



WELCOME

Legal & Compliance Training



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Legal & Compliance Training

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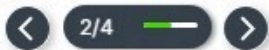


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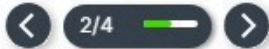


WELCOME

Who We Are

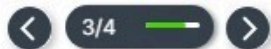


The Legal and Compliance team works to support all aspects of Crinetics' mission and values: Our Science, Our Colleagues, and the Patients, Healthcare Professionals (HCPs), and Healthcare Organizations (HCOs) we are committed to helping.



WELCOME

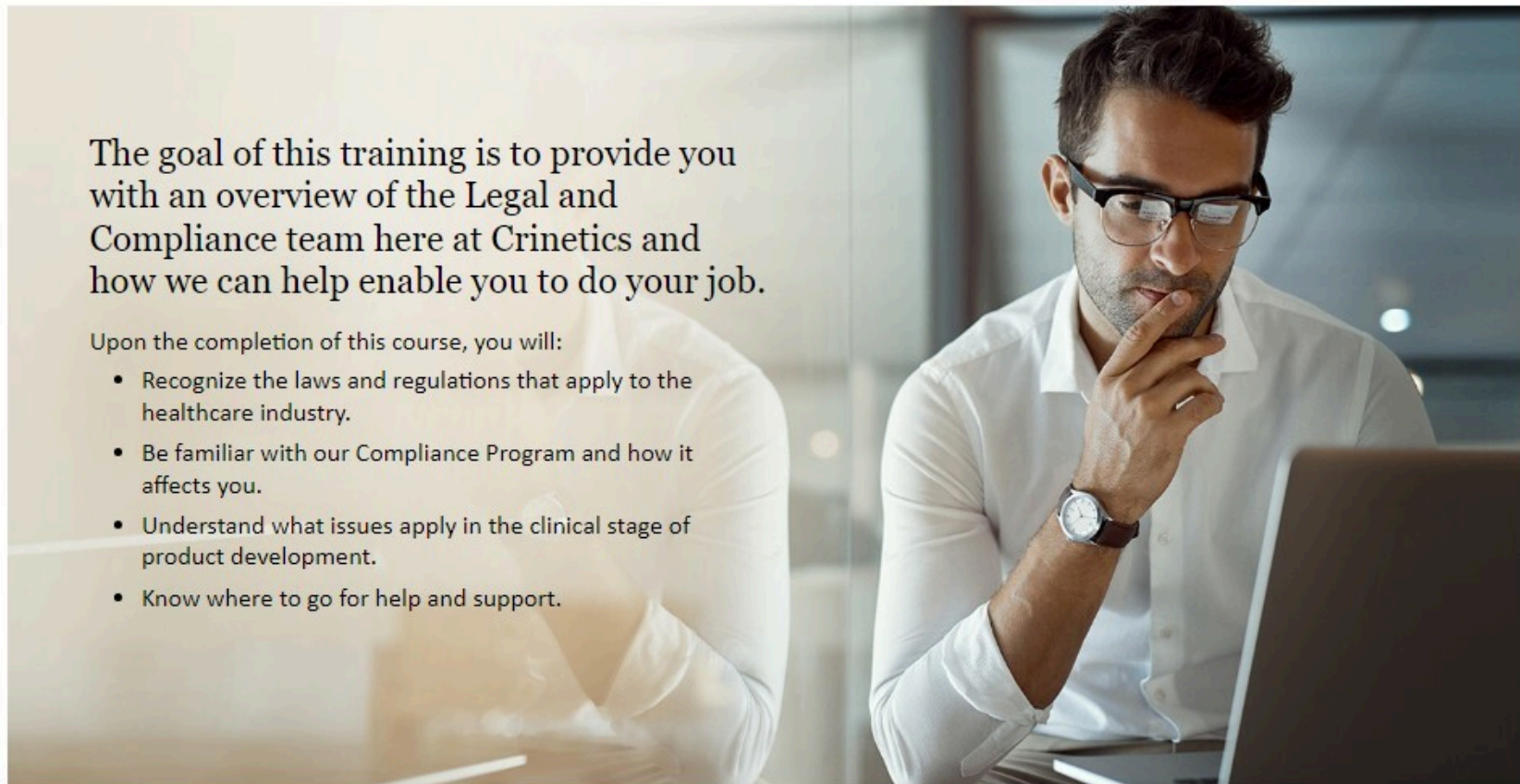
Objectives



The goal of this training is to provide you with an overview of the Legal and Compliance team here at Crinetics and how we can help enable you to do your job.

Upon the completion of this course, you will:

- Recognize the laws and regulations that apply to the healthcare industry.
- Be familiar with our Compliance Program and how it affects you.
- Understand what issues apply in the clinical stage of product development.
- Know where to go for help and support.



WELCOME

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8 minutes 
- 5 Asking Questions and Raising Concerns
2 minutes 

LEARNING PROGRESS

4%

Overview of the Pharmaceutical Industry



Our industry is governed by laws and regulations specific to each country.

For purposes of this training, we will focus on the United States, which regulates all aspects of drug development, manufacturing, promotion, supply and sales through a network of state and federal agencies. This regulatory enforcement environment helps to:

- Promote public health;
- Safeguard patient safety and privacy; and
- Protect government programs that reimburse or purchase pharmaceutical products.

LAWS AND REGULATIONS

Overview of the Pharmaceutical Industry

Failure to comply with these laws and regulations can result in stiff fines and penalties for companies and individuals.

It can also mean excluding individuals and entities from Federally funded healthcare programs.

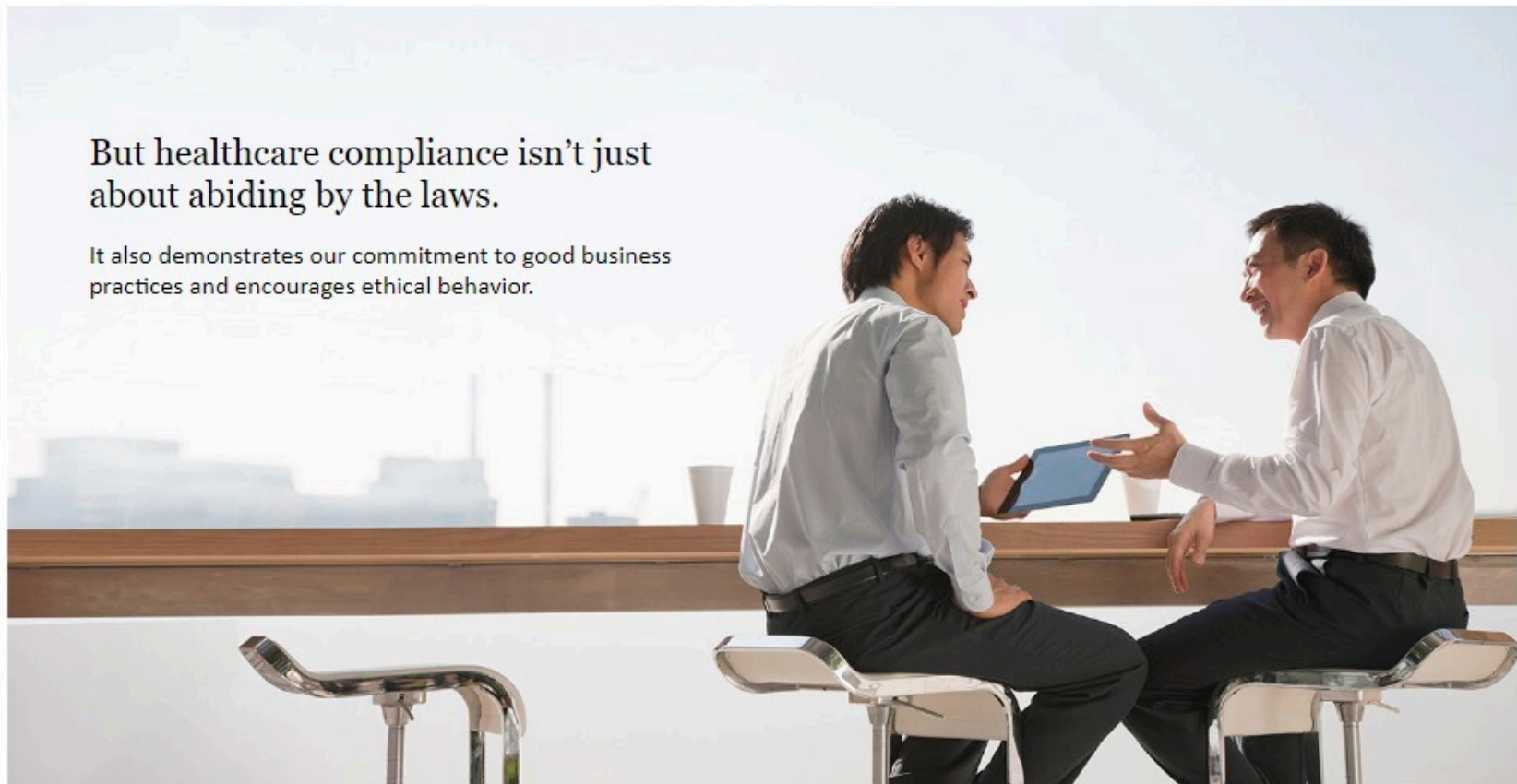


LAWS AND REGULATIONS

Overview of the Pharmaceutical Industry

But healthcare compliance isn't just about abiding by the laws.

It also demonstrates our commitment to good business practices and encourages ethical behavior.



LAWS AND REGULATIONS

Overview of the Pharmaceutical Industry

In the US there are a number of Federal regulators that oversee the biopharmaceutical industry.

CLICK EACH OF THE PANELS BELOW TO LEARN MORE.




LAWS AND REGULATIONS

Overview of the Pharmaceutical Industry

In the US there are a number of Federal regulators that oversee the biopharmaceutical industry.

CLICK EACH OF THE PANELS BELOW TO LEARN MORE.




Food and



US Securities and Exchange
Commission



Federal Trade Commission



Centers for Medicare & Medicaid
Services

Food and Drug Administration

The Food and Drug Administration (FDA) is an agency within the Department of Health & Human Services with primary responsibility for ensuring the products we manufacture are safe and effective for their intended use and promoted in accordance with the law. All pharmaceutical products must be approved by the FDA before they can be marketed or sold to the public. The Federal Food, Drug, and Cosmetic Act (FD&C Act) is the law that regulates prescription drugs and biologics. The FDA is the agency in charge of administration of that law.

LAWS AND REGULATIONS

Overview of the Pharmaceutical Industry

In the US there are a number of Federal regulators that oversee the biopharmaceutical industry.

CLICK EACH OF THE PANELS BELOW TO LEARN MORE.

Office of Inspector General ✕

The Office of Inspector General (OIG) is the agency within the Department of Health & Human Services that investigates Healthcare Fraud & Abuse and provides compliance guidelines for our industry.

Food and ➔

US Securities and Exchange Commission ➔

Federal Trade Commission ➔

Centers for Medicare & Medicaid Services ➔

LAWS AND REGULATIONS

Overview of the Pharmaceutical Industry

In the US there are a number of Federal regulators that oversee the biopharmaceutical industry.

CLICK EACH OF THE PANELS BELOW TO LEARN MORE.



Food and



Department of Justice

The Department of Justice (DOJ) investigates and prosecutes pharmaceutical companies suspected of violating the law, sometimes with the assistance of the FBI and the OIG.



US Securities and Exchange Commission



Federal Trade Commission



Centers for Medicare & Medicaid Services

LAWS AND REGULATIONS

Overview of the Pharmaceutical Industry

In the US there are a number of Federal regulators that oversee the biopharmaceutical industry.

CLICK EACH OF THE PANELS BELOW TO LEARN MORE.

A panel with a background image of a medical room with a bed and IV stand. The text "Food and" is visible at the bottom left.

A panel with a background image of a group of people in a meeting. The text "US Securities and Exchange Commission" is visible at the top left. A modal window is open over this panel.

✕

US Securities and Exchange Commission

The US Securities and Exchange Commission (SEC) has a three-part mission: to protect investors, maintain fair, orderly, and efficient markets, and facilitate capital formation.

A panel with a background image of a person pointing at a large screen displaying a line graph. The text "US Securities and Exchange Commission" is visible at the bottom left. A green checkmark is in the bottom right corner.

A panel with a background image of a world map. The text "Federal Trade Commission" is visible at the bottom left. A right arrow icon is in the bottom right corner.

A panel with a background image of a person sitting at a desk with multiple computer monitors. The text "Centers for Medicare & Medicaid Services" is visible at the bottom left. A right arrow icon is in the bottom right corner.

LAWS AND REGULATIONS

Overview of the Pharmaceutical Industry

In the US there are a number of Federal regulators that oversee the biopharmaceutical industry.

CLICK EACH OF THE PANELS BELOW TO LEARN MORE.



Food and



Federal Trade Commission

The Federal Trade Commission (FTC) regulates advertisements for products sold to customers.



US Securities and Exchange Commission



Federal Trade Commission



Centers for Medicare & Medicaid Services

LAWS AND REGULATIONS

Overview of the Pharmaceutical Industry

In the US there are a number of Federal regulators that oversee the biopharmaceutical industry.

CLICK EACH OF THE PANELS BELOW TO LEARN MORE.



Food and Drug Administration





US Securities and Exchange Commission





Federal Trade Commission





Centers for Medicare & Medicaid Services



The Centers for Medicare & Medicaid Services (CMS) oversees reimbursement and pricing practices for government healthcare programs and also requires companies to disclose payments and other “transfers of values” provided to Healthcare providers and “covered recipients” (e.g. teaching hospitals).

Overview of the Pharmaceutical Industry



Along with Federal regulators, there are a number of state and local agencies that regulate our industry.

Let's take a few minutes to look at some specific laws and regulations within the US that govern our industry.

LAWS AND REGULATIONS

Food Drug and Cosmetic Act



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The Food and Drug Administration (FDA) regulates almost every aspect of the pharmaceutical and medical device industries, from research and development to sales and marketing.

As part of its authority, the FDA regulates the activities that pharmaceutical/biotechnology and device manufacturers may engage in both before and after they obtain approval for a drug or biologic or clearance for a device. Violations of the FDA regulations are punishable by fines, imprisonment, or both.



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LAWS AND REGULATIONS

Food Drug and Cosmetic Act



Before the FDA approves a drug for use, it first determines that the drug is both safe and effective for the use intended by the manufacturer.

That process of approval requires that the FDA confirms the information the manufacturer submits about a drug is truthful and that it includes all the information required for the safe and effective use of the drug.

LAWS AND REGULATIONS

Food Drug and Cosmetic Act



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Prior to FDA approval, the FDA prohibits manufacturers from promoting a drug.

Pre-approval promotion is defined as discussing the safety profile and efficacy of the product prior to the FDA's approval of the product. Because the FD&C Act states that a drug shall be deemed misbranded unless its labeling bears adequate directions for use (which cannot happen until the drug is approved), care must be taken when discussing investigational drugs to avoid making what FDA will consider promotional claims of safety or effectiveness of the drug.

The FD&C Act does not allow an investigational drug sponsor to make conclusory representations regarding the safety and efficacy of any drug that has not been approved by the FDA. What is allowed is the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media.



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LAWS AND REGULATIONS

Food Drug and Cosmetic Act

Once approved, the pharmaceutical company is responsible for ensuring that its drug is only promoted on the basis of the information that has been approved.



LAWS AND REGULATIONS

Food Drug and Cosmetic Act



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When a drug is marketed for any use outside the approved prescribing information in the label, the promotion is considered “off-label.”

Off-label promotion includes both discussing a product or indication not yet approved by the FDA; as well as discussing information that is not consistent with the product label.

The FDA considers “off-label” promotion to be a potential danger to public health.



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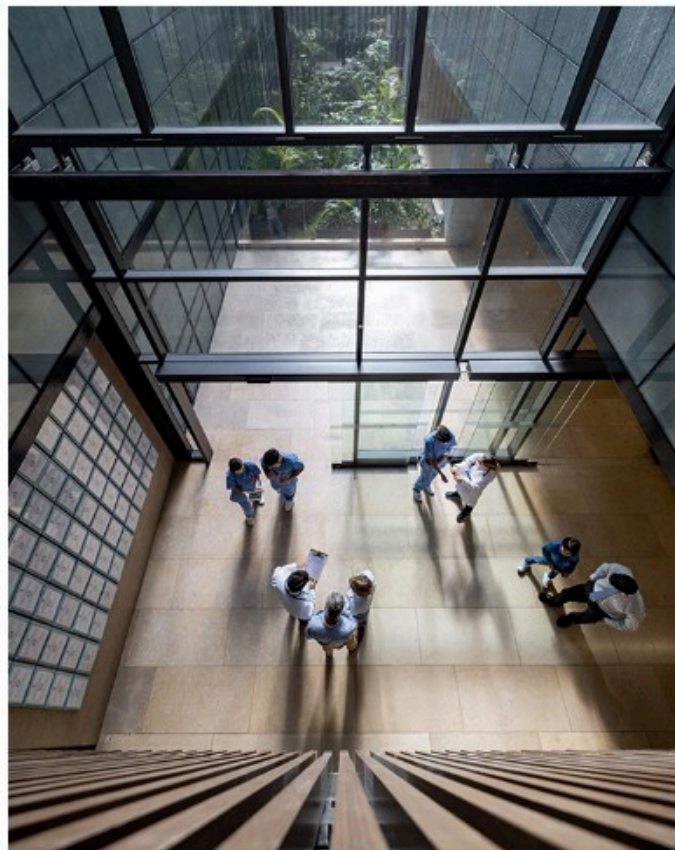


LAWS AND REGULATIONS

The Anti-Kickback Statute



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The Anti-Kickback Statute (AKS) is a federal law that aims to protect patients and federal healthcare programs by preventing fraud and abuse.

The Statute makes it a violation of law to offer or pay, directly or indirectly, “remuneration” (anything of value) to an HCP or customer, to induce that person to prescribe, order, or recommend Crinetics’ products, or to reward that person for past or future purchases, recommendations or use of products reimbursed, in whole or in part, by a federal healthcare program.

The Statute may apply even where a legitimate business need exists for an arrangement or offer, if one purpose of the arrangement or offer is to induce or reward referrals or orders.



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LAWS AND REGULATIONS

The Anti-Kickback Statute



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The scope of the Anti-Kickback Statute is broad.

It can be applied to any transaction we have with an HCP that involves providing the HCP with anything of value, including:

- Payments for services (e.g., in the form of cash, grants, gifts, and free products)
- Certain types of discounts or rebates
- Meals, travel, and entertainment
- Providing programs, advertising, or referral services



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LAWS AND REGULATIONS

The Anti-Kickback Statute

OIG "Safe Harbor" regulations describe various payment and business practices that, although they potentially implicate the Federal Anti-Kickback Statute, are not treated as offenses under the statute.

