



## CODE OF CONDUCT

Excellence and Integrity in All That We Do

## A LETTER FROM OUR CEO

Dear Colleague,

Welcome to Simtra BioPharma Solutions. Simtra is a premier CDMO with over 65 years of sterile injectable experience and a solid reputation for offering our customers world-class cGMP sterile fill/finish, development services, technical expertise, quality service, and a uniquely collaborative approach. We are committed to excellence and integrity in all that we do.

To be successful in our business, our customers rely on us to provide exceptional service and quality. Their trust in our ability – and our reputation – is based on a foundation of expertise, mutual respect, and integrity. It is imperative that we maintain the trust that our customers (and the regulatory agencies that audit us) have in our people and processes. Our Code of Conduct is a physical embodiment of that trust and provides a guide for each one of us in our daily jobs.

I encourage you to read our Code in detail and ask questions if you do not understand what something means or how you should behave. I also ask that you raise issues or concerns if you believe in good faith that the Company or someone with whom you work may be violating our Code or a policy or law. It is important to our collective success that each one of us plays a role in maintaining the trust that the Company has built over the years. Together, we can demonstrate that we really are the premier CDMO in the world.

**Franco Negron**  
CEO



## A LETTER FROM OUR CHIEF COMPLIANCE OFFICER

Dear Colleague,

As Franco mentioned, our reputation and success as a company is built on the trust that our customers and regulators have in us. That trust can be easily impacted if we inadvertently fail to comply with any one of the numerous rules, regulations and laws that govern our business. More than just a policy document, our Code helps provide us guidance how to comply with applicable legal and regulatory requirements in the locations where we do business. Our Code sets forth our corporate philosophy – to be excellent at everything we do – and how we should act – with courage, respect, integrity, leadership and accountability.

Our Code does not have all the answers, but it can help raise awareness of rules and regulations that we might not have known or understood, and it points us all in the right direction for where to get assistance. I encourage you to read our Code and ask questions if you do not understand it. If you cannot find the answer you are looking for or have any questions about are Code or any of the principles, standards or policies in it, I encourage you to reach out to me directly. You can reach me at [jagarrett@simtra.com](mailto:jagarrett@simtra.com) or at +1.973.765.4127 anytime.

Please remember, you are encouraged to ask questions and raise concerns – it is the only way that we can truly build a culture of integrity at Simtra.

**Jim Garrett**  
Chief Compliance Officer



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## OUR PURPOSE (Why we exist)

Bring vital injectable products to our customers' patients worldwide.

## OUR VISION (Where we aim to go)

Be the premier contract development and manufacturing organization for injectable products.



## OUR MISSION (What we do to achieve our vision)

To have an unwavering focus on integrity, high-quality, and technical expertise as well as delivering on our commitments.

## OUR VALUES GUIDE OUR ACTIONS

### Why We Have a Code

To enable our purpose and vision, Simtra is committed to being the premier customized aseptic fill-finish contract development manufacturer focused on high value and complex parenteral branded drugs for the biopharma industry. To be the best, we need to demonstrate excellence in everything that we do. This aspiration of excellence helps define our purpose and mission and impacts the way we interact with our customers, each other, and our communities. By fulfilling this aspiration of excellence, we can do our part to positively impact the production of sterile injectable drugs that can change the lives of patients around the world.

Our Code establishes the overarching principles that guide our corporate behavior, and it sets forth the general policies and procedures that apply to each one of us as representatives of the Company. Our Code is not intended to replace or conflict with any other Company policy or Standard Operating Procedure (SOP), but our Code governs to the extent our Code and a policy or SOP conflict. Where there is a difference between our Code and the terms of an applicable law or regulation, we are expected to adhere to the most stringent requirement consistent with our Code.

### Our Code Applies to All of Us

Our Code applies to all Simtra subsidiaries and affiliated companies and establishes the framework in which we interact with each other and with our customers, suppliers, competitors, government agencies and the public to ensure that we fulfill our legal, professional and ethical obligations. It applies to all our employees, officers, and directors, as well as our consultants, contractors, agents, and suppliers, regardless of where they are located.



