



## ONE FROM THE MIDDLE RBM Toolkit

# Support Tools

For sales training and educational  
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Proprietary and confidential  
Not for dissemination



# TONE FROM THE MIDDLE RBM Toolkit

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## Overview of Tone From the Middle

### Leading From the Front—A New Approach

Every organization aspires to have strong business relationships between sales and customers while ensuring the highest level of compliance. Traditionally, sales departments are responsible for training on product and selling skills, and compliance departments are responsible for training on company policies. However, there is not always a cohesive view on ‘what good looks like’ and what is needed to ensure a consistent organization wide approach to sales compliance excellence. At Sunovion, there are enormous opportunities and benefits to bringing sales and compliance closer together to develop and implement a collaborative strategy focused on sales excellence and compliance.

### THE “TONE FROM THE MIDDLE”

Both senior and middle management play important roles in communicating ethical standards and reinforcing compliance with these standards. Certainly, executives set the tone from the top that shapes the ethical culture throughout an organization. But when managers at all levels show they sincerely care about ethics, they influence the integration of ethics into the organization’s everyday activities.

“Tone From the Middle” is a strategy that focuses on first-line sales managers. It is a rallying point for organizations to create a consistent view on what ethical leadership and decision making looks like. It also provides an opportunity for additional training and tools to help managers establish a consistent tone and standards of performance across the organization.

The focus on first-line sales managers is based on the critical role they play. An organization of 500 representatives may have as many as 1,000,000 customer contacts per year! RBMs are primarily responsible for guiding and coaching these teams of Therapeutic Specialists who make the majority of those customer contacts. It is their responsibility to lead their TS group to make the right decisions for sales performance, compliance excellence, and integrity. Without an integrated, consistent strategy, the standards of what is considered the ‘right thing to do’ can change from one RBM and TS to another.





# Overview of Tone From the Middle

## WHY ETHICAL LEADERSHIP TRAINING FOR MANAGERS

All companies set standards of behavior and ethics which are typically outlined in company value statements and organizational codes of conduct. Sunovion requires employees to complete Code of Conduct and Ethics training, Compliance training and certifications throughout the year. A “Tone From the Middle” strategy embraces company values and the Code of Conduct and Ethics while focusing on the essential aspects of ethical leadership and decision making for RBMs and their teams.

Ethical Leadership is imperative in today’s complex regulatory world. An ethical leader is defined as one who uses communication, rewards, punishments, and behavior modeling to influence others to act in an ethical manner. By this definition, an ethical leader must have strong core values, the ability to communicate these values to others, and the courage to role model them at all times.

## CREATING “TONE FROM THE MIDDLE”

Establishing an effective “Tone From the Middle” strategy requires the organization to evolve from disconnected sales and compliance approaches to an approach that integrates these two functions. Achieving this integrated approach will depend on a high level of organizational commitment as well as dedicated resources and timelines. Without the appropriate commitment and resources, “Tone From the Middle” can quickly end up as a buzz word with little impact.

A focus on a comprehensive “Tone From the Middle” strategy and helping Regional Business Managers become ‘masters’ of ethical leadership and decision making will result in better role modeling, coaching, and monitoring of business activities. Well trained Therapeutic Specialists will be competent and confident in their decision making, thereby enabling them to know what they can do as well as cannot do while delivering sales excellence and building trust with customers.

At Sunovion, senior sales and compliance leadership recognize the importance of the RBM’s “Tone From the Middle” and are committed to enhancing their leadership role within this organization. With this commitment, RBMs can effectively lead the business and compliance efforts of the Sunovion organization through the hard work of their Therapeutic Specialists.



# Overview of Tone From the Middle

## Tone From the Middle: Benefits That Are Tangible

Such an integrated strategy can deliver enormous benefits. “Tone From the Middle” can:

- Build trust and satisfaction among first line sales leaders with their teams
- Help eliminate potential paralysis among Therapeutic Specialists and Regional Business Managers who are uncertain about the policies and procedures
- Build stronger communications and confidence between sales leaders, their teams and compliance groups
- Build a strong and consistent culture of business excellence and compliance with healthcare partners and stakeholders
- Encourage employees to speak up when they believe there are potential issues
- Protect patients, customers, employees and the company
- And importantly, build *trust and value* with our customer.





# Ethical Leadership and the Essential RBM Compliance Role

## Instead of Seeing Ethical Leadership as Preventing People From Doing the Wrong Thing, It Should Be Viewed as Enabling People to Do The Right Thing

Your Tone From the Middle and Ethical Leadership is critical to our business success. Being an ethical leader is more than just discussing the Sunovion policies and procedures and instructing and guiding your teams on the “dos” and “don’ts”. It involves a dedicated effort to examine how you think about compliance, and what you do to establish the appropriate tone and culture with your team and in turn establish consistent ethical behavior and compliance by each team member. To help lead your teams, below are some important concepts regarding ethical leadership that will help ensure your Sunovion sales teams are in full compliance, *all the time*.

## Important Aspects of Ethical Leadership for RBMs

Ethical Leadership represents the RBM’s proactive efforts to influence the Therapeutic Specialists’ ethical (and unethical) behavior:

- 1 Ethics are made an explicit part of their leadership agenda by regularly communicating an ethics, compliance and values message.
- 2 Leaders visibly and intentionally role model ethical and compliant behavior.
- 3 They use a reward system (rewards and discipline) to hold followers accountable for ethical and compliant conduct.
- 4 An ethical leadership message gets Therapeutic Specialists’ attention and can build trust in their leader.

### PREPARATION

Do I always prepare for each field coaching day with my TS by reviewing the RBM compliance checklist? Do I know the answers and/or know where to look for them? What are my resources?

### COMMUNICATION

Do I prioritize the value of compliance in our business through my e-mails, voicemails, and during our conference calls? Do I recognize and/or reward my team for outstanding compliance behavior?

### TRAINING

Am I quick to recognize a training need for my team when the landscape of their business changes and there are additional compliance considerations? Am I knowledgeable about Compliance training opportunities at Sunovion?

### ROLE MODELING

Do my own actions reflect my communication on compliance with my reps? Do I engage customers with the same expectations I have for my reps?

# Ethical Leadership and the Essential RBM Compliance Role

## QUESTIONS TO ASK MYSELF AS AN ETHICAL LEADER

- 1** Am I making a strong commitment to routinely discuss ethics, compliance and the value of doing the right thing?
- 2** Am I telling a compelling and morally rich story but also embodying and living this story at meetings, during field ride-alongs, and after hours with my team and other sales leaders?
- 3** How will my leadership impact my Therapeutic Specialist's trust in me? What would my TSs say my values are? Am I creating an open environment in which my team is comfortable discussing and learning about compliance?

