Simmons, William DEA Compliance Auditor

2014 Year-End Review

Organization: DEA Materials (Tom Napoli (21601))

Location: Parsippany, NJ Jan 1, 2014 - Dec 31, 2014

Manager: Tom Napoli (21601) Evaluated By: Tom Napoli (21601)

Overall Comments

Manager Overall Evaluation

Calculated Rating: 3.41

Rating: 3 Meets Expectations

Comment: Will is a dedicated and action oriented individual. During 2014, Will made significant

contribution to the team and organization through his efforts in support of several projects, key among them the Know Your Customer/SOM and Site Compliance initiatives, within a fast paced, dynamic, and challenging environment. During the year, Will took steps to continue of his developmental path and demonstrated a commitment to ensuring

compliance throughout the organization, Will is a focused individual who can be counted on to follow-through and work independently on assignments. Now that Will has his bearings and has built a foundation in regards to his role within the organization, I would like him to take on a stretch goal that fosters creativity and innovation, take an existing process such as SOM and re-invent the model. Manage the process from concept to fruition. I have also seen Will progress in the development of stronger relationships within the team and I feel that it is important to stay on this track. An important part of leadership development is the ability to connect with people and to display a sense of concern and empathy. Overall, Will

was a real asset in 2014, taking on significant projects, displaying real drive and commitment. Will should be pleased with his accomplishments this year and I am appreciative of his efforts and confident that 2015 will bring greater opportunities for

development and success.

Employee Overall Evaluation

Calculated Rating: 0

Rating: Comment:

Key Goals and Responsibilities

Compliance Projects/Activities Support

Compliance Projects/Activities Support

- 8. Support and execute compliance activities in support of business wide Diversion Prevention Campaign
- a. Provide selected program individuals understanding of Auditor Investigator and relation between manufacturing sites and end user as well as required compliance activities
- 9. Identify resources and key personnel to create a more comprehensive SOMS program to include leverage marketing personnel and chargeback data.
- a. Work with coworkers to develop a collaborative team approach to analyzing customer usage information in conjunction with marketing and chargeback data.
- 10. Develop relationships with all company Directors of National Accounts for the purpose of providing leverage in terms of customer communications.

Due Date: Dec 31, 2014 Status: On Track Completion Date:

Company Goal: Deploy capital to drive the continued expansion of our commercial, portfolio and technology

Supports: capabilities through strategic mergers, acquisitions and business development initiatives that deliver growth

PLAINTIFFS TRIAL EXHIBIT P-23046_00001

multiples that complement our investment in sustainable organic growth

Weight: 20

Notes:

Manager Evaluation

Rating: 3 Meets Expectations

In support of Departmental and Organizational CS compliance projects and activities, Will provided valuable contribution. Through his participation in the company-wide diversion prevention program "It Starts With Me", Will has been able to raise the level of awareness among the workforce connecting with them via educational events, During these events and various interactions at the operating sites, Will has provided a holistic view of the issues and articulated how we, as a work force and members of society can can play a role in prevention. In support of the Puerto Rico CS product transfer initiative, Will provided support by working collaboratively with our team as well as site stakeholders in the development of site operating procedures. Taking the initiative to seek out others within various functional areas, Will has been able to enhance our efforts to understand cs product ordering behavior from a holistic perspective and he has also made efforts to educate other team members on the "Know Your Customer" Process.

Employee Evaluation

Rating:

|Through meetings with both site personnel (DEA Compliance and other departments), there has been an enhanced understanding of the DEA Auditor role and the role of all departments have in compliance from the product lifecycle (cradle to grave). Each training session (discussed previously) has focused on the company's Diversion Prevention Campaign with more detailed discussion and interactions with the respective site champions.

Assistance was provided on an as-needed basis to Puerto Rico locations in terms of policy creation, development, and implementation as it relates to controlled substance compliance and auditing activities.

Collaborations with internal personnel have opened the door for the use of Chargeback data and marketing information as it relates to the sale/usage of controlled substance. This has provided more insight into the downstream process of controlled substance ordering but also has provided a better "whole picture" understanding of ordering behavior.

Relations with customer service personnel have been created to allow for a monthly (or more frequent) report of top customers to include buying groups and contract additions/ subtractions.

