White Paper

Veronica K. Contreras, P.C.



INTRODUCTION

Veronica K. Contreras, P.C. (“VKC-PC”) is a legal consulting firm specializing in data protection, cybersecurity, artificial intelligence (“AI”), and regulatory and quality compliance, including ICH guidelines and GxP requirements. We help companies meet these obligations and build the governance frameworks, and risk management programs, to sustain them.

Our attorneys, and subject matter experts, bring hands-on, in-house experience leading privacy, security, AI governance, and quality programs for organizations across industries, with particular depth in healthcare, life sciences, and biotech. Through clear communication and close collaboration, we help you meet your legal and regulatory obligations while advancing your business goals.

Our Services

Whether you’re a startup or a large corporation, data protection, cybersecurity, AI, and regulatory and quality compliance are more important than ever. We believe compliance is never one-size-fits-all. At VKC-PC, we take the time to learn about your business and create tailored compliance programs that are comprehensive and practical for your needs.

We offer services such as:

01
Framework Compliance

02
Governance and Risk Management

03
Custom Training Programs

04
Staff Augmentation

VKC-PC goes beyond guidance: we help companies operationalize their data protection, cybersecurity, AI, and regulatory and quality compliance programs. Unlike many data privacy and security law firms that only provide advisory services, we customize and implement compliance frameworks. We are there for you every step of the way.

Specialized Expertise



Organizations that develop or deploy AI, or operate in regulated healthcare, life sciences, and biotech environments, face overlapping obligations. VKC-PC brings hands-on experience in both, so your privacy, security, AI, and quality compliance programs work together rather than in silos.

AI Governance and Compliance

Practical governance that keeps pace with AI regulation, without slowing innovation, including:

- Applying the EU AI Act, NIST AI RMF, ISO 42001, and FDA and EMA guidance on AI;
- Conducting AI use-case risk reviews and impact assessments;
- Drafting AI governance policies, procedures, and transparency notices; and
- Reviewing AI vendors and negotiating AI-specific contract terms.

Regulated Industries

Data protection and quality compliance built for healthcare, life sciences, and clinical research, including:

- Aligning privacy and security programs with GxP and ICH guidelines, including ICH E6(R3);
- Protecting data integrity and privacy in GxP-regulated systems;
- Managing personal data across clinical, pharmacovigilance, and patient support programs; and
- Supporting EU CTR compliance and negotiating clinical research agreements.

What Sets Us Apart

We take time to understand your company's unique challenges and requirements, crafting customized compliance frameworks that align with your business goals and strategic initiatives.

Not only do we offer virtual DPO and CISO services, but we also offer the following:

Framework Compliance

Service	VKC-PC	Others
Develop and operationalize compliance frameworks	✓	X
Draft policies, procedures, notices, unique to a client's operational practices. Provide templates of all.	✓	*Only provide Templates*
Assess and review data privacy, cybersecurity, and AI compliance aligned to certification standards, such as ISO 27001:2022, SOC 2 Type 2, ISO 42001. Provide reports and next steps.	✓	*Assess Privacy only*
Extensive knowledge about GxP compliance.	✓	*Varies*
Monitor data privacy, cybersecurity, and AI legislation, expert analysis, proactive updates, and applying analysis.	✓	*Monitor Compliance data privacy only*

Governance and Risk Management

Service	VKC-PC	Others
Support client audits and response feedback.	✓	X
Annual governance planning: project roadmaps and plans.	✓	*Data Privacy only*
Enterprise risk registers.	✓	X
Security objectives and key results ("OKRs").	✓	X
Data protection, cybersecurity, AI, legal, and quality risk management.	✓	X
Help operationalize policies and procedures and supporting documentation.	✓	X
Create and execute business impact assessments ("BIAs").	✓	X

