

*Webinar Series*  
*Life Sciences with Nexsen Pruet*

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**Compliance Tips from the Trenches: How Effective  
Compliance is Good Business for Life Sciences  
Companies**

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# “From the Trenches”

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## ➤ **Special Guest Tom Bolton**

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Director of Regulatory Affairs & Compliance

## ➤ **Alice Harris**

Nexsen Pruet, LLC

Previous In-House Positions as Compliance Counsel,  
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# Agenda

- **What is “Compliance” in the Life Sciences Industries?**
- **Tip One:** Create a “Compliance Culture”
- **Tip Two:** Stay Ahead of Looming Regulatory Changes
- **Tip Three:** Pay Attention to Evolving Risk Factors
- **Tip Four:** Empower the Compliance Director/Officer
- **Tip Five:** Structure Your Compliance Team to be Flexible
- **Tip Six:** Bring in Legal Counsel When Needed
- **Tip Seven:** Compliance IS Good Business

➤ What is  
“Compliance” in  
the Life Sciences  
Industries?

*“The life sciences industry continues to face unprecedented challenges amid increasing regulatory scrutiny.*

*Globalization, alliances and partnerships, heightened transparency expectations, increased emphasis on innovative technologies, and the ever evolving needs of existing and emerging customers are driving companies to re-examine their approach to compliance.” Deloitte*

# ➤ What is “Compliance” in the Life Sciences Industries?

- **The Life Sciences industry includes a wide range of companies**
  - Pharmaceuticals, biotechnology, medical devices, biomedical technologies, nutraceuticals, cosmeceuticals, genetics, food processing, biotechnology firms, medical device companies, laboratories, and clinical trials and clinical research companies
- **How define “Compliance” to apply to this wide range?**
  - Broadly defined as a program to continually identify, evaluate and address regulatory changes and risk
  - A program to detect and correct compliance issues
  - A resource for workforce to turn to with concerns
  - Can and should be tailored to fit your company’s size and risks

## ➤ What is “Compliance” in the Life Sciences Industries?

### ➤ Elements can include:

- Proper controls and compliance measures to regularly evaluate and limit exposure to known risk factors
- Continual evaluation of new and evolving risks in the industry to ensure quick response and adaptation
- Continual preparations for regulatory inspections
- Designation of compliance leadership
- Written policies and procedures
- Regular education and training
- Effective lines of communication
- Internal auditing and monitoring
- Processes for identifying and correcting issues

# ➤ What is “Compliance” in the Life Sciences Industries?

*“If you don’t invest in risk management, it doesn’t matter what business you’re in, it’s a risky business.” Gary Cohn*

## **Risks Associated with Non-Compliance**

- High damages, fines, or penalties
- Company and individual criminal exposure
- Exclusion or debarment
- Remediation costs
- Reputational damage
- Threat to health and safety of patients

# ➤ What is “Compliance” in the Life Sciences Industries?

- **Pharmaceutical Associates, Inc. (PAI)**
  - Manufacturer of generic liquid pharmaceuticals and Unit Dose liquid products
  - Producing better-targeted suspensions, oral solutions, elixirs, syrups, and liquids for over 50 years
- **Compliance at PAI – Regulatory and Legal**
  - Systems for addressing FDA regulation and current Good Manufacturing Practices (cGMP)
  - Systems for addressing DEA regulations
  - Systems for keeping up with USP for both General Chapters and Drug Monographs



# ➤ What is “Compliance” in the Life Sciences Industries?

- **Entities Submitting Claims for Reimbursement to Federal Healthcare and Commercial Payors**
- **CMS, Medicaid, Tricare, Commercial**
  - Formal OIG-model reimbursement compliance program
  - HIPAA Privacy and Security
  - Compliance systems governing clinical research
- **Systems to address other regulatory laws and agency oversight**
  - SEC enforcement
  - OSHA
  - Foreign laws and regulations
  - Physician Payments Sunshine Act

# Tip One: Creating a “Compliance Culture”

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## ➤ Buy-in from the top-down

*“Ultimately, it’s on the company leaders to set the tone, not only the CEO, but the leaders across the company.” Tim Cook, CEO Apple*

## ➤ Who?

- The governing Board
- All executive and leaders

## ➤ How Do You Engage Leadership?

- Discussions and training on oversight role
- Discuss value of anticipating changes
- Discuss value of designing compliance programs to maintain business integrity
- Discuss ability to retain reimbursement paid for services

# Tip One: Creating a “Compliance Culture”

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## ➤ **How Can Leaders Demonstrate Support?**

- Visible and constant support of compliance initiatives
- Visible and constant support of compliance leaders and staff
- Inclusion of compliance as part of company strategy
- Knowledge of compliance efforts and integration of same into daily interactions