## What's Expected of Us

Each of us must comply with our Code and with all Company policies. If we fail to do so, we may face disciplinary action, including possible termination. Likewise, any supervisor, manager, officer, or director who is aware of any violation and does not promptly report and correct it may be subject to similar consequences. In appropriate circumstances, our Company will consider taking legal action or referring matters to public law enforcement authorities for possible prosecution. To demonstrate our commitment to abide by the Code, Simtra requires all employees to certify their acceptance to adhere to our Code upon hire and annually thereafter.

### Expectations of You

- Read, understand, and abide by the requirements in our Code.
- Embrace our Company's commitment to ethics and integrity.
- Do your part in enforcing compliance with our Code.
- Contact your manager, Human Resources, our Compliance Officer, or our Ethics Hot Line with any questions.
- Foster a culture that prevents retaliation against anyone who reports actual or suspected violations of our Code.

## Important Role of Managers

Individuals in management and leadership positions play an important role in upholding our Code because they can strongly influence the culture of their teams and encourage others to "do the right thing." Managers, supervisors, and leaders should clearly demonstrate their commitment to the standards and principles in our Code and help create an environment where compliance is expected, ethical behavior is the norm, and employees feel comfortable discussing questions or concerns without fear of retaliation. Managers are expected to be familiar enough with our Code to effectively communicate its guidelines and answer clarifying questions.

## Common Sense

Our Code helps guide how we perform our daily job duties, but it cannot address every challenging situation that may occur in our workplace. When in doubt as to whether an activity is proper, you should seek guidance from your Manager, Human Resources, or our Chief Compliance Officer.

### Ask Yourself:

- Does the action reflect our Company's commitment to acting with the highest ethics and integrity?
- Does the action harm our Company, clients, suppliers, shareholders, or our fellow employees?
- Would I take this action if it were published on the front page of a major newspaper?
- How would your family feel if they knew you took the action?

If the answers to these questions leave you feeling uncomfortable, it is safe to assume you should not take the proposed action. Instead, seek guidance from either your supervisor, the Human Resources department, or anyone in the Legal, Risk & Integrity (LRI) department, our Chief Compliance Officer at **[compliance@simtra.com](mailto:compliance@simtra.com)** or **[jagarrett@simtra.com](mailto:jagarrett@simtra.com)** or by filing a question with our Simtra's Ethics Hotline online at **<http://www.simtra.ethicspoint.com>**.

## No Retaliation

Anyone who, in good faith, seeks advice, raises a concern, or reports potential violations of our Code (or any Company policy, law, rule or regulation) will be protected against retaliation. It is a violation of our Code to discipline, discriminate, take any adverse employment action, or retaliate against anyone who reports a concern in good faith, regardless of whether such information is ultimately proven correct. Our commitment against retaliation extends to anyone who cooperates in any investigation or inquiry regarding such a concern.

## Raising Concerns

Our Legal, Risk and Integrity (LRI) function is responsible for the administration of our Code and reports to our General Counsel and Chief Compliance Officer. Any allegation of violation of our Code should be reported to your manager, Human Resources, or LRI and it will be investigated and acted upon by the Company based on the findings of the investigation. Upon completion of an investigation, our Compliance Officer will look at the results and work with other members of executive management to determine the appropriate actions to be taken. Responses may include remedial action (such as training, enhanced controls, coaching or communication) or disciplinary action. Disciplinary action involving potential termination of employment is reviewed by our Chief Compliance Officer and Chief Human Resources Officer.





## OUR COMMITMENTS TO CUSTOMERS

### Excellence in Quality

We maintain our Company's valuable reputation by meeting or exceeding the quality control and manufacturing requirements of our customers, as well as the various rules and regulations governing our industry. This means that the products we manufacture and the services we provide must meet our customer's needs, represent superior value and be reliable. We must follow all quality processes and safety requirements set forth in our Quality Management System (QMS) and comply with all applicable standards and regulations on the development of our products and services, including Good Manufacturing Practices (GMP), Good Documentation Practices (GDP), design controls, labeling, marketing controls, and manufacturing process controls.