## ETHICAL LEADERSHIP REQUIRES COMMITMENT

Becoming an ethical leader is relatively simple; it requires a commitment to examine your own behavior and values and the willingness and strength to accept responsibility for the effects of your actions on others. As an RBM, each day you reaffirm your own principles and values by making good ethical leadership decisions, you will dramatically impact compliance and your reputation with your sales team, your customers and their patients.





# Steps to Good Ethical Decision Making

Many compliance infractions result from individuals making decisions without full knowledge of the compliance requirements, or they make poor ethical decisions. As leaders, you want to avoid situations where a Therapeutic Specialist makes a poor ethical choice and then says *“I didn’t know”* or *“I misunderstood”* or *“I thought it was the right thing to do.”* Therapeutic Specialists need to know what they can’t do, but importantly they also need to be self-sufficient and make good ethical decisions on what they “can do” when they face compliance situations that may not seem clear cut during the course of their business day.

To help you train and coach your TSs on how to make good ethical and compliant decisions on a consistent basis, below are some important steps on how to make good ethical decisions *all the time*.

## Steps to Good Ethical Decision Making

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### 1 Be a Master and be Alert

- Become a master of the compliance policies and procedures so that you know when you might be facing a potential compliance risk.
- Always be alert; ask yourself if there is something about the situation that makes you uncomfortable.

### 2 Examine the Situation

- Potential issues may disappear upon closer examination of the situation, or may change significantly.
- Evaluate the situation from different perspectives; what is the context?
- Ask yourself if you are well prepared to make a decision; could personal feelings, biases, or self-interests affect your ethical judgment?

### 3 Refer to the Standards

- When possible, always refer to Sunovion’s Code of Conduct and Ethics, the Sunovion policies and any other relevant company standards.



# Steps to Good Ethical Decision Making

## Steps to Good Ethical Decision Making

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### 4 Test the Options

Before acting, evaluate different options with these questions:

- 🟡 Regulatory test—Do I put myself or Sunovion at risk for non-compliance with the FDA?
- 🟡 Harm test—Could patients, customers or others be potentially harmed?
- 🟡 Trust and Reputation test—What will be the impact on the Sunovion's reputation and business relationship with this HCP? Will I build or damage the trust I have with my customer?
- 🟡 Publicity test—Would I want this conduct to be published in the newspaper?
- 🟡 Organization test—What would Compliance or Legal counsel say about this conduct?
- 🟡 Colleague test—What might my supervisor and peers say about this conduct?
- 🟡 Defensibility test—Could I defend this conduct before a committee of peers?
- 🟡 Reversibility test—Would I still think my choice was good if I were adversely affected by it?

### 5 Reach Out

- 🟡 If possible and appropriate, discuss the situation with your manager or peers before acting.
- 🟡 As needed, contact the Compliance Department for their opinion.

### 6 Document, Document, Document

- 🟡 Always accurately document what the situation was and the decision that was made.

### 7 Learn and Improve

- 🟡 Could this situation have been prevented? What could you do to prevent such a situation again and make it less likely that you would have to make such a decision?
- 🟡 Is there any way to have more support next time?
- 🟡 Is there anything that the organization might need to change? (e.g. possible policy changes)

# Steps to Good Ethical Decision Making

## GOOD ETHICAL AND COMPLIANT DECISION MAKING IN ACTION

Frank scheduled lunch with a very important targeted physician in his territory. He had not had much success seeing this physician other than a quick introduction at the nurse's station. As he was setting up the lunch, the receptionist commented that the doctor often is so busy at lunch that he sometimes is not able to come to the lunch or comes very, very late. Frank knew the Sunovion guidelines for lunch with a customer and emphasized with the receptionist and the office manager that he would need to make a product presentation to the physician to meet his company's requirements for providing a meal. They assured Frank that they would have the physician attend the lunch.

Frank delivered the food at the scheduled time the following week. Unfortunately, the physician had been called away for an emergency and was unable to meet with Frank that day. Frank met with the office staff and discussed his product and the company's coupon program. The office manager assured Frank that if he scheduled another lunch, the physician would surely make time to sit down with Frank.

Frank thought about the situation. He was not permitted to provide a meal without a legitimate presentation with a targeted HCP. Obviously this had been a rare case with the emergency, but he had to consider taking the chance again. On his next visit to the office, he spoke briefly with the physician, but again did not have time for a product presentation. Because he wanted more time to speak with the physician, Frank decided to schedule one more lunch.

Frank again delivered the lunch to the office. This time the physician was in the office, but was 90 minutes behind with his patients. Frank waited over an hour in the lunch room, speaking with the office staff as they grabbed lunch, but the physician never came back to the lunch room. The office manager finally arrived and gave Frank the "bad news". The physician was unable to meet with him today. She offered to reschedule Frank for another lunch in the next few weeks. Frank politely declined.

Frank's in-depth knowledge of the compliance requirements for providing meals to a customer resulted in him making a decision about future meal opportunities with this customer. As important as this targeted physician was, he decided to make the right choice and not schedule lunch anymore in this office.

After the lunch, Frank documented what happened. On his way to the next appointment, he called his RBM to share his experience. The manager agreed with his decision about scheduling future lunches with this physician and asked him to present his story to his peers at their regional conference call.



# Steps to Good Ethical Decision Making

## ETHICAL DECISION MAKING BUILDS CONFIDENCE AND TRUST...EVERYWHERE

Having a solid foundation of ethical decision making allows your Therapeutic Specialist and you to focus on successful sales strategies and impact your business while maintaining the highest standards of compliance excellence and integrity.

Therapeutic Specialists no longer focus on what they *can't do* but have confidence in the strategies they *can do*. This sustains trust in Sunovion with our customers and patients by the ethical decisions our TSs and RBMs make on a daily basis.





# Compliance Coaching Best Practices

## Bringing Compliance Mentoring and Coaching to Life

RBM's are responsible for not only outstanding sales performance with their sales team but also ensuring 100% compliance. Coaching on sales performance has always been a part of the RBM's requirements but coaching on compliance is a relatively new skill. Compliance coaching requires RBMs to have a high level of comprehension of the Sunovion policies and procedures, as well as an understanding on how to provide the right guidance and coaching to motivate their teams to be fully compliant while achieving their sales goals.

Coaching Therapeutic Specialists can be one of the most rewarding responsibilities of an RBM's role as a sales and compliance leader. The best RBMs ensure their coaching creates outstanding sales performance as well as outstanding compliance performance.