Custom Training Programs

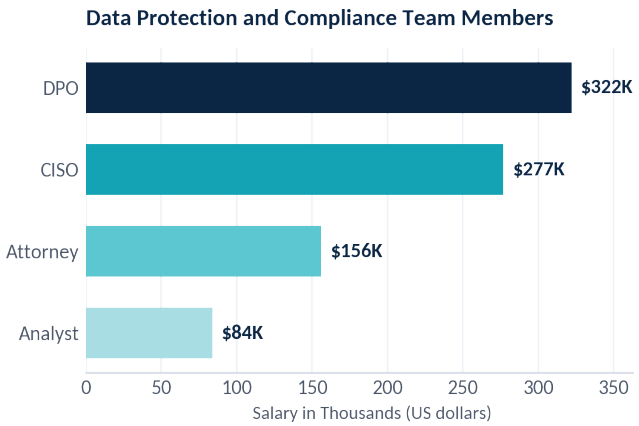
Service	VKC-PC	Others
Data protection, cybersecurity, AI, and quality compliance training tailored to your company's operational needs.	✓	*Generic training templates*
Perform live or recorded training.	✓	✓
Create training that can run in your company's LMS.	✓	X

Staff Augmentation

Service	VKC-PC	Others
Provide on-going support with DPIAs, regulatory impact compliance assessments ("RICAs"), and AI impact assessments.	✓	X
Incident reporting: manage, investigate, and report.	✓	✓
Process, complete, and respond to data subject requests.	✓	X
Review client and vendor contracts, including MSAs, SOWs, AI-specific terms, DPAs/BAAs, clinical research agreements, and quality agreements.	✓	*Limited*
Respond to client RFIs/RFPs.	✓	X
Collaborate with a company's internal teams.	✓	*Limited*
On-going support and monitoring, face-to-face support.	✓	*Limited face-to-face*

Market Competitive Pricing

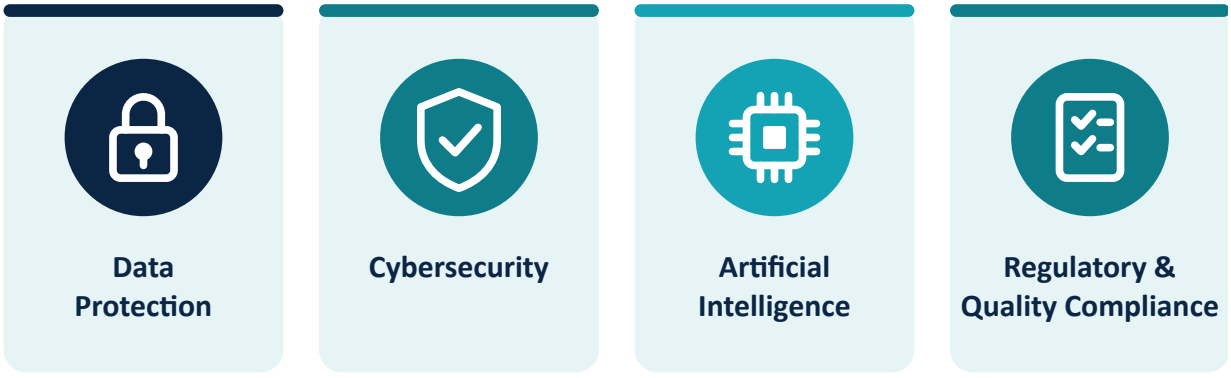
Our services are highly competitive. Clients benefit from a dedicated team rather than individual resources, often spending significantly less than hiring an in-house team. Chief Privacy Officer/Data Privacy Officer salaries can run upwards of $322K annually, and a CISO, $277K annually. These salaries are just for those individuals and do not account for the support staff typically needed for day-to-day operations. The chart illustrates the cost of assembling a small team to meet those needs.



A conservative estimate for a company's spend would be over $650,000 annually.

