

ALYSSA SMITH

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Compliance Director

life sciences | biotechnology | pharmaceutical | medical devices

COMPLIANCE MANAGEMENT:

Knowledgeable and highly motivated compliance leader with extensive experience developing and implementing transparency programs and continuous improvements. Knowledge of legislation and industry guidelines regarding transparency and disclosure of health costs and provider payments at the local, state, federal, and global levels. Develop and execute audit and monitoring plans. Thrives in fast-paced environments of continual change. Recognized for achievement, accountability, and ethics. Strong project management skills.

"Alyssa has exceeded my expectations across the board and I look to her as a key resource ... she is incredibly knowledgeable in the Aggregate Spend space and brings a skill set to the table that we are benefiting greatly from ... she is a pleasure to work with and has gone above and beyond in creating strong relationships with business partners in the U.S. and EU."

~ Manager, Callahan Pharmaceuticals

✓ **OIG | PHARMA | CIA AUDIT**

✓ **EFPIA | ABPA | FALSE CLAIMS ACT**

✓ **FOREIGN CORRUPT PRACTICES ACT**

✓ **STATE MARKETING & PRICE TRANSPARENCY**

✓ **PHYSICIAN PAYMENT SUNSHINE ACT (PPSA)**

✓ **FRENCH SUNSHINE ACT (BERTRAND)**

✓ **AGGREGATE SPEND | GLOBAL AGGREGATE SPEND**

✓ **U.S. FRAUD & ABUSE | FEDERAL ANTI-KICKBACK STATUTE**

LEADERSHIP | PROJECT MANAGEMENT: Manage and develop multiple direct reports and project teams. Cultivator of relationships. Easily build rapport and trust, resulting in stronger and more-productive cross-functional collaboration to achieve timely results.

DATA ANALYSIS | DATA WAREHOUSING: Analytical problem solver. Advanced Excel and other BI databases (see technology list).

FINANCE: 6+ years of prior experience as a Finance and Accounting professional; conducted complex financial analysis; built models.

Career History

CALLAHAN MEDICAL IMAGING | Jacksonville, FL

2016 – Present

Associate Director, Compliance - Sales and Operations

Compliance subject matter expert (SME) in the development, implementation, and maintenance of processes, resources, and systems that support regulatory requirements as they relate to global, federal, state, and locality reporting for healthcare provider payments.

- Lead the preparation, review, and approval of state and federal reports, ensuring timely and accurate reporting submissions.
- Direct regular internal audits of data and systems to ensure compliance with global, federal, and state Aggregate Spend programs, including recent State Price Transparency initiatives.
- Analyze operational/technological factors and make sound recommendations for compliance policy or process improvements.
- Initiate, create, and/or approve the creation of, or any corporate-wide amendments to, compliance-related SOPs.
- Main contact for external and internal audits, program reviews, and compliance training.
- Create and deploy compliance training programs, including Sales and Marketing, for U.S. and U.S. territory employees.
- Manage the models and analysis of potential sales incentive plans, performance forecasts, territory management design, and associated expenses. Review, and provide first-line approval for, all plans and payouts.
- Direct and manage implementation and maintenance of the CRM and other field sales-related applications. Drive projects related to the development of these tools. Develop and deliver corporate-wide training on the CRM and related data.
- Work with IT to translate complex reporting and compliance requirements into efficient systems. Develop processes to obtain internal and external data to monitor commercial performance and activity at the account, territory, district, and national levels. Assess data quality and develop controls to monitor and correct anomalies.

ERNST & YOUNG LLP | Jacksonville, FL

2013 – 2016

Advisory - Life Sciences

Consulted as SME on US-PPSA and EFPIA for large global pharmaceutical/biotech companies in newly launched EY Life Sciences group. Engagements leveraged knowledge and skills in Aggregate Spend, CIA auditing, process and data analysis, enterprise data warehousing, and conflict minerals. Service areas covered Finance, Shared Services, Compliance, IT, and Supply Chain.

- Advised life sciences organizations on strategies to optimize efficiency and effectiveness through the design and implementation of process improvements, technology, and business intelligence.
- Collaborated with major pharmaceutical companies to develop strategies for PPSA Aggregate Spend reporting compliance.
- Helped several pharmaceutical companies redesign business processes for capturing Sunshine Act reportable spend data, including current documentation review to ensure compliance with updated and new processes.

