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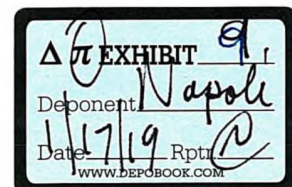
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DEA Affairs
Organizational
Achievements
Thomas Napoli, CPP
Manager, Security & DEA Affairs



What We Do

Ensure that our facilities operate in a manner that guards against theft and diversion of controlled substances by maintaining effective controls and procedures

- Reporting & Recordkeeping
- Operational & Physical Security Controls
- Procedural development



What We Do (Continued)

Ensure the uninterrupted flow of controlled substance materials to meet the needs of the operation and customers

- Quota facilitation
- Import/Export

Continually monitor the regulatory landscape and proactively anticipate needs

- Emerging trends
- Changes in regulatory requirements



Site Compliance Posture

Excellent 2010 Inspection History

- Gurnee DC
 - Cyclical Audit of Export & Distributor Registrations
 - No findings or observations
- Salt lake City
 - Cyclical Audit of all Registrations
 - One observation (remediated)
 - Pleased with overall program & established controls
- Florida
 - Cyclical Audit of Five Registrations
 - No findings or observations



Operational Security Programs



Establish & Maintain Effective Controls

- Designed to guard against theft & diversion throughout the product lifecycle
 - Designated Observer
 - Establishes employee accountability
 - Implemented in Corona 2010
 - Pocketless Uniform Initiative
 - Removes opportunity
 - Project completion Q1 2011(Corona)
 - CS Physical Protection Program
 - Holistic approach
 - Layered & balanced



Awareness & Training

- Increase the effectiveness of Security Program
- Effectively Deliver our message
- Senior Leadership Support
- Take into account our business objectives and ensure that they are met in a secure manner



Awareness & Training

- Phase I
 - “Zero Tolerance” Culture
 - Developed and delivered theft awareness training to management at all C/S manufacturing sites (400 employees)
 - Visual aid campaign promoting:
 - Compliant behaviors
 - Compliance/Ethics hotline “See something/Say something”
- Phase II
 - Engage the employees
 - What is expected of them
 - Re-enforce work behaviors
 - Video based & live Training



Suspicious Order Monitoring



- Evaluation & Enhancement
 - Effective relationship with Internal Customers
 - Sales & Marketing
 - Customer Relations
 - Increased Security Visibility
 - Order of Interest Review
 - Investigation
 - Communication w/customers
 - Systemic Upgrade
 - Enhance system logic
 - Increase efficiency



Site Subject Matter Expert

Position of local ownership/accountability

Ensuring:

- Each registered location maintains continual compliance, record keeping/reporting functions (ARCOS, Inventory, YER)
- Serve as the coordinator and facilitator of controlled substance related regulatory inspections
- liaison with Corporate DEA Affairs, regional DEA field office, as well as state and local regulatory agencies



Quota Facilitation



- Enhancements
 - Automated Compliance Reporting (JDE)
 - Quota Summary Report
- Collaboration with Stakeholders
 - Timely & Statistically Defensible requests
 - Uninterrupted supply of API to meet business needs
- Policy Development
 - Define roles & Responsibilities
 - Establish clear processes for product development and commercialization



2011 Goals & Objectives

- Corporate Compliance Strategy
 - Documented Policy
 - Establish consistent position with DEA
 - Define roles & responsibilities
 - Sharing of best practices
 - Liaison with regulators & industry peers



2011 Goals & Objectives (cont.)

- Training & Awareness
 - Establish formal program
 - Designed to communicate security message
 - Change behavior
 - Ensure accountability
 - Motivate employees to participate
 - On-going process
 - Continuous cycle
 - “Security & Compliance Week”



2011 Goals & Objectives (cont.)



- SOM's
 - Improve the system
 - Enhanced automation
 - Enhance investigation process
 - Procedure
 - Cross-training



2011 Goals & Objectives (cont.)



- Quota Facilitation
 - Continue to execute with excellence
 - Identify areas to continually improve communication
 - Steering Committee
 - Site participation



2011 Goals & Objectives (cont.)

- CS Lifecycle Protection Plan
 - Holistic Approach
 - Presented to Sr./Site Mgmt
 - Implemented as a multi-layer/balanced approach
 - Procedural
 - Physical
 - Technology
 - Core Elements
 - Designated Observer
 - Pocketless Uniforms
 - Physical Security Controls within Manufacturing



2011 Goals & Objectives (cont.)



- Emerging Markets
 - Import/Export Opportunities
 - Leverage Staff
 - Identify Challenges
 - Establish rapport with International Competent Authorities
 - Monitor the landscape