## Tip Two: Pay Attention to Looming Regulatory Changes

*“Some risks that are thought to be unknown, are not unknown.*

*With some foresight and critical thought, some risks that at first glance may seem unforeseen, can in fact be foreseen.*

*Armed with the right set of tools, procedures, knowledge and insight, light can be shed on variables that lead to risk, allowing us to manage them.” Daniel Wagner*

## Tip Two: Pay Attention to Looming Regulatory Changes

- **Identifying Upcoming Regulatory Changes**
  - Participate in a relevant trade group
  - Participate in relevant industry and advocacy groups and subscribe to related e-mail and other publications
  - Regularly review relevant agency websites and publications
- **Remember to monitor and address federal AND state laws**
  - Example: State regulation of controlled substances distribution
    - Suspicious Order Monitoring
- **If wait until the final regulatory announcements may be caught short**
  - Example: FDA Data Integrity Issues, USP changes to Elemental Impurities

# Tip Three: Pay Attention to Evolving Risk Factors

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*“The increasing weight of new regulatory legislation from regulators ... means that firms need to ensure that no risks fall through the cracks.” Thomson Reuters*

- Keep up with regulatory changes
- Examine prosecutor focus and published settlements
- Check out government auditor reports and alerts on risk areas
- Be involved with industry trade groups
- Keep track of government contractor audit areas
  - OIG Work Plan, RAC targets, UPIC targets

# Tip Four: Empower the Compliance Director/Officer

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*“The increasing weight of new regulatory legislation from regulators ... means that firms need to ensure that no risks fall through the cracks.” Thomson Reuters*

- Provide the Compliance Director/Officer with high visibility
- Ensure the Compliance Director/Officer reports to senior leadership but also has direct access to the Board
- Provide the Compliance Director/Officer with adequate resources in light of company’s risks and regulatory oversight
- Allow access to information necessary to identify risks and fulfill compliance responsibilities
- Include In strategic conversations and vetting new ventures
- Provide access to legal counsel as needed

## Tip Five: Structure Your Compliance Team to be Flexible

*“A great [Compliance] Officer and his/her team will have eyes and ears open at all times and be on the lookout for areas to improve, policies to create, and know when an issue needs to be raised to management/board due to potential legal liability.*

*This does not mean the role is to be a police officer focused on finding non-compliance.*

*Instead, an effective healthcare Compliance Officer will look for areas to increase efficiency and reduce risk. Thus, a healthcare company that truly adopts enterprise risk management will include compliance at the table and embed them with operations.” Provider Trust*



## Tip Five: Structure Your Compliance Team to be Flexible

- **For OIG Reimbursement Compliance Programs**
  - Ensure have all elements built out and that staffing and resources are appropriate for size of organization
  - One size does not fit all
- **Be prepared to adapt to changing regulatory challenges**
  - PAI Example: Had to change to become more flexible
  - Identified areas to outsource and core competencies which needed internal team support
  - Expanded DEA staff
  - Added in-house counsel
  - Identified external law firms with needed specialties

## Tip Six: Bring in Legal Counsel When Needed

- **Advantage of working with legal counsel**
  - “If you don’t know the rules of the game how can you play it?”
  - Compliance and legal should be collaborative players working in pursuit of the company’s best interests
- **In-house counsel?**
  - Valuable expertise in-house
  - Application of Attorney-Client privilege may be limited
- **External counsel?**
  - Seeking validation or clarification
  - Sensitive or high risk situations
  - Application of Attorney-Client privilege

# Tip Seven: Compliance IS Good Business

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*“If you think compliance is expense – try non-compliance.”* Former U.S. Deputy Attorney General Paul McNulty

- Damages and penalties
- Exclusion or debarment
- Attorneys fees
- Patient harm

*“It takes less time to do things right than to explain why you did it wrong...”* Henry Wadsworth Longfellow

- Administrative time to defend, fix, and correct

*“Finance is about the money you make. Compliance is about the money you keep.”*

- Look at Compliance as your means to keeping your hard-earned reimbursement

# Tip Seven: Compliance IS Good Business

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*“Sense and deal with problems in their smallest state, before they grow bigger and become fatal.” Pearl Zhu*

- At PAI, maintaining a Quality/Compliance culture and vigilantly paying attention to compliance staves off DEA, FDA, and other agency investigations and penalties. Communication with Regulatory authorities using the “early and often” philosophy also helps to prevent concerns from becoming non-compliance events.
- If you are submitting claims for reimbursement, are required to have a compliance program and your business partners expect you to have one

# Questions?

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# CONTACT INFORMATION

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