Auditing in the Biopharmaceuticals sector

Bespoke in-house

Seminar Focus and Features

In this intensive, highly interactive 2-3 day seminar you will review internal audit best practices and apply them to auditing in the (bio)pharmaceuticals sector. You will see for yourself how auditing in the biopharmaceuticals sector can benefit from practices in other sectors and identify the critical "hot spots" for pharmaceuticals risks and audit areas, including key sales and marketing compliance risks and compliance obligations.

What You Will Learn

- **Key General Governance, Internal Audit, Risk and Compliance Developments**
  - Learning from the 2007-2008 financial crisis
  - Key Pharma issues in recent years
- **Overseeing the universe of risks through a Value-Chain Approach**
  - understanding value-chain principles
  - applying these principles to BioPharma
- **Where Auditing Pharma Is the Same as Other Sectors and Where It Is Different**
- **Risk Hot Spots in BioPharma and Elsewhere: Considering Best-Practices Risk and Control Solutions**
  - Sales and marketing practices
  - GXP risk areas
  - Corporate functions and reputation management
  - Case study: Mapping these considerations to your organization
- **Implications for Audit Planning**
  - Hallmarks of a good audit plan
  - Key areas to cover in Biopharms and how to present them to key stakeholders
- **Assignment Management: Translating Key Risks into Assignment Specifics Without Losing Focus**
- **Sales and Marketing Compliance**
  - Key principles within major codes: EEPIA, US PhRMA, FCPA
  - The elements of an effective compliance program
  - Best-practice approaches
  - Current hot spots
- **Working with Compliance Functions**
  - Working with compliance functions to share information
  - The importance of role clarity between these functions
- **Tips for Auditing Overseas Units**
  - Compliance and risk governance in overseas units
  - Cultural differences
- **Tips for Interfacing with GCP and GMP Functions**
  - Best-practice thinking on roles between audit and compliance
  - How to coordinate assurance/assurance mapping

- **Risks and Controls in Research and Development**
  - portfolio management: clinical, regulatory compliance
  - headline risk areas and processes
  - potential hot spots
  - auditing tips
- **Manufacturing**
  - supply chain management: outsourcing and third-party
  - business continuity
  - safety, health and environmental risk management
  - risk areas and processes
  - hot spot review
- **IS/IT Privacy and Information Security**
  - IS/IT: an increasingly important bedrock for control
  - risk governance challenges and best practices: including the appropriate role for Internal Audit
  - risk hot spots: including privacy and information security
- **Finance, Including Shared Service Centers**
  - best practice risk and control mapping
  - finance and audit role boundaries
- **Corporate Functions, including Legal, Investor Relations, HR and PR**
  - excluding HR, functions that IA generally does not review in depth.
  - considering key risks
  - auditing tips

Dates on request UK, Europe or US

For more information email: Info@RiskAI.co.uk