To ensure the quality of the products we manufacture, we must: (i) recognize potential product complaints and adverse events, (ii) gather as much information as possible to report potential complaints and adverse events, and (iii) report potential complaints and adverse events to our Quality team as soon as we discover them.

Quality is the responsibility of every employee, no matter what position in the company they hold.

Our Quality Policy is to deliver safe and effective injectable drug products to our patients, make quality a competitive advantage for growth, and to always comply with the law.

### Data Security

We have an obligation to protect the information entrusted to us by our customers as part of our business operations and we must treat all such information as confidential. Such information should only be used for legitimate business purposes, and it should not be disclosed to anyone – even another Simtra employee – without authorization. The same is true for our employees' personal information. Only employees who have authorization and a clear business need should have access to certain records. It is imperative that we all take data privacy very seriously if we are going to be able to comply with the numerous federal, state, and international laws that govern privacy rights.

## Protecting Assets

We have a shared responsibility to safeguard Company assets and materials (as well as our customers' assets) against loss, damage, carelessness, waste, misuse, and theft. This means using Company assets only for legitimate purposes and promptly reporting any waste, loss, or damage. Assets include tangible things like machinery, vehicles, furniture, funds, computers, phones, electronic systems, and other physical items, as well as intangible items like proprietary information and intellectual property.

## No Use of "Inside" Information

Although Simtra is not a publicly traded company, we may learn "inside" information about the biopharmaceutical companies we work with. In many instances, that information may not be known to the public and it might be information that a reasonable investor might consider important when deciding to buy or sell our customer's stock or securities. We must keep this information confidential and should not buy or sell any publicly- traded securities if we are in possession of insider information. Likewise, we should not share or disclose such information to anyone else (including friends and family members), because both the person who provides the material information and the person who acts on it could be considered to have violated the law.

Information we receive from our customers is generally subject to confidentiality and non-disclosure restrictions. Such information should not be disclosed or used other than as required in connection with our provision of services to the customer.

## Fair Competition

It is important that we compete fairly in the marketplace and that our business dealings comply with all applicable antitrust and competition laws. We should not make agreements or engage in concerted actions with a competitor that could be construed as price-fixing or collusion. Similarly, we should avoid inappropriately discussing sensitive, potentially anti-competitive topics with third-parties, including: prices or pricing, output capacities, sales, bids, profits or profit margins or costs.

## Cybersecurity Measures

We must take all necessary steps to ensure the safety and integrity of our information and technology systems and networks. We have a responsibility to use computer, data, and telecommunication resources in a safe, ethical, lawful, efficient, and productive manner. Unauthorized, inappropriate, or unlawful use of the Company's telecommunication resources or equipment may result in disciplinary and legal action. Where allowed by law, the Company may monitor and access the use of Company assets, and employees in the United States should not have an expectation of privacy with respect to the use of Company information systems and networks, including computers and mobile phones.



## Truthful Advertising & Marketing

It is important that we accurately represent our products and services. We must not engage in unfair or deceptive practices, such as false or misleading advertising, untrue or misleading claims, testimonials, or comparison claims.

## Protecting Intellectual Property

Protecting our intellectual property is critically important and we must all take efforts to ensure that it is not misused or misappropriated. We must not allow our intellectual property (or the intellectual property of our customers) to be used or shared with people outside of our Company without appropriate non-disclosure or other legal documents in place. Likewise, we must not infringe the intellectual property rights of any other companies or allow the intellectual property of our customers or other third-parties we work with be misused or misappropriated.

Every employee is required to sign a proprietary information and inventions agreement. By signing this agreement, each employee agrees to protect the confidential information of both our Company and others with whom we do business.

## Third Party Management

Our suppliers and vendors are, by extension, a part of our culture, and in some cases their conduct can be legally attributed to Simtra. Because of this, we should perform reasonable diligence on third-parties with whom we do business in an effort to make sure that they are equally committed to compliance with applicable laws and regulations in the jurisdictions where we do business, including but not limited to those relating to compliance with anti-boycott, economic sanctions and trade embargoes; debarred individuals or entities; import and export of goods and services; anti-terrorism and money-laundering; and regulations regarding trade in conflict minerals.

