

MONITORING PROGRAMS



Sérgio Alberto Pinto, CCEP

**Regional Sector Lead – Medical Devices Latin America, Health Care Compliance
Johnson & Johnson Indústria e Comércio de Produtos para a Saúde Ltda.**



The information contained in this presentation merely reflects the personal opinion of the professionals and does not express opinions of the company they work for.



COMPONENTS OF AN EFFECTIVE INTEGRITY PLAN

Prevention	Detection	Response
Board/audit committee oversight Executive and line management functions Internal audit, compliance, and monitoring functions		
<ul style="list-style-type: none">● Fraud and misconduct risk assessment● Code of conduct and related standards● Employee and third-party due diligence● Communication and training● Process-specific fraud risk controls● Proactive forensic data analysis	<ul style="list-style-type: none">● Hotlines and whistleblower mechanisms● Auditing and monitoring● Retrospective forensic data analysis	<ul style="list-style-type: none">● Internal investigation protocols● Enforcement and accountability protocols● Disclosure protocols● Remedial action protocols



AUDITING VS. MONITORING

	Auditing	Monitoring
Timeframe	Retrospective	Real time
Formality	Formal	Formal or informal
Core Activity	Testing against established controls	Review transactions to determine compliance
Conduction	Internal Audit/3rd Party	Compliance/Business/3rd Party



MONITORING IS ABOUT...

- Mitigating Risk
- Partnering
- Managing through ambiguity
- Proactive Solution



MONITORING

- It is like a radar
- It is key to know country/culture/scope
- Prepare a risk assessment
- If you can't do it, don't do it
- "Tone at top"



MONITORING - WHY?

- Assess your Compliance program
- Compliance with laws and regulations
- Compliance with settlement or agreement
- Part of the 7 elements of OIG-US & UKBA compliance program



10 ELEMENTS OF A SUCCESSFUL MONITORING PLAN

1. Risk based
2. Strengthens business insights
3. Dynamic
4. Actionable with timely outputs
5. Feeds other 7 element areas
6. Align with escalation and investigation processes
7. Specific to region/business/sector
8. Drives accountability and business ownership
9. Insights into future risk assessments and other mitigation strategies
10. Diversity of monitoring types



DEVELOP MONITORING PLAN: IDENTIFY WHAT REQUIRES MONITORING

- Consider reporting and/or policies
- Gain Consensus
- Include key stakeholders: Legal, Finance, Compliance, SMEs, Business

BRAINSTORMING CHECKLIST	SETTING PRIORITIES
✓ Which activities will strengthen the compliance program?	✓ Prioritize activities to strengthen the compliance program? Ensure resource consideration
✓ Are there new strategies, programs or product launches that may introduce risk?	✓ Which activities expand the knowledge of the business
✓ Which activities will provide a diverse mix of monitoring types?	✓ How achievable is the activity?
✓ Have you monitored the area in the past?	✓ Which activities duplicate existing controls or test plans?
✓ Are there potentially risky areas or processes that haven't been monitored in the past?	✓ Maximize the plan while considering resource requirements.



WORK PLAN

- Background
- Pre work and planning
- Testing analysis
- Findings and recommendations



WORK PLAN

1. Background

- ✓ Country specific research
- ✓ Industry best practices
- ✓ SOPs
- ✓ Workflows

2. Pre work and planning

- ✓ Data gathering
- ✓ Comparison
- ✓ Interviews
- ✓ Kick off meeting

3. Testing analysis

4. Findings and recommendations

- ✓ Aggregate, reconcile and organize findings
- ✓ Review with business learders, legal and compliance



EXECUTING THE MONITORING ACTIVITY

- **Choose a Monitoring Activity**

- The type of monitoring activity you choose will differ by business, product, customer and other variables.
- Some activity will lend themselves to in-person observation and others may be audits or documentation

- **Determine Resources**

- What people resources are needed? i.e., SMEs, Monitoring Services through Sector Resources or TMS, etc.
- What data resources are needed? i.e. what information is relevant around the monitoring controls

- **Be Smart About Data**

- When requesting data, understand all available data fields and then determine the data needed

- **Flexibility is Critical**

- Create a timeline and adjust as needed
- Check your assumptions. Change direction if the data indicates a need to revisit any assumption



OUTCOME IMPLICATIONS AND FOLLOW-UP

- The primary purpose of any monitoring activity is to confirm the effectiveness of controls and strengthen the compliance program.