The following best practices will help you effectively mentor and coach and will create a positive culture of compliance along with greater compliance comprehension and expertise. Ultimately it will ensure a high level of compliance, all the time.

## Compliance Coaching Best Practices

### PERSONAL BELIEF AND CONVICTION

- Inspiring leadership always begins with a strong vision, personal belief and conviction. Compliance is a requirement, but an effective tone from the middle is driven by personal beliefs.
- As an RBM, you should know that compliance is not an obstacle to sales performance but a benefit that protects customers, patients, and employees, as well as builds trust and enhances the reputation of sales colleagues and the company.
- When coaching on compliance, you should be able to convey not only the compliance requirements, but also share your personal belief and convictions about the benefits and value of compliance to your sales team, the organization and customers.
- Share best practices of your team, or other teams within your area or nation.





# Compliance Coaching Best Practices

## PLANNING AND PREPARATION

Compliance coaching should be included on every field ride-along. Prior to the meeting:

- Review recent field coaching reports, expense reports, speaker program forms and reports, training status and other reports regarding the individual's compliance performance.
- Plan on discussing any new or updated company policies and procedures and any recent compliance training, Code of Conduct training or compliance hot-topics. Even if there are no compliance issues to discuss, always plan on a compliance reminder discussion.
- Plan for compliance questions that the Therapeutic Specialists may have, or for any sensitive or difficult discussions. Think about the mindset and messages you will use to ensure the discussion is clear and the messages and direction are well understood.
- Gather any documents (such as Sunovion policy documents) that you may use to support the topics to be discussed.

## DURING THE COACHING DAY

Listen and create an environment of open and honest communication with your TS. During your field ride-along and coaching day:

- Silence your cell phones and give your undivided attention to the TS.
- Listen carefully to the compliance challenges they may be facing. Ask questions to clarify details and avoid any misunderstanding.
- Reinforce the policies and procedures and provide the rationale of the compliance requirements.
- Always be sure to explain the benefits and value of a highly effective and compliant sales call.
- Explore together the answers to any compliance questions from your TS. Remind them of the compliance resources they have at their disposal and where to find them, and encourage them to be compliance experts on topics they are unsure of, and to be appropriately self-sufficient.
- Role-play with the TS on compliant messaging and compliance activities, including how to prevent compliance issues. For example, discuss ways to communicate appropriate product clinical messaging or how to handle difficult situations.

# Compliance Coaching Best Practices

## ACTION PLANS

At the end of your field ride-along and coaching day:

- Reiterate and reinforce the key compliance discussions that you had.
- For areas of need, ask the TS to create a brief compliance action plan.
- Be part of the plan: Follow-up promptly with the TS on any compliance questions that may need additional input from sales leadership or the Compliance and Ethics Department.

## ROLE MODELING

You are the most visible member of the Sunovion leadership team for your Therapeutic Specialists and as such, it is essential to be consistent in what you say and what you do regarding compliance. You can role model 'what good looks like' by:

- Demonstrating a mastery of the Sunovion Code of Conduct and Ethics and Sunovion policies with your team, customers, peers and Senior Leadership.
- Encouraging your Therapeutic Specialists to share their compliance comprehension and expertise with their sales colleagues.
- Being clear and consistent... in your communications, messages, tone and in your actions. Therapeutic Specialists need to know that consistency is a key component of good compliance.
- Modeling good compliance behavior such as interactions with their HCP customers.
- Championing the compliance efforts within your own area management team.
- Never compromising your own ethical and compliant behavior regardless of the circumstances (meetings, ride-alongs, conference calls, etc.).

## FIND OTHER WAYS TO COMMUNICATE ON COMPLIANCE

RBM's may have limited time at region, area and national meetings to share compliance information and best practices. Use other avenues to regularly communicate to your teams on compliance such as:

- Include compliance on every regional conference call agenda.
- Select a regional compliance champion from your team to help lead discussions on compliance and ethics, creating a team approach to compliance.
- On occasion, invite a member of Sunovion's Compliance and Ethics Department to join your Regional conference call.
- Leave a group "friendly reminder" voice mail on a compliance related topic.

# Compliance Coaching Best Practices

## TRAINING

Be the first to become a master of the compliance training material. Quickly embrace any new training with your sales team. Other ideas include:

- On a regular basis, evaluate your TS's compliance knowledge with questions or discussions about compliance.
- Use the Therapeutic Specialist Compliance Assessment to evaluate your team's compliance comprehension, mindset and skills.
- Create an action plan of additional training for your sales team when needed.
- Engage Sunovion's Compliance and Ethics Department in dialogue about ideas and suggestions for additional training.

## REWARD AND RECOGNIZE

Acknowledge your sales representatives for outstanding compliance behavior and share those successes and compliance best practices with your team. Some examples include:

- Recognizing individual best practices on a conference call or at a regional or national meeting.
- Sending a note to your Area Sales Director and copying the TS on a best practice or compliance success story.
- Share with senior leadership any compliance ideas that may come up from your team on how to improve compliance performance.

## RESOURCES

Be sure you know where to find compliance resources such as:

- Exploring the Compliance and Ethics page on the Source.
- Training sales reps to find their own answers. Consider assigning one of your sales reps to lead a compliance resource workshop or discussion.
- Reviewing the compliance policies during field coaching days.
- Referring to the RBM Compliance Checklist before, during and after each field coaching day.



# Compliance Monitoring Best Practices

## Compliance Monitoring—An Essential Skill

RBM's have a unique and essential role of a leader and coach of not only sales performance but also sales compliance performance.

Ongoing, comprehensive monitoring for compliance helps you become a more effective sales leader. It provides you with essential information that will help ensure your team is compliant every day, but also provides you with an opportunity to provide encouragement, recognition, coaching and training on areas of improvement. The purpose of all performance management systems, including compliance monitoring, is not only to know how the business and Therapeutic Specialists are performing but to *enable them to perform better*.

The following *Compliance Monitoring Best Practices* will help you ensure a high level of compliance, all the time. It will also help you lead a positive culture of compliance and reinforce greater compliance skills, comprehension and expertise within your sales team. Remember, monitoring for compliance performance entails not only identifying potential gaps, but also identifying your TSs doing something "good" as well!