## Social Networking

We should exercise caution when using social media and conduct ourselves appropriately in accordance with Company standards and our Code. This means that we must never disclose Company confidential information. This means not posting names or logos of our customers or any statement that could identify our customers or their products, including merely stating that we render services to such customers. We must also ensure that we do not attribute our personal opinions to the Company or give the impression that we are speaking on behalf of the Company unless authorized to do so.



## OUR COMMITMENTS TO BEING A GREAT PLACE TO WORK

### **Diversity, Inclusion & Equal Opportunities**

Simtra is a merit-based, equal opportunity employer. All employment-related decisions must be made only after evaluating an individual's skillset, qualifications, and job performance considering our business needs and other appropriate and lawful factors. We must not base any decisions on unlawful discriminatory factors including, but not limited to, race, ethnicity, religion, color, gender identity, age, sexual orientation, disability, religion, national origin, or marital, veteran, or citizenship status. We should actively cultivate an inclusive environment that leverages our employees' individual differences to improve the services we provide to our customers and, in turn, to drive business success. We are all responsible for maintaining a positive and welcoming professional work environment, and for ensuring that everyone we work with is treated with respect.

### **Anti-Harassment**

We absolutely will not tolerate harassment at Simtra. We do not tolerate any type of verbal or physical harassment, including sexual harassment, bullying or any behavior that creates an intimidating, offensive, abusive, or hostile work environment. This includes, but is not limited to, racist, sexist, or ethnic jokes or other comments. Such harassment is unacceptable and will be eliminated from our manufacturing facilities, our offices, and in every work setting in which a Simtra colleague could be exposed to such behavior by another employee, contactor, or business partner. We show respect for each other by speaking out if a coworker's conduct makes us uncomfortable.

We believe in treating one other with respect, whether it is a co-worker, supplier, customer, or anyone doing business with us.

### **Environmental Health and Safety**

We must conduct ourselves and all Company activities in a safe and environmentally responsible manner, as well as proactively inspect our workplace to correct and continuously improve conditions that may create a risk of personal injury or adverse environmental impact. We must report all workplace injuries, near-misses, or environmental concerns as soon as reasonably possible after the incident occurs and provide coaching and feedback to avoid unsafe practices and conditions.



## **Preventing Violence**

We have a zero-tolerance policy for acts or threats of violence. We should never threaten or take part in hostile behavior, even in a joking manner, or engage in physical or verbal abuse. To keep our workplace safe, weapons are not allowed on Company property.

## **Prohibiting Substance Abuse**

We all have an obligation to report to work free from the influence of any substance that could impair the effective and safe performance of our jobs. Given the nature of our business, we must perform optimally every day to ensure quality, safety, and compliance.

We recognize that substance abuse and alcohol-related problems, as well as other problems, can be treated. Confidential assistance is available through our Employee Assistance Program (EAP).

## **Potential Conflicts of Interest**

We have a responsibility to avoid personal behavior that conflicts with or appears to conflict with our job duties at Simtra or with Simtra's business interests. A personal conflict of interest arises when an employee has a personal interest, such as a financial interest or loyalty to a family member, that is or could be inconsistent with Simtra's business interests or that could influence the employee's decision-making in Simtra activities. We should disclose any actual or potential personal conflict of interest to our Compliance Officer for review and determination of whether mitigation is appropriate.



## OUR COMMITMENTS TO THE PUBLIC

### Sustainable Practices

We are committed to the principles of corporate social responsibility and strive to minimize our impact on the environment, respect human life, support the communities in which we live and work, appropriately respond to media, investor, public, and government inquiries, and act with corporate integrity consistent with best practices and in compliance with all applicable laws and regulations.