Safe Harbor practices include:

- Personal services contracts, such as consultant agreements
- Payments of certain discounts and rebates with the appropriate contractual arrangement
- Care coordination and value-based care arrangements



LAWS AND REGULATIONS

The Anti-Kickback Statute



Violations of the AKS are a felony, punishable by fines up to \$25K per violation, a prison term of five years, exclusion from government-funded programs, or all three.

LAWS AND REGULATIONS

The False Claims Act

The Federal False Claims Act (FCA) is another law aimed at protecting Government interests by preventing fraud and abuse in Government healthcare programs.

The FCA makes it a violation of law for anyone knowingly to make, or cause others to make, false statements or claims to the government.



LAWS AND REGULATIONS

The False Claims Act



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Healthcare companies can face prosecution under the FCA if they:

- Submit or cause someone else to submit incorrect or inaccurate statements or claims;
- Promote products for non-approved uses; or
- Engage in kickbacks.

The government has asserted that off-label promotion can lead to a violation of the FCA. Violations of the FCA may be punished by fines of \$5.5K to \$11K per violation as well as exclusion from government-funded programs.



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LAWS AND REGULATIONS

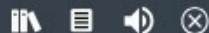
Patient Protection and Affordable Care Act

The Patient Protection and Affordable Care Act (PPACA) requires pharmaceutical and medical device manufacturers to report any “payment or transfer of value” to certain HCPs, including mid-level practitioners, and teaching hospitals.

Reporting requirements for the PPACA include:

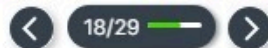
- HCP's name and address
- Nature and form of payment
- Date of the transaction
- Amount





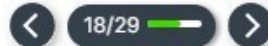
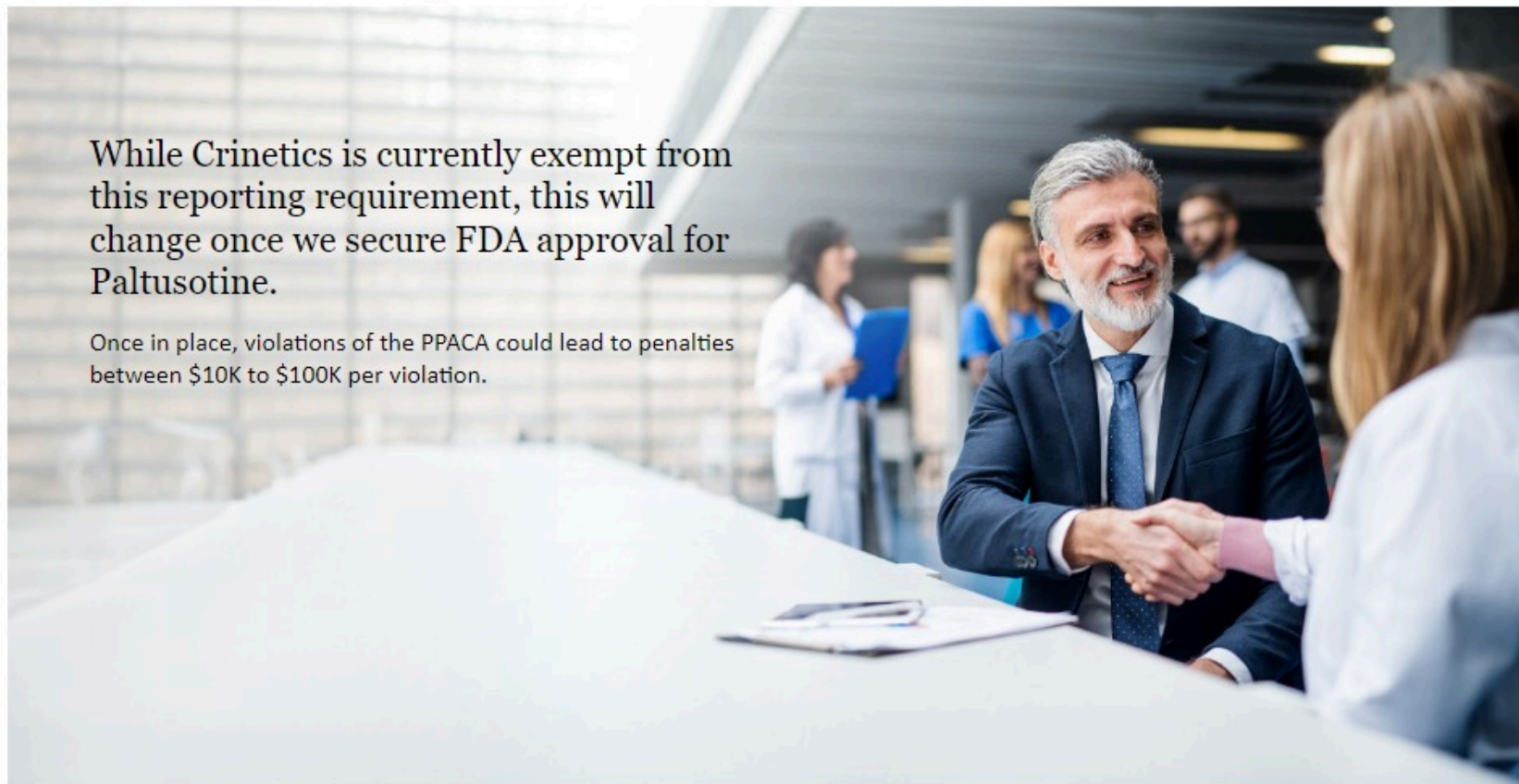
LAWS AND REGULATIONS

Patient Protection and Affordable Care Act



While Crinetics is currently exempt from this reporting requirement, this will change once we secure FDA approval for Paltusotine.

Once in place, violations of the PPACA could lead to penalties between \$10K to \$100K per violation.



LAWS AND REGULATIONS

Global Data Privacy Laws & Requirements

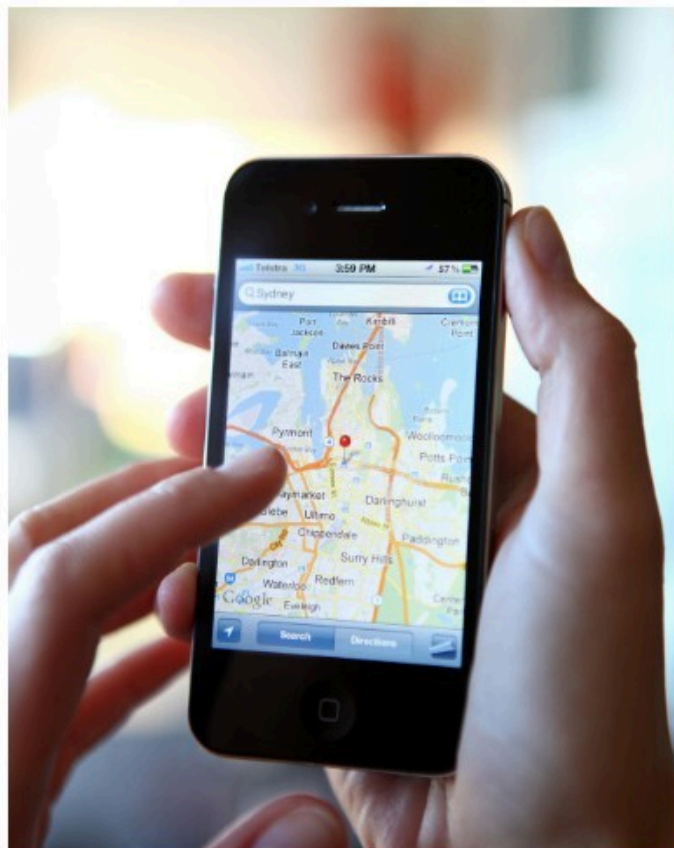
In most countries in which Crinetics conducts business, there are laws and regulations in place designed to protect personal information, including protected health information.



Global Data Privacy Laws & Requirements



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Personal information is any information that can be used to contact, locate, or otherwise identify an individual.

It can include:

- Biographical information, such as name, date of birth, email address and phone number;
- Information relating to an individual's appearance, such as hair color or weight; and,
- Information relating to an individual's personal life, such as photos, browser cookies, or location tracking information.



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LAWS AND REGULATIONS

Global Data Privacy Laws & Requirements

Personal information also includes protected health information (PHI).

PHI is a particularly sensitive type of personal information used in the healthcare industry. It includes any personally identifiable information in medical records, including conversations between medical professionals about treatment.



LAWS AND REGULATIONS

Global Data Privacy Laws & Requirements

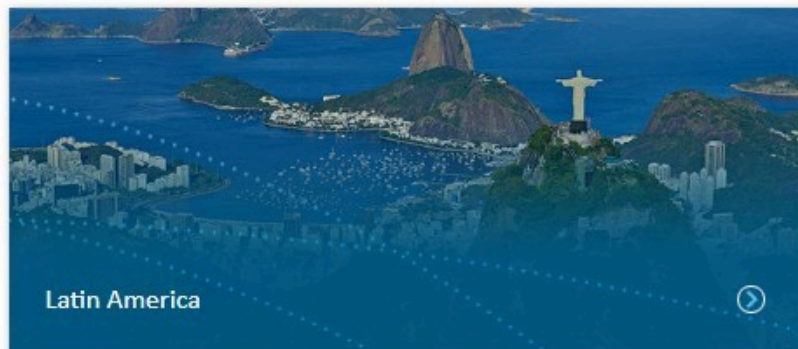
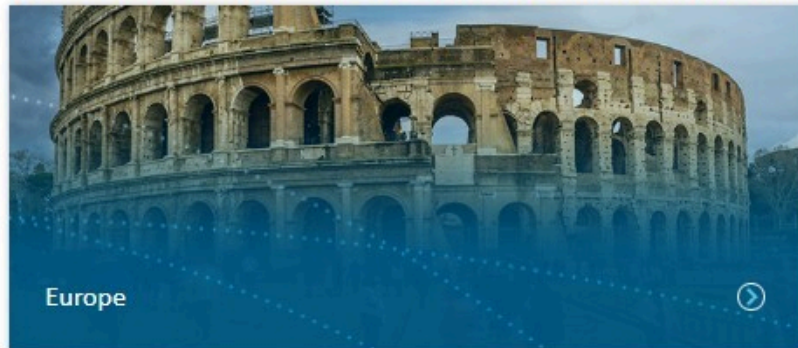


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Laws relating to privacy and protection of personal information differ from one country to the next, but often embrace the same core principles.

CLICK EACH OF THE PANELS TO LEARN ABOUT THE DIFFERENT TYPES OF PRIVACY LAWS AND REQUIREMENTS IN PLACE AROUND THE WORLD.



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LAWS AND REGULATIONS

Global Data Privacy Laws & Requirements



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Europe

In Europe, the General Data Protection Regulation (GDPR) is one of the most comprehensive privacy laws globally. GDPR is particularly relevant to Crinetics because much of the Personal Data that we process during the course of clinical trials comes from the EU (e.g. data subjects taking part in a clinical trial).

GDPR establishes Personal Data protection as a fundamental right, including individuals' rights to access, correct, erase, or transport their Personal Data.

Violations of GDPR can result in heavy fines and penalties for the unlawful processing of Personal Data, including clinical trial data.





Latin America





United States





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LAWS AND REGULATIONS

Global Data Privacy Laws & Requirements



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Europe



United Kingdom's GDPR

The UK privacy laws seek to maintain GDPR's high standard of data protection while tailoring certain aspects to align with UK's legal framework. The UK's law applies to organizations based in the UK or those outside the UK that process Personal Data of UK individuals. Additional safeguards may be required for the transfer of Personal Data from the EU to the UK to ensure protections of a similar level as under EU GDPR.



Latin America



United States



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LAWS AND REGULATIONS

Global Data Privacy Laws & Requirements



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Laws relating to privacy and protection of personal information differ from one country to the next, but often embrace the same core principles.

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Latin America

Most Latin American countries have laws in place that protect the privacy of individuals. However, many countries in the region have recently revised their existing privacy regulations to stay current with international standards.

For example, both Argentina and Brazil have privacy laws that apply in connection with the processing of Personal Data of individuals domiciled in Argentina or Brazil by foreign companies like Crinetics. Both align closely with the EU's GDPR and set similar standards when it comes to transparency, lawfulness of collection, and use limitation.

Europe

Latin America

United States



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LAWS AND REGULATIONS

Global Data Privacy Laws & Requirements




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Laws relating to privacy and protection of personal information differ from one country to the next, but often embrace the same core principles.

CLICK EACH OF THE PANELS TO LEARN ABOUT THE DIFFERENT TYPES OF PRIVACY LAWS AND REQUIREMENTS IN PLACE AROUND THE WORLD.



Europe




United States


In the United States, there is no single law that protects all personal information. Instead, there are privacy laws and regulations that apply to specific industries and types of data. For example, the Health Insurance Portability and Accountability Act (HIPAA) protects the privacy of healthcare data, while the Fair Credit Reporting Act protects credit information.

However, states have begun enacting their own comprehensive data privacy laws. For instance, California has the California Consumer Privacy Act (CCPA) and California Privacy Rights Act (CPRA). These laws provide protections for CA residents with broader applicability than HIPAA. CA residents have certain rights over their Personal Information (e.g. the right to know what is collected, how it is stored and used, the right to deletion of personal information, and the right to “opt-out” of data collection).

Other states that have passed their own data privacy laws include Virginia, Colorado, Utah, and Connecticut. While each state’s law is different, they all generally give people rights to their data and require companies to provide certain disclosures about their data processing activities.



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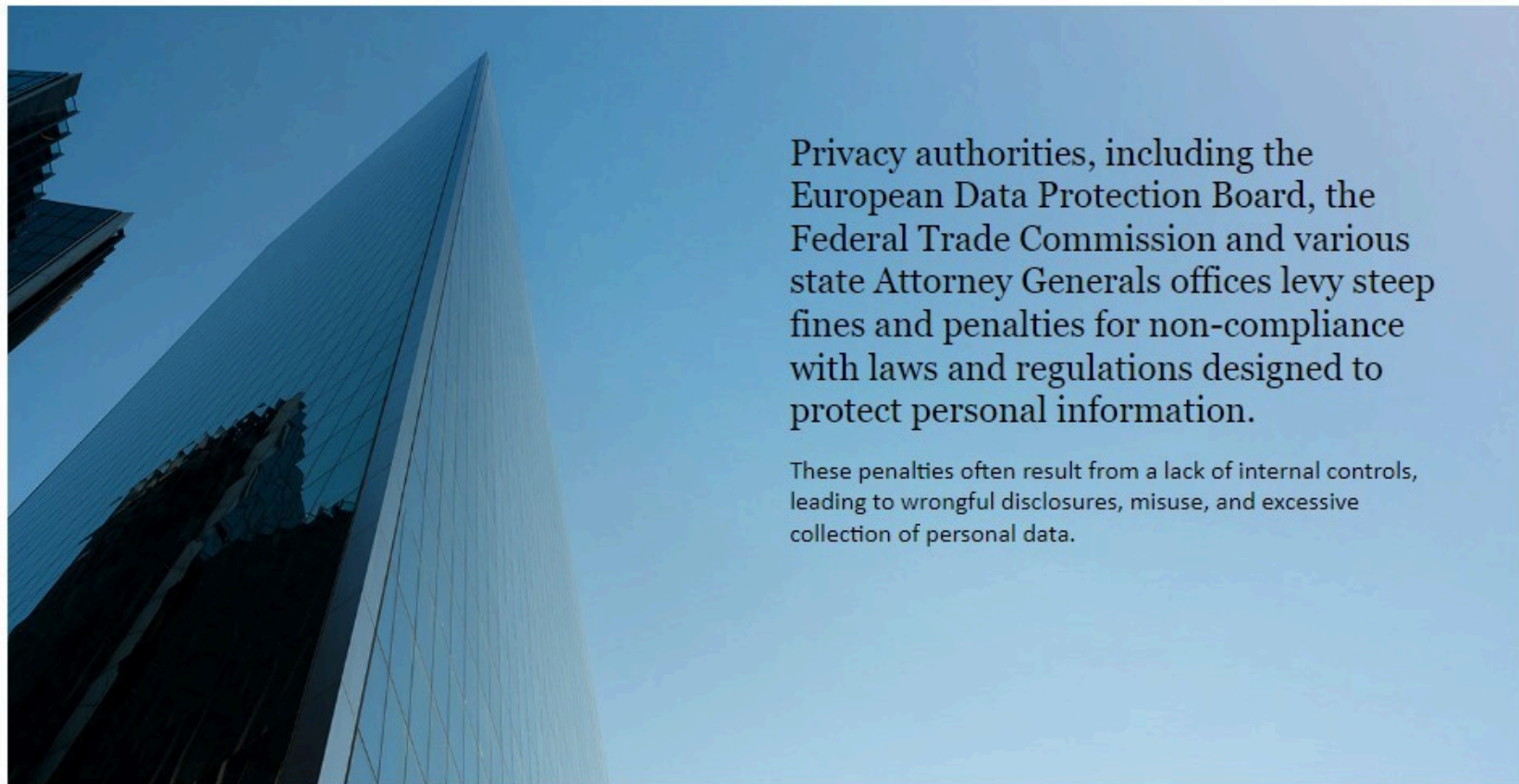
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Global Data Privacy Laws & Requirements



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Privacy authorities, including the European Data Protection Board, the Federal Trade Commission and various state Attorney Generals offices levy steep fines and penalties for non-compliance with laws and regulations designed to protect personal information.

These penalties often result from a lack of internal controls, leading to wrongful disclosures, misuse, and excessive collection of personal data.



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LAWS AND REGULATIONS

Global Data Privacy Laws & Requirements



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Crinetics employees are responsible for safeguarding personal data in accordance with our policies and SOPs, as well as reporting violations to our Privacy Team.

The Legal department delivers annual privacy trainings, and access to on-demand privacy training is also available on the Legal ARC page.

If you have any questions about data privacy, your obligations as an employee, or need to report a violation, contact our Privacy Team at dataprivacy@crinetics.com.



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Industry Standards



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In addition to the laws discussed, research-based pharmaceutical and biotech companies in the U.S. have set out their own voluntary codes of conduct.

These PhRMA codes stipulate the basic principles for interacting with HCPs and conducting clinical trials in compliance with all the regulatory requirements that govern our industry.



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LAWS AND REGULATIONS

Quick Check

Only pharmaceutical manufacturers can be penalized for fraud and abuse violations; never their employees.

True

False

SUBMIT



Quick Check



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Only pharmaceutical manufacturers can be penalized for fraud and abuse violations; never their employees.

True

False

SUBMIT

That's Correct!

Both manufacturers and their employees can be penalized with fines and even prison sentences.



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LAWS AND REGULATIONS

Quick Check



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The European General Data Protection Regulation (GDPR) is one of the most comprehensive privacy laws in the world. GDPR provides data protection rights to subjects whose data is processed in which country?

Check all that apply.

US

Europe

UK

SUBMIT



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LAWS AND REGULATIONS

Quick Check



27/29



The European General Data Protection Regulation (GDPR) is one of the most comprehensive privacy laws in the world. GDPR provides data protection rights to subjects whose data is processed in which country?

