operational and R&D sites developed a set of SOPs to meet the above guidelines, in accordance to its specifications and needs.

Main Findings

General

The DEA department consists of experienced professionals.

The work processes are, in most cases, well organized and closely monitored.

Dept. personnel are aware of the nature of their role and perform it with appropriate attention to and awareness inherent in the handling of CSs, in accordance with regulatory requirements.

Other functions that deal with various aspects of CS, do so out of point awareness for the importance of correct handling of CS and good coordination with DEA functions.

The DEA department handles cross functions in a manner that enables reasonable control of DEA processes at the various sites.

Export / Import

Export / import processes are not smooth and they encounter many obstacles from various countries that delay the processes and that sometimes even result with the destruction of materials and violation of DEA regulations.

Some weak points that cause a disruption of the export / import processes were identified:

- It is difficult to identify Teva's international counterparts. Export/import activities are delayed because of the long time required to locate counterparts who will constitute owners and focal points for handling the regulatory requirements.
- There is limited knowledge globally when it comes to importing/exporting CSs to the US in or out of the respective countries. In countries of destination (for export from the US) and countries of origin (for import to the US), the knowledge required for performing these processes in accordance with the regulatory DEA requirements is limited.

Risk Management

In general, the overall theoretical risk of the DEA operation is in noncompliance with DEA requirements. This can lead to anything from issue a "letter of admonition" up to withdrawal of the sites' registrations.
DEA dept. has no organized overall risk management process and no centralized list of DEA risks.
The main risks of the DEA are handled in routine management processes, but there is no centralized Risk Management approach that includes systematic and comprehensive procedures for identification, assessment and mitigation of the associated risks.

Physical Security

DEA vs. Security: the roles for handling all physical security aspects of the CSs is in the hands of site facilities functions, but the responsibility for the proper performance of the security activities pertaining to the DEA ultimately lies with both entities - site facilities and DEA dept.
There is no guideline that fully identifies the shared work processes, defines the manner of the involvement required by both entities in the entire processes, interfaces required, the entities' authorities and areas of responsibility, work methods, etc.

Access to CS areas: In order to increase the control over the entries and activities of people in the CS areas, it has been decided that "there shall be always two authorized employees present when accessing the vault or cage areas". This guideline is not enforced through physical controls in Virginia and in SLC and in fact the entrance to the manufacturing vaults at these sites by only one authorized employee is possible.
This deficiency contributes to an additional risk - the entry of a person who is not authorized for CS areas. This risk exists in any event, if any authorized person enables his entry, but it is reduced if dependent upon the presence of two authorized employees to enable the entry.

Reports: There is no system of issuing basic reports and alerts in regard to anomalous entries of people to the CS areas.

KPIs

There is no overall systematic KPIs system that is regularly maintained by the DEA dept. Some isolated matrixes are measured, but with no subsequent process that leads to conclusions and means for improvement deriving therefrom.

Second Person Review project

In order to strengthen control and reduce the extent of errors in the various forms that are transmitted to the DEA, it has been decided that the documents sent to the DEA or those subject to inspection by DEA shall be checked by a second person. The goal of the project is to create and implement a monitoring process for a two-person review of DEA documents.
Obviously, double checking the data transmitted or presented to the DEA reduces the chances of errors, but in the absence of a consistent measurement of the performance of this activity, it is difficult to assess the success of the project with a volume reduction in erroneous documents.

Suspicious Order Monitoring (SOM)

In order to identify anomalous sales activity, an overall process of reviewing all sales orders is conducted by a dedicated system - "DefOps" - Defensible Operations. The Suspicious Order Monitoring process relates not only to Teva's direct customers, but also to secondary customers (customers of direct customers). DefOps sifts through Teva's approximately 10,000 monthly order lines and automatically releases approximately 95% of the orders that are within a customer's typical ordering pattern. The remaining 5% that did not pass initial sorting are manually checked and placed "on hold" until they are rechecked by trained team members of SOM, and their release are enabled (by approval of only one person). The review includes investigations into all order lines of interest as identified by the DefOps.

The manual testing process for the segment of suspicious orders and the release of approx. 5% of them is conducted by one person who has the authority to change the status of the orders from "hold" to "release". Granting exclusive authority to a single person to release a suspicious order constitutes a risk for mistakes, and it is advisable to operate a tighter control mechanism on the process.