Benefits of Outsourced Services

BENEFIT	WHAT THIS MEANS
Cost Efficiency	Outsourcing can be more cost-effective than hiring full-time employees. It avoids the recruitment, training, salary, and benefits costs of building an in-house team.
Access to Expertise	VKC-PC brings specialized knowledge and experience in data protection, cybersecurity, AI, and regulatory and quality compliance, helping you keep pace with the latest laws and regulations.
Scalability and Flexibility	VKC-PC services can be scaled up or down based on your organization's needs, providing flexibility that in-house teams may not offer.
Focus on Core Business	By outsourcing, your internal team can focus on core business activities while our experts handle data protection, cybersecurity, AI, and regulatory and quality compliance matters.
Enhanced Compliance	The VKC-PC team is well-versed in legal, regulatory, and quality requirements and helps companies meet their compliance obligations, reducing the risk of fines and penalties.
Continuous Monitoring	Our services often include regular and systematic monitoring of data protection, cybersecurity, AI, and regulatory and quality developments, helping you maintain on-going compliance.



Our Team



Veronica Contreras

President/Founder

Veronica Contreras is the founder of Veronica K. Contreras, P.C., a legal consulting practice specializing in data protection, cybersecurity, AI, and regulatory and quality compliance consulting services, with over nineteen (19) years of experience.

Before devoting her work to Veronica K. Contreras, P.C., Veronica worked at Clario (formerly eResearch Technology, Inc.), a global data management technology company, as the company's global Data Privacy Officer, Counsel. While there, Veronica was responsible for the development and implementation of the company's global data privacy compliance program, including without limitation: compliance with GDPR, HIPAA, and CCPA; on-going administration (and maintenance) related to data privacy policies and procedures, privacy (and security) risk assessments, data privacy compliance training, and client-related audit requirements.

Prior to joining Clario, Veronica worked at MultiPlan, Inc. (now Claritev), a healthcare technology company, as the company's Data Privacy Officer, Associate Counsel, responsible for the company's data privacy program, including without limitation: compliance with HIPAA, TCPA, CAN-SPAM, and HITRUST certification requirements; on-going administration (and maintenance) related to data privacy policies and procedures, client risk assessments, privacy training, and third-party risk management requirements.

A lawyer by training, Veronica earned her Juris Doctor from the Western Michigan Cooley Law School and her Bachelor of Arts, in Philosophy, from the University of Wisconsin – Madison.



Mike Yacubian

Sr. Associate, Data Protection Attorney

Michael "Mike" Yacubian is a Sr. Associate, Data Protection Attorney with Veronica K. Contreras, P.C. ("VKC-PC"), and a licensed attorney in Massachusetts, specializing in data protection and cybersecurity for over nine (9) years.

Before joining VKC-PC, Mike served as Senior Associate Counsel for Data Privacy at Clario (formerly eResearch Technology, Inc.), a global data management technology company.

There, he played a key role in developing and implementing the company's global data privacy compliance program. His responsibilities included ensuring adherence to GDPR, HIPAA, and CCPA regulations; managing a team of privacy attorneys; negotiating privacy-related contracts; conducting data privacy impact assessments; developing global data privacy training programs; and overseeing related policies and procedures.

Earlier in his career, Mike gained extensive legal experience in the technology and financial sectors. At Pegasystems, Inc., a leading customer relationship management software company, he addressed contracting and legal issues related to software as a service (SaaS). At Boston Financial Data Services, he reviewed formation documents for trusts, corporations, LLCs, and hedge funds to ensure compliance with Anti-Money Laundering (AML) regulations.

Mike earned his Juris Doctor in 2015 from Suffolk University Law School – Boston, Massachusetts, and a Bachelor of Arts in Criminology in 2011 from Merrimack College – North Andover, Massachusetts.



Ted Crawford

Chief Information Security Officer

Ted Crawford is a senior, hands-on technology leader with Veronica K. Contreras, P.C. ("VKC-PC").

Ted has a proven record of leading cross-functional teams to execute business-critical initiatives for CIOs, COOs, and CISOs. He builds security programs spanning network, infrastructure, application, and data security, identifies gaps in existing technologies and processes, and guides companies moving from enterprise application architectures to cloud-native applications.

