



Building an International Compliance Program

An Operational Approach

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Sr. Director Quality & Compliance

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Overview

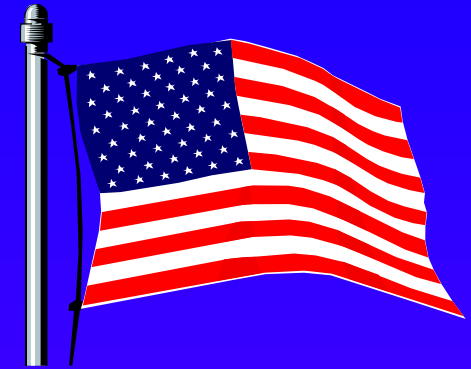
- **Challenges and Requirements**
- **Organizational Mindset and Approach**
- **Quality & Continuous Improvement - 7 Steps**
- **Measure Your Progress**
- **Excellence in Implementation**
- **Take Home Messages**

Challenges

- **Business vs. Compliance Mindset**
- **Centralization / Decentralization**
- **Business Risks - Different Priorities**
- **Local Laws vs. US Laws**
- **Political & Economic Differences & Risks**
- **Changing Regulatory & Legal Environments**
- **Materiality - Company / Subsidiary Size**
- **Cultural & Competitive Differences**
- **Language Differences**

International Compliance Requirements

- **U.S. Laws**
 - ▶ **U.S. Federal Sentencing Guidelines**
 - ▶ **Foreign Corrupt Practices Act**
- **Country & Local Laws**
- **Company Policy**
 - ▶ **Company View vs. Country View**
- **Newspaper Test**



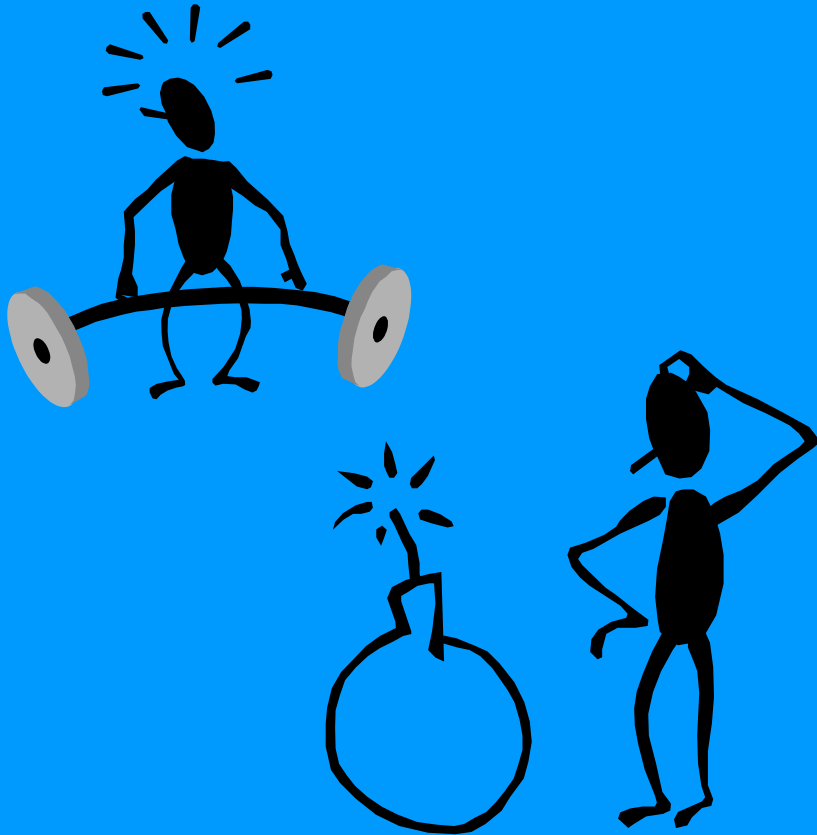
Organizational Mindset

- Integrity & Values
- Legal Compliance Program
- Patient / Employee / Community Benefits
- Keep Management Out of Trouble