BIOTECH TECHNOLOGIES | Omaha, NE 2012 – 2013**Business Analyst – Hitek Pharmaceuticals (Chicago, IL) | consulting engagement**

Conducted tactical/manual efforts of data aggregation, remediation, and interim reporting with Global Information Systems (GIS) and Compliance Department representatives. Identified required changes to existing feeds; adjusted documentation and processes. Drafted the Production Support Guidelines. Collaborated internally on day-to-day production issues oversight and as a key analyst on system changes. Managed project resources, ensuring timely delivery of on-budget milestones.

TECHPOINT SOLUTIONS | Chicago, IL 2011 – 2012

Consultant for life sciences industry consulting firm. Subject matter expert (SME) for state aggregate spend and PPSA. Designed and implemented cutting-edge compliance programs and/or program components for clients. Key engagements:

LAKE LABS (MA) | Business Intelligence Analyst

Completed Unit and UAT testing for state Aggregate Spend state reporting, utilizing HP Quality Center and SAP BI for validating reported data, ensuring that reporting abided by the UFRS (user functional requirement specifications), Wireframe document, and the SDS (system design specifications). Drafted detailed Aggregate Spend Project Operations Manual for end users. Created disclosure state reporting documentation and federal report documentation for end users.

MORGAN & MORGAN HEALTHCARE SERVICES (MA) | PMO Support Consultant

Project-managed the Pricing and Contract project, identifying the expectations, deliverables (in scope & out of scope), tasks, resources, and assumptions associated with the project within the IT CCI group. Worked with key senior management to coordinate and manage documentation.

NEWAGE PHARMACEUTICALS (MA) | Aggregate Spend Business Analyst Consultant

Created and documented process flow procedures of aggregate spend to achieve business consistency and internal accountability. Identified gaps in categories of spend and worked with project teams and IT to load data into aggregate spend-related databases/systems. Organized a series of internal reviews and approvals to leverage as part of the ongoing testing of the overall Aggregate Spend infrastructure and technology initiative. Presented to CEO and senior leadership.

XYZ PRODUCTS, INC. | Boston, MA 2004 – 2010**Senior Analyst, Trade & Product Security** | 2008 – 2010**Financial Compliance Specialist** | 2004 – 2008

Developed and implemented compliance program for state-level regulations for 8 states, each with distinct compliance mandates.

- Mitigated risk by creating and executing a new program for streamlining and automating data capture to meet increasing healthcare professionals/organization (HCP/O) spend disclosure reporting requirements for multiple states and federal reporting; collaborated with Director of Compliance and led a cross-functional project team.
- Functioned as the Transparency Program's compliance lead, including for Corporate Integrity Agreement (CIA) reporting.
- Earned the *CHARGE Award for Accountability* on the HCP/O process rollout. Drove continuous process improvements.
- Proactively monitored and responded to new and emerging legislation pertaining to healthcare industry transparency.
- Identified policy loopholes that caused new policies to be mandated, i.e. Splitting Bills, HCP Speaker, and Attendance of Event.
- Ensured compliance to company policies by writing SOPs, conducting investigations, and managing multiple audits of expenses including auditing the Excluded Parties List System (EPLS) for the Office of Inspector General (OIG).
- Developed training programs and webcasts to educate internal customers on policies and process changes.
- Monitored and validated progress on corrective action plans and conducted compliance investigations.
- Administered annual filings for VT, ME, WV, MN, and D.C.
- Developed compliance-related reports ranging from status updates to complex ad hoc executive reports utilizing Access, including monthly Compliance OOP (expenses out of policy) Report.
- Performed quality assurance on data to identify "missed" spend, reducing risk from improper account categorization.
- Customized Gelco (now Concur) to create functionality to capture and report expenses with prescribers.
- Directed and managed 11 staff members including training, goal setting, and performance management.

Relevant Work History – Finance

From 1998 to 2004 developed a successful career in Finance and Accounting. Roles included heavy analysis and process improvement.

JOHNSON FINANCIAL 1998 – 2001 | ADVANCED SERVICES 2001 – 2002 | VERTICAL, LTD. 2003 – 2004**Technology**

SAP, Oracle, Concur, PeopleSoft, JDE, Cognos, ADP, ValueTrak (Wholesaler EDI data application), Cegedim, Salesforce, Microsoft Office: PowerPoint, Access, Project, Visio, SharePoint, Advanced Excel

Education | Affiliation

BOSTON UNIVERSITY | Boston, MA

Bachelor of Science in Business Management (BSBM), emphasis in Accounting

Certificate in Pharmaceutical and Medical Device Law and Compliance (CPMDLC) | study in progress

Member of Eastern Compliance Group since 2016