Building Internal Compliance Systems

Dr Robert Skinner
GSK
March 2013 Johannesburg
Pharmaceutical Industry Business Environment

- Regulatory and legal requirements becoming stricter
- High risk, long term & costly
- Multi-national:
  - different regulations in every country
  - different culture in every country
  - actions in one country may impact another
- Negative public view of ‘Big Pharma’
- Significant media attention
- Our business is people’s health – we **must** get it right!
Regulators are flexing their muscles
Why does a Company Need a Compliance System?

Ethics and Compliance are vital to the success of the business

Examples of Ethics and Compliance failures:

- GlaxoSmithKline (GSK) fined $3 billion (£1.9 billion) in the US in 2012 for off-label marketing – and a Corporate Integrity Agreement (CIA)
- Pfizer: $2.3bn fine and CIA in US in 2009 for un-ethical/non-compliant sales and marketing activities
- Merck withdrawal of Vioxx in 2004 due to cardiac risks that are estimated to have led to 88-139,000 heart attacks
What is ‘Corporate Compliance’?

A system (or Internal Control Framework) that:

- Strengthens ethical decision-making and behaviour in the company
- Identifies and oversees the management of risks
  - Assist with development of policy
  - Communicate and train policy
  - Guide, investigate and enforce policy compliance
Internal Control Framework

Company Values

- Risk Management
- Written standards
- Education
- Communication
- Monitoring / Auditing
- Response
- Enforcement

Oversight
(Risk Management / Compliance Governing Bodies)
The 7 Key Components of a Compliance Programme

1. Written Policies & Procedures
2. Designated Compliance Officer and Committee
3. Effective Training and Education
4. Clear Lines of Communication / Reporting Lines
5. Auditing and Monitoring
6. Enforcement and Disciplinary Actions
7. Response to Detected Problems & Corrective Actions
The 7 Key Components of a Compliance Programme

1. Written Policies & Procedures
   - Include the ‘Code of Conduct’
   - Foster a culture of compliance
   - Aid compliance to the ‘rules’
   - Address all key risk areas
   - Express company values & behaviours
The 7 Key Components of a Compliance Programme

2. Designated Compliance Officer and Committee

- Oversee & monitor the compliance programme
- Appropriate authority (reporting into Board / CEO)
- Set the ‘tone from the top’
- ‘Risk Management & Compliance Committee’ to assist CO (possibly at multiple levels)
- Independent investigation of issues
- Key links with HR & Legal functions
- Organise ‘risk management’ activities
- Have a ‘compliance plan’
Chemical and Pharmaceutical Companies’ 2012 Compliance and Ethics Program Priorities
(Survey conducted by Compliance and Ethics Leadership Council)

How Important Are the Following Goals to Your Company in the Next 12-18 Months?

Top 10 Priorities:

- Identify Emerging Compliance Risks (100%)
- Improve Third-Party Risk Management and Oversight
- Strengthen Ethical Leadership Among Senior and Middle Management
- Improve Design and Delivery of Training and Communication
- Improve Compliance/Legal Risk Prioritization
- Support the Expansion of the Business Overseas
- Build a More Uniform Culture of Integrity Across Global Operations
- Manage Global Whistleblower Processes and Reporting
- Integrate Compliance into ERM or GRC Efforts
- Develop Metrics That Meaningfully Measure and Demonstrate Program Effectiveness (62%)
## Risk Assessment

### Inherent Risk Area

<table>
<thead>
<tr>
<th>Inherent Risk Area</th>
<th>Risk Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Very High</td>
</tr>
<tr>
<td>Product Quality</td>
<td></td>
</tr>
<tr>
<td>Supply Chain Continuity</td>
<td></td>
</tr>
<tr>
<td>Environment Health and Safety</td>
<td></td>
</tr>
<tr>
<td>Commercial Practices</td>
<td></td>
</tr>
<tr>
<td>Patient Safety</td>
<td></td>
</tr>
<tr>
<td>Research Practices</td>
<td></td>
</tr>
<tr>
<td>Business Continuity</td>
<td></td>
</tr>
</tbody>
</table>

### Emerging Risk Area

<table>
<thead>
<tr>
<th>Emerging Risk Area</th>
<th>Risk Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Very High</td>
</tr>
<tr>
<td>Price &amp; Access Pressures</td>
<td></td>
</tr>
<tr>
<td>Investment in Emerging Markets</td>
<td></td>
</tr>
</tbody>
</table>

- **- Current Risk Level**
- **- Objective (3 – 5 year timeframe)**
## Business Maturity Model

