

## Biopharmaceutical Regulatory Compliance Track

The Biopharmaceutical Regulatory Compliance track is designed to meet the educational needs of students who aspire to positions as regulatory compliance officers working for pharmaceutical manufacturers, drug wholesalers, medical centers or clinics, and pharmacy businesses. The goal of the regulatory compliance officer is to establish regulatory compliance systems that facilitate compliance with relevant regulations by professional personnel who work for the regulated employer. Graduates of the Biopharmaceutical Regulatory Compliance track also may find employment with federal and state government agencies, as well as non-governmental professional and trade associations. They may serve on government affairs committees of professional organizations, and they may be appointed to regulatory boards such as the state board of pharmacy.

Term (Fall Starters)	Course Title	Credits	Delivery Method
<b>Fall I</b>	The Evolution of American Health Services	2	Online Synchronous
	Intro to Biopharmaceutical Regulatory Compliance	3	Online Synchronous
	Health Services Administration Seminar	1	Residential-Laramie
<b>Spring I</b>	The Food & Drug Administration	2	Online Blended
	The Drug Enforcement Administration	2	Online Blended
	State Regulation of Health Professions	2	Online Blended
<b>Summer I</b>	Health Services Administration Research Methods	2	Online Blended
	Statistics for Health Services Administration	3	Online Synchronous
<b>Fall II</b>	Empirical Analysis for Health Services Administration	3	Online Synchronous
	Prescription Benefit Management Decisions	2	Online Blended
	Medicare, Medicaid & the Affordable Care Act	2	Online Blended
<b>Spring II</b>	Preventing Fraud, Abuse & Waste OR Health Economics & Policy	2	Online Blended
	Health Services Administration Independent Project	3	Online Synchronous
	Health Services Administration Seminar	1	Residential-Laramie
	Comprehensive Final Exam	0	Residential-Laramie

Term (Spring Starters)	Course Title	Credits	Delivery Method
<b>Spring I</b>	The Evolution of American Health Services	2	Online Synchronous
	Intro to Biopharmaceutical Regulatory Compliance	3	Online Synchronous
	Health Services Administration Seminar	1	Residential-Laramie
<b>Summer I</b>	Health Services Administration Research Methods	2	Online Blended
	Statistics for Health Services Administration	3	Online Synchronous
<b>Fall I</b>	Empirical Analysis for Health Services Administration	3	Online Synchronous
	Prescription Benefit Management Decisions	2	Online Blended
	Medicare, Medicaid & The Affordable Care Act	2	Online Blended
<b>Spring II</b>	The Food & Drug Administration	2	Online Blended
	The Drug Enforcement Administration	2	Online Blended
	State Regulation of Health Professions	2	Online Blended
	Health Services Administration Seminar	1	Residential-Laramie
<b>Summer II</b>	Comprehensive Final Exam	0	Residential-Laramie
	Health Services Administration Independent Project	3	Online Synchronous
	Preventing Fraud, Abuse & Waste OR Health Economics & Policy	2	Online Blended

The following are sample Job Descriptions for Biopharmaceutical Regulatory Compliance graduates (these are real job postings that likely have expired, but they give an idea of the jobs that are available in the field of regulatory compliance). Keep in mind that experience may be a requirement for a position, and that an advanced degree can substitute for experience.

**Job Title : Analytics, Regulatory Reporting & Compliance Advisor**

Location :

AZ – Scottsdale Street Address : 9501 E Shea Blvd

Category : Analytics

**Job Description**

We have an exciting new opportunity in our Scottsdale, Arizona location! This position on our Government Reporting and Process Optimization team will be responsible for driving automation and efficiencies to ensure accurate and timely delivery of regulatory and customer reports supporting current and future government reporting deliverables.

This position provides operational guidance and support for programming, generating and submission of Medicare D CMS (Center for Medicare & Medicaid) required reports using data provided by internal partners. In this position, you would be responsible for the collection, analysis, compiling and reporting of Medicare D data generated from multiple internal/external data systems in order to ensure accurate and complete reporting. You will be working with colleagues to identify and investigate quality issues, and is responsible for maintaining relationships with internal/external partners to ensure effective and accurate communication.

This position will also be responsible for driving enhancement of our existing reporting and modeling tools; including design and implementation of programs, reports, and analysis to improve customer satisfaction; provide transparency and identify gaps. Responsibilities also include development of process improvement and documentation to meet the needs of internal/external customers and ensuring all reports are running as efficiently and accurately as possible. This position will leverage dashboard functionality to track performance of cross-enterprise processes to ensure that all stakeholders required to deliver against our reporting standards and SLAs are aligned against reporting goals.