Organizational Mindset

Business Or Compliance



Business With Compliance



Strategic Approach

Employees

#1
Integrity
& Values

#2
Quality
Standards

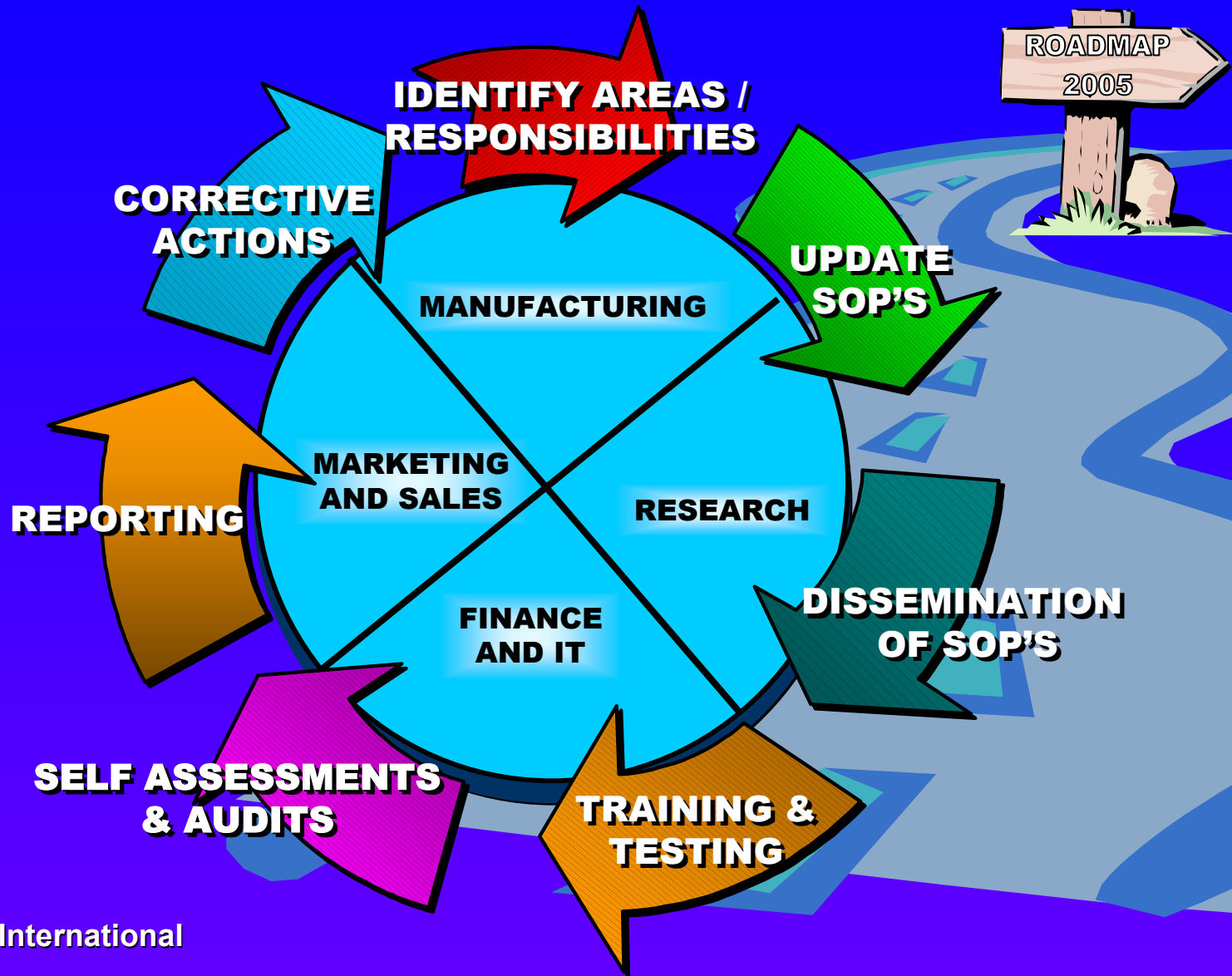
#3
Empowerment

#4
Management
Systems

**RESULTS AND
COMPLIANCE**

The Goal

7 STEPS TO CONTINUOUS QUALITY



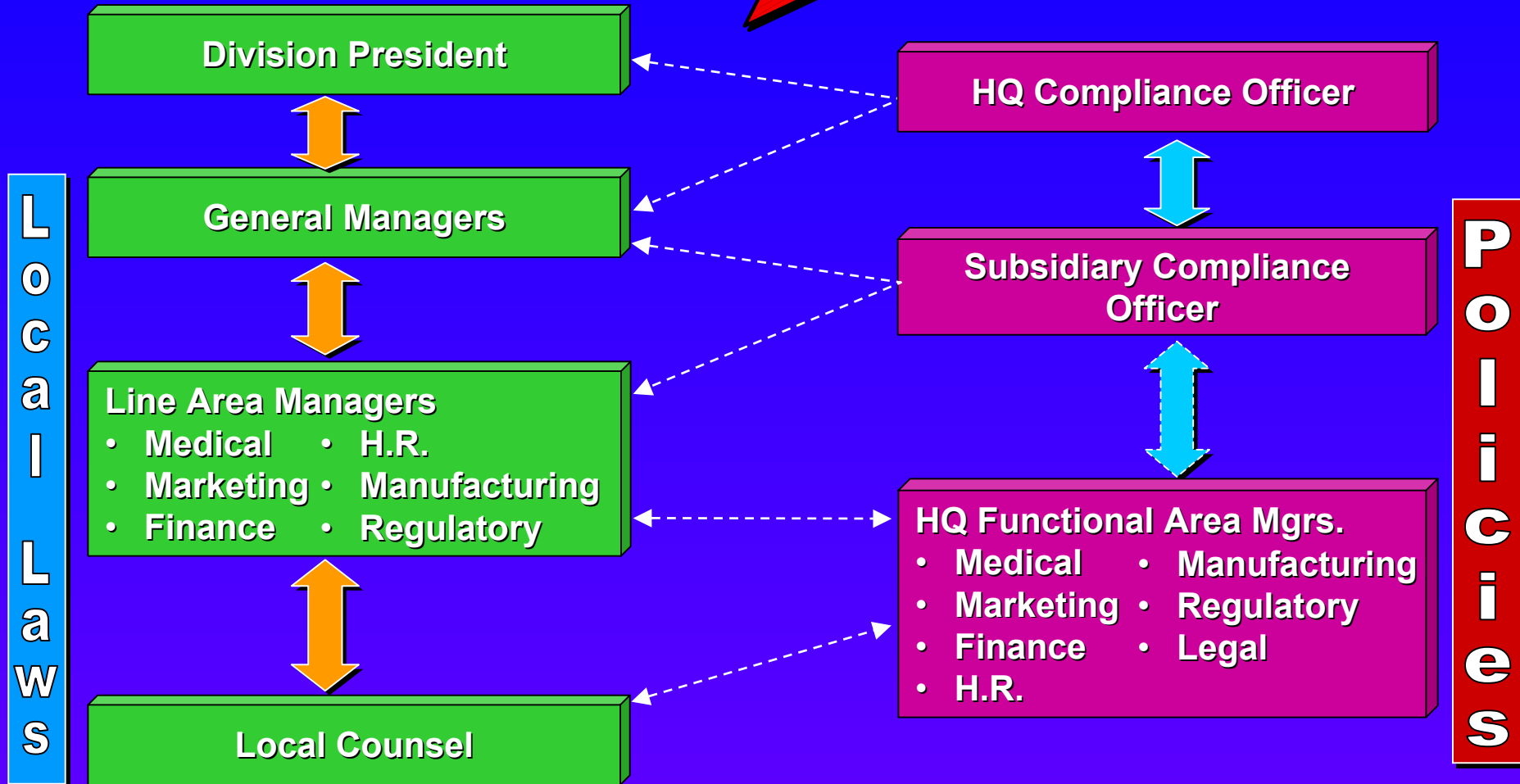


IDENTIFY AREAS / RESPONSIBILITIES

Line Management

- Business Conduct Policy
- Adverse Event Reporting
- Medical and Scientific Practices
- Promotional Activities
- Finance Policies
- Data Privacy
- Distribution of Samples
- Good Clinical and Laboratory Practices
- Antitrust / Pricing / Competition Laws
- Conformance
- Anti-Boycott
- Foreign Corrupt Practices Act
- US Foreign Trade Controls
- Anti-Bribery
- Environmental and Safety
- Good Manufacturing Practices
- Employment Law & Policies
- Company Confidential Information
- Records Retention
- Import/Export Restrictions for unapproved Drugs

IDENTIFY AREAS / RESPONSIBILITIES



**IDENTIFY AREAS /
RESPONSIBILITIES**

Compliance Officer

- **Fiduciary Reporting Responsibility**
 - ▶ **Assure Effective Compliance Program**