### THE BENEFITS OF ONGOING SALES COMPLIANCE MONITORING

- Ensures standards are met and reduces risk
- Helps prioritize areas for improvement
- Helps with reinforcement, motivation and influencing behavior
- Gives a view to 'best practices'
- Helps improve productivity and effectiveness

### WHAT IS EFFECTIVE COMPLIANCE MONITORING?

Effective compliance monitoring is more than a check-the-box approach. It includes a dedicated, ongoing effort to quantitatively and qualitatively evaluate performance to the compliance standards as well as compliance skills. It includes a focus on the details of records and documents as well as keen observations of activities. It is an on-going process, not an occasional or periodic activity. As a rule of thumb, monitoring for compliance performance should happen to the same degree as daily monitoring of sales performance.





# Compliance Monitoring Best Practices

Listed below are two essential areas for RBM compliance monitoring:

## 1 Are Compliance Standards Consistently Met?

Regularly monitor the records, documents and activities of each team member to ensure the compliance standards are being consistently met.

REGULAR REVIEW OF DOCUMENTS AND RECORDS	REGULAR OBSERVATIONS OF SALES ACTIVITIES
<ul style="list-style-type: none"><li>• Target lists and Call plans</li><li>• Entry of Sales Calls and Call Notes (where applicable)</li><li>• Sampling Reports/Volumes</li><li>• Expense Submissions/Timeliness</li><li>• Exhibit Funding Requests</li><li>• Medical Information Requests</li><li>• Completion of Mandatory Training</li><li>• Communications You Receive</li></ul>	<ul style="list-style-type: none"><li>• Sales Calls</li><li>• Lunch and Learns</li><li>• Other Customer Interactions</li><li>• Speaker Programs</li><li>• Sampling</li><li>• Exhibiting</li><li>• Adverse Event Reporting</li></ul>

## 2 Are Individuals Demonstrating Effective Compliance Mindset, Comprehension and Skills?

Regularly monitor the compliance mindset, comprehension and skills of your team members to ensure they have the skills and behaviors to be compliant, all the time.

COMPLIANCE MINDSET	Embracing compliance and knowing the value and benefits of compliance
COMPLIANCE COMPREHENSION	Deep level of knowledge, understanding and expertise on compliance requirements
COMPLIANCE SKILLS	<p><b>Decision making:</b> Making good ethical decisions when there is uncertainty</p> <p><b>Communications:</b> Effective tone and careful communications regarding compliance</p> <p><b>Use of Tools:</b> Use of compliance tools and resources daily</p> <p><b>Being Proactive:</b> Thinking ahead and acting proactively to prevent potential issues</p> <p><b>Raising Issues:</b> Recognize and inquire about new compliance issues to an RBM or member of the Compliance &amp; Ethics Department</p> <p><b>Consistency:</b> Ensuring consistent behavior and actions regarding compliance</p> <p><b>Monitoring:</b> Continuous self-monitoring for improvement</p> <p><b>Documentation:</b> Accurately documenting compliance information</p> <p><b>Reporting:</b> Reporting information and issues in a timely and accurate manner</p>

# Compliance Monitoring Best Practices

## COMPLIANCE MONITORING: WHAT TO LOOK FOR

**ADHERENCE TO STANDARDS:** Are all of the policies and procedures being met?

**POTENTIAL LIABILITY:** Does the activity potentially expose Sunovion to liability? (intentional or not)

**CONSISTENCY:** Is compliance performance happening consistently? Is good judgment being applied all the time?

**REPEATING BEHAVIOR AND PATTERNS:** Are there compliance gaps that are repeating, or compliance gaps happening in a number of different areas?

**INTENTION:** Is there a deliberate effort not to be compliant?

**RESISTANCE:** Is there resistance to discussing or divulging information, or resistance to coaching?

**OPPORTUNITIES TO RECOGNIZE:** Are there areas of compliance performance that the individual has excelled at which could be recognized and possibly shared as a best practice?

## MONITORING AND ASSESSMENT CRITERIA

Based on your review of documents and records as well as your observations, assess each area of a team member's compliance performance using the following criteria:

**DEMONSTRATING:** The team member consistently meets the compliance requirements, and consistently demonstrates compliance mindset and skills

**COACHING/TRAINING:** The team member needs additional coaching and training in specific areas

**ESCALATE:** There is sufficient information or reason to believe that the team member's compliance performance needs to be escalated (e.g. areas of potential liability, clear intent, and/or repetitive)



# Compliance Monitoring Best Practices

## STEPS TO GREAT COMPLIANCE MONITORING

Listed below are the essential steps to ensuring effective compliance monitoring by RBMs:

- 1 Be a Master:** Be a master of the details of the compliance policies and procedures and fully understand the compliance standards and how to drive great compliance performance via a positive compliance mindset, comprehension and skills. Become fully knowledgeable and self-sufficient on compliance standards, including any compliance updates or new compliance requirements.
- 2 Plan and Prioritize:** Create a detailed compliance monitoring schedule for each of your team member's compliance performance. Identify areas of strength and areas for potential monitoring and enhancement. Monitor all areas of an individual's compliance performance throughout the year. Monitoring should take place on a daily and weekly basis. Reviews of records and documents should take place on an ongoing basis and ride-alongs should be regularly planned. Always include a priority focus on (1) areas of high risk such as off-label discussions and potential anti-kickback activities (e.g. meals and the provision of value), (2) past concerns or areas of improvement, (3) any updated or new compliance policies or procedures or training that need immediate implementation, (4) aggregate spend reporting activity, and (5) timely call and Lunch and Learn recording.
- 3 Gather/Observe and Assess:** Based on the planned monitoring schedule for each team member, review past and recent records and conduct ride-alongs to observe and coach on compliance. During ride-alongs, remember to observe and participate as necessary in the sales call. Use the RBM Compliance Checklist to assess, monitor and coach on the compliance mindset, skills and comprehension of each team member. Verify and double-check any findings from your compliance monitoring to make sure the information is correct. And finally, create clear and accurate documentation of your monitoring findings.
- 4 Action Plans:** After each monitoring activity, develop specific action plans for that team member to help them become masters of compliance. Include in your action plan a brief description of what action is being taken, and when. For areas that don't need to be escalated, schedule time with the team member to discuss the findings of your monitoring, and coach and train them on areas of improvement as well as recognize them for great compliance performance.

## COMPLIANCE MONITORING—AN INVESTMENT

Raising the level of sales force compliance requires sustained commitment and effort. Performance management systems can often fail because managers don't fully implement effective measurement and monitoring processes. Measuring and monitoring compliance performance is as important as measuring and monitoring sales performance. As leaders, ongoing, comprehensive compliance monitoring is a requirement but it is also an excellent investment in your time; it provides you with an opportunity to evaluate how your team is performing and importantly, it will enable you to help them perform even better.