Check all that apply.

US

Europe

UK

SUBMIT

That's Correct!

GDPR is a European law. However, global companies, like Crinetics, that process the data of EU citizens must comply with GDPR, regardless of where the company is based. This means that an EU citizen's rights under GDPR are protected even if their data is processed outside the EU.



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LAWS AND REGULATIONS

Review

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Review

Take a moment to review some of the key concepts in this section.

Click the arrow to begin your review.



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Review



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FDA

The Food and Drug Administration (FDA) ensures pharmaceutical products are safe, effective, and promoted legally.



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Review



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Anti-Kickback Statute

The Anti-Kickback Statute (AKS) prohibits anyone working on behalf of a healthcare company from offering, soliciting, receiving, or paying anything of value to an HCP in exchange for the purchase, prescription, recommendation, or referral of the company's products.



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Review



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Federal False Claims Act

The Federal False Claims Act (FCA) is aimed at protecting Government interests by preventing fraud and abuse in Government healthcare programs.



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Review



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Patient Protection and Affordable Care Act

The Patient Protection and Affordable Care Act (PPACA) requires pharmaceutical and medical device manufacturers to report any "payment or transfer of value" to certain HCPs and teaching hospitals.



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Review



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Personal Information

In most countries in which Crinetics conducts business, there are laws and regulations in place designed to protect personal information, including protected health information.



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Review



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Violations of Fraud and Abuse Laws

Violations of Fraud and Abuse laws carry a range of penalties for companies and individuals, including large criminal and civil fines.



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LAWS AND REGULATIONS

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1 minutes



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Laws and Regulations

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Our Compliance Program

10 minutes



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Where We Are Now

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Asking Questions and Raising Concerns

2 minutes



LEARNING PROGRESS

35%



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Introduction



In 2003, the Department of Health and Human Services Office of Inspector General (OIG) released the baseline elements outlining the minimum expectations for an effective compliance program.

The principles outlined from the OIG are the following “Seven (7) Elements”:

- Establish a Governance Structure with Oversight and Accountability
- Develop Written Standards of Conduct
- Provide Effective Training & Open Lines of Communication
- Develop a Robust Reporting & Investigation Process
- Implement Auditing & Monitoring
- Enforce Standards and Disciplinary Guidelines
- Respond to Detected Problems with Corrective Actions



Introduction



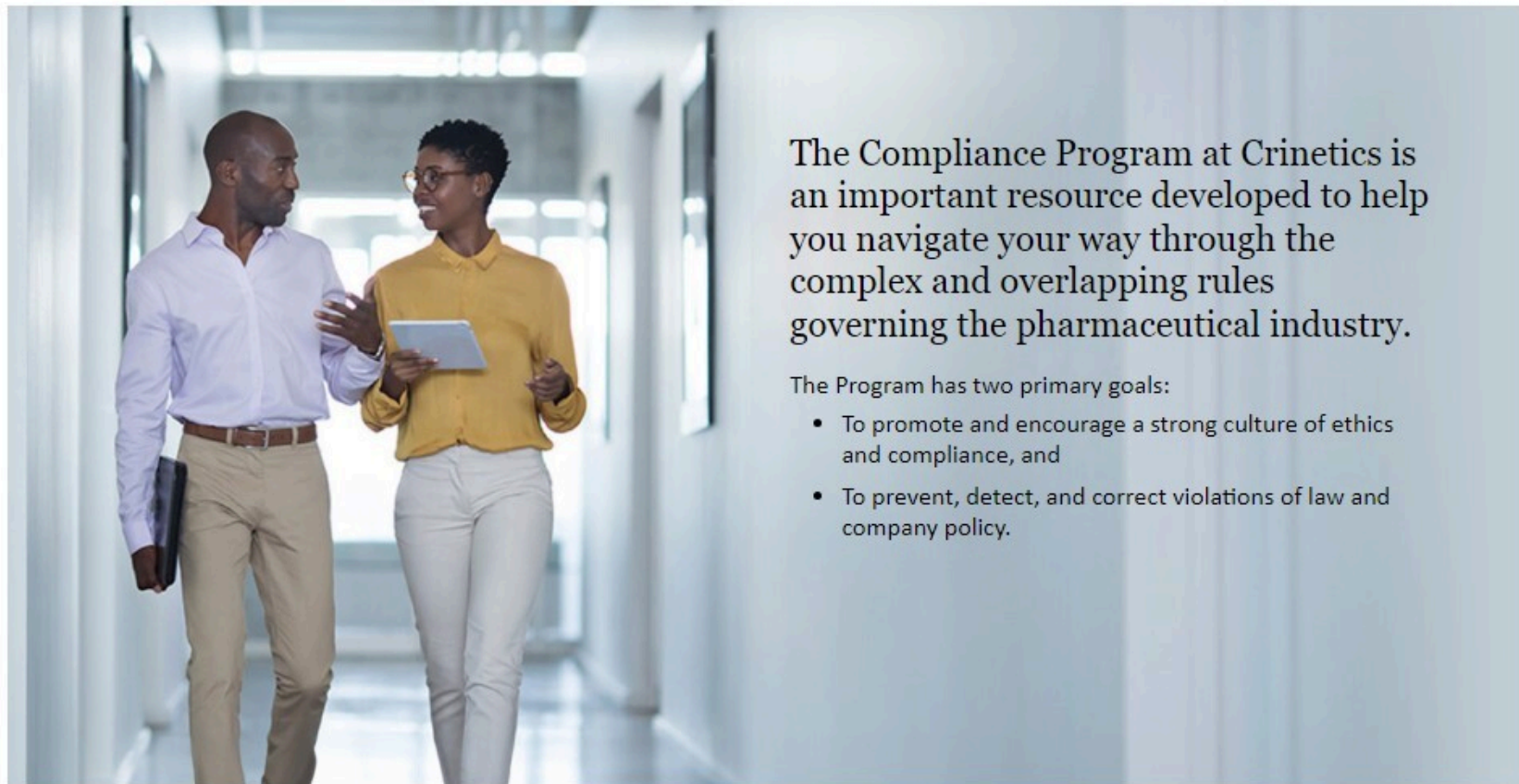
In November of 2023, the OIG issued an update of its “General Compliance Program Guidance” (GCPG) as the first step towards modernizing its healthcare compliance resources.

While the specific language and format has changed, the GCPG retains its Seven (7) elements framework. The GCPG largely reiterates HHS-OIG’s longstanding guidance and expectations for healthcare compliance programs.

Introduction



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The Compliance Program at Crinetics is an important resource developed to help you navigate your way through the complex and overlapping rules governing the pharmaceutical industry.

The Program has two primary goals:

- To promote and encourage a strong culture of ethics and compliance, and
- To prevent, detect, and correct violations of law and company policy.



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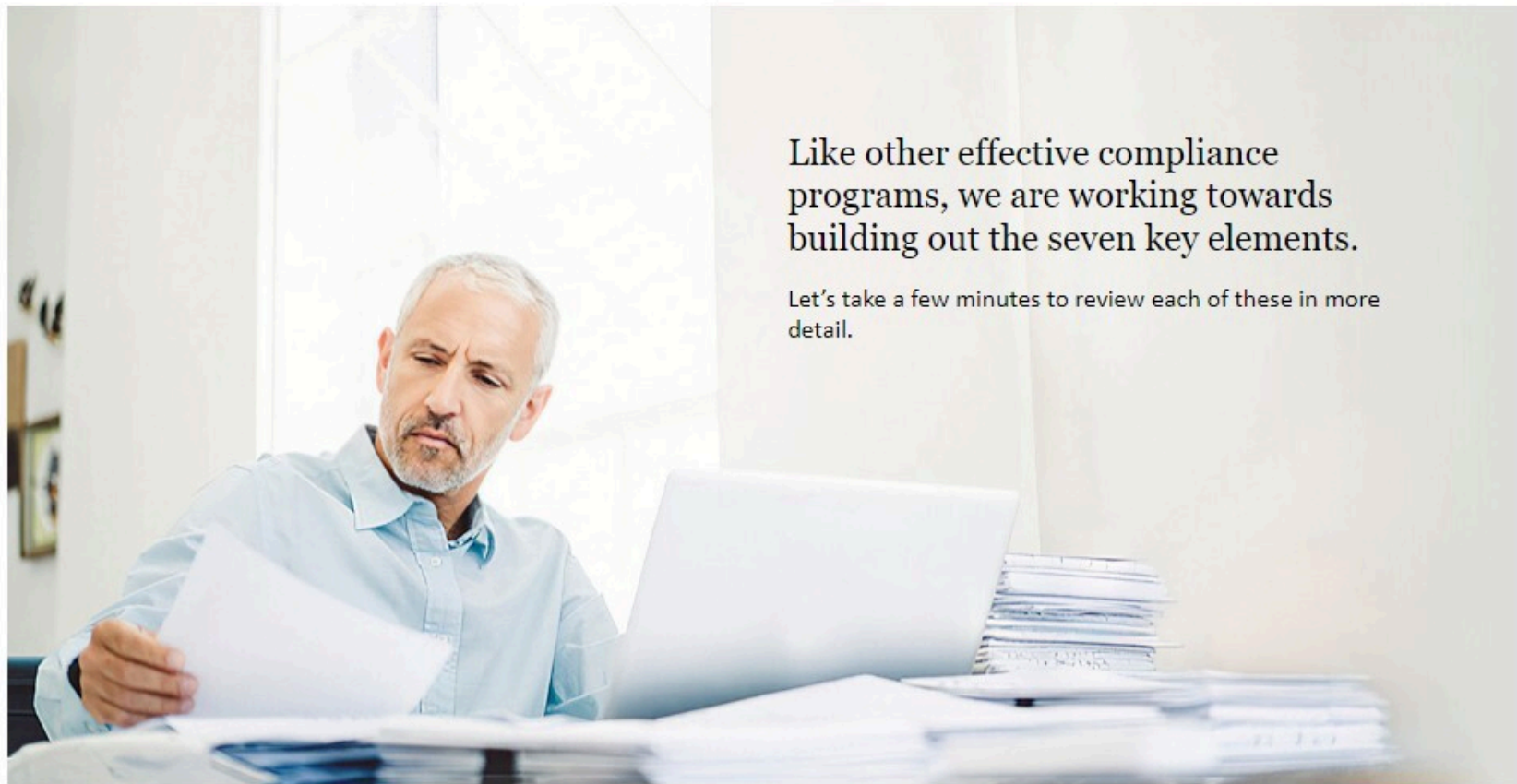


OUR COMPLIANCE PROGRAM

Introduction



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Like other effective compliance programs, we are working towards building out the seven key elements.

Let's take a few minutes to review each of these in more detail.



4/18



OUR COMPLIANCE PROGRAM

The Seven Elements of an Effective Compliance Program



The first element of an effective compliance program is having a governance structure. Our leadership structure will include a Compliance Officer and a Compliance Committee that will be responsible, amongst other things, for:

- Overseeing and monitoring the implementation and operation of the compliance program;
- Advising the board, and other senior leaders on compliance risks facing the entity, compliance risks related to strategic and operational decisions of the entity, and the operation of the entity's compliance program.

The Seven Elements of an Effective Compliance Program

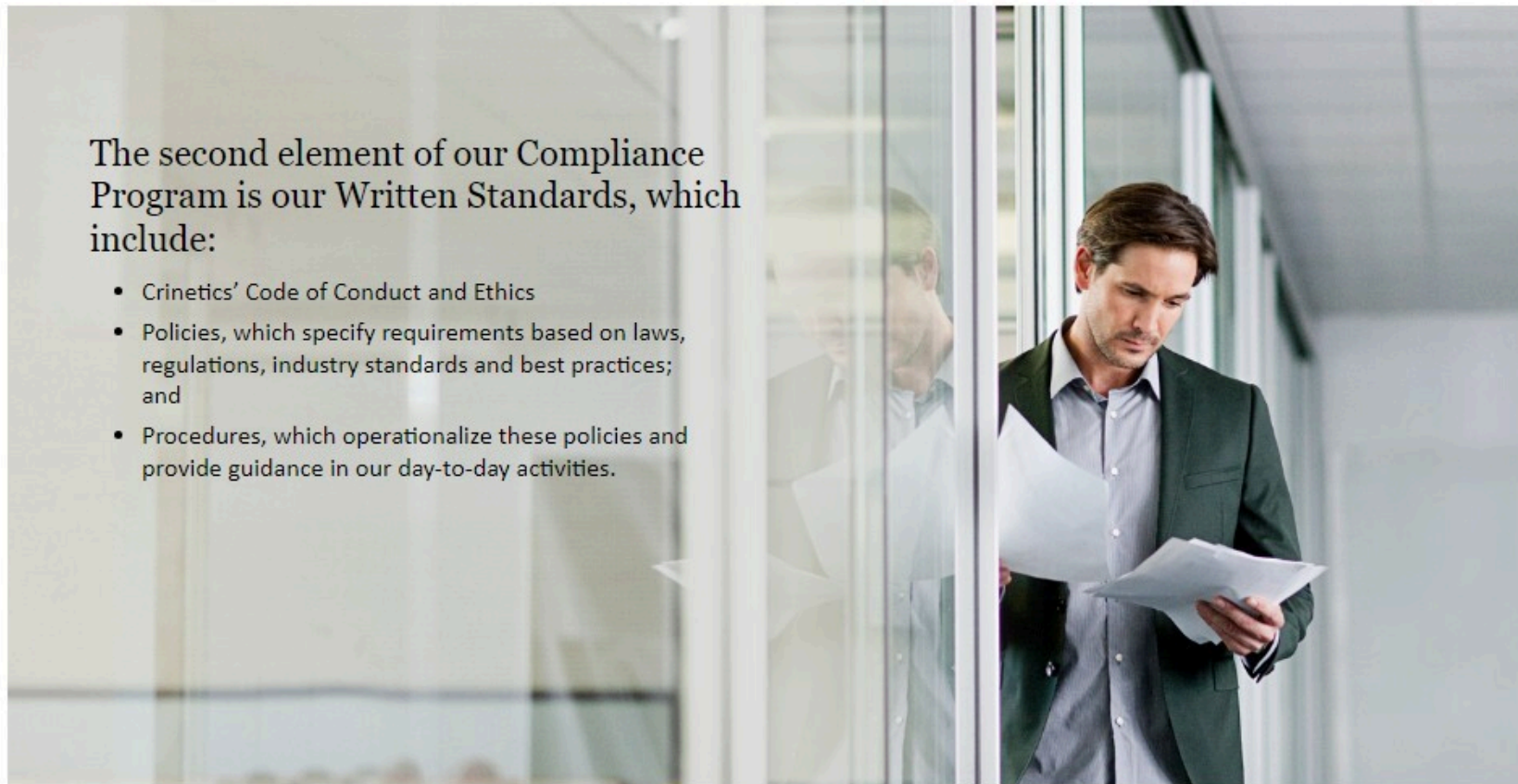


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The second element of our Compliance Program is our Written Standards, which include:

- Crinetics' Code of Conduct and Ethics
- Policies, which specify requirements based on laws, regulations, industry standards and best practices; and
- Procedures, which operationalize these policies and provide guidance in our day-to-day activities.



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OUR COMPLIANCE PROGRAM

The Seven Elements of an Effective Compliance Program



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Our Code of Conduct is our foundational compliance document.

It codifies our overarching standards of behavior in areas such as:

- Conflict of Interest
- Insider Trading
- Confidentiality
- Proper Use of Company Assets
- Accurate Records
- Gifts and Favors
- Discrimination and Harassment
- Personal Conduct and Social Media



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OUR COMPLIANCE PROGRAM

The Seven Elements of an Effective Compliance Program



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The third element of an effective compliance program is training and open lines of communication.



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OUR COMPLIANCE PROGRAM

The Seven Elements of an Effective Compliance Program



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As part of our Compliance Program, you will receive training on a variety of compliance-related topics.

Once you complete your training, we hold you responsible for both knowing which policies and procedures that directly impact your job and for following them.



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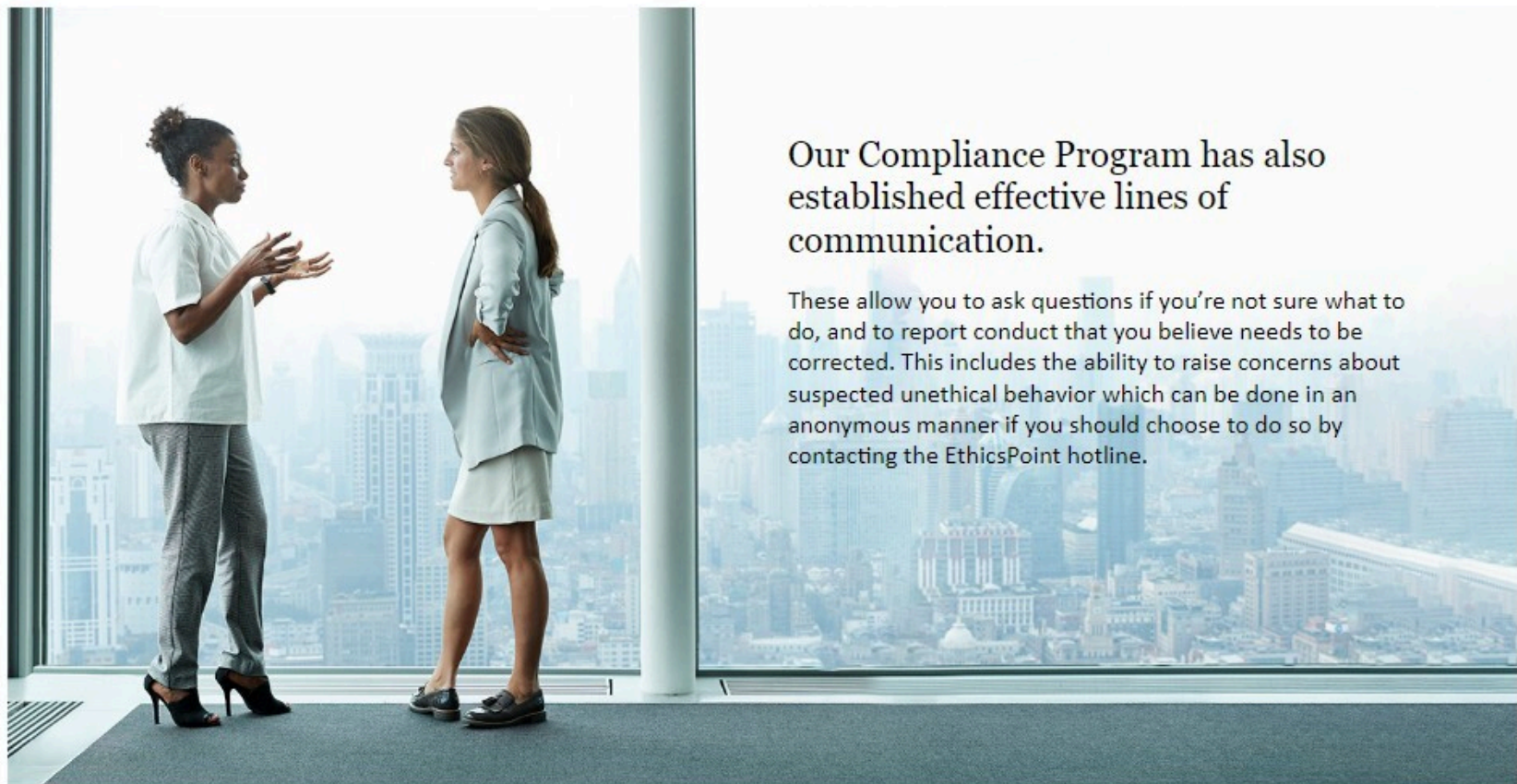


OUR COMPLIANCE PROGRAM

The Seven Elements of an Effective Compliance Program



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Our Compliance Program has also established effective lines of communication.