Groundwork has been laid to start a collaborative relationship with coworkers as it relates to customer order usage.

Know Your Customer/Suspicious Order Monitoring

Know Your Customer/Suspicious Order Monitoring

- 1. Execute a desktop and "in person" review/meeting of controlled substances customers to ensure compliance with due diligence and "Know Your Customer" initiatives as required by DEA and corporate regulations.
- a. Track customer communication and meetings to provide "real time" customer status in terms of compliance with Actavis "Know Your Customer" initiative.
- b. Conduct in person reviews and audits with top customers to gain perspective of their respective Suspicious Order Monitoring systems and due diligence practices.
- c. Perform monthly review on NLT 10% of current customers to ensure order practices/history/behaviors are within compliant terms according to previously provided documentation.
- d. Ensure applicable DEA paperwork filed within 1 business day of investigation completion
- 2. Streamline Suspicious Order Monitoring system to allow for more in-depth review of suspicious orders and/or vetting processes.
- b. Aid in creation/use of digital signing technology to allow for auditable SOMS forms in the releasing of all orders
- c. Implement statistically based system SOM system to increase investigative capabilities

Due Date: Dec 31, 2014 Status: Completed Completion Date: Jan 31, 2015

Company Goal: Ensure continued focus on organic growth through maximization of our research and

development expertise

Weight: 25

Supports:

Manager Evaluation

Rating: 4 Exceeds Expectations

In support of our "Know Your Customer" and Suspicious Order Monitoring Program, Will has made significant contribution to the enhancement and transformation of the established program. Through out 2014, as Will became better acclimated to his role and responsibilities in relations to the SOM program, he took the initiative to seize various opportunities to take this important program to the next level. Will accomplished this goal by seeking out educational opportunities, networking with industry peers and meeting with internal stakeholders. Through a greater understanding of the regulatory requirements, and the identification of internal resources, Will was able to leverage new avenues for release for Orders of Interest have been approximately 24 obtaining information that provides a more thorough picture of customer ordering behavior. Will was bale to translate this information into a meaningful process which resulted in a more efficient process reducing time spent on order investigation. This improvement had a significant impact on turnaround time for the release of orders, increasing customer satisfaction without sacrificing compliance. Also during 2014, Will embarked on an aggressive travel campaign focused on meeting our top customers and performing compliance audits. In addition to these efforts, Will has provided contribution to SOM aspect of Project "AIM". Will approached this goal with energy, often working independently. Will demonstrated ownership of this critical function and was focused on protecting the best interest of the Company by mitigating risk.

Employee Evaluation

Rating:

- Within the KYC initiative, we have achieved a 95% completion of all our top 20 customers with only 1 customer outstanding visit cheduled). As a whole, we have a 89% completion of all customers with the outstanding customers contacted. Of the outstanding customers, their make-up is small scale veterinary supply stores. In terms of top 20 customers, we have performed in person visits with 6 and have coordinated with an additional 4 via teleconference.
- In terms of SOMS, all orders have been released well within the 12 hour goal window (excluding those pending additional justification from the customer). Month over month average minute turnaround (from the time of notification to DEA Affairs). Additionally, each order is tracked by DEA Affairs with customer responses/information being documented thus allowing for a better historical review. Digital signatures have also been created in conjunction with the order tracking which provides a more "real-time" documentation of any correspondence with the customer. Finally, towards the end of 2014; progress has been made in the implementation of a "cloud" based statistical system for SOMS management.

North Brunswick Compliance Activities

North Brunswick Compliance Activities

- 11. Identify/remediate any discrepancies with North Brunswick controlled substance policies and procedures.
- a. Provide "DEA 101" and "DEA Inspection Preparedness" training to all personnel responsible for handling controlled substances.
- b. Assist site management with the identification of procedural gaps and potential process improvements.