# Compliance Monitoring Best Practices

## RBM COMPLIANCE MONITORING CHECKLIST—OBSERVATIONS

	What RBMs Should Monitor for:	Other Things to Watch for:
SALES CALL OBSERVATIONS	<ul style="list-style-type: none"><li>• Appropriate audience and location</li><li>• Appropriate indications and fair balance</li><li>• Approved and current materials used</li><li>• No altering of the sales materials</li><li>• Appropriate handling of off-label questions and Medical Information Requests</li><li>• Appropriate handling of Adverse Events</li><li>• Appropriate field medical interactions</li><li>• Appropriate and timely recording of sales calls</li></ul>	<ul style="list-style-type: none"><li>• Competitive interactions</li><li>• Waiting room and patient interactions</li><li>• Government interactions (as applicable)</li><li>• Days with no sampling transactions</li><li>• Recording “out of territory” days timely</li><li>• Record absences/vacations in Oracle under iTime.</li></ul>
LUNCH AND LEARN OBSERVATIONS	<ul style="list-style-type: none"><li>• Appropriate attendees</li><li>• Appropriate setting</li><li>• Modest meal guidelines followed</li><li>• No meals for non-attendees</li><li>• All attendees received a presentation</li></ul>	<ul style="list-style-type: none"><li>• Non-attendees and food/beverages</li><li>• Handling of left-over food</li></ul>
SPEAKER PROGRAM OBSERVATIONS	<ul style="list-style-type: none"><li>• Appropriate program venue and set-up</li><li>• Appropriate attendees and sign-in</li><li>• Appropriate meals</li><li>• Appropriate speaker briefing by TS</li><li>• Appropriate TS onsite monitoring</li><li>• Appropriate handling of off-label discussions</li><li>• Appropriate discretion on issues (e.g. “walk-ins”, inappropriate attendees)</li><li>• Appropriate receipt and program close-out</li></ul>	<ul style="list-style-type: none"><li>• Arrival time and preparation</li><li>• Location of presentation screen</li><li>• Consumption of alcohol</li></ul>



# Compliance Monitoring Best Practices

## RBM COMPLIANCE MONITORING CHECKLIST—OBSERVATIONS

	What RBMs Should Monitor for:	Other Things to Watch for:
EXHIBITING OBSERVATIONS	<ul style="list-style-type: none"><li>• Appropriate audience and location</li><li>• Appropriate indications and fair balance</li><li>• Approved and current materials used</li><li>• No altering of the sales materials</li><li>• Appropriate handling of off-label questions and Medical Information Requests</li><li>• Appropriate handling of AEs</li><li>• Appropriate field medical interactions</li></ul>	<ul style="list-style-type: none"><li>• Patient interactions</li><li>• Unattended exhibit</li></ul>
SAMPLE OBSERVATIONS	<ul style="list-style-type: none"><li>• Appropriate transportation</li><li>• Appropriate car storage</li><li>• Appropriate home storage</li><li>• Appropriate signature</li><li>• No handling of competitive samples</li><li>• No samples for personal use</li></ul>	

# Compliance Monitoring Best Practices

## RBM COMPLIANCE MONITORING—RECORD REVIEWS

	What RBMs Should Monitor for:	Other Things to Watch for:
SALES CALL RECORDS	<ul style="list-style-type: none"><li>• Sales Call plans</li><li>• Sales Call notes (where applicable)</li><li>• Promotional Materials ordering and inventories</li></ul>	<ul style="list-style-type: none"><li>• Timeliness of input data</li><li>• Accuracy of attendee data</li><li>• Past email and text communications you received</li></ul>
LUNCH AND LEARN RECORDS	<ul style="list-style-type: none"><li>• Attendee forms</li><li>• Expense submissions</li><li>• Update office roster that is maintained within Veeva</li></ul>	<ul style="list-style-type: none"><li>• Timeliness</li><li>• Legibility</li><li>• Legitimacy (no fabrication)</li><li>• Potential conflicts of interest</li><li>• Items other than food and beverage</li><li>• Quantity of meals matches number of appropriate attendees</li></ul>
SPEAKER PROGRAM RECORDS	<ul style="list-style-type: none"><li>• Attendee evaluation forms</li><li>• Expense submissions</li><li>• Speaker program monitoring checklist</li></ul>	<ul style="list-style-type: none"><li>• Timeliness</li><li>• Legibility</li><li>• Legitimacy (no fabrication or lack of candor)</li><li>• Items other than food and beverage</li></ul>
EXHIBITING RECORDS	<ul style="list-style-type: none"><li>• Exhibit fund request records</li><li>• Expense submissions</li></ul>	<ul style="list-style-type: none"><li>• Sales Call notes for sales call entries</li></ul>
EXPENSE RECORDS	<ul style="list-style-type: none"><li>• Attendees match Veeva data or reinforce Veeva attendance record</li><li>• Amounts and policy limits</li><li>• Receipts</li><li>• Payment method</li><li>• Coding of expenses</li><li>• Any exceptions</li></ul>	<ul style="list-style-type: none"><li>• Timeliness</li><li>• Legibility</li><li>• Legitimacy (no fabrication or lack of candor)</li><li>• Potential conflicts of interest</li><li>• Items other than food and beverage</li></ul>
SAMPLE RECORDS	<ul style="list-style-type: none"><li>• Sample inventory reports</li><li>• Sample requests</li><li>• Timely month end of inventories</li></ul>	<ul style="list-style-type: none"><li>• Regularly synchronization to upload data</li></ul>
MANDATORY TRAINING RECORDS	<ul style="list-style-type: none"><li>• Training records for completion</li><li>• EDGE completion reports</li></ul>	<ul style="list-style-type: none"><li>• Attendance and participation at district and other sales meetings where compliance training and requirements are being discussed</li></ul>



# RBM Compliance Checklist

As sales leaders, you know that great sales performance is directly linked to effective selling competencies and skills. Great compliance performance is the same; the right compliance competencies and skills are needed.

This RBM Compliance Checklist is designed to help you assess and coach your team on what ‘good looks like’ regarding compliance competencies and skills. It is intended to be used as a coaching tool; it is not intended to be a report card on specific, detailed compliance policies, a performance evaluation or to replace the field coaching report. It should be used as a tool to help facilitate a conversation with your Therapeutic Specialists on their compliance skills.