Audits

Internal Audits of the DEA dept. are overall managed by a dedicated DEA Audit function, which was established in order to conduct onsite internal compliance audits of US Teva facilities that hold valid DEA registrations, ensure compliance with Federal regulations & company SOPs relevant to DEA compliance.
Although internal auditing activity has already been conducted for more than a year and a half, a significant portion of the processes are still insufficiently formulated.

Training

The Training Support function acts in a limited way and focuses mostly on arranging an annual session for all DEA members, which combines training with team building and social gathering.
Training sessions for DEA department staff are properly maintained on regular needs, but it is not falling under the responsibility of the Training Support function of the DEA.
Unlikely, the training cross program for other functions that keep regular interactions with the DEA dept. (Production, R&D, Supply Chain, Warehouses, QA/QC Security, Sales) is not well organized and performed on a need base and /or through a F2F method. Some weaknesses in the design of the training program for these functions were identified.

Additional observations, which also require management's attention, can be found in the detailed observations section of this report.

In conclusion, we appreciate the cooperation and courtesies extended to us and would like to thank the DEA team for their assistance during this review.

If you have any questions, or if we can be of further assistance, please do not hesitate to contact us.

Regards,

Itai Rigbi
Global Internal Audit
Senior Director, Global Head of Operations and R&D

Distribution

To: Carlo De Notaristefani
Karin Shanahan
Colleen McGinn

cc: Nir Baron

Detailed Report

A) Export / Import

Observations	Potential Risk(s)	Recommendations	Management Response/ Action Plan	Category	Due Date
Import/export processes are not smooth and they encounter many obstacles from various countries that delay the processes and sometimes even cause the destruction of materials. Below are several examples (it should be noted that the examples provided are mostly result of poor planning but having a regulatory contact would improve these situation): 1. **Product** - Effentora **Destination** - Denmark through France. **Delivery Due date** - 15.7.14 **Situation** - The product was shipped to France but Denmark never issued an import permit to France. **Destruction** - Yes 2. **Product** - Effentora **Destination** - Denmark through France. **Delivery Due date** - 2.9.14 **Situation** - The product was shipped to France but Denmark never issued an import permit to France. **Destruction** - Yes 3. **Product** - Effentora **Destination** - Denmark through France. **Delivery Due date** - 1.3.15 **Situation** - Product was delivered to France in March of 2015. The market blocked the shipment of the order due to a change in artwork. **Destruction** - Most likely to be destroyed in France.	Delay or destructions of import / export CSs, including all financial and image aspects involved therein.	1. Create a database of all international counterparts at Teva's sites that are responsible for Regulatory aspects of CS export / import from/to the US. 2. Issue a focused document of the "DEA Compliance Import/Export Guidelines." Examine issuance of the document in the language of the country for which it is intended and accompany it with a short presentation.	Agreed	Moderate	Q1-2016 Q4-2015

Observations	Potential Risk(s)	Recommendations	Management Response/ Action Plan	Category	Due Date
4. Product - Effentora **Destination** - Denmark through France. **Delivery Due date** - 10.6.15 **Situation** - Product was due to ship in June. DEA have made the product and still waiting for the import permit from France. **Destruction** - No. **5. Product** - Effen Bucca **Destination** - Japan (Taiho/ Teikoku). **Delivery Due date** - 1.5.15 **Situation** - Ordered 200mcg, 400mcg, 600mcg, 800mcg. Japan still has not issued import permits. They indicate that they will only import a portion of the order due to declining sales. DEA will destroy some of the product in SLC and will charge Taiho. **Destruction** – Partial will be destroyed in SLC. **6. Product** - Actiq **Destination** - Ireland **Delivery Due date** - 1.2.15 **Situation** - Order was due in February. DEA made the product, but was unable to ship until May due to delays in getting import permits in place. **Destruction** – No					