These allow you to ask questions if you're not sure what to do, and to report conduct that you believe needs to be corrected. This includes the ability to raise concerns about suspected unethical behavior which can be done in an anonymous manner if you should choose to do so by contacting the EthicsPoint hotline.



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OUR COMPLIANCE PROGRAM

The Seven Elements of an Effective Compliance Program

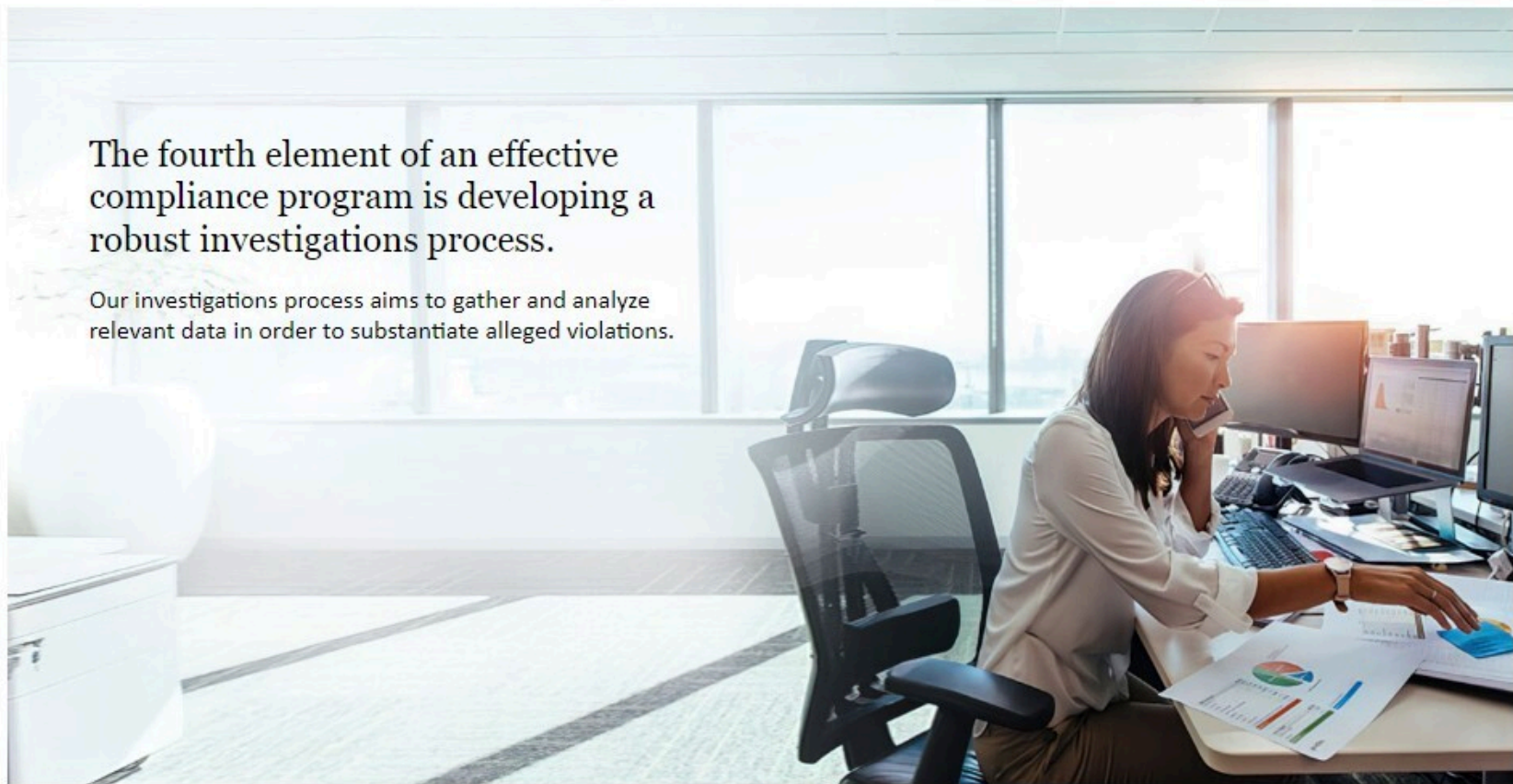


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The fourth element of an effective compliance program is developing a robust investigations process.

Our investigations process aims to gather and analyze relevant data in order to substantiate alleged violations.



11/18



OUR COMPLIANCE PROGRAM

The Seven Elements of an Effective Compliance Program

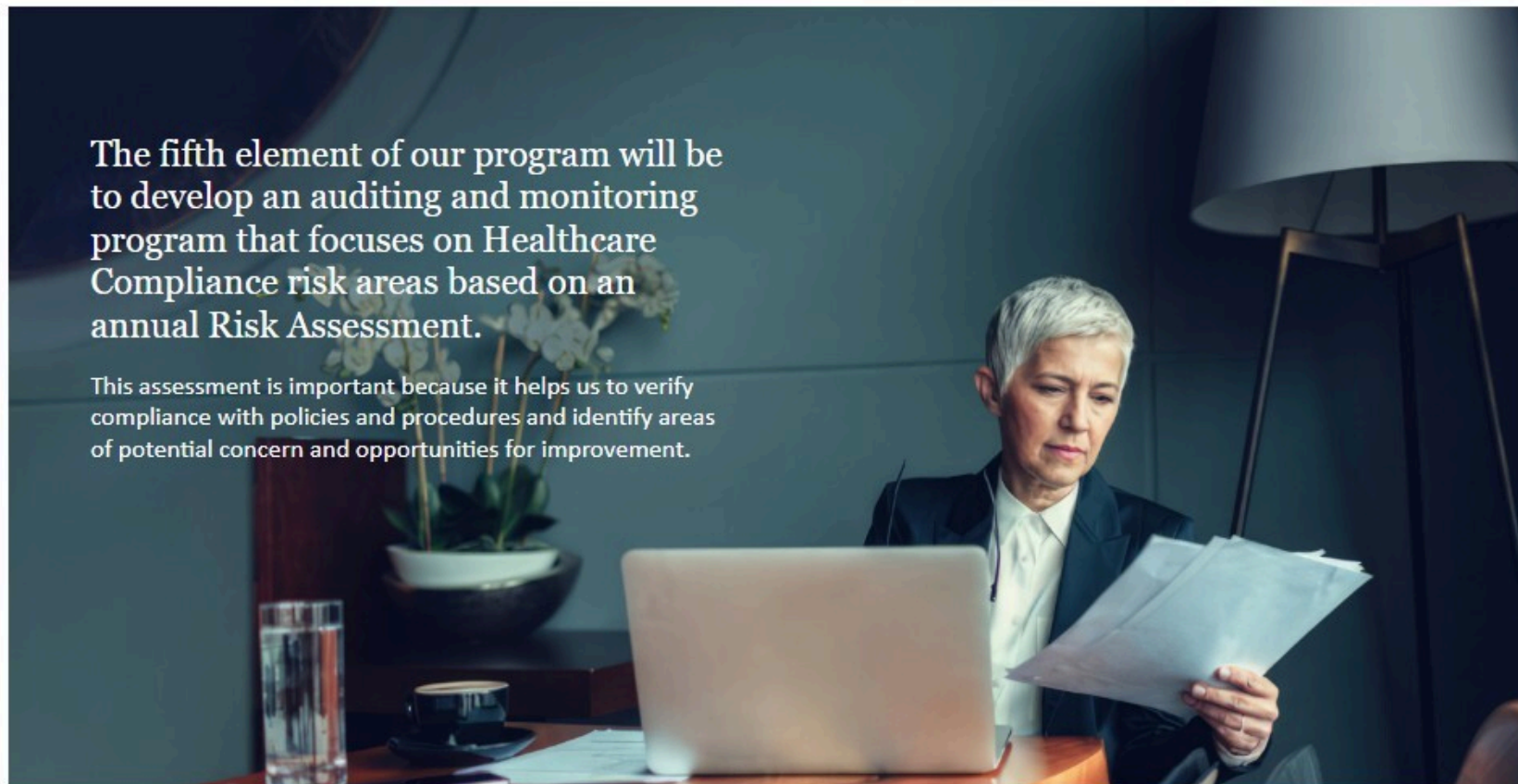


12/18



The fifth element of our program will be to develop an auditing and monitoring program that focuses on Healthcare Compliance risk areas based on an annual Risk Assessment.

This assessment is important because it helps us to verify compliance with policies and procedures and identify areas of potential concern and opportunities for improvement.



12/18



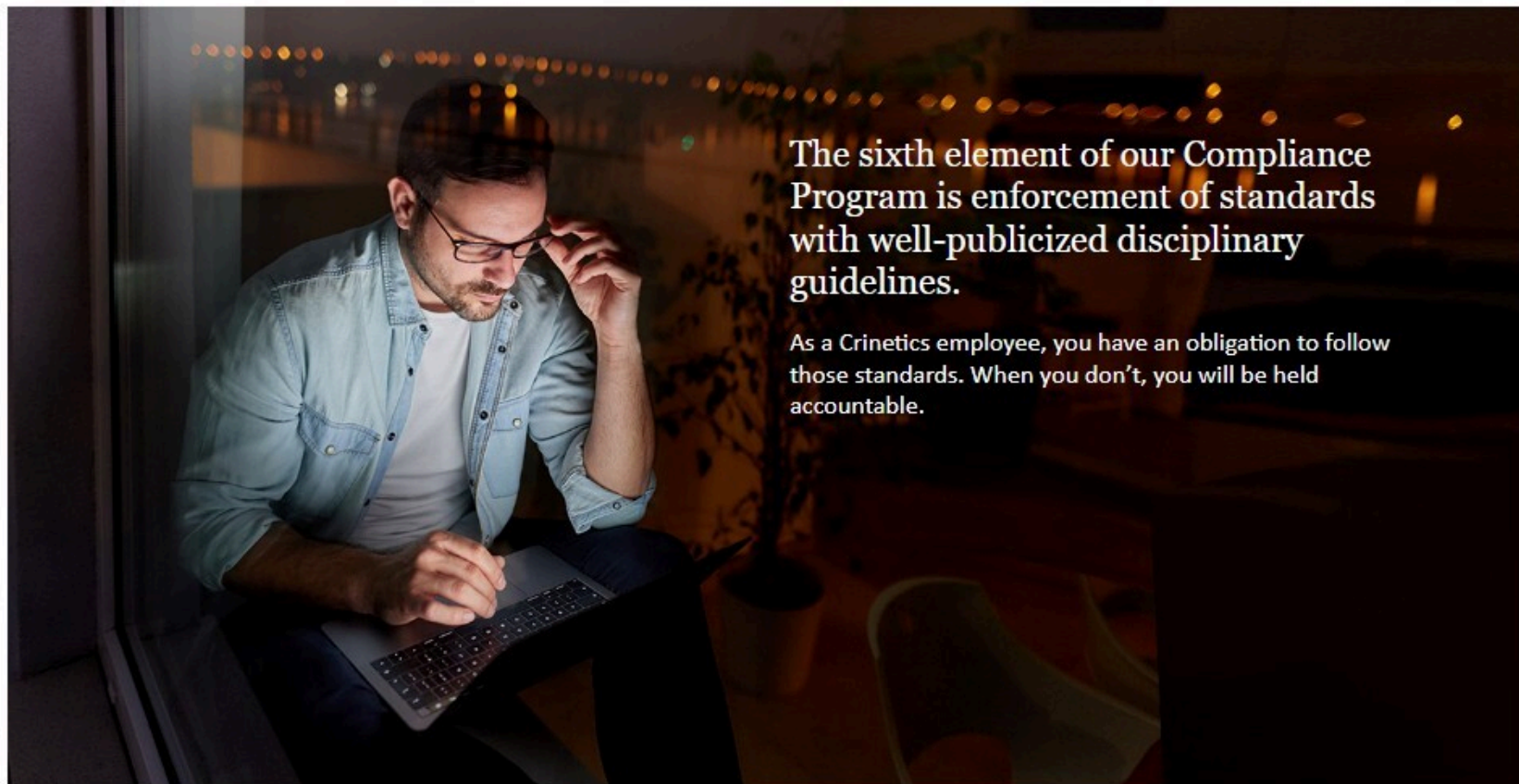


OUR COMPLIANCE PROGRAM

The Seven Elements of an Effective Compliance Program



13/18



The sixth element of our Compliance Program is enforcement of standards with well-publicized disciplinary guidelines.

As a Crinetics employee, you have an obligation to follow those standards. When you don't, you will be held accountable.



13/18





OUR COMPLIANCE PROGRAM

The Seven Elements of an Effective Compliance Program

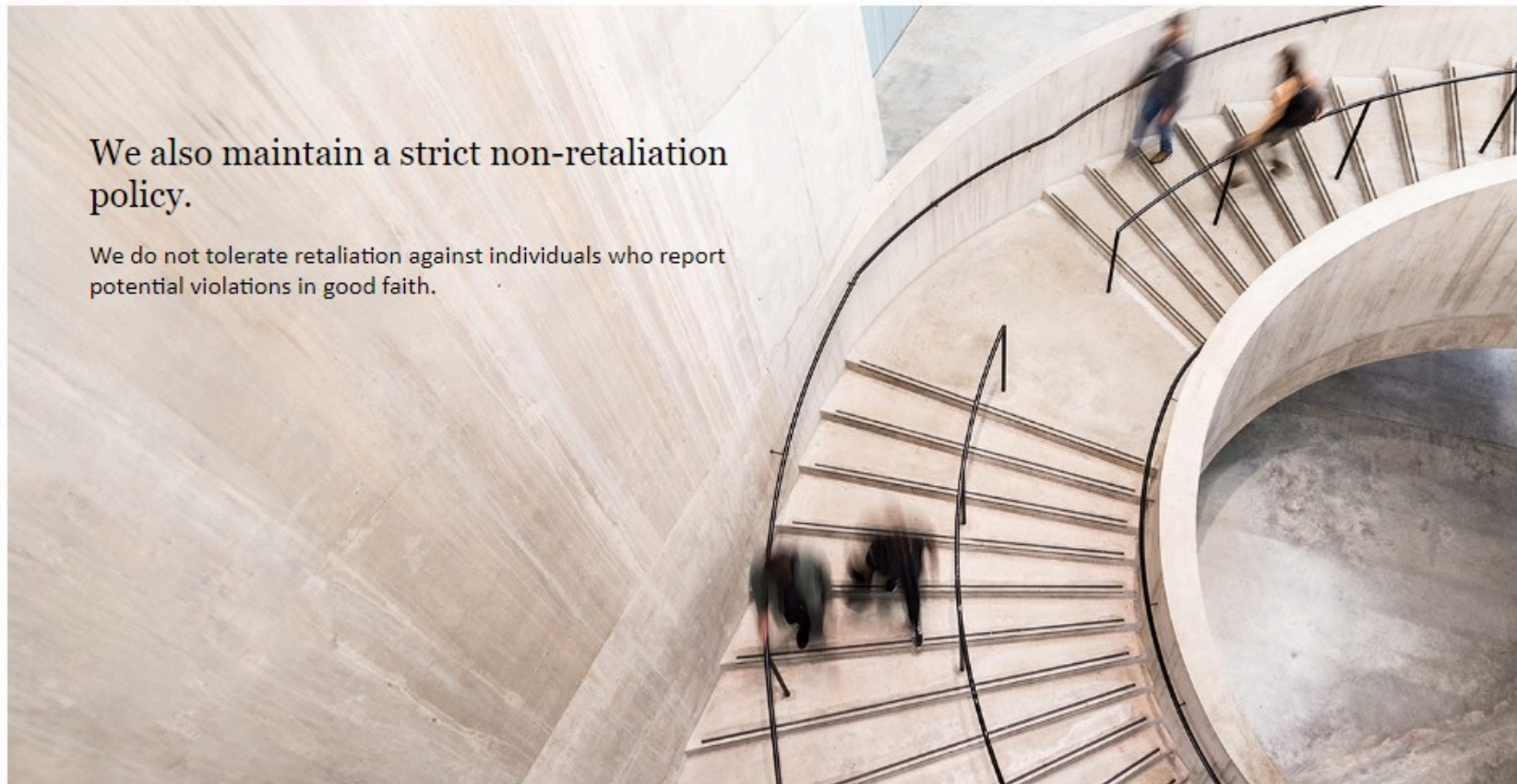


14/18



We also maintain a strict non-retaliation policy.

We do not tolerate retaliation against individuals who report potential violations in good faith.



14/18



The Seven Elements of an Effective Compliance Program



15/18



The seventh and final element of an effective compliance program is our ability to respond promptly and effectively to the results of our investigations through corrective action.

Corrective action is important because it provides us with an opportunity to not only correct existing issues, but also to prevent future occurrences and make improvements in our processes.



15/18



OUR COMPLIANCE PROGRAM

Quick Check



16/18



What are some of the key goals of Crinetics' Compliance Program?

Check all that apply.

To promote a culture of compliance.

To stop managers communicating about compliance-related issues.

To prevent violations of law and company policy.

To mitigate risk.

SUBMIT



16/18



Quick Check



16/18



What are some of the key goals of Crinetics' Compliance Program?

Check all that apply.

To promote a culture of compliance.

To stop managers communicating about compliance-related issues.

To prevent violations of law and company policy.

To mitigate risk.

SUBMIT

That's Correct!

Our Compliance Program has a number of goals, including:

- Promoting and encouraging a strong culture of compliance;
- Preventing, detecting, and correcting violations of law and company policy; and
- Mitigating risk.

Our Compliance Program also aims to establish effective lines of communication. This includes asking questions of, and raising concerns with, managers.



16/18





OUR COMPLIANCE PROGRAM

Review



17/18



Review

Take a moment to review some of the key concepts in this section.

Click the arrow to begin your review.



17/18





OUR COMPLIANCE PROGRAM

Review



17/18



Crinetics' Compliance Program

Our Compliance Program promotes and encourages a strong culture of compliance to prevent violations of law and company policy.



