

# Maintaining an Effective Compliance Program

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**COMPLIANCE WEEK 2012**

## *Maintaining an Effective Compliance Program*

### **Maxwell Technologies Inc. (NASDAQ: MXWL)**

- Revenue: 2011 - \$157M; 2010 - \$122M (customers in 40+ countries)
- 400 employees located in five offices: San Diego (corporate office), Switzerland, Britain, Germany and China

#### **Products:**

- Radiation harden space electronics
- High-voltage capacitors
- Ultra-capacitors (energy/electrical storage & delivery product/device)

## *Maintaining an Effective Compliance Program*

### **Compliance Issue:**

- 2009 investigated 3<sup>rd</sup> party sales agent in China for our Swiss-based subsidiary
- January 2011 reached DPA totaling \$14.4M and three-year self-monitoring requirement

### **Responsibilities:**

- Oversee the self-monitoring requirements of the DPA.

### **Staff:**

- Assistance by outside consultants.

## ***Maintaining an Effective Compliance Program***

### **Focus on six primary compliance areas:**

1. Corporate Policies
2. Tone at Top
3. Education
4. Channel Partner Review
5. Hotline
6. Payment processes review

These six areas summarize the 13 requirements for a corporate compliance program detailed in Maxwell's DPA with Justice Department.

## *Maintaining an Effective Compliance Program*

### **Six-month compliance cycle:**

- Assess risks
- Plan
- Execute
- Evaluate
- Report
- And then... Repeat

## ***Maintaining an Effective Compliance Program***

### **Separate the compliance activities:**

- ✓ Legal department implements and maintains key compliance items (i.e. corporate policies, hotline, training, channel partner review).
- ✓ Compliance Department assesses, verifies and reports on compliance activities.

### **Challenge/Risk:**

- ✓ Obtaining the entire population of transactions and agreements that need to be included in reoccurring risk assessment.

# Maintaining an Effective Compliance Program

***Brian S. Roman***

*Senior VP and Chief Compliance Officer  
Mylan Inc.*



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# Our mission began when we did... 50 years ago



**Received first FDA approval and began manufacturing**



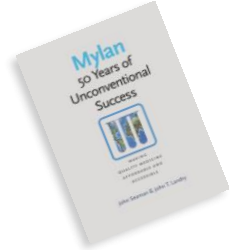
**Patented a new drug — a first for a generics company**



**\$100M in revenue**



**Went global with acquisitions of Matrix and Merck Generics**



**Celebrated 50 years of unconventional success**

**'61**

**'66**

**'73**

**'84**

**'86**

**'92**

**'02**

**'07**

**'09**

**'11**

**Founded as a pharmaceutical distributor in White Sulphur Springs, W. Va to provide rural Americans access to medicine**

**Became a publicly traded company**

**Nationally recognized for efforts to expose industry corruption**

**\$1B in revenue**

**\$5B in revenue**



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# To achieve our mission, we built a strong foundation

- One of the world's leading generics and specialty pharmaceutical companies
- Global workforce of more than 18,000
- 2011 revenue of more than \$6 billion
- 1 of every 11 prescriptions in U.S. is filled with a Mylan product, brand name or generic
- More than 1,100 separate therapies
- Manufacturing capacity of 45 billion doses
- Products dispensed in ~150 countries and territories
- One of the world's largest active pharmaceutical ingredient manufacturers
- World-class allergy and respiratory specialty franchise, including EpiPen® auto-injector

## *Maintaining an Effective Compliance Program*

**To support business expansion while maintaining effectiveness, a Compliance program should be:**

- Sustainable
- Scalable
- Strategically aligned
- Mapped

# *Maintaining an Effective Compliance Program*

## **Mapping your Compliance Program**

- Start with a program charter
- Inventory all program processes
- Assess each process on critical dimensions
  - Who owns it?
  - What technology supports it?
  - What are the KPIs?
  - Is it supported by a policy or written procedure?
  - Is it necessary? Efficient? Scalable?

# *Maintaining an Effective Compliance Program*

## **What processes need priority attention?**

- Missing processes / filling gaps
- Process depends on knowledge of a single person
- Process is undocumented / no supporting policy
- Process lacks metrics or KPIs
- Developed in response to a particular situation
- Does not tie back to program charter
- “Time sinks”

# *Maintaining an Effective Compliance Program*

## **Developing your next generation of leadership**

- Do you have the bench strength to support expansion?
- Are you training people to take on more responsibility?
- Are your people's roles well defined?
- Do you have the right people in the right roles?
- Do the people on your team understand the priorities and other processes beyond their own roles?

to strengthen Mylan's ability to operate responsibly, and well above the legal minimum. Compliance champions Mylan's core value of doing business with integrity. As we continue to grow, we make sure that all Mylan team members understand and embrace our shared responsibility for compliance, and for meeting Mylan's high ethical standard of "doing it right or not doing it at all."

- **Policies & Procedures.** We write policies and assist other functions with policy development. We maintain a repository of all Global policies to ensure they are readily accessible to all personnel. We are always reviewing our risk and policy landscape to ensure we have identified and closed any gaps, and that our general & administrative policies are relevant, current, easily understood, and effective.
  - **Training & Education.** We educate all Mylan team members about the rules by which they must abide, through innovative and engaging training and education programs.
  - **Compliance Auditing and Monitoring.** We actively audit and monitor business operations and transactions, based on risk. We do this in close collaboration with Internal Audit, Legal, HR, Security and other governance and risk functions as appropriate.
  - **Open Lines of Communication.** We provide an open channel of communication for everyone, everywhere, to raise compliance related concerns. We will review, refer, and/or investigate every matter so raised.
  - **Engagement with the Business.** Our compliance officers must maintain a regular and deep connection with the businesses we serve. We will fail if we sit back and wait to be engaged. Compliance doesn't just partner with the business; we are part of the business.
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- We are accountable to making the compliance program real and effective. We succeed not only through the absence of compliance violations, but also if, when a violation occurs, we can show that Mylan has a rule prohibiting the misconduct; the person committing the violation knew the rule and the consequences of violating it; and the company took swift action to investigate and correct the violation. If we succeed in this mission, the institution should be given meaningful credit for having behaved responsibly through its constant efforts to deter, detect, and correct wrongdoing.

# *Maintaining an Effective Compliance Program*

## **Example Process Inventory**

PROCESS	DESCRIPTION	OWNER	KEY INTERDEPENDENCIES	KPIs	POLICY or SOP