Observations	Potential Risk(s)	Recommendations	Management Response/ Action Plan	Category	Due Date
Some weak points that cause a disruption the import / export processes were identified: A. There is no available database to the DEA dept. of the people in each country responsible for the import/export issues. Import/export activities are delayed because of the long time required to locate Teva's international counterparts who will constitute owners and focal points for handling the regulatory requirements. Consequently, this causes complications of the processes. B. There is limited global knowledge in the respective countries when it comes to importing/exporting CSs to or from the US. In countries of destination (export from US) and countries of origin (import to US), the knowledge required for performing these processes in accordance with the DEA requirements is limited. This delays the import/export processes and sometimes could potentially cause the destruction of the CSs in the process. In an attempt to solve the problem, the import/export unit of the DEA dept. has issued a detailed document - entitled "DEA Compliance Import/Export Guidelines", which is serve as a tool for all importers and exporters of DEA CSs. The document includes definitions, list of requested forms, exporting, re-exporting and importing process flows, and contacts names within the DEA dept. The document was written with a good intension to fully cover all processes that relates to importers / exporters of DEA CSs. In fact it is loaded with details and cumbersome. Therefore, it makes it difficult for someone in the destinations countries, who normally not intended to deal exclusively with the subject, and it is written in a manner that does not serve the good objective for which it was created.					

B) Risk Management

Observations	Potential Risk(s)	Recommendations	Management Response/ Action Plan	Category	Due Date
The overall risk of the DEA operation is in non-compliance with DEA requirements. This can lead to anything from issuing "letter of admonition" up to withdrawal of the sites' registrations. Various risks (security, quota, suspicious monitoring, import/export and handling of documentations) are handled at differing levels of performance, but not in an overall, methodological and orderly way. There is no organized overall risk management process, no centralized and orderly list of DEA risks, and no orderly heat-map of the risks that the DEA department deals with. The main risks of the DEA are somehow handled in routine management processes, but there is no centralized Risk Management approach led by the DEA dept. that includes systematic and comprehensive procedures for identification, assessment and mitigation of the associated risks. Such an approach should be implemented through a systematic assessment of the potential severity and likelihood of the risks and creation of an overall risks heat-map for all DEA risks, as well as a separate heat map for each risk that should be detailed by sites.	Lack of overall vision of the risks and unfocused handling thereof, mistaken prioritization of the time and manner in which they should be handled.	3. Implement an overall systematic risk management approach of DEA processes at the plants (this should include methodological risk identification, systematic assessment of their potential severity and likelihood, create overall and site heat-maps of all DEA risks, define risk mitigations and risk control processes.	Agreed	High	Q4-2015

C) Physical Security

Observations	Potential Risk(s)	Recommendations	Management Response/ Action Plan	Category	Due Date
DEA Vs. Security: The roles for maintaining physical security aspects of the CSs is in the hands of site facilities functions, but obviously, the responsibility for the proper performance of the security activities pertaining to the DEA ultimately lies with both entities - site facilities and DEA dept. (in the case of DEA auditing that finds defects in security aspects, the comments will be also pointed to the DEA dept.). There is a variety of security processes between the entities (approval/rejection of initiatives and investments in security infrastructure, a definition of access processes for CS areas, conducting diversion investigations). At the sites in SLC and Virginia, the work interfaces between the security entities and the DEA are based upon professional courtesy between the entities. Security is one of the most significant risks in DEA activity, and it is not possible to ensure good cooperation between the parties based only on mutual respect and awareness by the parties of the importance of ensuring security for CS. It should be noted that DEA activity constitutes only a portion of all security activities at the sites. There is no guideline that fully identifies the shared work processes, defines the manner of the involvement required by both entities in the entire processes, the interfaces required, the entities' authorities and areas of responsibility, work methods, etc.	Incomplete coverage of the CSs physical security activities.	4. Create an overall guideline applicable to all DEA sites that will define the work relations between the DEA and security entities, the manner of the involvement required of both entities in every process, the interfaces required, the authorities and areas of responsibility of the entities, work methods, etc.	Agreed	Moderate	Q4-2015