Listed below are the components of what good compliance competencies and skills look like:

## COMPLIANCE ‘WHAT GOOD LOOKS LIKE’

MINDSET	Embracing compliance and knowing the value and benefits of compliance	
COMPREHENSION	Level of knowledge, understanding and expertise on compliance requirements	
COMPLIANCE SKILLS	Decision Making	Making good ethical decisions when there is uncertainty
	Communications	Effective tone and careful communications regarding compliance
	Use of Tools	Use of compliance tools and resources on a daily basis
	Being Proactive	Thinking ahead and acting proactively to prevent potential issues
	Consistency	Ensuring consistent behavior and actions regarding compliance
	Monitoring	Continuous monitoring of and enhancing compliance
	Documentation	Appropriately and accurately documenting compliance information
	Reporting	Reporting information and issues in a timely and accurate manner

# RBM Compliance Checklist

The RBM Compliance Checklist should be used on a periodic basis to assess the compliance skills, performance and needs of your TSs:

## 1 Assess

- ▲ Prior to meeting with your TS, you should review the compliance performance of that individual (e.g. previous expense reports, call logs, MIRF activity, speaker program reports, email communications, etc.).
- ▲ Review the RBM Compliance checklist and think about how the individual performs in each area, making any notes that you may want to discuss with them.

## 2 Discuss

- ▲ During the ride-along, discuss compliance performance with your Therapeutic Specialist.
- ▲ Engage in a dialogue with them on the compliance skills above. Discuss the different skills needed for great compliance and see if there are areas to improve upon.
- ▲ Get their views on how they think about compliance and if they understand the benefits of adding trust and value to customers.
- ▲ Explore their compliance knowledge and understanding on various topics.

## 3 Action Plans and Follow-up

- ▲ At the end of your discussion with the representative, establish some specific action plans on compliance skills, mindset and/or comprehension that they might need to improve upon.
- ▲ Always be sure to promptly follow-up with your representatives with any unanswered questions that came from your discussion.





# RBM Compliance Checklist

## COMPLIANCE ‘WHAT GOOD LOOKS LIKE’

			NOTES
MINDSET	Embracing compliance and knowing the value and benefits of compliance		
COMPREHENSION	Level of knowledge, understanding and expertise on compliance requirements		
COMPLIANCE SKILLS	Decision Making	Making good ethical decisions when there is uncertainty	
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# RBM Compliance Checklist

## SALES CALLS—QUICK HIT COMPLIANCE REQUIREMENTS

Appropriate Messaging	<ul style="list-style-type: none"><li>• Provision of approved clinical messages</li><li>• Provision of fair balance</li><li>• How to deal with off-label questions and discussions</li><li>• Offer MIRF for unsolicited off-label questions</li></ul>
Appropriate Use of Materials	<ul style="list-style-type: none"><li>• Using approved materials only</li><li>• No ‘home-made bread’</li><li>• Consistent distribution of prescribing information</li></ul>
Appropriate Management of Samples	<ul style="list-style-type: none"><li>• Appropriate storage</li><li>• Non-handling of competitive samples</li><li>• Consistent sample documentation and record keeping</li></ul>
Appropriate Adverse Event Reporting	<ul style="list-style-type: none"><li>• Accurate and timely documentation and reporting of Adverse Events</li></ul>

## LUNCH AND LEARNS—QUICK HIT COMPLIANCE REQUIREMENTS

Appropriate Meal and Beverages	<ul style="list-style-type: none"><li>• Meets modest cost and quantity guidelines</li><li>• Meal was consumed during medical/educational discussion only</li><li>• Meets in-office limit of \$25 per HCP</li><li>• Provided on an Occasional basis</li></ul>
Appropriate Attendee	<ul style="list-style-type: none"><li>• Meets the Sunovion criteria for a legitimate attendee</li><li>• Meal included a medically relevant discussion</li><li>• Not to induce a “Quid Pro Quo”</li></ul>
Appropriate Venue	<ul style="list-style-type: none"><li>• Was conducive for a medically relevant discussion</li><li>• Meal was consumed in-office only</li></ul>

## COMMUNICATIONS (EMAILING, TEXT MESSAGING)—QUICK HIT COMPLIANCE REQUIREMENTS

Emailing and Text Messaging Guidelines	<ul style="list-style-type: none"><li>• Scheduling appointments and confirming meetings only</li><li>• Do not use Sunovion product names unless using a PMRC approved email</li></ul>
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# RBM Compliance Checklist

## SPEAKER PROGRAMS—QUICK HIT COMPLIANCE REQUIREMENTS

Appropriate Speaker	<ul style="list-style-type: none"><li>Contracted with Sunovion</li><li>Trained on Sunovion product</li></ul>
Appropriate Venue	<ul style="list-style-type: none"><li>Conference center, hotel meeting room, private room in a restaurant</li><li>No recreation involved</li></ul>
Appropriate Meals and Beverages	<ul style="list-style-type: none"><li>Modest in comparison to local standards</li><li>Meal and Beverage Policy followed</li></ul>
Appropriate Attendees	<ul style="list-style-type: none"><li>At least three legitimate attendees confirmed</li><li>No spouses unless they are legitimate attendees (nurses, medical assistants, etc)</li><li>Sign-In Sheet available for documentation of attendees</li></ul>
Appropriate Monitoring of Speaker Presentation	<ul style="list-style-type: none"><li>Uses only approved Sunovion slide deck</li><li>Refers unsolicited off-label questions to Medical Information</li><li>Does not solicit off-label discussion from the audience</li><li>Declines to answer off-label questions during Q &amp; A</li></ul>
Reporting Speaker Infractions	<ul style="list-style-type: none"><li>Follows Sunovion policy on speaker infractions</li><li>Contacts RBM within 24 hours for serious infractions</li></ul>

## LOCAL EXHIBITS—QUICK HIT COMPLIANCE REQUIREMENTS

Promotional Exhibits	<ul style="list-style-type: none"><li>Fees do not exceed FMV (Fair Market Value) for this venue</li><li>Only approved material used</li><li>Exhibit contract is processed appropriately through legal</li></ul>
Community-based Fund Raising Events	<ul style="list-style-type: none"><li>Participate in therapeutic areas that are relevant to their products</li><li>Purchase exhibit space at this event based on Sunovion policies</li><li>Use only materials approved for Direct-to-Consumer advertising</li><li>Will not answer patient questions about disease state or Sunovion products</li></ul>



# Therapeutic Specialist Compliance Assessment

FOR RBM THERAPEUTIC SPECIALIST DIALOGUE

As Sales colleagues, you know that great sales performance is linked to selling knowledge and skills. Compliance is the same; the right compliance knowledge and skills are needed for great compliance performance. Great selling skills combined with great *compliance* skills will help you drive greater sales performance and it will help enhance the trust and value that you create and bring each day to your customers.

This Compliance Assessment is not a performance evaluation. It is designed to help you evaluate your compliance mindset, compliance comprehension and compliance skills and determine areas of strength and opportunities to improve upon.

