



Making Outsourced Compliance Programs Work for Small to Mid-Cap Life Sciences Companies



Making Outsourced Compliance Programs Work

Jocelyn Lafond,
General Counsel and Corporate Secretary

Steve Vincze, Interim U.S. Compliance Officer
(Outsourced through TRESTLE Compliance, Founder, President & CEO)

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Agenda

1. Introduction
2. Thera Case Study
3. Advantages of Outsourced Compliance and Privacy Officers
4. Key Challenges
5. Mitigation Strategies
6. Best Practices
7. Conclusion

Steve Vincze, TRESTLE Compliance, LLC.

- Prior to forming TRESTLE, Steve split his private-sector career between service as an in-house or outsourced Sr. VP or VP Chief Compliance Officer for several life science and healthcare companies and as a consultant, forming his own firms as well as serving as a non-equity partner for a “Big 4” firm.
- Counsel to a U.S. House of Representatives Oversight Committee
- 25+ years of experience in regulatory compliance matters, from government policy and enforcement to private sector business implementation considerations.
- High-Profile Compliance Cases – Starting with the TAP case in 2001, which at \$885 million was for many years the largest settlement in the pharmaceutical industry and which directly led to key reforms that changed commercial compliance practices, such as the OIG Compliance Guidance to Pharmaceutical Manufacturers and the PhRMA Code, to Warner Chilcott, which in 2013 was under federal criminal and civil investigation for alleged improper commercial activities, Steve has been recruited to address high-profile cases and to support legal, commercial and executive teams and Boards of Directors with his compliance expertise.
- Service as a Compliance Expert/IRO for CIA’s.
- Certified as a Privacy Professional by the IAPP (CIPM) and as a OneTrust Privacy Professional and corporate partner.
- Global Expertise – Steve has worked with a range of life science companies globally, including the very largest and most prominent U.S., Japanese and European companies.
- Officer, U.S. Marine Corps (USMC) – Received various citations, decorations and a full scholarship to law school; served as a prosecutor and defense counsel; , served in the Office of the Secretary of Defense; and later was selected to serve as a counsel and professional staff member of the Government Operations Committee in the U.S. House of Representatives.
- A.B. Degree, Columbia University
- J.D., Southern Methodist University School of Law
- LL.M. in International & Comparative Law with distinction, Georgetown University Law Center
- MBA, University of Chicago Booth School of Business
- Guest Lecturer: University of Chicago, Harvard, U.C. Berkeley, University of Miami School of Business and INSEAD.



Steve Vincze,
Founder, President & CEO



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Supporting the Business of Life Sciences

Jocelyn Lafond Biography

Jocelyn Lafond, LL.B., LL.M. | General Counsel and Corporate Secretary

Jocelyn joined Theratechnologies in 2007 and has been acting as General Counsel and Corporate Secretary since.

Prior to joining Theratechnologies, Jocelyn was a partner at the Montreal-based offices of an international law firm where he practiced in the areas of commercial and securities regulation.

He holds a Law Degree from Laval University, a Master of Laws from the University of Toronto, and was called to the Quebec Bar in 1992.

As General Counsel and Corporate Secretary, he is involved in various areas of the business, such as:

- Pharmaceutical Compliance;
- Privacy law matters;
- Intellectual Property matters;
- Contractual matters;
- Financing and securities regulation; and
- Governance matters.