Access to CS areas: In order to increase the control over the entry and activity of people in the domains of CS areas, it has been decided that entering and remaining shall be permitted only and solely to two authorized persons at one time. The Guideline entitled "Product Security Work-in-Process Controlled Substances and Listed Chemicals" (SOP 8326 dated 10.10.2014) is intended to ensure secure handling during storage, processing, packaging and distribution stages in accordance with the DEA regulations. The guideline determines in paragraph A1 that "There shall be always two authorized employees present when accessing the vault or cage areas." To enforce this guideline, a mechanism was developed in SLC whereby in order to enter such areas, the first authorized person must swipe a personal card and enter a PIN. The second authorized person must take the same actions and only then the access to the vault or cage will be possible. Finally, in order to open the vault, a key or number combination must be used. It was found that the guideline is not enforced in Virginia, through physical security control, and in fact there is a potential risk of one authorized employee to enter the manufacturing vault. In fact, swiping the card of one authorized employee combined with entering his PIN is sufficient to open the gate that will allow access to the vault or cage (in other CS areas, one can even make do with entering the PIN without swiping an authorized employee card beforehand). This deficiency contributes to an additional risk - the entry of a person who is not authorized for CS areas. This risk exists in any event, if any authorized person enables his entry, but it is reduced if dependent upon the presence of two authorized employees to enable the entry.	Entry to CS areas by one authorized person and increase the risk of entry by a person who is not authorized.	5. Physically enforce, in all CS areas of the facilities, the guideline, whereby entering and remaining in CS areas is permitted only and solely to two authorized persons at one time (e.g., two card readers).	Agreed		Q3-2016

Reports: There is no system of issuing reports and alerts in regard to anomalous entries of people to the confines of CS areas (for example, a mechanism that warns of entry by an employee during his vacation or at a time when he was not in the plant).	Uncontrolled entry into the CS areas.	6. Examine the possibility of issuing basic managerial reports regarding entries to CS areas by creating mechanisms for raising red flags of anomalous movements.	Agreed		Q4-2015

D) KPIs

Observations	Potential Risk(s)	Recommendations	Management Response/ Action Plan	Category	Due Date
There is no overall systematic KPI system that is regularly maintained by the DEA department. Some measurements are collected, but with no subsequent process that leads to conclusions and means for improvement deriving therefrom. The DEA dept. does not coordinate any form of DEA KPIs from the plants, and it has no overall quantified picture of the extent or quality of the activity which could support any decision-making processes. The absence of a global definition of DEA KPIs prevents the development of benchmarks for all the sites. Basic DEA KPIs that represent the volume of DEA work[1] compare with different resources variables[2] are not measured in an orderly and comparative way.	Difficulty in identifying trends that emerge (for example: increase in work load volume may have no effect on the number of DEA people). Lack of a KPI system creates a situation in which there is no incentive to improve DEA's performance.	7. Define and implement a set of DEA KPIs for periodic measurement of DEA performance at the sites and overall levels.	Agreed	Moderate	Q1-2016

[1] Such as: amount of shipments or products in the schedule or registrations segment, number of Suspicious Orders and breakdown of their delay times, number of 222 forms, amount of CS destructions, number of exports/imports
[2] Such as: the number of DEA people, storage capacity.

E) Second Person Review Project

Observations	Potential Risk(s)	Recommendations	Management Response/ Action Plan	Category	Due Date
In order to strengthen control measures and reduce the extent of errors in the various forms that are transmitted to the DEA, it has been decided that the documents sent to the DEA or those subject to inspection by DEA shall be checked by a second person. The goal of the project is to create and implement a monitoring process for a two-person review of DEA documents. This project is expected to be completed in November 2015. It includes identification of approximately 25 relevant documents and records (222 forms, Import/Export documents, ARCOS, Year End reporting), definitions of what should be checked by the second person and identifications of the second person or his position. Double checking the data transmitted or presented to the DEA reduces the chances of errors, but in the absence of a consistent measurement of the performance of this activity, it is difficult to assess the success of the Second Person Review Project with a reduction in erroneous documents. An additional measure for better control and consistent improvement in filling out the various forms can be reflected in measuring the "right the first time" of filling out the forms, i.e. what is the percentage of errors appearing in the initially filled out of the forms.	Weaken the quality of the documents sent or inspected by the DEA agency.	8. Implement a 'Right First Time' KPI for forms transmitted to DEA agency. For this purpose the KPI, processes required in order to enable its measurement, the manner of registering and documenting the events, and frequency & type of reporting should be defined.	Agreed	Moderate	Q4-2015