## 1 EACH THERAPEUTIC SPECIALIST COMPLETES EACH SECTION OF THE ASSESSMENT

- Section 1—Your mindset; how you think and integrate compliance into your day-to-day selling
- Section 2—Your compliance comprehension; your understanding of key compliance areas
- Section 3—Your compliance skills

- Be honest—your ability to improve and become a master of compliance will depend on an honest assessment of your strengths and areas to potentially improve upon. This Assessment is just for you; it will not be submitted.

## 2 FOLLOW-UP INDIVIDUAL DISCUSSIONS WITH YOUR MANAGER

- At the next ride-along/coaching day, discuss the compliance assessment and your 1-2 individual compliance training needs with your RBM and develop an action plan to enhance your compliance mindset, comprehension and skills.



# Therapeutic Specialist Compliance Assessment

FOR RBM THERAPEUTIC SPECIALIST DIALOGUE

## 1 HAVING THE RIGHT COMPLIANCE MINDSET

Compliance excellence also depends on how you think, discuss and integrate compliance into your day-to-day selling activities. Take 5 minutes to assess how you would rate yourself compared to these common characteristics of mastering compliance

	YES / ALWAYS	MAYBE/ SOMETIMES	NO / NEVER
Do you see compliance as potentially adding value to achieving your sales goals?			
Do you see compliance as a barrier to achieving your sales goals?			
When discussing compliance requirements with HCPs and customers, do you express them in a positive tone and explain the rationale and benefits?			
Do you proactively share best practices regarding compliance situations with your manager and teammates?			
Do you proactively look for compliance answers?			
Do you feel confident that you can handle any unexpected compliance situations?			

List three benefits of compliance:

1.
2.
3.

# Therapeutic Specialist Compliance Assessment

FOR RBM THERAPEUTIC SPECIALIST DIALOGUE

## 2 BUILDING YOUR COMPLIANCE COMPREHENSION

- True understanding and comprehension is ‘being able to accurately describe the details to another person.’
- For each category, write down at least one area in which you could enhance your compliance comprehension, e.g. either a recent situation that came up, a common or recent question from HCPs or customers, or compliance areas you may be uncertain of.

- Clinical Messaging
- Effectiveness claims
  - Safety and fair balance
  - Off-label questions
  - Use of materials
  - Providing prescribing information

- Speaker Programs
- Invitations
  - Cancellations
  - Attendees
  - Off-label questions
  - Monitoring and Speaker Infractions
  - Meals and receipts

- Lunch and Learns
- Ordering food
  - Attendees
  - Location
  - Left-over food
  - Medically relevant discussion

- Local Exhibits
- Contracting process
  - Materials used
  - Location
  - Patient focused exhibits
  - Interactions with patients

# Therapeutic Specialist Compliance Assessment

FOR RBM THERAPEUTIC SPECIALIST DIALOGUE

## 2 BUILDING YOUR COMPLIANCE COMPREHENSION

- True understanding and comprehension is ‘being able to accurately describe the details to another person.’
- For each category, write down at least one area in which you could enhance your compliance comprehension, e.g. either a recent situation that came up, a common or recent question from HCPs or customers, or compliance areas you may be uncertain of.

Email, Texts and Social Media

- Use of brand names
- Purpose of email/texts
- Use of Twitter, Facebook

Adverse Event Reporting

- What is an AE?
- What you need to report
- How to report

Sunshine Act

- How to handle questions from HCPs and customers

# Therapeutic Specialist Compliance Assessment

FOR RBM THERAPEUTIC SPECIALIST DIALOGUE

## 3 ENHANCING YOUR COMPLIANCE SKILLS

Compliance skills are similar to selling skills; they are essential to ensuring great compliance performance. In selling you learn about introductory benefit statements, how to deliver clinical messaging, and how to close. In compliance, the following skills will help you achieve great compliance performance. Answer the following questions to determine how well you rate your own compliance skills.

		OFTEN	SOMETIMES	RARELY/NEVER
Decision Making	Do you <u>NOT</u> do something because you are not sure of the compliance requirements?			
	Do you delay decisions because you need to find out the answers?			
	In complex situations, are you confident that you can make a good ethical and compliant decision <i>in the moment</i> ?			
Communications	Do you speak effectively and positively about the rationale and benefits of compliance?			
	Are you careful about your compliance communications and therefore the choice of words and language so that you accurately describe a situation?			
	Do you speak up when you feel there has been a potential violation of compliance policies and procedures?			
Use of Tools	Do you use compliance tools and resources on a daily basis?			
Proactive	Do you think ahead and act proactively to prevent potential issues?			
Consistency	Do you ensure that you apply the compliance requirements consistently to all customers and situations?			
Documentation	Do you appropriately document compliance information in a timely basis?			



# Guide to Investigations

## Investigations

Compliance investigations are an infrequent but important component of the overall Sunovion compliance program. Sunovion conducts compliance investigations when actual or suspected violations of policies are reported. The investigations process is designed to ensure confidentiality, prevent retaliation, accurately and fairly assess what happened, and ensure the situation is resolved and the appropriate corrective action is implemented.

An investigation is a confidential, impartial fact-gathering process that allows Sunovion to evaluate a reported violation and achieve a resolution that is fair and appropriate. Typically, an investigation involves information and document gathering, interviews of those being investigated and witnesses, and a final resolution. The results of an investigation may include additional training and coaching on policies or processes but may also include disciplinary action.

The Compliance and Ethics Department handles all reports of fraud or misconduct, whether actual or suspected and is responsible for ensuring each case is appropriately handled and that the required corrective action takes place.

## REPORTING POTENTIAL VIOLATIONS— YOUR DUTY

All employees are required to report any suspected or potential violations of company policy. Not reporting an actual or potential infraction is also a violation of company policy. All employees can report a potential or suspected violation through their supervisors, Human Resources, Sunovion Compliance and Ethics, Legal or the anonymous Sunovion hot-line at <http://www.ethicspoint.com> or 1-866-886-1348.

Remember, violations of company policy can potentially impact patient safety as well as the trust and reputation of Sunovion with our customers and the public. There can also be serious legal ramifications for those involved and the company. So it is important that you speak up if you feel there has been a breach in policy.

## THE INVESTIGATIONS PROCESS DEMYSTIFIED

### DATA COLLECTION AND INTERVIEWS:

Compliance and Ethics collects relevant documents and typically conducts confidential interviews with those who reported the issue, the person (or people) who the report is about, and others who may have observed or be aware of the reported situation.