- **Work with Line Managers to Understand Status of Compliance & Actions Being Taken**
- **Keep GM updated Regarding Key Issues and Action Steps Required in each Compliance Area**
- **Monitor to verify that Business Processes are Working as Designed**
- **Track Corrective Actions Required and Progress**



- SOP's approved and ensure compliance with local laws and corporate policies.
 - Establish simple framework in which we conduct business
 - Enable management to make faster decisions
- Keep Current - Monitor Changes in the Law



DISSEMINATION OF SOP'S

DISSEMINATION
OF SOP'S

- **Communicate SOP's to every employee that needs to know it to do their job**
- **Format must be easily understandable to the reader (language)**
 - ➔ **EZ Reference Guides**



- **“How Do You Know Your Employees Understand What Is Necessary to Perform Their Jobs?”**
- **Results of all Testing is Measured and Documented**
- **Utilize Testing to Focus Training Resources [Time & \$]**
- **Self-Development Plans vs. One Size Fits All Training**



- **Training & Testing Development**

- ▶ Training Department, Law Department, 3rd Party, Line Management

- **Training Systems**

- ▶ Integrated Compliance Systems
- ▶ E-Training vs. Paper based
- ▶ Integrate with Product Knowledge

Corporate Audit - Microsoft Internet Explorer provided by Schering Laboratories

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites History Mail Print Edit

Links Best of the Web Channel Guide Customize Links Free HotMail Internet Start Micr

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Schering-Plough CORPORATE

select another corporate department

audit

SELF ASSESSMENTS & AUDITS

Self-Guided Assessments

SGA Index.pdf	30-May-2001
SGA User Guide.pdf	30-May-2001
SGA-Accounts Payable.pdf	30-May-2001
SGA-Accounts Receivable.pdf	30-May-2001
SGA-Compliance.pdf	30-May-2001
SGA-Credit and Collection.pdf	30-May-2001
SGA-DisbursementCashControl.pdf	30-May-2001
SGA-Fixed Assets.pdf	30-May-2001
SGA-Foreign Trade Sanctions.pdf	30-May-2001
SGA-Inventory.pdf	30-May-2001
SGA-IT General Control Environment.pdf	30-May-2001
SGA-IT Program Changes.pdf	30-May-2001
SGA-Medical & Scientific.pdf	30-May-2001
SGA-Promotion&Information.pdf	30-May-2001
SGA-Purchasing.pdf	30-May-2001
SGA-Returned Goods.pdf	30-May-2001
SGA-Travel and Entertainment.pdf	30-May-2001
SGA-Use of Consultants.pdf	30-May-2001