F) Suspicious Order Monitoring

Observations	Potential Risk(s)	Recommendations	Management Response/ Action Plan	Category	Due Date
In order to identify anomalous sales activity, an overall process of reviewing all sales orders is conducted by the "DefOps"[3]. The process is based on a variety of inputs from supportive tools, algorithms, criteria, BI, Oracle and Excel that are combined in the software. Suspicious Order Monitoring relates not only to Teva's direct customers, but also to secondary customers (customers of direct customers). DefOps sifts through approximately 10,000 monthly order line items and automatically releases approximately 95% of the orders that fit a customer's normal ordering pattern. The remaining 5% of the orders that did not pass initial sorting are manually checked and placed on hold until they will be rechecked by trained team members of SOM, and then the release is enabled. The review includes investigations into all order lines of interest as identified by the DefOps, when liaising with Teva customer Service and Sales departments regarding order lines of interest that need further customer clarifications. The SOM unit investigates approx. 15 customers a month. From a total share of delayed orders, only a small quantity are delayed for more than one day (approx. 25 orders a month), and during the last year, only 2 suspicious order reports were submitted to the DEA agency. The manual testing process for the segment of suspicious orders and the release of approximately 5% of them is conducted by one person who has the authority to change the status of the orders from "hold" to "release". Granting exclusive authority to a single person to release a suspicious order constitutes a risk for mistakes.	False Approval and release of suspicious sales orders.	9. Define and conduct a monthly review, to be performed by a second person, of the released orders. This process should be integrated into relevant SOM procedures 10. Additional people with the appropriate skills set need to be trained, and have the authority to release sales orders rejected by DefOps	Agreed	Moderate	Q4-2015

[3] DefOps - Deficiency Operations: a system which was self-developed and went live in March, 2015.

G) Audits

Observations	Potential Risk(s)	Recommendations	Management Response/ Action Plan	Category	Due Date
Internal Audits of the DEA dep. are overall managed by a dedicated DEA Audit function. The unit which was established in early 2014 in order to conduct onsite internal compliance audits of Teva facilities in the US that hold valid DEA registrations, ensure compliance with Federal regulations & company SOPs relevant to DEA compliance. During 2014, 14 audits were conducted and during 2015, 5 audits have been conducted. Although internal auditing activity has already been conducted for more than a year and a half, it was found that it is still in its premature steps, and that a significant portion of the processes are insufficiently formulated: - There is still no orderly check lists for each of the six registrations. - During the Audit, there was no final check list of the units' performance that has work relations with the DEA: Production, R&D, Supply Chain, Warehouses, QA/QC, Security and Sales. - The auditing methodology and all its stages of implementation are not fully formulated (for example: the manner of reviewing audit findings with senior management) - The audit activity is not supported by a computerized system - During the Audit, the SOP defining the DEA's internal auditing processes have not yet been finalized. - The monitoring process for implementation of recommendations has not been defined. - An escalation reporting process for major findings to the senior management level is not in place. - Establishing how to determine due dates for the various recommendations has not been defined. During the Audit, the Definition to determine scoring of findings was lacking.	Weak controls over compliance with regulatory requirements.	11. Enhance the Internal Audit Program with an emphasis on improving weak points identified in this report.	Agreed	Low	Q4-2015

H) Training

Observations	Potential Risk(s)	Recommendations	Management Response/ Action Plan	Category	Due Date
The Training Support function acts in a limited way and focuses mostly on arranging an annual session for all DEA members, which combines training with team building and social gathering. In fact, the Training Support function of the DEA is not a real cross function that is in charge of all DEA training aspects. Training sessions **for DEA department staff** are properly maintained on regular needs, but it does not fall under the responsibility of the Training Support function of the DEA. Unlikely, the training cross program for **other functions that keep regular interactions with the DEA department** (Production, R&D, Supply Chain, Warehouses, QA/QC Security and Sales) in topics such as new regulations and requirements, DefOps, SOM is not well organized and performed on a need base. There are some weaknesses in the design of the training program for these functions: - Determination of the topics and contents of the training sessions - Identifying target departments - Appointment of instructors - Schedule of the training program - Development of training tools and methods	Negatively impact the professional ability of personnel from units supporting DEA department.	12. Consider centralizing all DEA training under one Training Support function at DEA 13. Develop a methodological DEA cross training program for other functions that maintain regular interactions with the DEA. The process of developing the training program should include a proposal for training sessions for each site, required topics and curriculum of the training, target departments, appointment of instructors, schedule, training tools, etc. Proposal should be sent for approval by head of the DEA.	Agreed	Moderate	Q1-2016