Before working with VKC-PC, Ted held senior leadership roles including:

- Chief Information Security Officer ("CISO") – Clario, a provider of clinical data management services to pharmaceutical companies. In this role he was responsible for Information Security architecture, Operations, Security and IT Compliance.
- Chief Information Officer ("CIO") – ERT, merged with Clario and Bioclinica in 2021. Senior technical leader supporting M&A due diligence assessments and managing complex integration IT and Security projects.
- Sr. Director Cloud Platform Services ("PaaS") Global Solutions and Service Delivery – Oracle Cloud.
- Solutions Architect – PhaseForward (acquired by Oracle) providing consulting services to large pharmaceutical companies in integration of PhaseForward's clinical and drug safety solutions with pharma's internal CTMS, clinical data warehouse and drug safety systems.



Devon Dray

Associate, Data Protection Attorney

Devon Dray is an Associate, Data Protection Attorney with Veronica K. Contreras, P.C., and has more than six (6) years of experience in data protection law.

Before joining VKC-PC, Devon served as Senior Corporate Counsel, Data Privacy at Clario (now a part of Thermo Fisher Scientific), a data management technology company. At Clario, Devon was responsible for overseeing the company's data privacy compliance program and advising company leadership, product teams, and other stakeholders on legal obligations relating to global data privacy laws, regulations, and mandates, including the GDPR, the CCPA, China's PIPL, and the U.S. Department of Justice final rule implementing Executive Order 14117. In addition to his internal advisory role, Devon worked directly with clients and vendors and led initiatives to improve Clario's compliance framework, including the company's achievement of its ISO 27701 (data privacy) certification.

Devon is a licensed attorney in Massachusetts, where he earned his Juris Doctor from Boston College Law School and his Bachelor of Arts from Boston University.



Maxim Lyashok

Senior Governance and Risk Management Expert

Maxim Lyashok is a senior governance and risk management expert supporting Veronica K. Contreras, P.C. ("VKC-PC"). He has over sixteen (16) years of experience building governance, risk, and compliance programs for healthcare, health tech, and global technology organizations, with expertise across HIPAA/HITECH, HITRUST CSF, SOC 2, NIST CSF, and GDPR.

Most recently, Maxim served as Director, Information Security at Take-Two Interactive. There, he standardized regulatory oversight across more than fifty (50) business units, led third-party risk integration following a $12.7 billion acquisition, and co-founded the company's AI Governance Committee.

Before that, as Director, Risk Management at Claritev (formerly MultiPlan, Inc.), he built the company's risk management practice and directed its first HITRUST CSF certification and SOC 2 Type 2 attestation. He also developed a risk-tiered vendor program covering more than five hundred (500) third parties.

Earlier in his career, Maxim was a Consultant in Deloitte & Touche LLP's Cyber Risk Services practice, where he helped health systems and life sciences companies protect clinical trial data and R&D systems.

Maxim earned his Master of Business Administration and Master of Science in Information Systems from Kennesaw State University, and his Bachelor of Science in Computer Information Systems from Valdosta State University. He is a Certified Information Systems Security Professional ("CISSP") and HITRUST Certified CSF Practitioner ("CCSFP").



Richard A. Miller

Quality Management Expert

Richard A. Miller is a quality management expert supporting VKC-PC, with more than twenty-five (25) years in the pharmaceutical and biotech industry, including more than fifteen (15) years at the executive level. He is an experienced GCP/GMP quality and regulatory compliance executive with expertise in strategic leadership and planning, global regulatory authority engagement (e.g., FDA, EMA, MHRA), medical device data systems ("MDDS"), hardware/software medical device development, data privacy, and computer system validation (i.e., computerized systems used in clinical trials).

Richard earned his Bachelor of Science in Environmental Sciences from Drexel University.

Our Promise

Whether you are building a privacy or security program, governing AI, or meeting GxP and ICH requirements, we don't just give you a plan and walk away. Our team works closely with you, providing hands-on support from initial assessment through implementation and beyond. We also help you prioritize the solutions that matter most and deliver the best value for your budget.

For more information about VKC-PC's services, our team, or how we can support your organization's data protection, cybersecurity, AI, and regulatory and quality compliance needs, please visit https://vkc-pc.com/