17/18



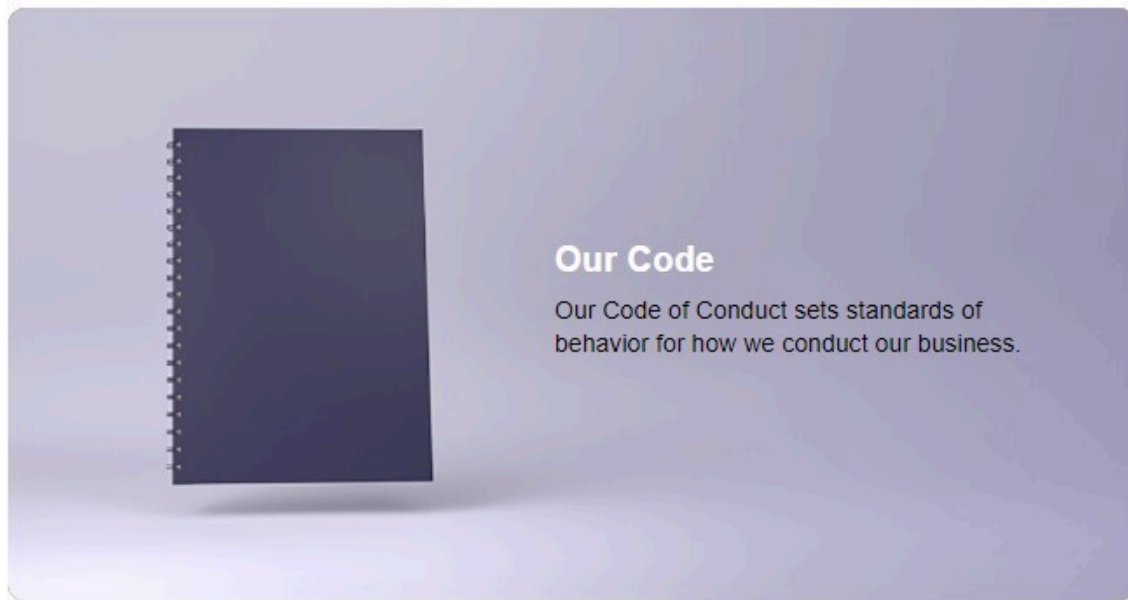


OUR COMPLIANCE PROGRAM

Review



17/18



17/18



Review



17/18



Your Role in Compliance

All employees have a responsibility to follow and maintain our Compliance standards and to raise any concerns over potential violations.



17/18





Review



17/18



Non-retaliation Policy

We do not tolerate retaliation against individuals who report potential violations in good faith.



17/18



OUR COMPLIANCE PROGRAM

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- 4 Where We Are Now
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- 5 Asking Questions and Raising Concerns
2 minutes

LEARNING PROGRESS



54%

WHERE WE ARE NOW

The FDA's Authority over Investigational Products

< 1/34 — >

As we prepare for the commercialization of Paltusotine, it is important to be aware of the FDA's broad authority to regulate communications about Investigational Products, that is, products that have not yet received FDA approval.



< 1/34 — >

WHERE WE ARE NOW

The FDA's Authority over Investigational Products

< 2/34 — >

The FDA's intention in restricting communication about Investigational Products is:

- To preclude commercialization of products before the FDA has determined them to be safe and effective to use; and
- To prevent potential customers from developing unsubstantiated or misleading beliefs about a product's safety and effectiveness.

< 2/34 — >

WHERE WE ARE NOW

The FDA's Authority over Investigational Products



3/34



FDA laws and regulations are not intended to limit scientific exchange regarding Investigational Products. Nor is the intention to restrict other non-promotional communications and activities, such as:

- Presentations to investors;
- Interactions at advisory board meetings; and
- Communications intended for the recruitment of clinical study investigators and subjects.



3/34



WHERE WE ARE NOW

The FDA's Authority over Investigational Products

< 4/34 >



To remain compliant, always ensure that any information that is shared about Investigational Products is:

- Truthful and not misleading; and
- Approved by Crinetics for dissemination.

Never suggest that an Investigational Product is safe or effective for any use.



< 4/34 >

WHERE WE ARE NOW

Clinical / “Pre-Approval” Phase



5/34



During the clinical phase of product development, we are engaged in activities that are crucial to our organization, and carry a level of regulatory, legal and reputational risk.

CLICK EACH OF THE PANELS TO LEARN MORE.



5/34



WHERE WE ARE NOW

Clinical / “Pre-Approval” Phase

< 5/34 >

During the clinical phase of product development, we are engaged in activities that are crucial to our organization, and carry a level of regulatory, legal and reputational risk.

CLICK EACH OF THE PANELS TO LEARN MORE.

Clinical Trials Obligations

- Protect research participants
- Conduct high quality research
- Ensure objectivity/accuracy of data
- Disclose complete/accurate results

Clinical Trials

Engaging with Medical and Scientific Community

Patient Advocacy Activities

Corporate Communications

< 5/34 >

WHERE WE ARE NOW

Clinical / “Pre-Approval” Phase



5/34



During the clinical phase of product development, we are engaged in activities that are crucial to our organization, and carry a level of regulatory, legal and reputational risk.

CLICK EACH OF THE PANELS TO LEARN MORE.

Product Labeling Expectations

- Use & indication
- Dosage & administration
- Safety & risk profile

Clinical Trials

Engaging with Medical and Scientific Community

Patient Advocacy Activities

Corporate Communications



5/34



WHERE WE ARE NOW

Clinical / “Pre-Approval” Phase



5/34



During the clinical phase of product development, we are engaged in activities that are crucial to our organization, and carry a level of regulatory, legal and reputational risk.

CLICK EACH OF THE PANELS TO LEARN MORE.

Manufacturing Requirements

- Quality control
- Product supply/packaging/storage

Clinical Trials

Engaging with Medical and Scientific Community

Patient Advocacy Activities

Corporate Communications



5/34



WHERE WE ARE NOW

Clinical / “Pre-Approval” Phase



5/34



During the clinical phase of product development, we are engaged in activities that are crucial to our organization, and carry a level of regulatory, legal and reputational risk.

CLICK EACH OF THE PANELS TO LEARN MORE.

Engaging with Medical and Scientific Community

- Sharing and gathering insights
- Scientific exchange and presentations
- Responding to Medical Information Requests

Clinical Trial

Engaging with Medical and Scientific Community

Patient Advocacy Activities

Corporate Communications



5/34



WHERE WE ARE NOW

Clinical / “Pre-Approval” Phase



5/34



During the clinical phase of product development, we are engaged in activities that are crucial to our organization, and carry a level of regulatory, legal and reputational risk.

CLICK EACH OF THE PANELS TO LEARN MORE.

Patient Advocacy Activities

- Disease awareness
- Privacy considerations
- Appropriate engagement with Patient Groups
- Respecting the independence of HCP & Patient relationship

Clinical Trials

Engaging with Medical and Scientific Community

Patient Advocacy Activities

Corporate Communications



5/34



WHERE WE ARE NOW

Clinical / “Pre-Approval” Phase

< 5/34 >

During the clinical phase of product development, we are engaged in activities that are crucial to our organization, and carry a level of regulatory, legal and reputational risk.

CLICK EACH OF THE PANELS TO LEARN MORE.

Corporate Communications

- Investor Relations
- Press Releases and Social Media

Clinical Trials

Engaging with Medical and Scientific Community

Patient Advocacy Activities

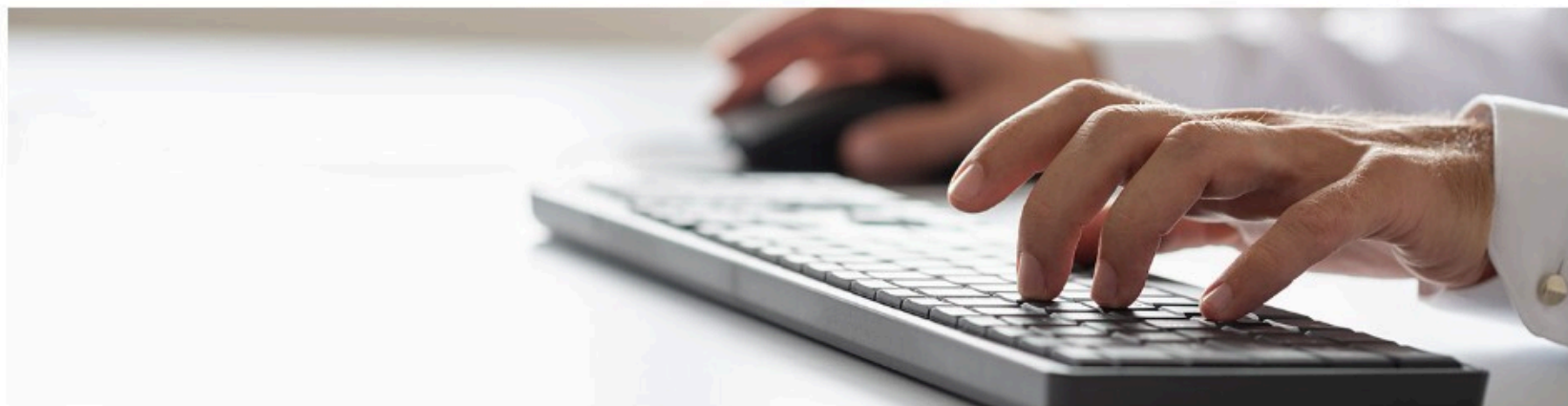
Corporate Communications

< 5/34 >

WHERE WE ARE NOW

Clinical / “Pre-Approval” Phase

< 6/34 >



As we progress towards commercialization of Paltusotine, we are engaging in additional activities that carry greater risks and are subject to even more scrutiny.

- Medical Affairs Activities
 - Interactions with HCPs /HCOs
 - Scientific Exchange
 - Disease State Education
- Publications
- Funding & Support
 - Sponsorship & Charitable Contribution Requests
 - Grant Requests from HCPs
 - Inquiries about Investigator Initiated Studies
- Independent Medical Education/Continuing Medical Education Events
- Patient Advocacy Activities
 - Patient Outreach and Product Support
- HCP/HCO Consulting Engagements
 - Advisory Boards
 - Contracting
- Pre-approval Advertisements
 - Institutional and Disease Awareness

< 6/34 >

WHERE WE ARE NOW

Intellectual Property

< 7/34 >

Protecting our intellectual property is essential to maintaining Crinetics' competitive advantage.

Not surprisingly, the improper use or disclosure of this information can result in significant harm to Crinetics.



< 7/34 >

WHERE WE ARE NOW

Intellectual Property



8/34



Intellectual property includes:

- Trade secrets;
- Our patents;
- Clinical trial data;
- Pre-approval regulatory information;
- Financial data that has not been released to the public;
- Trademarks; and
- Scientific and technical knowledge and experience developed by the company



8/34



WHERE WE ARE NOW

Intellectual Property

< 9/34 >

All Crinetics employees are responsible for establishing, protecting, maintaining, and defending the company's intellectual property rights and safeguarding confidential information.

Some examples of confidential information include product plans and strategies, investigator and employee records, research and technical data, manufacturing techniques, information pertaining to business development opportunities, and new products in development.

Protecting our intellectual property is essential and everyone's responsibility.



< 9/34 >

WHERE WE ARE NOW

Intellectual Property



10/34



Crinetics also respects the valid intellectual property rights of others.

Unauthorized use, theft, or misappropriation of intellectual property rights of others may result in significant fines and criminal penalties for both you and the Company.



10/34

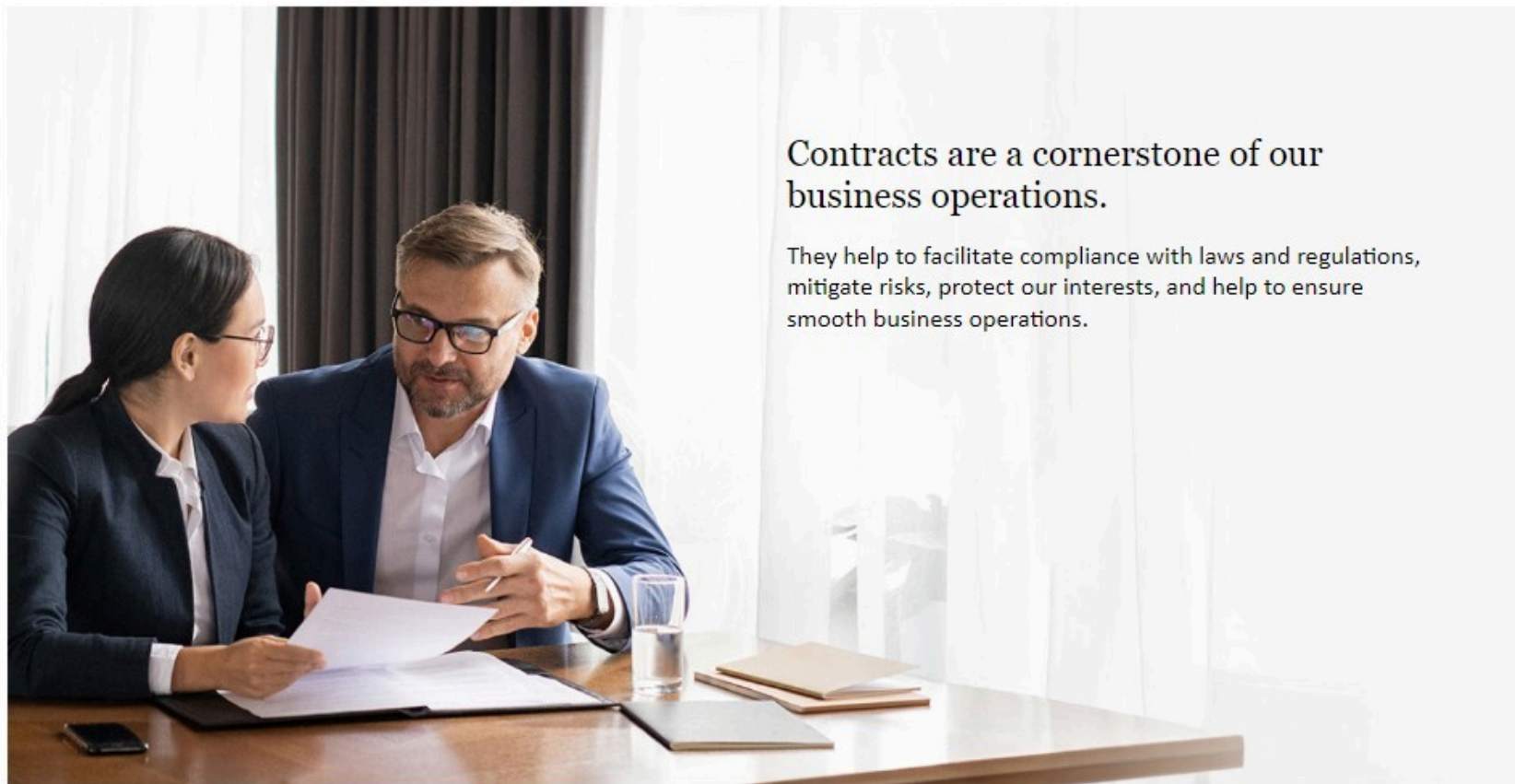


WHERE WE ARE NOW

Contracting



11/34



Contracts are a cornerstone of our business operations.

They help to facilitate compliance with laws and regulations, mitigate risks, protect our interests, and help to ensure smooth business operations.



11/34



WHERE WE ARE NOW

Contracting

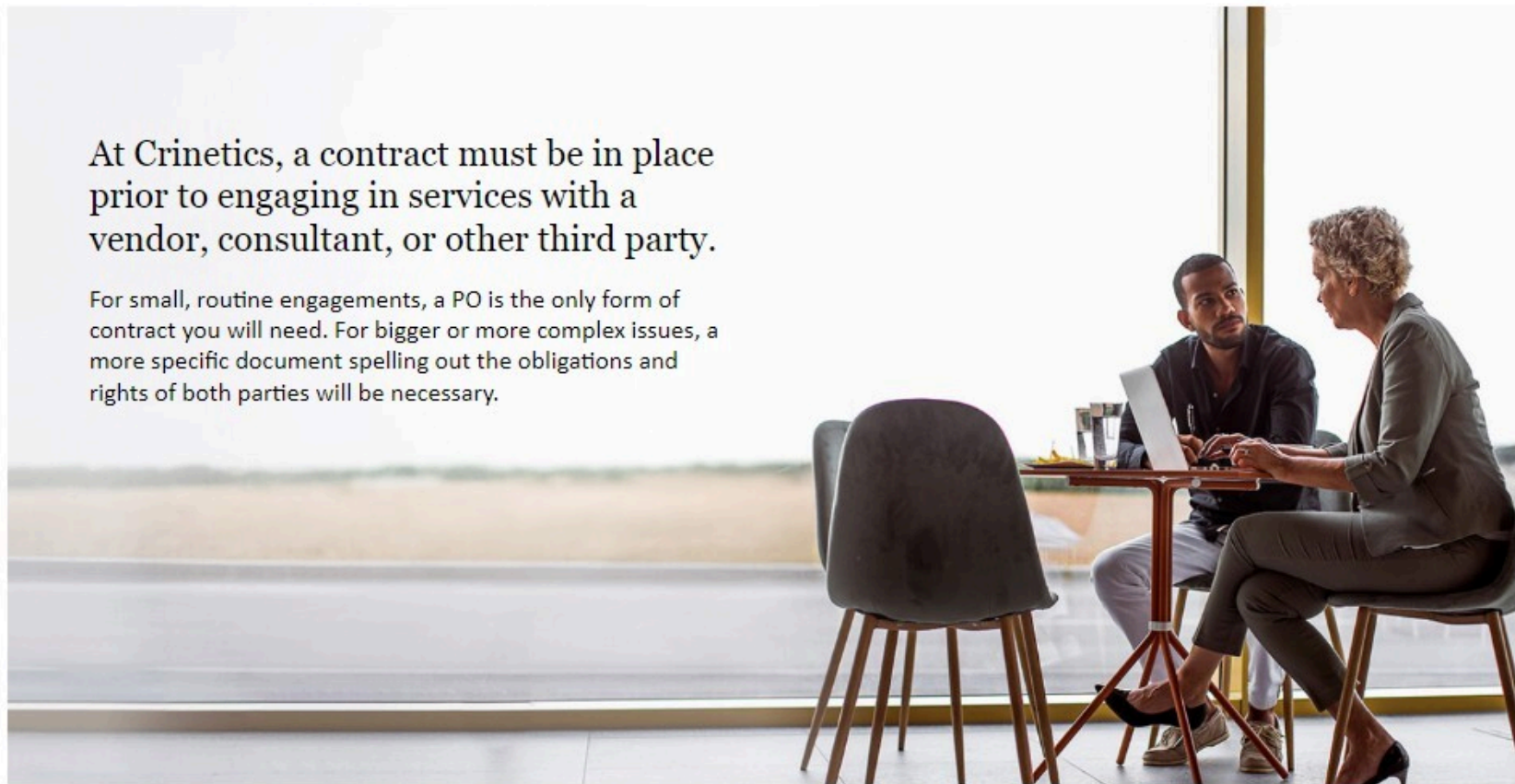


12/34



At Crinetics, a contract must be in place prior to engaging in services with a vendor, consultant, or other third party.