Many interviews are conducted over the phone, however, employees may be asked to travel for in-person interviews. Investigations are usually conducted in conjunction with Human Resources or Legal.

Once all the information is gathered, the investigator presents key findings and recommendations and sends this to the Compliance Investigation Committee (CIC). The CIC is composed of Compliance and Ethics, Legal and Human Resources and will make a final decision on the case. Business Leadership is then informed of the decisions and required actions.

### CORRECTIVE ACTION:

Business Leadership is responsible for carrying out the recommended corrective or disciplinary action, including notifying the employee who was investigated and their leadership.

# Guide to Investigations

## SUNOVION NON-RETALIATION POLICY

You may report any misconduct, either openly or anonymously, without fear of retaliation. Sunovion will not discipline, discriminate, or retaliate against any employee who reports a complaint or concern in good faith, or who cooperates in any investigations or inquiry regarding such conduct whether or not such information is ultimately proven to be correct. Moreover, Sunovion will not tolerate any adverse action or retaliation taken against any employee or agent by a supervisor or other employee on account of any compliant or concern raised.

## THE IMPORTANCE OF CONFIDENTIALITY

The investigations process and the results are confidential. Each RBM and TS has a responsibility to keep the contents of the investigations confidential. Only the people who need to know about an investigation are involved; this helps protect everyone’s privacy. A breach of confidentiality could impact the impartiality and legitimacy of an investigation, and could also disrupt the lives and careers of those involved. Sunovion Compliance and Ethics take extensive precautions to maintain confidentiality around an investigation which allows the outcome to be determined through an impartial process and reduces the risk of retaliation.

## YOUR ROLE IF YOU ARE INVOLVED IN AN INVESTIGATIONS INTERVIEW

COOPERATE AND ACTIVELY PARTICIPATE	<ul style="list-style-type: none"><li>■ You must fully cooperate with an investigation, including accepting requests for interviews with the investigator.</li><li>■ Your active participation is required, including being forthright and answering all questions honestly and disclosing all known information.</li></ul>
MAINTAIN COMPLETE CONFIDENTIALITY	<ul style="list-style-type: none"><li>■ Do not discuss the case—including the fact you are being interviewed or that an interview took place—with anyone other than the investigator, <i>including your regional business manager</i>. A breach of confidentiality can damage the investigations process or expose an employee to retaliation and could have serious disciplinary consequences, including termination.</li><li>■ If a colleague wants to discuss or share information about an investigation with you (whether actual or rumored), do not engage in a discussion. Politely decline and inform them that discussing an investigation can have serious ramifications. In addition remind them that any such investigation would be confidential and that if any investigation is on-going, they wouldn’t be able to speak of it anyway.</li></ul>

# Guide to Investigations

## YOUR ROLE IF YOU ARE INVOLVED IN AN INVESTIGATIONS INTERVIEW

BE TRUTHFUL AND DETAILED	<ul style="list-style-type: none"><li>Provide honest, detailed answers and don't misrepresent the situation or information.</li><li>Do not omit information you might consider related to the case but insignificant. Sometimes, information that may seem trivial to you can help the investigator better understand the context of a situation.</li><li>Remember you have a duty under the Code of Conduct to report any potential misconduct even if it is beyond the scope of the investigation.</li></ul>
BE CLEAR AND CLARIFY	<ul style="list-style-type: none"><li>Make sure the investigator understands all the points you are making.</li><li>If the investigator asks a question that is unclear, ask for clarification.</li></ul>
DO NOT RECORD	<ul style="list-style-type: none"><li>Interviews relating to an investigation may not be recorded by the interviewer or the interviewee in any way.</li><li>Recording of an interview is a violation of Sunovion policy and will result in dismissal.</li></ul>
NON-RETALIATION	<ul style="list-style-type: none"><li>If you feel someone is retaliating against you, report it to Compliance and Ethics, HR, the Sunovion Hot-line or Legal immediately.</li><li>You may not retaliate or 'get back' at someone who initiated or participated in the investigative process.</li><li>Retaliation is a violation of company policy that can have serious disciplinary consequences, including termination.</li></ul>
FOLLOWING THE INTERVIEW	<ul style="list-style-type: none"><li>The investigations and resolution process may take some time. While the process is underway, continue with your regular business activities unless otherwise notified and do not discuss the investigation.</li><li>You will not be informed of the disciplinary/corrective outcome of the case, and you should not ask. You should not discuss the investigation in any way after the case is closed.</li><li>For those being investigated, only that person and his/her management will be informed once an outcome action has been decided and carried out.</li></ul>

# Compliance Resources and Contacts

Listed below are the broad range of compliance resources that are available to you. It is important that you are self-sufficient and are able to make compliance-related decisions locally.

For any compliance-related questions, as a first step, become fully knowledgeable of Sunovion policies and procedures. If you still have questions, you can contact your RBM for guidance and clarification. If there are still questions, you can access the compliance resources online. The Compliance and Ethics Department is available to answer questions after you have exhausted all other avenues. It is likely that you will be able to find the answer to the vast majority of your questions via your manager, colleagues, or online resources.

## ON-LINE RESOURCES

<b>Website</b> <a href="http://source.sunovion.com/GA/CorpCompliance/Pages/default.aspx">http://source.sunovion.com/GA/CorpCompliance/Pages/default.aspx</a>	Policies and Procedures
<b>Tone from Middle Support Tools</b> <a href="http://source.sunovion.com">http://source.sunovion.com</a>	List of TFM tools
<a href="http://www.phrma.org/about/principles-guidelines/code-interactions-healthcare-professionals">http://www.phrma.org/about/principles-guidelines/code-interactions-healthcare-professionals</a>	Interactions with Healthcare Professional Guidelines

## COMPLIANCE CONTACTS

<b>Anonymous Compliance Hot-line</b>		1-866-886-1348 or <a href="http://www.ethicspoint.com">http://www.ethicspoint.com</a>
<b>Compliance Department</b>	Matthew D'Ambrosio	matthew.dambrosio@sunovion.com
	Paul Ham	paul.ham@sunovion.com
	Averi Price	averi.price@sunovion.com
	Joe Wholley	joseph.wholley@sunovion.com
<b>Questions about the Sunshine Act</b>	Joe Wholley	joseph.wholley@sunovion.com
<b>Off-Label Inquiries</b>	Medical Information	1-800-739-0565
<b>Adverse Event Reporting</b>	Pharmacovigilance & Risk Management and Quality Complaints & Audits	1-800-737-7226
<b>Educational Grants</b>	Questions about educational grants	<a href="http://www.sunoviongrantsandcontributions.com">www.sunoviongrantsandcontributions.com</a>