<table>
<thead>
<tr>
<th>Compliance Elements</th>
<th>BU 1</th>
<th>BU 2</th>
<th>BU 3</th>
<th>BU 4</th>
<th>BU 5</th>
<th>BU 6</th>
<th>BU 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Oversight</td>
<td>Developing</td>
<td>Leading Edge</td>
<td>Established</td>
<td>Established</td>
<td>Established</td>
<td>Established</td>
<td>Established</td>
</tr>
<tr>
<td>B. Written Standards</td>
<td>Established</td>
<td>Established</td>
<td>Developing</td>
<td>Established</td>
<td>Established</td>
<td>Established</td>
<td>Established</td>
</tr>
<tr>
<td>C. Training and Education</td>
<td>Developing</td>
<td>Established</td>
<td>Developing</td>
<td>Developing</td>
<td>Established</td>
<td>Established</td>
<td>Developing</td>
</tr>
<tr>
<td>D. Monitoring</td>
<td>Developing</td>
<td>Developing</td>
<td>Developing</td>
<td>Developing</td>
<td>Leading Edge</td>
<td>Developing</td>
<td>Developing</td>
</tr>
<tr>
<td>E. Communication</td>
<td>Developing</td>
<td>Established</td>
<td>Established</td>
<td>Developing</td>
<td>Leading Edge</td>
<td>Established</td>
<td>Developing</td>
</tr>
<tr>
<td>F. Responding to Detected Problems</td>
<td>Developing</td>
<td>Established</td>
<td>Established</td>
<td>Developing</td>
<td>Leading Edge</td>
<td>Established</td>
<td>Developing</td>
</tr>
<tr>
<td>G. Discipline and Enforcement</td>
<td>Basic</td>
<td>Established</td>
<td>Established</td>
<td>Developing</td>
<td>Established</td>
<td>Established</td>
<td>Established</td>
</tr>
<tr>
<td>H. Risk Identification and Treatment</td>
<td>Developing</td>
<td>Established</td>
<td>Developing</td>
<td>Developing</td>
<td>Established</td>
<td>Developing</td>
<td>Established</td>
</tr>
</tbody>
</table>
Compliance Roadmap

2013
- Risk Mapping & GRC in some depts
- Employee Engagement on Values
- L2 gap analysis
- Increase comfort to speak up

3 years
- L2 monitoring in place across all BUs
- Simplified Process document system
- Learning Organisation and Induction Process in place
- Values translated in behaviors

> 5 years
- Make Compliance a competitive edge
- Best in class in audits
- Every employee is a compliance leader
- Full comfort to speak up
The Role of a Compliance Officer?

Police Officer?

Judge?

Business Partner?
3. Effective Training and Education

- Ensure policies / SOPs / Codes are understood
- Induction & ongoing training
- Maintain training records
- Certification of agreement to comply
- Interactive & web-based programmes
- Allows for assessment (when useful)
- 3rd Party Contractors!
The 7 Key Components of a Compliance Programme

4. Clear Lines of Communication / Reporting Lines

- Access to their Manager or the Compliance Officer
- External as well as internal reporting
  - Sarbanes-Oxley Act (2002) requirements for senior management to certify the accuracy of public company financial records
- Protection of whistleblowers / Non-retaliation
- Empower every employee
  - Speak-Up culture
  - Confidential helplines (maybe via unbiased 3rd party?)
SPEAK UP!
The 7 Key Components of a Compliance Programme

5. Auditing and Monitoring

- Monitor & audit internal systems to verify compliance
- Also 3rd party contractors
- Levels 1, 2 & 3 ‘monitoring’ (next slide)
The ‘Golden Triangle’

Level 4
External Audit / Inspection

Level 3
Internal Audit

Level 2
QA Assessments

Level 1
Mgmt Reviews, Approvals, QC
The 7 Key Components of a Compliance Programme

6. Enforcement and Disciplinary Actions

- Need well publicised disciplinary guidelines
- Must be consequences to act as a deterrent (levied consistently)
- Disciplinary action must be appropriate
The 7 Key Components of a Compliance Programme

7. Response to Detected Problems & Corrective Actions

- Company must continue to respond
  - to continually improve
  - to prevent recurrence
- Enhancement to policies / SOPs / Code
- Clarification of newly emerged risks
- Reporting externally to Regulatory Authorities (e.g. if laws were broken)
  - prompt reporting demonstrates good faith
  - mitigating factor if subsequent investigation
Company policies are designed to be compliant with national laws.

Policies cannot clarify everything.

We must be compliant with the ‘letter’ and the ‘spirit’ of our policies – to behave ethically & true to our values.
“It sort of makes you stop and think, doesn’t it?”
Use the Ethical Compass

- Is it consistent with our mission, values and spirit?
- Is it legal and ethical?
- Is it consistent with Company policy and Code of Conduct?
- Can I explain it to my family and friends?
- Would I be comfortable if it appeared in the newspaper?
The Spirit of GSK

Mission

Improve the quality of human life by enabling people to do more, feel better and live longer

Strategies

- Grow a diversified global company
- Deliver more products of value
- Simplify the operating model
- Individual Empowerment
- Build Trust

Values

- Respect for People
- Patient Focused
- Transparency
- Integrity

Behaviours

- Flexible Thinking
- Continuous Improvement
- Customer Driven
- Developing People
- Enable & Drive Change
- Building Relationships

Deliver excellence by being the best you can be
Thank You.  Any Questions?