Corporate Policies and Procedures | Finance Policies | IT Policies and Guidelines

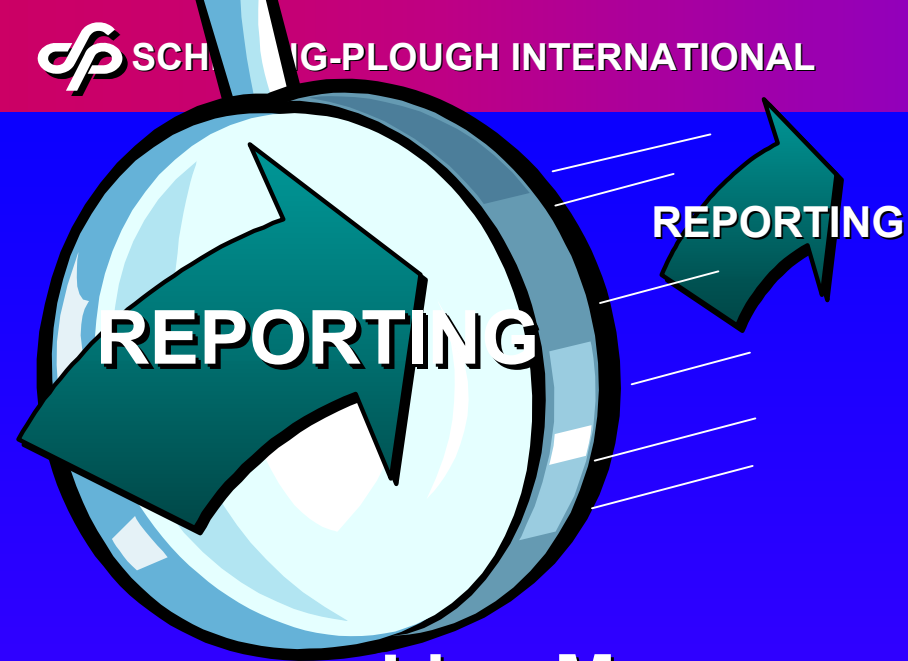
My Computer



SELF ASSESSMENTS & AUDITS

Self-Guided Assessment: Medical and Scientific Practices

		Yes/No N/A	Comments
	SELF-GUIDED ASSESSMENT QUESTIONS:		
1.	Has a formal evaluation been made as to whether each physician (or similar groups of physicians) should be considered a government employee?		
2.	Has this determination been reflected in each of the SOPs referenced in Step 1 above?		
3.	<p>Note that the following questions should generally be addressed in the SOPs. However, you will need to complete the remainder of this SGA before determining if your location is in compliance. For payments made to or for the benefit of or on behalf of healthcare professionals:</p> <ul style="list-style-type: none"> • Are payments made for bona-fide business purposes? • Is the purpose and amount of payments made supported by adequate documentation: <ul style="list-style-type: none"> - proving that services were received? - that fair value was paid? - that payments are in compliance with the SOPs? • Are the payments for actual services received by the Company? • Do the payments represent the fair market value of the services provided? • Has the Company made legitimate use of the services provided? • Have the level and extent of payments made to and on behalf of any or each individual physician periodically reviewed to evaluate whether the total amount and frequency of the payments to the individual is reasonable both for individual payments and aggregate payments to individual physicians? • Consider running an extract or report from the Accounts Payable system highlighting payments of this type. Consult with your IS department head for assistance. • If physicians are government employees, have the confirmation and notification requirements of Schering-Plough Finance Policy 0503, Internal Control Standard C - Cash Control, Section: "Payments to Government Physicians," been complied with for: <ul style="list-style-type: none"> - all direct payments to the healthcare professional? - payments made on behalf of or for the benefit of the healthcare professional (e.g., airline tickets purchased from a travel agency for use by the physician to attend a congress)? 	ACTION STEP	
4.	Are the Finance Department personnel responsible for processing payments trained in recognizing acceptable and unacceptable activities and the related supporting documentation requirements, so that they can adequately monitor this activity?		
5.	Is a procedure in place to determine if commitments/payments are made to an institution or healthcare professional?		