You will use your strong communication skills to articulate business partner and/or government requirements into technology enabled solutions, measures and/or dashboards. This position will interface directly internal stakeholders and data owners, and will interface directly with CVSCaremark clients, CMS, CMS vendors, and external data auditors.

**Required Qualifications**

To be considered for this opportunity, candidates must have Medicare/Medicaid or other government reporting experience and a minimum of 5 years experience supporting internal/external customers with data and reporting needs. Candidates must have demonstrated experience in leading cross functional initiatives, along with demonstrated experience documenting and presenting perceptions in a comprehensible, concise and logical way. Strong customer service, communication skills and ability to multi-task and work in a fast paced environment.

**Preferred Qualifications**

Solid understanding of government reporting and deep understanding of data structures and methodologies. Ideal candidate would leverage tools and methodologies to improve our reporting processes by leading root cause analysis and providing systematic approach to eliminating gaps. Ideal candidate must possess advanced Microsoft Excel/Access skills and ability to develop queries utilizing VBA macros or SQL.

**Education**

Bachelors degree required in business, technical or related field.

**Drug Diversion Specialist SERVICES | CLEARWATER**

FairWarning is hiring a Drug Diversion Specialist to work directly with our customers to help identify suspected acts of drug diversion. This role will work with our Privacy, Fraud and Security experts who have successfully detected over 6,000 incidents. The Managed Privacy Services department monitors over 750,000 healthcare employees and non-employees every day. While maintaining customer centric focus, our team uses analytical skills and techniques to conduct investigatory work, assist in troubleshooting and data gathering for customers, training of new and advanced end-users, providing product feedback, project management, OCR Audit assistance, forensic investigations, and much more. This team member will provide oversight and direction for the Drug Diversion initiative within the Managed Services offering at FairWarning. The Drug Diversion Specialist will oversee the investigation process of suspected medication diversion incidents, provide support for the Drug Diversion Task Force, as well as participate in continuous improvement, education, and planning activities.

This team member is responsible for ensuring controlled substance accountability throughout the medication use process, preventing controlled substance misuse/abuse/diversion, and compliance with regulatory requirements throughout our customers. This team member designs and executes audits and proactive monitoring strategies to monitor for discrepant use of controlled medications, maintains records and educates customers on requirements and best practices.

**Below is more about our customer base and what the role entails:**

Managed Privacy Services has over 400% growth in the last 3 years

Overall Customer Rating of an 'A'

FairWarning has been voted a Top Workplace for five (6) consecutive years

Serve as point of contact when potential diversion is identified, or evidence leads to suspicion of diversion

Responsible for ongoing routine controlled substance auditing, including but not limited to reviewing reports and analysis of unresolved discrepancies and medication overrides

Assist with development of up-to-date drug handling, diversion prevention, detection, and reporting policies and procedures

Monitors controlled substance handling processes and audits for compliance  
Analyzes data regarding controlled medications, high cost medications, and other medications that have an appeal for diversion  
Maintains current knowledge of relevant DEA, FDA, Department of Health, Boards of Pharmacy, Nursing, Medicine, and the Joint Commission (TJC) regulations related to controlled substance management and diversion activities  
Oversees the investigation process of suspected medication diversion incidents  
Participates in continuous improvement, education, and planning activities  
Help customers prepare, understand, and acquire their EPCS Certification

**Successful candidates have the following background:**

Bachelor's degree  
Experience in conducting drug diversion investigations and investigative report processing  
5+ years' experience in healthcare and/or pharmaceuticals  
Strong interpersonal, analytical, organizational, and problem-solving skills  
Familiarity with TJC Medication Management Standard; DEA, FDA, and EPA regulations; federal and state medication handling and controlled substances regulations  
Thorough understanding of medication dispensing process and technology. Experience in drug diversion prevention processes  
Previous experience in trending and analyzing data  
Thorough understanding of Medication Management systems and technologies  
Commitment to healthcare ethics and confidentiality  
Comprehensive knowledge of medical terminology as related to drug usage

**Characteristics of Successful Candidates**

FairWarning operates a customer-centric business model with strong teamwork across the business. FairWarning's Managed Privacy Services philosophies begin with listening and problem solving for our customers. As such, successful candidates have the following characteristics:

Consistently positive and highly self-motivated  
Outstanding listening and discovery skills  
Problem solving skills  
Team-player who buys into FairWarning values and the "FairWarning Way"  
Relentless learner  
Self-Motivated  
Desires coaching, training and understanding of best practices  
Persistent and competitive  
Attention to Detail  
Follow-up and follow-through Multi-tasker Eagerness to take on new challenges

**Manager of TLC Regulatory Compliance - Cincinnati - FT**

**Company Name:** Kroger General Office

**Position Type:** Employee

Position Summary:

Oversee The Little Clinic (TLC) regulatory compliance and government relations activities. Identify areas of most significant TLC compliance risk, for developing compliance programs, and for assuring execution of the TLC compliance programs. Serve as TLC HIPAA Privacy Official working in coordination with The Kroger Co.'s Chief HIPAA Privacy Officer and Kroger Health HIPAA Team. TLC compliance responsibilities include, but are not limited to: Safety, Credentialing, Hazardous Waste, HIPAA, Fraud Waste & Abuse, Medicaid and Medicare Compliance Demonstrate the company's core values of respect, honesty, integrity, diversity, inclusion and safety.

Essential Job Functions:

Develop, maintain and oversee the TLC Regulatory Compliance Program in a manner consistent with the Kroger Health Compliance Program  
Develop, maintain, communicate, and update for relevancy and currency all TLC compliance materials, including the TLC Code of Conduct, and policies and procedures for operation of TLC Compliance Program  
Chair and ensure the effectiveness of the TLC Compliance Committee  
Facilitate investigations of complaints and alleged violations of the TLC Code of Conduct, compliance policies and procedures, and state/federal laws and regulations; work with the Manager of Pharmacy Regulatory Compliance and Government Relations and Chief Ethics and Compliance Officer (CECO) to coordinate communication efforts  
Monitor legal and regulatory changes that affect the TLC Compliance Program, establish a process to implement necessary changes, and communicate these changes to appropriate individuals  
Develop and oversee an audit program to monitor compliance and identify areas of vulnerability; oversee corrective action plans for resolution of problematic issues, and provide guidance to divisions on how to avoid or deal with similar situations in the future; regularly report results to the CECO

Coordinate TLC Government Relations activities with industry organizations, divisions and Corporate Affairs  
Consult with legal counsel to resolve issues  
Provide support on TLC regulatory issues  
Serve as the TLC HIPAA Privacy Official; work in coordination with the Kroger Health HIPAA team  
Work closely with Corporate Security Officer to ensure all HIPAA Privacy and Security rules are followed  
Work with divisions, TLC Leadership team and Corporate Auditing to ensure compliance  
Assist with special projects at discretion of the Manager of Pharmacy Regulatory Compliance and Government Relations  
Must be able to perform the essential functions of this position with or without reasonable accommodation

Minimum Position Qualifications:

Bachelor's degree

3+ years of successful and progressive experience in regulatory compliance

Working knowledge of healthcare regulatory environment, HIPAA rules, and Joint Commission standards

Excellent oral and written communications

Desired Previous Job Experience: Healthcare Compliance experience, Degree in healthcare, legal or paralegal studies

Law degree

**Education Level:** J.D. Desired

**Required Travel:** Up to 25%

**Required Certifications/Licenses:** None

**Position Type:** Full-Time

**Regions:** General Office- Cincinnati

### **Safety Compliance Project Manager**

**Position:** Safety Compliance Project Manager

**Reports to:** Senior Safety Compliance Manager

**Location:** Richmond, Virginia

**POSITION SUMMARY:** Responsible for developing and managing compliance across business units and with established vendors globally. By serving as a business partner and compliance advisor, he/she will continually enhance processes and systems and assist in structuring programs to ensure that processes are efficient and comply with policies, codes, laws and regulations impacting business operations. Promote a worldwide business culture that accepts regulatory compliance as an expectation, with continuous process improvement as an outcome and goal.

#### **ESSENTIAL FUNCTIONS:**

The responsibilities of this job include, but are not limited to, the following:

Develop, manage, and maintain the Pharmacovigilance System Master File (PSMF).

Schedule, integrate, and coordinate stakeholder contributions and deliver this business critical document according to regularly scheduled timelines, and on demand.

Ensure document is of high quality, inspection ready, reflects current business systems, processes, technologies, and organizational structures, and is in compliance with current EU legislation.

