

Working With the Sales Operation

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Sunovion Pharmaceuticals Inc.

US Subsidiary of Sumitomo Dainippon Pharma, a multi-billion top 10 Japanese pharmaceutical company based in Tokyo

Headquartered in Marlborough, MA

(Offices also located in Fort Lee, NJ; Mississauga, Ontario, Canada; and London, England)

More than 1,500 employees – approximately 800 in field sales

Eight commercialized products in United States

Therapeutic areas of focus: psychiatry, neurology and respiratory

2014 revenues: Approximately \$1.5 Billion

Sunovion's Corporate Compliance & Ethics Organization

Vision:

To create a culture of compliance and integrity at Sunovion through the establishment of a best-in-class corporate compliance and ethics program.

Strategies:

- Strike the right balance between a rules-based and values-based compliance program, focused on emerging areas of compliance
- Tone From the Top, Tone From the Middle
- Greater ownership and accountability for compliance outside of department
- Ensure that an environment exists where employees are comfortable raising issues without fear of retaliation
- Work to coordinate compliance across the company incrementally

Partnering with the Sales & Marketing Organization

A Business Partner Approach

- Compliance Rotation Program
- The 'Tone from the Middle' Program
- Compliance Liaison Board
- The CCO and CCO Road Show
- 'Baking' compliance into sales training
- Compliance awareness campaigns



Trust, but Verify

Compliance Monitoring

- Risk assessment and mitigation programs by brand
- Internal and external monitors
- Compliance 'ride-alongs'
- Cheat sheets, checklists and self-certifications
- Manager assessment tools

Compliance Investigations

- Involvement of sales in the Compliance Investigations Committee (CIC)

Follow the Money

‘Principles & Performance’

- Corporate Objectives include forecast attainment in ... *“full compliance with company policies and the Code of Conduct and Ethics”*.
- Compliance approval of the formal Incentive Compensation Program (ICP).
- Sales contests require winners to be ‘in good standing’ with the company.
- Sales representatives and their managers can have bonuses withheld or reduced for misconduct.

Working With the Sales Operation

Darrell Coleman, VP, Chief Compliance Officer
Dyncorp International



Managing An International Marketing Team

In today's global economy, increasing numbers of companies are entering the international marketplace. For many companies, the role played by the compliance officer will ultimately determine the success of the firm. Whereas all compliance officers plan, implement, and control activities, these areas of responsibility become far more complex in the global arena.

In some cases that pursuit may be in developing nations and, in some cases, directly with various governments, government agencies, and government-owned or controlled enterprises.

Additionally, many of the potential buyers may be deemed to be government officials pursuant to applicable local laws and/or the U.S. Foreign Corrupt Practices Act.

Definition of an Agent

“A person authorized by another (principal) to act for or in place of him [or her]”

“A business representative, whose function is to bring about, modify, affect, accept performance of, or terminate contractual obligations between principal and third persons”

Black’s Law Dictionary, Sixth Edition

“one who is authorized to act for or in the place of another”

“a business representative”

Merriam-Webster



Before retaining or working with an agent, be smart: first exercise "due diligence" by conducting a thorough background check of the agent's identity, methods of doing business, and conduct. If there are any "red flags," you must be especially thorough. Also, get all agreements with your agent in writing and have them reviewed by Company legal counsel.

Foreign Country Reps or Agents

Many companies are attempting to make strategic thrusts into the international market place to meet their growth objectives.

The anticipated increase in a international business portfolio will require that companies expand the use of local national citizens as business partners and representatives to assist in understanding the local customs and business practices.

These agents will assist in identifying business opportunities, in-country business partners and enhance your probability of success in your pursuits.

Pros:

- Local knowledge/connection
- Cost efficient
- Multiply resources and save travel costs
- Professional/social relationships established

Cons:

- Communication
- Control
- Local influences
- Transparency/Visibility

Managing Agents

Management process: Must be in place to control marketing content, determine compensation, set communication controls and for approval of ALL CHANGES once agreement is in force.

- Executives managing agents must be schooled in and understand FCPA rules
- Avoid agents with sub-agents
- In-depth professional due diligence is essential
- A strong written agreement is essential
- FCPA must be discussed with agent and agent must sign off
- Frequent management communications with agent and periodic summary reporting from agent, to demonstrate level of effort consistent with compensation
- Payments must be reasonable and consistent with local norms

Flat Fees: Must be paid on a weekly, monthly, or quarterly basis *prior to a sale* and *continue after a sale* – not just as a result of a sale (otherwise it will be considered a contingent fee or commission).

- Year-to-year performance must show results

What you don't know CAN hurt you!