For small, routine engagements, a PO is the only form of contract you will need. For bigger or more complex issues, a more specific document spelling out the obligations and rights of both parties will be necessary.



12/34

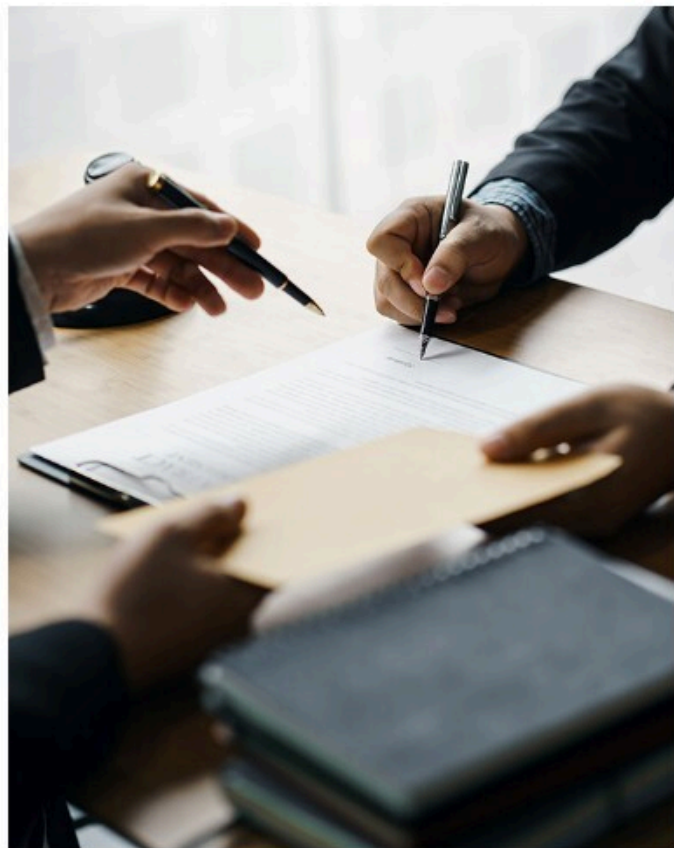


WHERE WE ARE NOW

Contracting



13/34



All contracts should reflect the three "C's" of contracting:

Clarity

A clear statement of the rights and obligations of the parties.

Common Understanding

A mutual understanding of the parties' rights and obligations.

Completeness

Documenting the complete understanding of all parties.



13/34



WHERE WE ARE NOW

Contracting

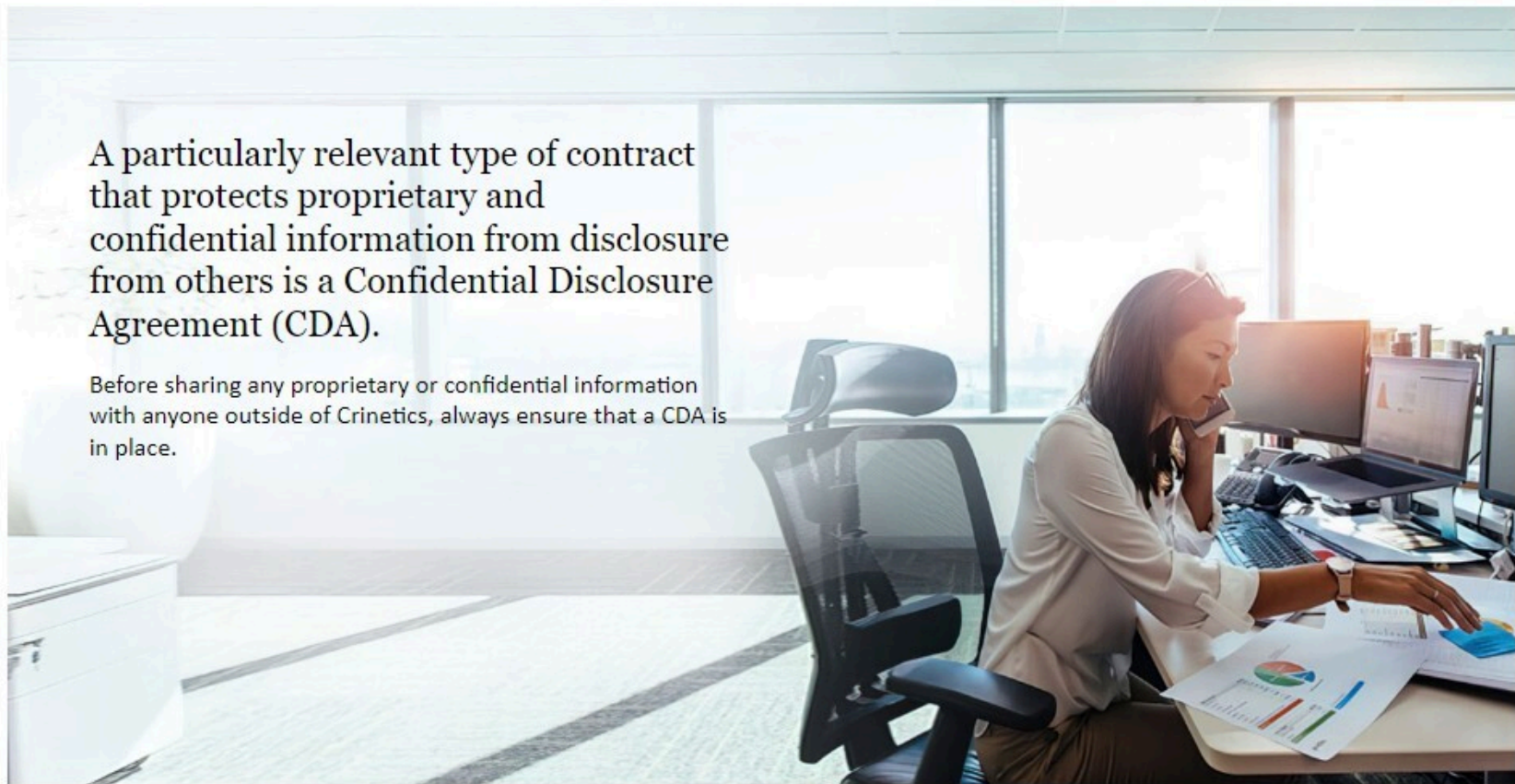


14/34



A particularly relevant type of contract that protects proprietary and confidential information from disclosure from others is a Confidential Disclosure Agreement (CDA).

Before sharing any proprietary or confidential information with anyone outside of Crinetics, always ensure that a CDA is in place.



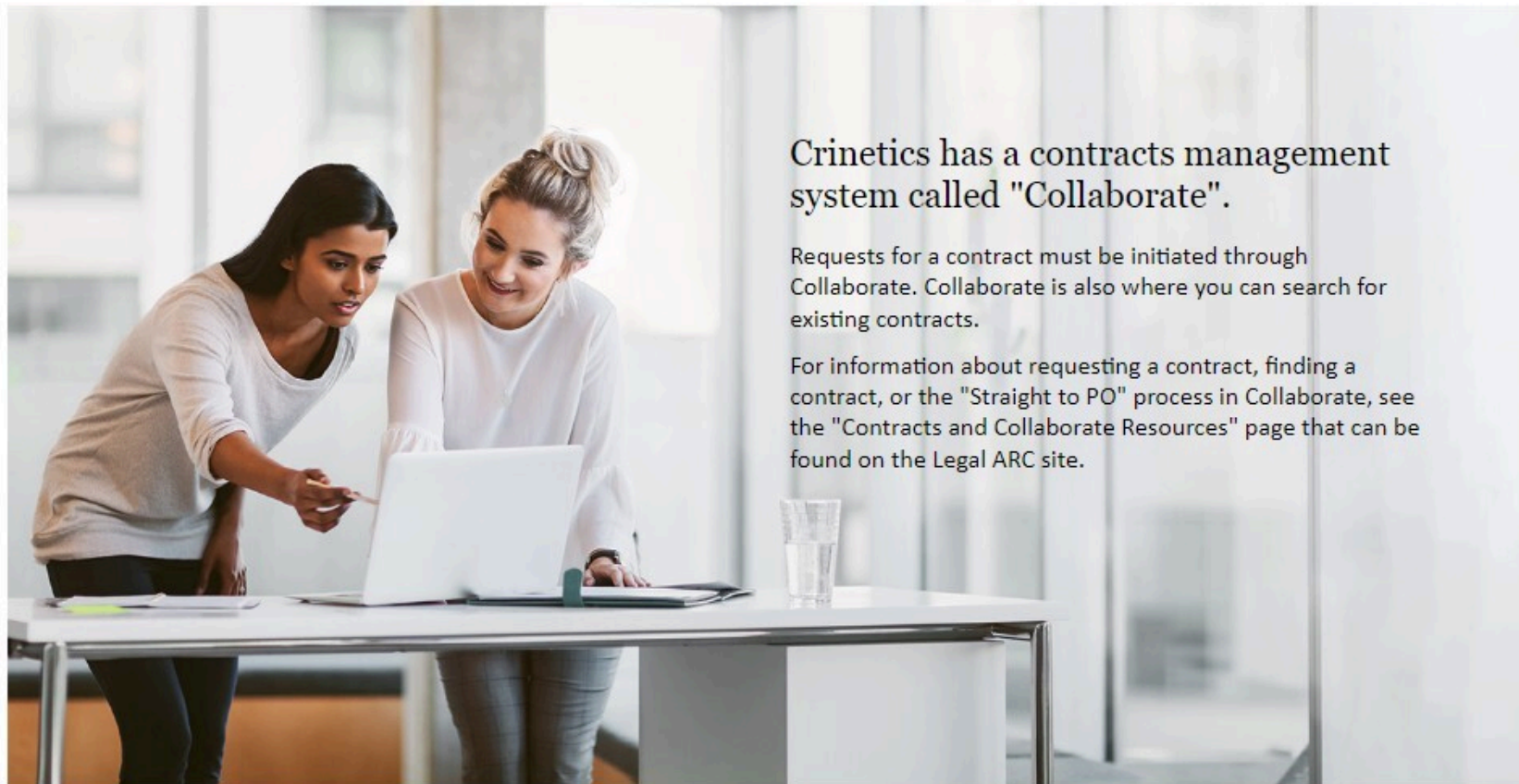
14/34



WHERE WE ARE NOW

Contracting

< 15/34 >



Crinetics has a contracts management system called "Collaborate".

Requests for a contract must be initiated through Collaborate. Collaborate is also where you can search for existing contracts.

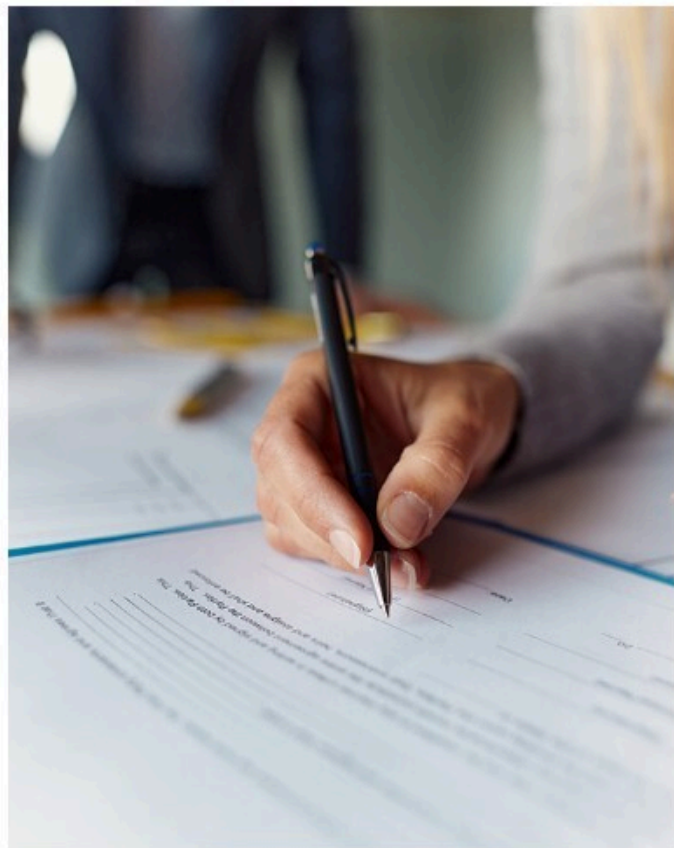
For information about requesting a contract, finding a contract, or the "Straight to PO" process in Collaborate, see the "Contracts and Collaborate Resources" page that can be found on the Legal ARC site.

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WHERE WE ARE NOW

Contracting

< 16/34 >



For general information about contracts, see the "Contracts 101" presentation that can be found on the Legal ARC site under "Contracts and Collaborate Resources".

For information about CDAs including using the self-service option, review the "Confidentiality Agreements" link that can be found on the Legal ARC site.

Additionally, any contracts with HCPs or HCOs will require compliance review to confirm appropriate rates and screening have been completed. Refer to Compliance for questions or additional guidance.

< 16/34 >

WHERE WE ARE NOW

Good Communication Practices



17/34



Good communication requires the use of clear, concise, unambiguous language.

This is especially true in the pharmaceutical industry because our products have an impact on people's health. Given the serious nature of our work, care must be taken, or documents and emails can be used against you or the company in legal proceedings, disciplinary meetings, or regulatory interactions.



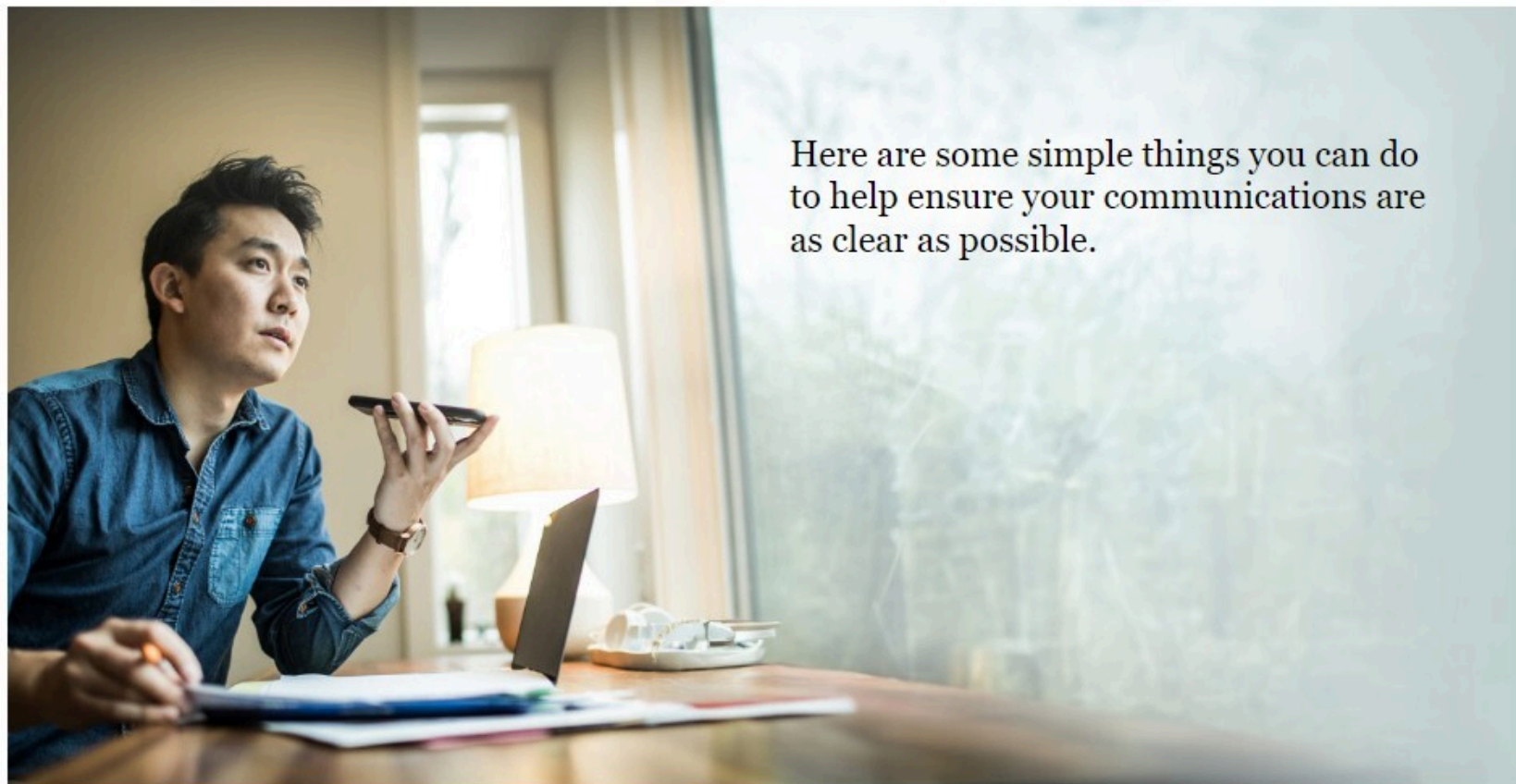
17/34



WHERE WE ARE NOW

Good Communication Practices

< 18/34 >



Here are some simple things you can do to help ensure your communications are as clear as possible.

< 18/34 >

WHERE WE ARE NOW

Good Communication Practices

< 18/34 >

Always state facts and questions clearly.

Make sure that the words you are using are clear, precise, and unambiguous. Simply put, choose words that are simple to understand.



< 18/34 >

WHERE WE ARE NOW

Good Communication Practices



18/34



Avoid assumptions and the presentation of opinions as facts.

This doesn't mean that you can't speculate on something. It means that if you do, you should be clear that you are expressing your opinion and not presenting a fact. Similarly, if you have a question about something, ask the question rather than stating your assumption or conclusion.



18/34



WHERE WE ARE NOW

Good Communication Practices

< 18/34 >

Keep your language neutral; avoid exaggeration.

For example, phrases such as “Keep this between us,” “You won’t believe this, but,” or “For your eyes only” can make a completely appropriate activity appear inappropriate or unlawful.



< 18/34 >

WHERE WE ARE NOW

Good Communication Practices



18/34



Always use professional language.

Never lie, embellish, or make maliciously false statements.



18/34



WHERE WE ARE NOW

Good Communication Practices

< 18/34 >

Avoid using legal terms or speculating on legal matters.

Inadvertent use of legal language can have serious repercussions. Unless you are a lawyer and have been authorized to provide a legal opinion, do not use legal terms, such as “negligent,” “illegal,” “reckless,” or “liable.” These terms can alter the meaning of your message. They can also be interpreted and/or used by third parties as admissions of liability or wrongdoing.