Track document history, apply version control, and archive PSMF components

Stay current with evolving regulatory legislation and guidelines which have a direct impact on pharmacovigilance regulatory compliance, and incorporate into PSMF.

Stay current with internal Pharmacovigilance systems, processes, and organizational structures and incorporate into PSMF.

Collaborate with stakeholders to influence and lead continuous improvement activities.

Provide leadership and management of global or regional projects ensuring that communications and processes are harmonized for assigned projects.

Monitor and manage the workflow for assigned projects to ensure all deadlines are met and are in accordance with compliance regulations, Standard Operating Procedures (SOPs) and guidelines set forth by departmental management team and within corporate standards.

Generation of status reports and other project-specific reports ensuring the quality and accuracy of metrics and data provided.

Manage audit and inspection readiness processes and provide support for the required quality performance improvement across functions.

Provide cross functional support to ensure regulatory and corporate compliance, (including funding and product supply) for non-company-sponsored trials (IIS).

Assume responsibility for additional compliance projects, as needed.

#### **Minimum Requirements**

**Education:** BS or PharmD from an accredited school of pharmacy.

**Field of study:** Pharmacy.

**Experience:** 1-3 years.

**Industry:** Clinical Pharmacy. Medicare Part D experience required.

**Computer Skills: MS Office Applications.**

**Licenses, Certifications, etc.: Active registered pharmacist license in good standing., Preferred Qualifications**

**Education: PharmD.**

**Experience: Managed care.**

**Knowledge, Skills, Abilities: Strong drug product and clinical pharmacy knowledge.**

**MINIMUM QUALIFICATIONS:**

**Education:** Bachelors in Life Science field, plus 4 years of relevant PV/Clinical/QA experience

**Experience:**

Experience or knowledge of writing, editing, and compiling regulatory documents

Understanding of the processes associated with Safety, Regulatory or Clinical development

Knowledge of basic auditing procedures

Demonstrated knowledge of the relevant worldwide pharmacovigilance regulations and guidelines

Demonstrated knowledge of GVP guidelines and general understanding of GxP principles.

Experience with presenting and communicating project objectives and details to groups.

Awareness of the regulatory environment regarding Risk Management and Pharmacovigilance.

**COMPETENCIES/CONDUCT:**

In addition to the minimum qualifications, the employee will demonstrate:

Excellent written and verbal communication skills.

Excellent organizational skills and organizational agility.

Ability to manage time and multiple priorities as a project manager.

Ability to drive self and team performance for timely deliveries

Ability to collaborate with stakeholders to influence and lead continuous improvement activities.

**Regulatory Affairs Manager**

Swoon Group is hiring a Regulatory Affairs Manager for our client in Exton, PA.

This is a contract position with benefits (medical, dental, vision)

Duties of a Regulatory Affairs Manager:

Designs and implements regulatory strategies to obtain, maintain product investigative and marketing applications, and extend product registrations. Single point of contact and accountability for regulatory and leads the regulatory subteams as well as represents regulatory on key internal decision making teams such as PSTs and GDTs.

Functions as the global regulatory lead for assigned projects, working with a cross-departmental group of regulators as part of Global Regulatory Team, including CMC, Operations, Labeling, International, Advertising/Promotion and Intel/Policy to drive global regulatory strategies.

Leads the development of strategic plans and tactical implementation leading to the creation and submission of Regulatory documents, e.g., INDs, NDAs/BLAs, CTAs, MAAs, supplemental NDAs/BLAs and other relevant regulatory filings.

Serves as corporate liaison with regulatory Health Authority (HA) agencies to develop effective professional relationships as well as our positive company image.

Provides guidance to all appropriate departments in company to assure compliance with applicable regulations.

Actively trains/mentors junior staff; provides broader guidance on regulatory interpretation to staff.

Makes recommendations for regulatory department operating procedures. May be responsible for creating and reviewing SOPs as needed.

May supervise a changing number of Regulatory Affairs Associates.

Qualifications of a Regulatory Affairs Manager:

BS, BSc, MS, MSc, PhD, PharmD, J.D., M.D. in science or healthcare preferred or equivalent relevant experience.

Generally has at least 8-15 years of Regulatory Affairs experience, including equivalent experience in the biopharmaceutical industry.

The regulatory experience should be broad (across the life cycle of pharmaceutical products and across main regions such as the US, EU, Japan and Canada) to ensure appropriate leadership and mentoring for regulatory staff within Shire.

2-5 years of management experience preferred