- **Line Managers to General Manager**
 - ▶▶▶ Monthly Executive Meetings
- **Formal Reports to Division President**
 - ▶▶▶ Actions Taken & Next Steps Forward
 - ▶▶▶ Participation in Executive Team Staff Meetings
- **Annual Plan & Progress Reports**



CORRECTIVE
ACTIONS

CORRECTIVE
ACTIONS

- “Visibility” - Tracking System
- Assess Cause - SOP, Distribution, Training, Testing or Employee Disciplinary Issues
- Eliminates Risk of Repeat Findings
- Assures Continuous Improvement

Measuring Quality

- ***“What Gets Measured Gets Done!”***

- **Status Report - Identifies Gaps**
- **1 Page Per Country**
- **Measures Progress by Area**

Scale

- 0 Not Started or Documented**
- 1 < 50% completed or documented**
- 2 > 50% completed but not finished**
- 3 Completed and Documented**

The Quality Index

Country: Headquarters (DRAFT Example)

Functional Area	Responsibility	I	II	III	IV	V	VI	VII	Total	Total Possible
		Identified Areas for SOP's	Updated SOP's	Distributed	Training & Testing	Self Audits & Assessments	Reporting	Corrective Actions		
Medical & Scientific Practices	Galland	2	1	1	0	0	2	0	6	21
Promotion & Information	Cabellero	3	2	2	1	0	2	0	10	21
AE Reporting	Cobert	3	3	0	0	0	2	0	8	21
U.S Foreign Trade Controls / DPSS	Hunter	2	2	2	2	1	1	0	10	21
Anti-Boycott	Hunter	2	2	1	0	0	1	0	6	21
Finance	Elli	2	2	1	1	0	2	0	8	21
Competition / Anti-Trust	Hunter	2	0	0	0	0	2	0	4	21
Data Privacy	Trainor	0	0	0	0	0	2	0	2	21
FCPA / Business Conduct Policy	Hunter	3	3	3	3	0	2	0	14	21
Employment Laws / Regulations	Botas	3	2	2	1	0	1	0	9	21
GMP	Columbeen	2	2	2	2	2	1	0	11	21
Conformance	Columbeen	2	2	2	2	2	3	0	13	21
Total Score		26	21	16	12	5	21	0	101	252

Excellence in Implementation

Sharing Experiences

Adverse Event Reporting - October 15, 2001

Schering-Plough International

Quality & Compliance Bulletin

Implementation & Compliance

THINK
BIG
&
GET IT
DONE

Background

The FDA recently sent a letter to the CEO of Sanofi giving him 15 days to respond to FDA's finding that the company failed to report a number of serious and unexpected adverse drug experience reports to the FDA within 15 calendar days of initial receipt of the information. The FDA letter reads, in part, as follows:

"In a September 21 warning letter to Sanofi-Synthelabo, the FDA requested that the French drug maker promptly improve its procedures for reporting adverse events from overseas. The FDA claimed that Sanofi failed to submit more than half of the 72 overseas adverse event reports concerning its blood-thinning drug Plavix within the required 15-day frame. The delays were discovered during an FDA inspection in August. Sanofi and Bristol-Myers Squibb co-market the drug (Health News Daily/ Reuters)"

A full copy of FDA letter to the CEO of Sanofi is at www.fda.gov/foi/warning_letters/g1781d.pdf.