- It is incumbent on you, as the compliance leader in your company, to manage your international marketing team as if they are all in the office.
- Training
 - ITAR
 - EAR
 - FCPA
 - Global anti-corruption
- Auditing expense reports
- Monitoring contacts with foreign persons & governments



Out of sight does not mean out of mind!

Gifts and Entertainment

- In general, anything other than a nominal gift to a government official is prohibited.
 - Regardless of the value, employees who wish to offer gifts, entertainment, or travel to a government official must receive pre-approval from the CCO or director of trade compliance prior to offering or incurring the expense.
- Your CCO or GC should determine whether the proposed gift, entertainment, or travel is permissible under U.S. laws, the local laws applicable to the government official, and any applicable policies.
- All expenses incurred by employees in connection with any gifts, entertainment, or travel provided to a government official must be well documented and supported by legible and legitimately issued receipts, etc.
- All such expenses must be reported to the CCO or GC in addition to being submitted for reimbursement (if permitted) through the accounting department.

Under no circumstances should employees even consider using personal funds to pay for gifts, entertainment or travel to a government official and not submitting such expenses for reimbursement.

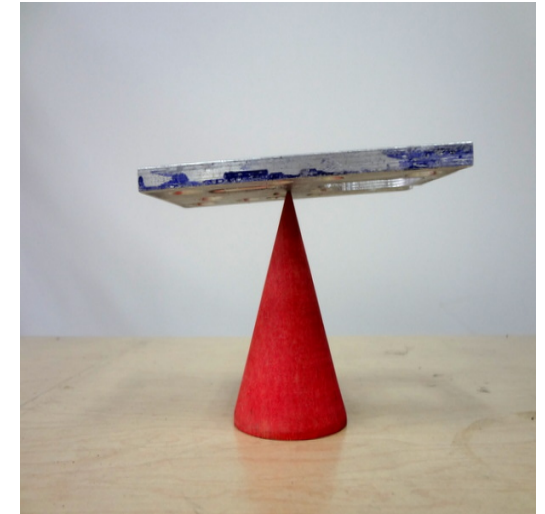
Balancing Act!

Outcome control

'...no matter how you work, the only thing that counts is achieving objectives'

Activity/Behavior Control

'...no matter the objective, the only thing that counts is how you work'



Navigating the labyrinth of compliance is difficult for many companies regardless of their size. Those who fail to be vigilant may face hefty fines and criminal charges as well as see their businesses fail.

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Agfa Corp.



Background Issues

- Today's marketplace demands increased
 - Oversight
 - Transparency
 - Engagement
- Some traditional compliance work focuses on sales in responsive way
- Sales vs. compliance = tensions
- Proper view: Sales has keen access to info about risk

Risk Topics for Sales

Define risk broadly, consistent with ERM:

- Behavioral: antitrust issues, etc.
- Corruption
- Customer credit risk
- Supply chain risk
- Expense reporting

**** Risk assessments will NOT prevent
the next big failure**

Define 'Risk Assessment'

Risk assessment = systematic process for identifying and evaluating adverse events

- **Risk:** probability that an event will occur and adversely affect achievement of objectives
- Internal vs. external; material vs. immaterial
- Need to view risk across the sales cycle: from prospect to sale to post-sale obligations
- Need for clear policies
- Focus on gaps between policies and behavior

Challenges vs. Value

Understand the Challenges – and focus on the *value propositions*:

- Sales understands the marketplace and customers
- Sales touches customers
- Sales has to understand external and internal challenges
- Sales is the link to the field

Ideas for Engaging Sales in R/A

1. Start with business planning and budgeting
 - Include compliance in annual objectives
 - Use budgeting process as discussion opportunity with sales leaders
2. Compliance leaders review annual business plans
 - Identify certain risks, customer issues
3. Compliance = elements of individual goals for sales leaders
 - e.g., fully-trained employees

Ideas for Engaging Sales in R/A

4. As part of annual planning process, include compliance topics and specific issues; develop action plans for risk avoidance or minimization
 - Rally around mission and corporate goals
 - Operations in risky regions
 - Avoid repeating prior infractions or risky behavior
 - Encourage risk discussion among leaders

Ideas for Engaging Sales in R/A

5. Spend time with the sales organization:
 - Live facilitated workshops
 - Live interviews
 - Ride-alongs: see what they see
 - Site visits, attend business meetings
 - Focus on policies and protocols that are missing, map sales process, typical operations

6. Identify compliance leaders within sales
 - Act as resource, may facilitate self-assessments
 - Help identify policy and training needs

Ideas for Engaging Sales in R/A

7. Encourage (or mandate) self-assessments
 - Segment level, site-specific, etc.
8. Annual surveys
 - Make responding easy but mandatory
 - Include comment opportunities
9. Monitor electronic communications
 - Check policies, authorization reqs.
10. Include compliance topics in annual reviews
11. Train at the sales kick-off meeting and before trade shows