Due Date: Dec 31, 2014 Status: Completion Date: Dec 17, 2014 Completed

Company Goal: Emphasize operational excellence and cost control across our global manufacturing and Supports:

distribution network

Weight: 15

Notes:

Manager Evaluation

3 Meets Expectations

During 2014, Will developed a strong rapport with the North Brunswick Research and Development team, establishing himself as their compliance resource and subject matter expert. At several points throughout the year, the site had

Employee Evaluation

Rating:

Through multiple visits with the NB site, potential compliance issues have been discovered and resolved. DEA 101 and DEA Inspection Preparedness training was provided in addition to POA training.

experienced some compliance challenges that Will has happy to help them navigate through. In addition to remediating any issues, Will provided awareness training, assisted with the enhancement of local policies and practices, enhancing overall compliance. Will also serves as a compliance adviser, guiding the team and ensuring that record keeping and compliance obligations are met. By seizing this initiative to connect and maintain an ongoing dialogue with the NB team, Will has really demonstrated a strong sense customer focus and commitment.

While working with management, a new controlled substance compliance structure was identified and has been implemented.

Personal/Professional Development

Personal/Professional Development

- 12. Attend at least one (1) externally provided seminar to increase controlled substance regulation/compliance knowledge.
- 13. Gain a better insight into the Quota process in terms of request, approval, and utilization.

Due Date: Completion Date: Status: Dec 31, 2014 Completed

Company Goal: Deploy capital to drive the continued expansion of our commercial, portfolio and technology

capabilities through strategic mergers, acquisitions and business development initiatives that deliver growth Supports:

multiples that complement our investment in sustainable organic growth

Weight: 10

Notes:

Manager Evaluation

Rating: 3 Meets Expectations

Throughout 2014, Will has taken the initiative to seek out learning opportunities, both internally and externally in an effort to sharpen his auditing skill set. Will has attended industry sponsored events as well as participating on internal with learning experiences regarding Elizabeth and Corona audits with compliance consultants. Will has also worked with quota issues. Bill throughout the year to gain insight into the quota process. I encourage Will to continue to seize opportunities within and outside of the department to enhance is business acumen and organizational savvy.

Employee Evaluation

Rating:

Attended Jeiven Pharmaceutical Consulting training. Through working with Bill, I have gained insight into the Quota process beyond the basics. This was complimented

Site Support

Site Support

- 3. Identify and close gaps at U.S. Sites on Controlled Substances issues and ensure compliance to all governing regulations.
- a. Complete audit/remediation activities at Edison and Elizabeth facilities
- b. Create/implement site policies to ensure preparedness and compliance for all future inspections
- c. Perform "spot check" audits of Edison and Elizabeth facilities to ensure adherence with aforementioned policies and remediation actions.
- 4. Conduct collaborative audits of all U.S. based sites (FL, SLC, NJ, IL)
- a. Participate in after action review of inspection and aid in development/drafting of any required action items
- b. Provide hands on training for all site locations in terms of DEA Inspection Audit teams
- c. Provide management and all applicable parties "DEA 101 Training" as needed
- 5. Complete all investigative findings on as needed basis for any loss/thefts within U.S.
- 6. Develop and draft a comprehensive inspection plan policy to be provided to the sites detailing actions and requirements

for the completion of a DEA registration inspection.

7. Assist the Puerto Rico locations in terms of policy creation, development, and implementation as it relates to controlled substance compliance and auditing activities.

Due Date: Dec 31, 2014 Status: Completion Date: On Track

Company Goal: Deploy capital to drive the continued expansion of our commercial, portfolio and technology Supports:

capabilities through strategic mergers, acquisitions and business development initiatives that deliver growth

multiples that complement our investment in sustainable organic growth

30 Weight:

Notes:

Manager Evaluation

Rating: 4 Exceeds Expectations

During 2104, the Edison Manufacturing facility experienced a Each (active) manufacturing site within the US was audited regulatory challenge as a result of record keeping deficiencies identified during a cyclical audit. As part of an initial response team, Will played significant role in the identification of problems and the corrective actions necessary to remediate. Will put many hours in at the Edison been moving forward with an additional audit (performed Q4) facility, supporting the local team, assisting in the reinventory process and identification of root cause. Based on his previous work experience within manufacturing at the ELZ/EDN site, Will did a very effective job as he had established relationships with the site stakeholders and a thorough knowledge of the operations & procedures. Will remained very focused throughout the entire process and kept a focus on correcting all the issues in a timely manner. Upon establishment of the CAPA, Will played a key role in ensuring that the actions were completed in a timely manner. During this challenging period, Will demonstrated poise, leadership, and commitment.