Adverse Event Reporting Requirements

AE reporting requirements include all **Marketed and Investigational** drugs, biologicals or medical devices. At Schering-Plough, every International subsidiary has a local SOP for Adverse Event (AE) reporting that is approved by Drug Safety Surveillance (DSS) and the VP of Medical and Safety Services in Clinical Research. These local SOP's for AE reporting include the following:

- All serious AE's for both marketed drugs and post-marketing studies, must be sent to the subsidiary safety officer generally **within 1 or 2 working days** depending on the local SOP's. The timing for non-serious AE's is more variable as also prescribed by the local SOP's.
- All International subsidiaries must collect AE's from within their territory(ies) and transmit these to DSS as well as submit AE reports to the local regulatory authorities as required.
- All International subsidiaries must also transmit AE reports for a licensed product to DSS and the licensor/licensee, as required.

The purpose of this communication is to remind every International subsidiary that it is imperative that AE reporting requirements are strictly adhered to. **AE reporting requirements include both marketed drugs as well as all trials, IS's and medical affairs activities.** This is required to ensure the safety of all our patients. In addition, we never want to be asked to respond to a letter like the one sent to the CEO of Sanofi noted above.

GROUPS	FUNCTIONAL AREA	
<input checked="" type="checkbox"/> Total SP	<input checked="" type="checkbox"/> Medical & Scientific	<input type="checkbox"/> Finance
<input type="checkbox"/> Europe/Canada	<input type="checkbox"/> Legal	<input type="checkbox"/> Regulatory Affairs
<input type="checkbox"/> LA/FE	<input type="checkbox"/> Human Resources	<input type="checkbox"/> Marketing & Sales
<input type="checkbox"/> Japan	<input type="checkbox"/> Technical Operations	<input type="checkbox"/> _____
<input type="checkbox"/> Headquarters		

- E-Mail, Websites, Training Videos, E Training
- Communications & Bulletins
 - 2001-01: Q & C Bulletins
 - 2001-02: Adverse Events
 - 2002-01: Role & Responsibilities
 - 2002-02: SP Venezuela
 - 2002-03: Audit Responses
 - 2002-04: Competition Law
 - 2002-05: Compliance Committee
- Monthly SP CO Meetings

Excellence in Implementation

Open Communication

- **Company Culture, Trust & Responsibility**
- **Formal Compliance Plan - Report to the Board of Directors**
- **Compliance Review Committee**
- **Company Helplines & Hot Lines**

Excellence in Implementation

Employee Performance

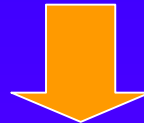
Hiring Characteristics



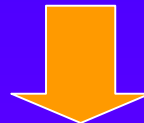
Orientation



Daily Reinforcement



Performance Appraisals



Disciplinary Action

Excellence in Implementation

SP Venezuela



2001 Results

- **Sales Growth**
- **Profit Contribution**
- **Market Share**
- **Corporate Audit Results**

Making it Happen

- **Company Value**
- **Recruitment & Development**
- **SOP's**
- **Open Communication**
- **Daily Reinforcement**

Summary

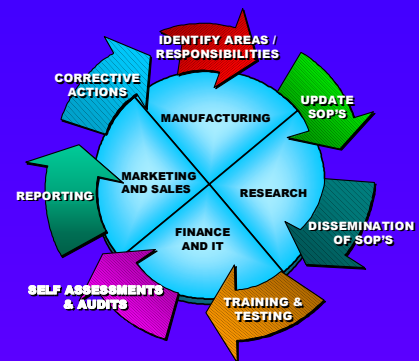
Take Home Messages

**#1 Align Program with Strategic Plan -
*Image and Role in Marketplace***

#2 Organizational Mindset

- Integrity & Values Based
- Business with Compliance
- Empowerment with Quality Standards

**#3 Assure Quality & Continuous
Improvement - 7 Steps**



Summary

Take Home Messages

#4 Assess Quality & Measure Progress

#5 Excellence in Implementation

- **Share, Share & Share Experiences Among Countries**
- **Open Communication**
- **Employee Recruitment, Development and Performance**

Daily Reinforcement!