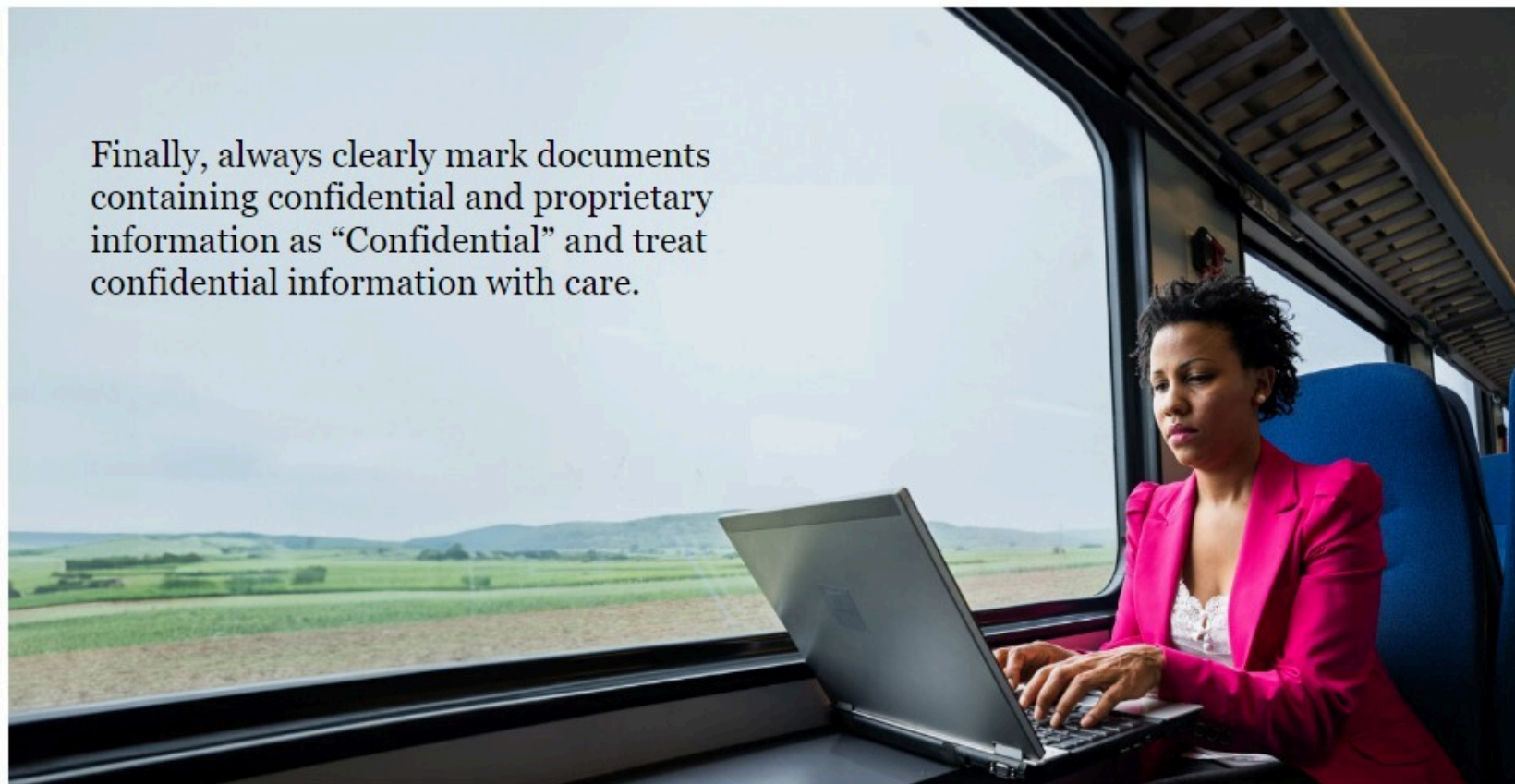
< 18/34 >

WHERE WE ARE NOW

Good Communication Practices

< 19/34 >

Finally, always clearly mark documents containing confidential and proprietary information as “Confidential” and treat confidential information with care.



< 19/34 >

WHERE WE ARE NOW

Good Documentation Practices



20/34



Good documentation in the pharmaceutical industry is vital in ensuring regulatory compliance and data integrity.

There are industry standards by which documents are created, modified, maintained, and archived. All personnel are encouraged to follow good documentation practices, but any personnel engaged in GxP activities **must** adhere to the Good Documentation Practice SOP to be in compliance with regulatory requirements and to ensure data integrity.



20/34



WHERE WE ARE NOW

Good Documentation Practices



21/34



GxPs are various "good practice" regulations and guidelines that apply to organizations that manufacture drug products.

The "x" variable covers a wide range of processes utilized in the development, manufacturing, and distribution of regulated products. For example, Good Clinical Practices (GCPs), Good Laboratory Practices (GLPs), Good Manufacturing Practices (cGMPs), Good Pharmacovigilance Practices (GVPs), Good Storage Practices (GSPs), Good Distribution Practices (GDPs). Other jurisdictions outside the US have similar guidelines.



21/34



WHERE WE ARE NOW

Good Documentation Practices



22/34



It is important to be familiar with the key Principles of Good Documentation Practices (GDPs).

These include:

- Maintaining all documents with original signatures
- Confirming information is not falsified or overwritten.

Handwritten entries on any GxP documents should only be indelible ink and follow ALCOA principles (e.g. must be clear, concise, permanent, legible, accurate, complete, and truthful).



22/34



WHERE WE ARE NOW

Good Documentation Practices



23/34



GDP is designed to avoid bad or lazy practices.

- Under GDP you must not use symbols for repeated data entries
- Make unauthorized changes to original documents without using the change control process
- Backdate documents
- Leave blank spaces on forms.



23/34

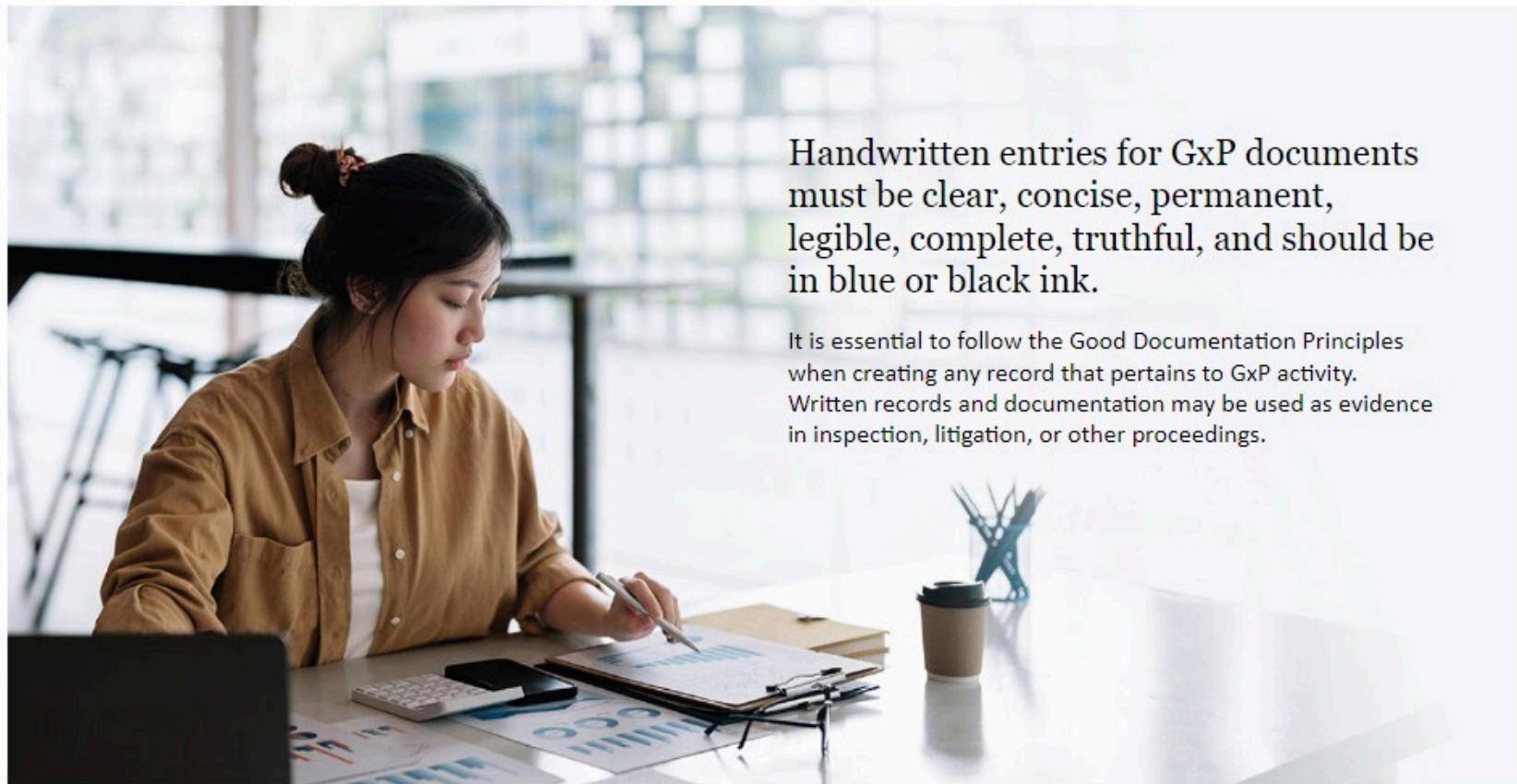


WHERE WE ARE NOW

Good Documentation Practices



24/34



Handwritten entries for GxP documents must be clear, concise, permanent, legible, complete, truthful, and should be in blue or black ink.

It is essential to follow the Good Documentation Principles when creating any record that pertains to GxP activity. Written records and documentation may be used as evidence in inspection, litigation, or other proceedings.



24/34



WHERE WE ARE NOW

Good Documentation Practices



25/34



Good Documentation Practice (“GDP”) aims to ensure compliance with Regulatory requirements such as the FDA, Medicines and Healthcare Regulatory Agency (MHRA), European Medicines Agency (EMA), Pharmaceuticals and Medical Devices Agency (PMDA).

Specifically, GDP helps to:

- Prevent warning letters, inspection findings, bans; and
- Reduce risks to organization.



25/34

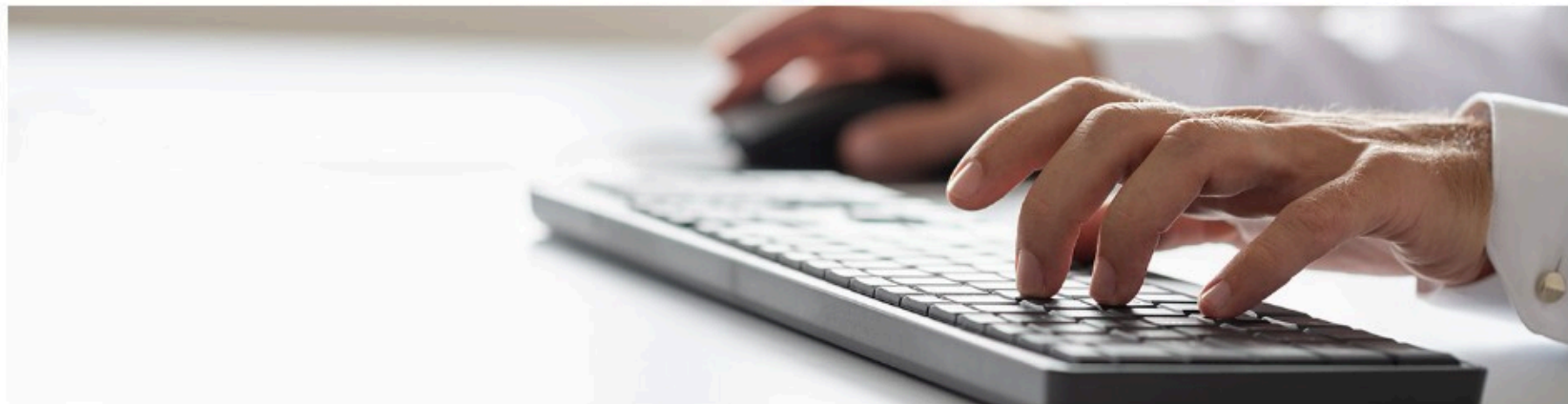


WHERE WE ARE NOW

Good Documentation Practices



26/34



GDP can also bring benefits to Crinetics' operations and business.

Adherence to GDP:

- Helps to reduce risks to the organization, including the prevention of warning letters, inspection findings, and bans;
- Builds confidence in the corporate system, practice and integrity of data;
- Provides correct, complete, current and consistent information;
- Ensures traceability;
- Helps during investigations and Corrective and Preventive Actions (CAPAs);
- Reduces or eliminates assumptions or second-guessing of intent; and
- Delivers consistent quality, yield and performance of staff.



26/34



WHERE WE ARE NOW

Proper Use of Email



27/34



Email is a great channel for creating and transmitting day-to-day business information.

Its speed and convenience make it a great tool for answering queries, updating colleagues on projects, forwarding proposals and reports, etc.

However, using electronic communications can sometimes result in us saying things we don't intend or sharing information with people we shouldn't.



27/34



WHERE WE ARE NOW

Proper Use of Email



28/34



Here are some tips to help ensure you use email thoughtfully.

- Always ensure confidential communication is appropriately labeled.
- Beware the pitfalls of "REPLY ALL". Before sending any email, always check the recipient list so you don't inadvertently send proprietary, confidential, or sensitive information to those outside the company or unintended recipient.
- Avoid humor - even well-meaning jokes or lighthearted comments can be misinterpreted in business communications. This is especially true in written communications, where visual cues (such as body language) and oral cues (such as vocal inflections) are absent.



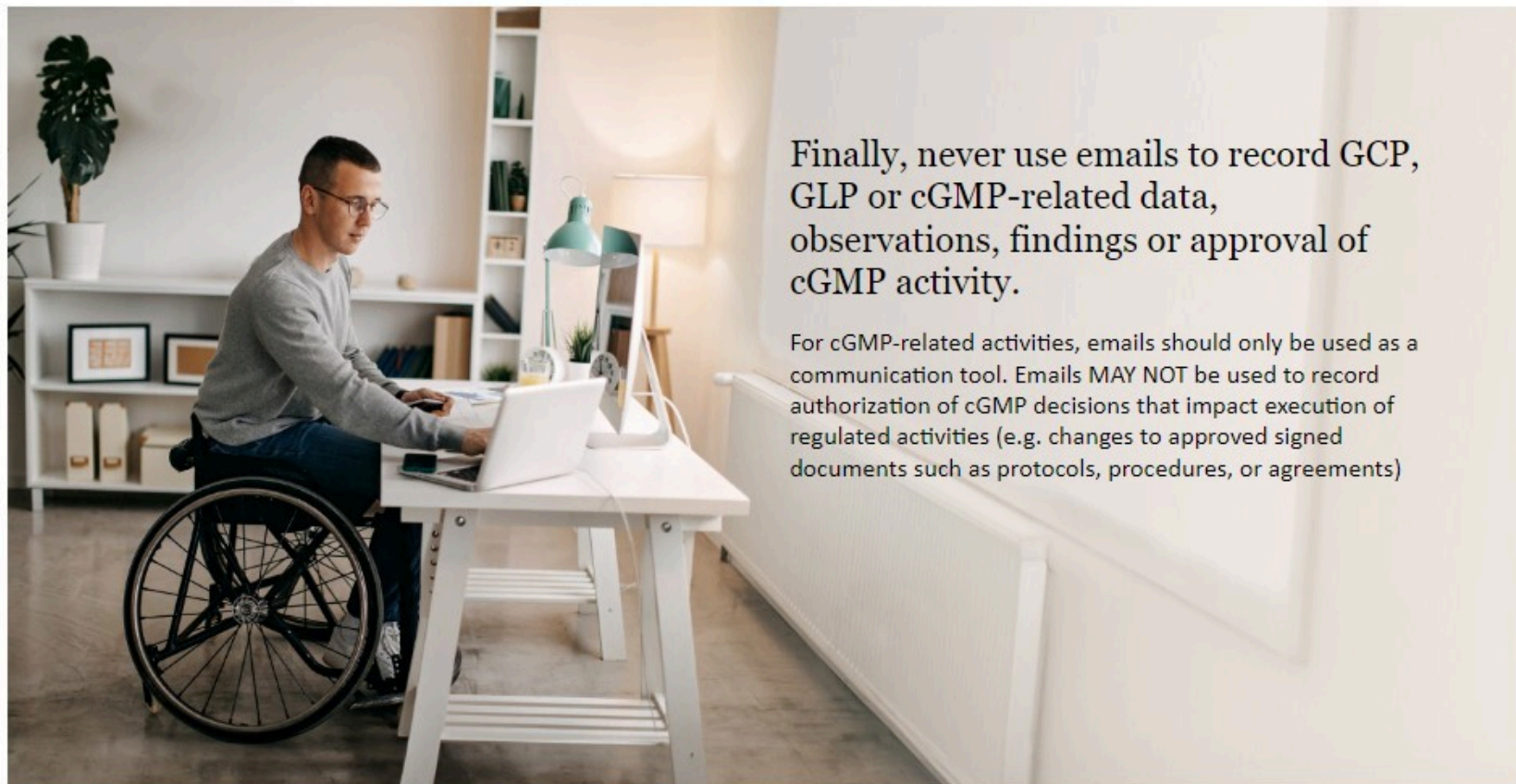
28/34



WHERE WE ARE NOW

Proper Use of Email

◀ 29/34 ▶



Finally, never use emails to record GCP, GLP or cGMP-related data, observations, findings or approval of cGMP activity.

For cGMP-related activities, emails should only be used as a communication tool. Emails MAY NOT be used to record authorization of cGMP decisions that impact execution of regulated activities (e.g. changes to approved signed documents such as protocols, procedures, or agreements)

◀ 29/34 ▶

WHERE WE ARE NOW

Quick Check



30/34



The FDA's authority to regulate what a manufacturer can say about its product only begins once the product has been approved for use.

True

False

SUBMIT



30/34



WHERE WE ARE NOW

Quick Check



30/34



The FDA's authority to regulate what a manufacturer can say about its product only begins once the product has been approved for use.

True

False

SUBMIT

That's Correct!

The FDA has broad authority to regulate not only communications about products that have been approved for use, but also communications about "Investigational Products".



30/34



WHERE WE ARE NOW

Quick Check

< 31/34 >

Intellectual property includes which of the following.

Check all that apply.

Trade secrets

Clinical trial data

Pre-approval regulatory information

Financial data that has not been released to the public

SUBMIT



< 31/34 >

WHERE WE ARE NOW

Quick Check



31/34



Intellectual property includes which of the following.

Check all that apply.

Trade secrets

Clinical trial data

Pre-approval regulatory information

Financial data that has not been released to the public

SUBMIT

That's Correct!

Intellectual property includes but is not limited to: trade secrets; clinical trial data; pre-approval regulatory information; and financial data that has not been released to the public.



31/34



WHERE WE ARE NOW

Quick Check



32/34



Which type of contract needs to be in place before you share any proprietary or confidential information with an outside party?