TYPES OF MONITORING OBSERVATIONS	IMPLICATIONS AND FOLLOW-UP
Singular Deviation	<ul style="list-style-type: none">• Often due to human error• Generally low risk but, if systemic or higher risk, consider increasing or improving the existing process controls.• Usually addressed with retraining. However, if the issue is systemic, consider whether existing training approach is appropriate.
Process Gaps and Control Failures	<ul style="list-style-type: none">• Risk level varies, depending upon the gap. Some gaps are business opportunities that represent little or no HCC risk.• Consider whether the gap(s) may warrant Escalation.• Minor issues, such as an SOP gap, may be easily addressed. Gaps that require resources and time to close should prompt creation of a MAP item.
Systemic Departures from Policy	<ul style="list-style-type: none">• May trigger follow-up investigations to understand risk and scope.• Consider whether departures require Escalation.• May prompt disciplinary action, in alignment with responsible management and Human Resources.• If widespread, corrective actions should be captured as a MAP item.
Positive or Negative Trends	<ul style="list-style-type: none">• May reflect effectiveness of prior corrective actions.• Good source of feedback for the business.• Consider if the data represents an opportunity to modify the Annual Plan.• If widespread, corrective actions should be captured as a MAP item.



DATA ANALYSIS - STRENGTHENING THE COMPLIANCE PROGRAM

TYPE OF ANALYSIS	DESCRIPTION	PRACTICAL EXAMPLES
Trend Analysis	<ul style="list-style-type: none">- Usually used with large volumes of data- High level scan of data intended to identify trends and summary-level insight	<ul style="list-style-type: none">- A pareto chart of noncompliant transactions- A quarter on quarter review of policy deviations
Excursion/Outlier Identification	<ul style="list-style-type: none">- Works well in a discovery activity or an activity designed to confirm controls- A review of information to identify unusual or unexpected data points	<ul style="list-style-type: none">- A discovery activity designed to determine the level of control in a new process or program- A monitoring activity designed to test effectiveness of corrective actions prior to closing a MAP item
Qualitative Review	<ul style="list-style-type: none">- Considers context and relevancy, beyond data points analytics- more complex than trend analysis and Excursion	<ul style="list-style-type: none">- Review of call notes- Review of documentation related to the conduct of advisory boards



WHAT TO DO WITH MONITORING RESULTS

- Is the process or control working the way we thought?
- Are people behaving the way we expected?
- Do we need to make a change?

When data reveals departures from policy or process, moving to corrective action is tempting. Be sure the corrective action addresses the root cause of the problem.....

Ask the 5 Why's ... Continue to ask "Why" to bring the root problem forward



CONSIDERATION FOR PREPARING REPORTS

Key Questions to Ask:

- 1. What process specific insights can you identify?
- 2. Does the governing SOP align with actual practice?
- 3. Could process steps or documentation be streamlined?
- 4. Does the data reflect a need to update the governing policy?
- 5. What are the key insights that need to be included in the report?



SUSTAINABILITY - ENSURING A DYNAMIC MONITORING PROCESS

- The results of your analysis may point to a need to change OR eliminate a certain monitoring process
- Monitoring results should be used to validate assumptions, guide improvement of key controls and drive business ownership.



MONITORING PROGRAMS

THANK YOU!!!



Sérgio Alberto Pinto, CCEP

**Regional Sector Lead – Medical Devices Latin America, Health Care Compliance
Johnson & Johnson Indústria e Comércio de Produtos para a Saúde Ltda.**