I) Portal

Observations	Potential Risk(s)	Recommendations	Management Response/ Action Plan	Category	Due Date
The decentralized structure of the DEA dept. makes optimal communication between its members difficult. At present, sharing of documents and data is performed on a shared drive that is not intuitive and create difficulties in making quick cataloging and pinpointing of a range of work documents stored on it, such as: DEA regulatory requirements, Guidelines, SOPs, Inspection reports, Audit reports, Organizational announcements / notices, Forms library, Year End Reports, Destruction Records, Quota Reports, ARCOS Reports, Investigation Reports, various presentations, etc.	Difficulty in locating and retrieving work documents.	14. Centralize and categorize all DEA department documents in a portal team Room.	Agreed	Low	Q4-2015

Appendix A: **General GIA Definitions of Report Ratings and Risk Rankings**

Definitions of Report Ratings	
	**Effective** ▪ Control environment and business practices for the areas reviewed are in line with company requirements and standards and provide reasonable assurance regarding the safeguarding of assets, reliability of financial records and compliance with company policies and procedures. ▪ Controls provide reasonable assurance regarding the safeguarding of assets, reliability of financial records and compliance with laws, regulations and company policies.
	**Effective with Opportunities for Enhancement** ▪ Overall control environment and business practices for the areas reviewed are in line with company requirements and standards and provide reasonable assurance regarding the safeguarding of assets, reliability of financial records and compliance with laws, regulations and company policies. ▪ Isolated control deficiencies were identified which neither individually nor collectively compromise the control environment, however remediation is necessary to better align with company requirements and standards.
	**Requires Improvement** ▪ There are control systems in place for processes under review; however, control deficiencies, including noncompliance with laws, regulations, and company policies, were identified that require prompt remediation in order for the control environment to be in line with company requirements and standards and/or acceptable overall level of control system effectiveness. ▪ Either individually and/or collectively these control deficiencies may compromise the control environment.
	**Requires Significant Improvement** ▪ Although controls and business practices exist, major weaknesses have been identified which could lead to deterioration of the control environment which require immediate remediation. ▪ These ineffective controls could result in significant exposure to the business unit and at the global organization level. ▪ Significant issues identified that are material at the local or regional level.
	**Unsatisfactory** ▪ The control environment and business practices are deficient. ▪ Significant observations of non-compliance exist including non-compliance with laws, regulations, and company policies (i.e. FCPA, Anti-Corruption, etc. ▪ Immediate remediation is required by management (including oversight and monitoring) to mitigate business and legal risks to achieve an acceptable overall level of control system effectiveness. ▪ Significant issues identified that are material and have opportunity to have impact at the global organization level.

Special Note: A rating of "Requires Significant Improvement" or "Unsatisfactory" will require a follow-up compliance audit within six to twelve months.

Category	Definition of Risk Rankings
Critical	This is a serious internal control or risk management issue that if not mitigated, may, with a high degree of certainty, lead to substantial losses at global level, possibly in conjunction with other weaknesses in the control framework or the organizational entity or process being audited. As a critical risk issue, immediate management attention is required. The finding is reported to the Audit Committee quarterly.
High	This is a serious internal control or risk management issue that if not mitigated, may, with a high degree of certainty, lead to: ▪ Substantial losses (at Local level), possibly in conjunction with other weaknesses in the control framework or the organizational entity or process being audited. ▪ Serious violation of corporate strategies, policies, or values. ▪ Serious reputation damage, such as negative publicity in national or international media. ▪ Significant adverse regulatory impact, such as loss of operating licenses or material fines. As a high risk issue, immediate management attention is required. The finding is reported to the Audit Committee quarterly.
Moderate	This is an internal control or risk management issue that could lead to: ▪ Financial losses (stipulate levels). ▪ Loss of controls within the organizational entity or process being audited. ▪ Reputation damage, such as negative publicity in local or regional media. ▪ Adverse regulatory impact, such as public sanctions or immaterial fines. As a moderate risk issue, timely management attention is warranted. This finding should be reported to the Audit Committee as necessary.
Low	This is an internal control or risk management issue, the solution to which may lead to improvement in the quality and/or efficiency of the organizational entity or process being audited. Risks are limited. As a low risk issue, routine management attention is warranted.
Other Matters	▪ Finding already identified to/by management, reported correctly and appropriate corrective action in progress. ▪ Finding likely to be efficiency issues or missed opportunities. ▪ Finding recommended for implementation with some management discretion allowed.