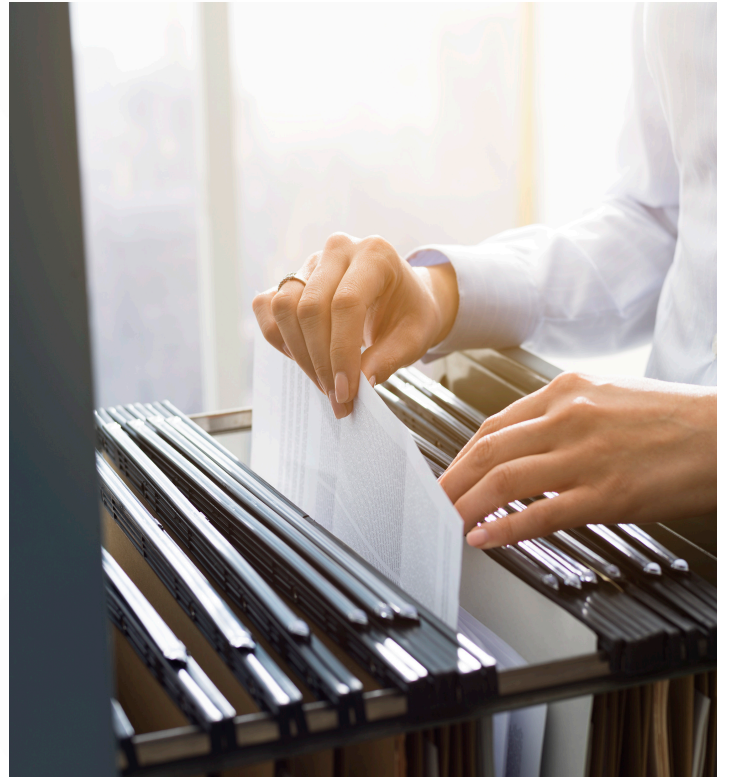
1. Introduction

- Importance of Compliance and Privacy in Pharmaceuticals
- Why Consider Outsourcing?
- Key Objectives of the Presentation



2. Thera Case Study

- Who is Thera?
- Compliance challenges for our company



3. Advantages of Outsourced Officers

1. Cost-Efficiency
2. Specialized Expertise
3. Scalability
4. Focus on Core Functions
5. Flexibility



4. Key Challenges

1. Loss of Control
2. Data Security and Privacy Concerns
3. Communication Challenges
4. Integration with Internal Teams
5. Vendor Dependence



5. Mitigation Strategies

1. Vendor Selection
2. Service Agreements
3. Regular Audits and Assessments
4. Internal Team Training
5. Continuous Communication



6. Best Practices

- Consistent Communications
- Encourage Collaboration and Knowledge Sharing
- Measure Progress
- Inspire & Motivate



7. Conclusion

- Balancing Cost and Effectiveness
- Strategic Alternative for Small to Mid-Cap Pharma Companies
- Embracing Outsourcing to Enhance Compliance and Privacy

Q&A

- *The floor is now open for questions and discussions.*



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Thank You



Additional Resources

- [U.S. Department of Justice Criminal Division, Evaluation of Corporate Compliance Programs \(Updated March 2023\)](#)
- SWOT Analysis: Outsourced Compliance Officer Services

SWOT Analysis: Outsourced Compliance Officer Services

INTERNAL	<h3>Strengths</h3> <ol style="list-style-type: none">1. Specialized Expertise: Outsourced compliance officers often bring deep knowledge and experience in regulatory compliance, staying up-to-date with evolving regulations.2. Cost Efficiency: Outsourcing compliance can be cost-effective compared to hiring full-time in-house compliance staff, as it reduces overhead, benefits, and recruitment costs.3. Scalability: Outsourcing allows companies to easily adjust compliance resources as needed, accommodating growth or changes in compliance demands.4. Focus on Core Competencies: By outsourcing compliance, internal teams can concentrate on core business functions and strategic initiatives.5. Access to Technology: Compliance service providers often have advanced compliance management tools and technologies, enhancing efficiency.	<h3>Weaknesses</h3> <ol style="list-style-type: none">1. Loss of Control: Outsourcing compliance may lead to a perceived loss of control over critical compliance functions and decision-making.2. Communication Challenges: Managing outsourced teams across different time zones and locations can lead to communication difficulties and misalignment.3. Vendor Dependence: Overreliance on an outsourcing partner can create vulnerability if the vendor experiences issues or changes in service quality.4. Cultural Misalignment: Differences in organizational culture between the company and the outsourced compliance provider can hinder seamless collaboration.5. Data Security Concerns: Sharing sensitive compliance data with a third party may raise data security and privacy concerns, particularly in highly regulated industries.
	<h3>Opportunities</h3> <ol style="list-style-type: none">1. Global Reach: Outsourced compliance services can facilitate international expansion and help companies navigate diverse regulatory landscapes.2. Enhanced Compliance: Leveraging the expertise of compliance specialists can lead to better adherence to regulations and reduced risks.3. Innovation: Outsourced compliance providers often embrace cutting-edge technologies and methodologies, fostering innovation in compliance processes.4. Cost Savings: The potential for significant cost savings through outsourcing can free up resources for investment in other strategic areas.5. Adaptive Solutions: Outsourced compliance services can adapt quickly to changing compliance requirements, providing flexibility.	<h3>Threats</h3> <ol style="list-style-type: none">1. Regulatory Changes: Frequent changes in regulations can pose challenges for outsourced compliance services in keeping up with evolving compliance requirements.2. Data Breaches: The risk of data breaches or cybersecurity incidents can be elevated when sharing sensitive compliance data with third parties.3. Reputation Risks: If the outsourced compliance provider fails to meet regulatory standards, it can negatively impact the client company's reputation.4. Vendor Instability: The financial instability or changes in leadership of an outsourced provider can disrupt services and compliance efforts.
EXTERNAL		



THANK YOU