In addition to his efforts and contributions relative to the Edison compliance event, Will also put a significant effort forth in support of our established compliance plan, With a primary focus on record keeping and accountability, Will participated as a key member of a core audit team dedicated to ensuring compliance across the network. Will took the lead on the manufacturing site audits, drafting subsequent reports, developing CAPA's and collaborating with site stakeholders to enhance their respective compliance posture. In addition to these efforts, Will also participated in the site wide roll-out of DEA 101 and Inspection Preparedness Training that was delivered in-person across our domestic network. Will also contributed to the development of the corporate inspection policy which will be effective in Q1. Will did a great job in support of our site compliance efforts and has truly made a difference. I am appreciative of his efforts.

Employee Evaluation

Rating:

during 2014 with comprehensive reports being drafted for management. Items found during audits had CAPA plans drafted (as needed) and were tracked on a monthly basis. Remediation activities at Edison and Elizabeth facilities have finding serious discrepancies which are currently being addressed. Spot checks have been performed at both sites multiple times per month. Coordination with the respective sites generated the drafting and/or editing of SOPS/Forms/ Checklists to aid in controlled substance compliance. Inspections at the North Brunswick facility identified discrepancies that were immediately addressed thus preventing a state of non-compliance. All US sites were provided hands-on "DEA 101 Training" and "DEA Inspection Preparedness Training". All DEA 106s were filed within 24 hours upon gaining all required information.

A draft inspection policy has been created and is pending approval and site "buy-in" before being made official.

Section Summary

Manager Evaluation

Employee Evaluation

Rating: 4 Exceeds Expectations Rating:

Our Winning Way

How did you demonstrate Our Winning Way (Challenge, Connect, Commit) in achieving your Key Goals and Responsibilities?

Manager Evaluation

Rating: 3 Meets Expectations

During 2014, Will has demonstrated "Our Winning Way" competencies in the successful achievement of his goals. In support of the Know Your Customer and SOM programs, Will came up with new ideas to achieve greater overall compliance and efficiency. Will's connection and development of a rapport with the North Brunswick team exhibited a strong sense of customer focus, enhanced compliance and gained trust and respect. In support of the the Edison compliance effort, Will demonstrated his drive for results and commitment in his efforts to protect the best interest of the Company.

Employee Evaluation

Rating:

I believe 2014 provided me multiple instances to demonstrate the Winning Way of challenge, connect, commit.

The year started with great progress on the KYC customer program with visits to top customers and a better understanding of their controlled substance compliance programs. While the list of customers is large, through a systematic approach we were able to break them down into manageable amounts and move through them. The DEA inspection at the Edison facility provided without a doubt one of the most challenging times of 2014 however instead of simply backing down, tremendous efforts were made to bring the site into compliance while also proactively connecting with all other sites (nationwide) to ensure that no similar instances occurred. It was challenging to balance site inspections, customer inspections, KYC information gathering, and corrective actions but we were able to persevere and complete audits of each site, multiple customers, and see the completion of almost all possible 2014 capa activities. Even as the year started to close, the commitment to compliance helped identify additional issues at sites that were able to be stopped before coming compliance issues.

The results are that we have almost completely closed out our KYC files and have established (connected) with the sites on a new level in terms of compliance inspections and audits. Customer relationships in terms of DEA Compliance are at a new level with a much more proactive approach and issues identified both internally and externally have action plans and a detailed "path forward".

Section Summary

Manager Evaluation

Employee Evaluation

Rating:

3 Meets Expectations

Rating:

Development Priorities

Compliance

Status: In Progress Supports: DEA Compliance Auditor

Further knowledge of Controlled Substance Compliance

Status: In Progress Supports: DEA Compliance Auditor

Personal Connections

Status: In Progress Supports: Connect: I Communicate

Section Summary

Manager Evaluation

Employee Evaluation

Within Will's role it is important for him to continue to build upon his controlled substance compliance knowledge as well as to further develop relationships both within the organization as well as with our customer base. I feel that by interacting more with various functional area team members, such as sales/marketing, he can continue to develop his business acumen and organizational savvy, which will aid him as he develops within his current role and beyond.