An Indemnity Agreement

A Licensing Agreement

A Confidential Disclosure Agreement

SUBMIT



32/34



WHERE WE ARE NOW

Quick Check



32/34



Which type of contract needs to be in place before you share any proprietary or confidential information with an outside party?

An Indemnity Agreement

A Licensing Agreement

A Confidential Disclosure Agreement

SUBMIT

That's Correct!

Before sharing any proprietary or confidential information with anyone outside of Crinetics, always ensure that a Confidential Disclosure Agreement (CDA) is in place.



32/34





WHERE WE ARE NOW

Review



33/34



Review

Take a moment to review some of the key concepts in this section.

Click the arrow to begin your review.



33/34



WHERE WE ARE NOW

Review



33/34



Communications relating to Investigational Products

Any information that is shared about products awaiting FDA approval must be truthful and sanctioned by the Company.



33/34





WHERE WE ARE NOW

Review



33/34



Intellectual property

Protecting our intellectual property is essential to maintaining the company's competitive advantage.



33/34



WHERE WE ARE NOW

Review



33/34



Contracts

Contracts help to facilitate compliance with laws and regulations, mitigate risks, protect our interests, and help to ensure smooth business operations.



33/34





WHERE WE ARE NOW

Review



33/34



Third-party intellectual property

Crinetics respects the valid intellectual property rights of others.



33/34



WHERE WE ARE NOW

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2 minutes 🔒

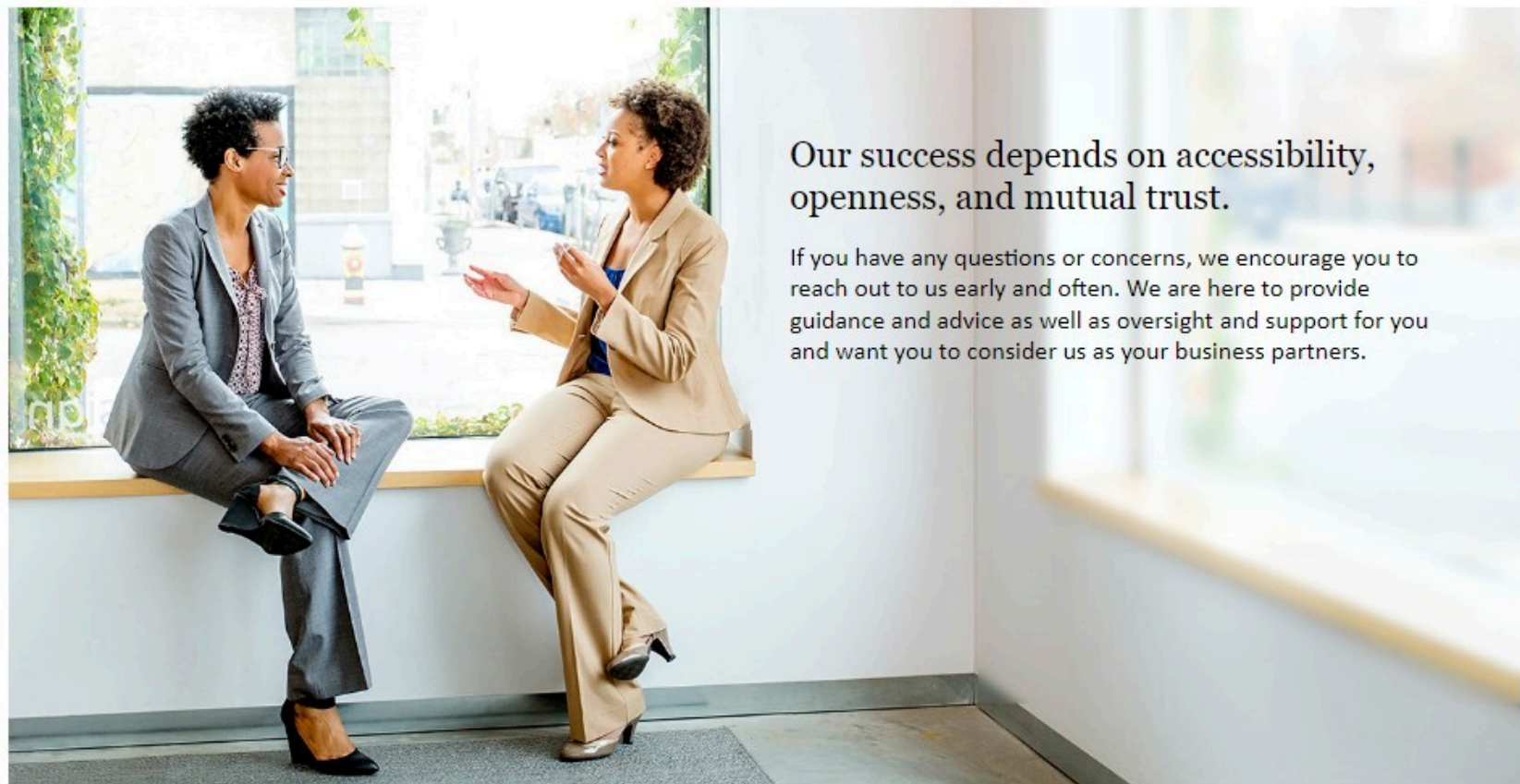
LEARNING PROGRESS

91%

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ASKING QUESTIONS AND RAISING CONCERNS

Asking Questions and Raising Concerns



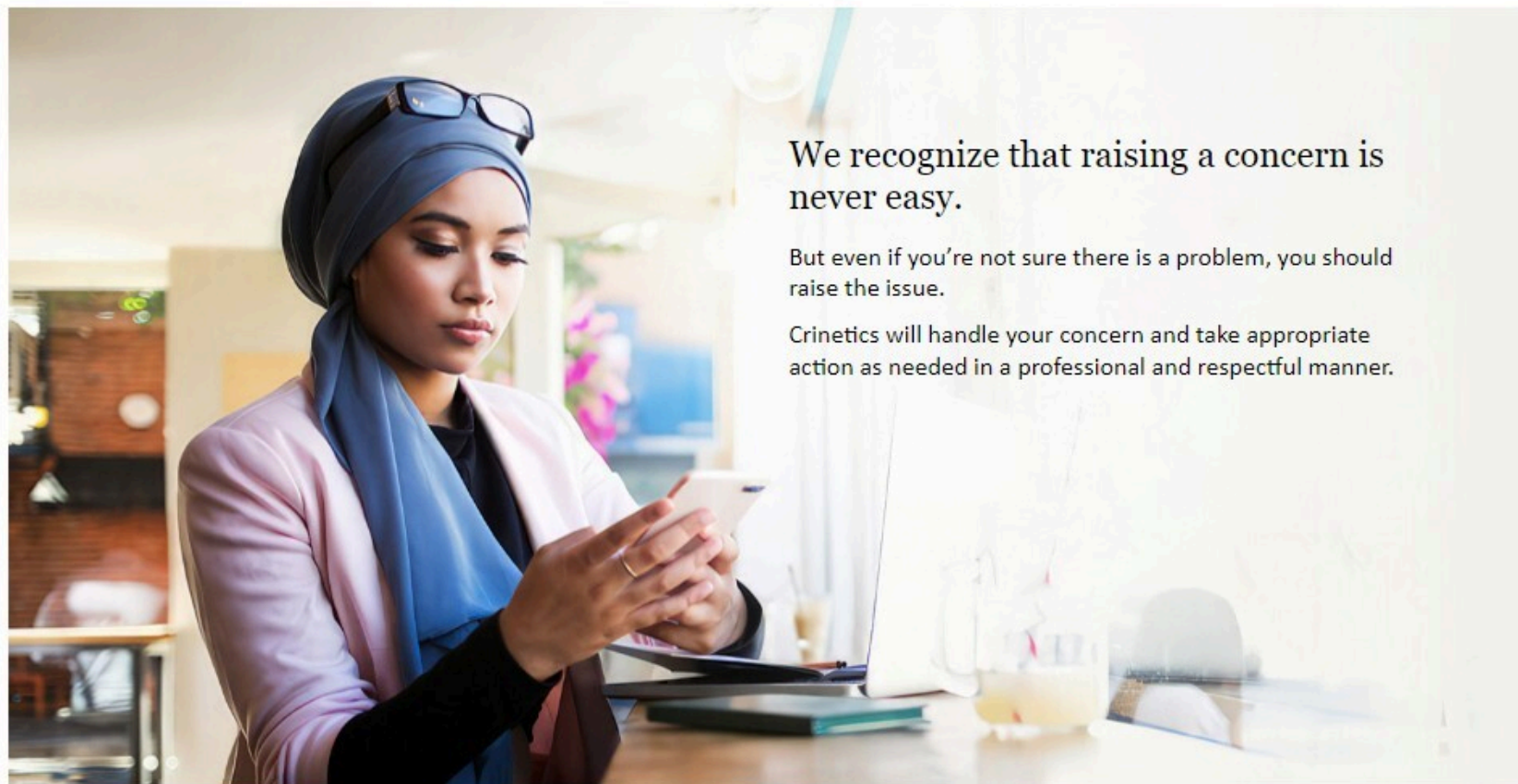
Our success depends on accessibility, openness, and mutual trust.

If you have any questions or concerns, we encourage you to reach out to us early and often. We are here to provide guidance and advice as well as oversight and support for you and want you to consider us as your business partners.

Asking Questions and Raising Concerns



2/8



We recognize that raising a concern is never easy.

But even if you're not sure there is a problem, you should raise the issue.

Crinetics will handle your concern and take appropriate action as needed in a professional and respectful manner.



2/8



ASKING QUESTIONS AND RAISING CONCERNS

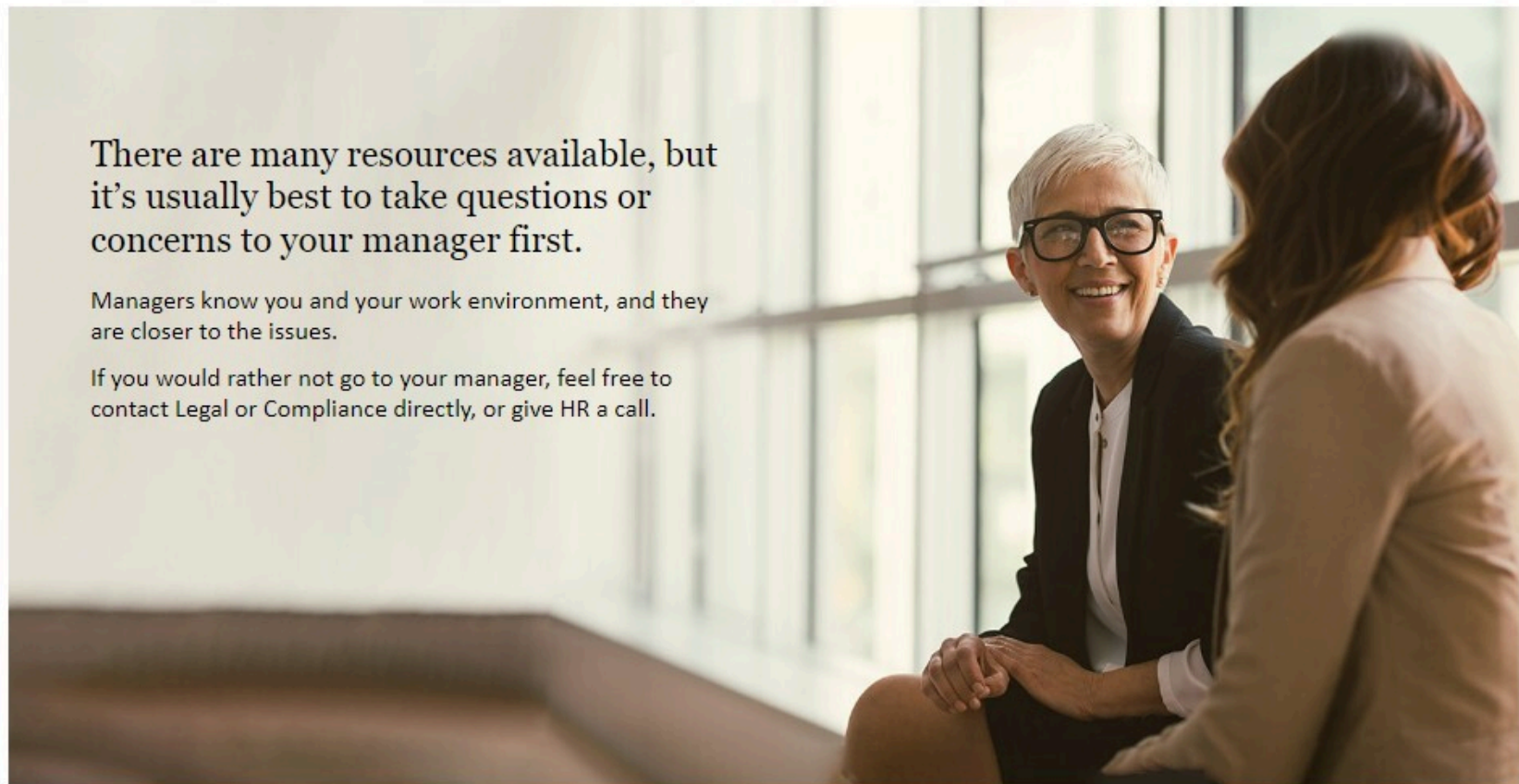
Asking Questions and Raising Concerns



There are many resources available, but it's usually best to take questions or concerns to your manager first.

Managers know you and your work environment, and they are closer to the issues.

If you would rather not go to your manager, feel free to contact Legal or Compliance directly, or give HR a call.



ASKING QUESTIONS AND RAISING CONCERNS

Asking Questions and Raising Concerns



4/8



Together.

Together... we can build a successful organization. Together... we can ensure an outstanding reputation. Together... we can protect our values.

Your role on our team is to speak up if you know of or suspect any unethical behavior. Our role is to listen.



Safely report any violations or get more information by contacting the hotline.



Mobile:
crineticsmobile.ethicspoint.com

Online:
crinetics.ethicspoint.com

Phone:
844-235-9720

Confidential. Easy-to-Use and Always Available

You can also raise a concern anonymously through the Crinetics EthicsPoint Hotline.

The EthicsPoint site is administered by an independent third party that can be accessed 24 hours a day, 7 days a week.



4/8



ASKING QUESTIONS AND RAISING CONCERNS

Asking Questions and Raising Concerns

< 5/8 >

Remember, Crinetics has a strict non-retaliation policy.

We will not tolerate retaliatory conduct against individuals who report potential violations in good faith at any time.

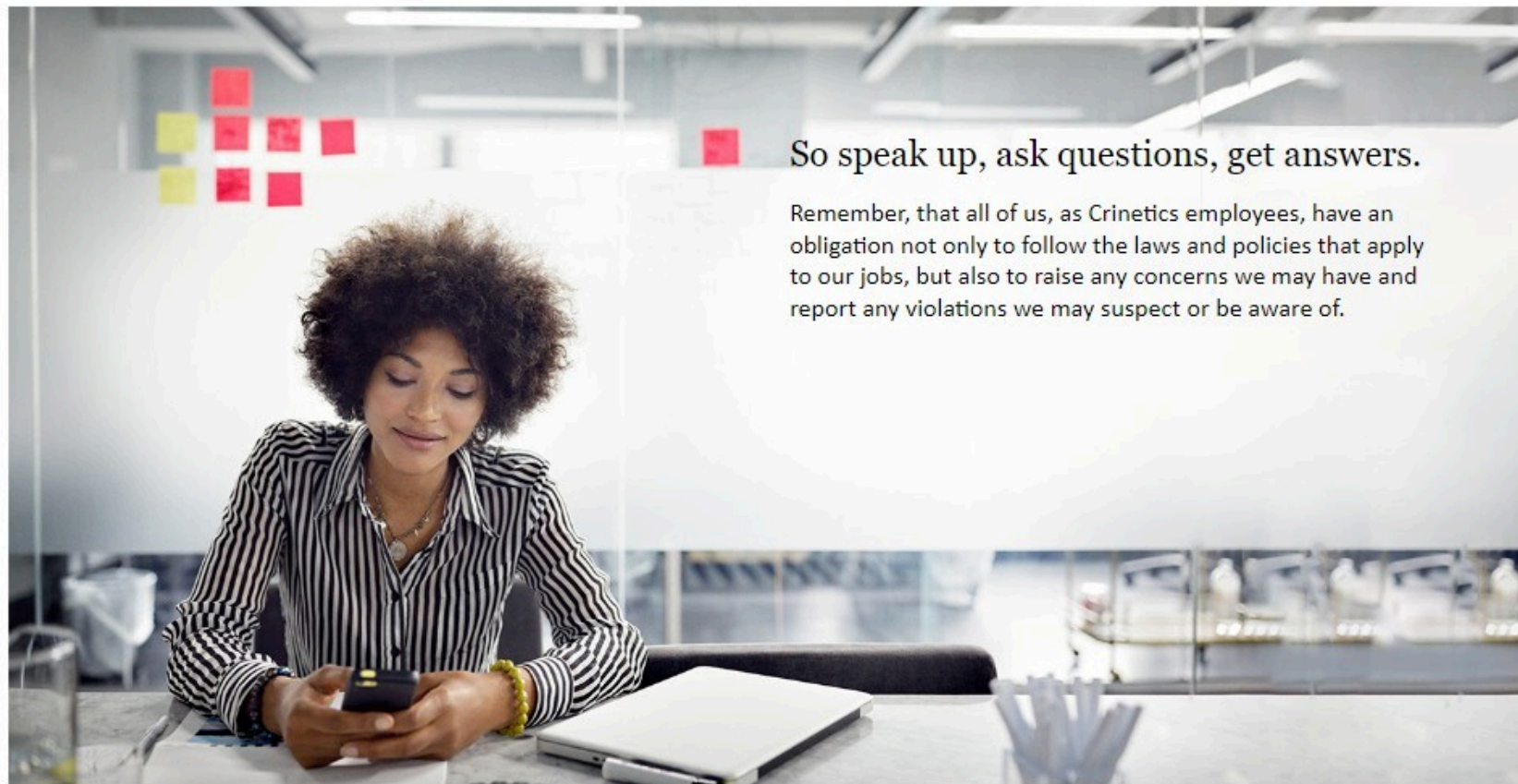
< 5/8 >

ASKING QUESTIONS AND RAISING CONCERNS

Asking Questions and Raising Concerns



6/8



So speak up, ask questions, get answers.

Remember, that all of us, as Crinetics employees, have an obligation not only to follow the laws and policies that apply to our jobs, but also to raise any concerns we may have and report any violations we may suspect or be aware of.



6/8



ASKING QUESTIONS AND RAISING CONCERNS

Asking Questions and Raising Concerns



7/8



Thank you for joining us and thank you
for your commitment.

Click Submit to confirm completion of the course.

SUBMIT



7/8



ASKING QUESTIONS AND RAISING CONCERNS

Asking Questions and Raising Concerns



Congratulations, you have successfully completed your training.

You must click the EXIT (X) icon in the course window or course title bar to upload your results.