### Environmental Protection

Simtra is committed to being a good corporate citizen. We should follow environmentally sound business practices to help protect the environment in compliance with all applicable environmental laws and regulations, and continually look for ways to reduce waste and more efficiently use energy, water, and other natural resources to do our part.

#### We are committed to:

- Being a good corporate citizen and improving the impact our operations make on the environment.
- Creating a great place for people to work and live in the communities where we operate.
- Acting with integrity and doing the right thing.

### Human Rights

We are committed to respecting and advancing the human rights of all individuals globally. We comply with all applicable laws related to forced labor, child labor, and human trafficking, and will not tolerate the abuse of human rights in our operations or in our supply chains.

### Volunteerism & Community Involvement

We are proud to be a responsible corporate citizen and neighbor, both globally and in every community where we operate. We encourage our sites and employees to be good citizens by promoting their engagement with local organizations and by volunteering in the communities in which they work and live. All Simtra charitable activities, contributions and donations should be made without any demand or expectation of a business return.



## Political Activities

Simtra is an “apolitical” company. We do not have a general practice of making political contributions with respect to any party, candidate, or issue. We are free – as individuals – to participate in political processes, including making contributions, in our personal capacity, but we must not do anything to create a perception that our individual activity is on behalf of Simtra.

## Media and Public Relations

We are committed to providing accurate and consistent information to the media and the public. As such, only authorized persons may speak on behalf of Simtra. We should direct all external inquiries about the Company to our Head of Marketing immediately.

## Interactions with Government Officials

It is important that we fully cooperate and effectively work with government and regulatory agencies and officials to ensure compliance with applicable rules, regulations, audits and investigations. Any business relationship the Company enters into with government and regulatory entities should be obtained through bona fide means and conducted transparently.





## OUR COMMITMENTS TO ETHICS & INTEGRITY

### **Maintaining Accurate Books & Records**

We must ensure that our books and records contain accurate and honest information and that they reflect the truth of underlying transactions or events. Records are defined as all physical or electronic documents we create as part of our work at the Company. Accurate records are crucial to Simtra's ability to comply with the regulatory audits, as well as the law. Under no circumstances should anyone sign, approve, or transmit a record on behalf of the Company if he or she knows or has reason to believe the record is false.

### **Preventing Bribery & Corruption**

We may never offer, attempt to offer, authorize, or promise any sort of bribe or kickback or facilitation payments for the purpose of obtaining or retaining business or an unfair business advantage on behalf of Simtra. Moreover, we may never solicit or accept a bribe or kickback, and we may not hire a third party to do something that we cannot legally or ethically do ourselves. Simtra will win business by demonstrating our excellence—not by providing improper benefits. Employees with duties involving transactions or international travel should be familiar with the Foreign Corrupt Practices Act (FCPA), the UK Anti-Bribery Act, and similar local laws to ensure compliance with applicable anti-bribery and anti-corruption laws.

### **Engagements with Healthcare Providers (HCPs)**

We must take care in our interactions with HCPs to ensure that our business dealings comply with all applicable laws, regulations and industry codes (e.g., the PhRMA Code). Accordingly, we must follow applicable due diligence, review, pre-approval record keeping requirements, laws and local limits and other applicable local procedures in providing anything of value to an HCP. HCP means any individual (with a clinical or non-clinical role; whether a government official, or employee or representative of a government agency or other public or private sector organization; including but not limited to, physicians, nurses, technicians, laboratory scientists, researchers, or procurement professionals) that in the course of their professional activities may directly or indirectly purchase, lease, recommend, administer, use, supply, procure or determine the purchase or lease of, or who may prescribe medical technologies or related services. Many countries have strict anti-bribery and corruption regulations regarding interactions with HCPs and it is important that we know and follow all country-specific requirements. We must never submit false, fraudulent, or misleading data or information to any government agency or a third-party payor to obtain commercial drug approval or to gain or retain participation in a particular program.

## **Business Courtesies**

We should consider the reasonableness of all meals, gifts, travel and hospitality given the totality of circumstances to avoid even the appearance that the giving or accepting of meals, gifts, travel or hospitality might be considered a bribe. Building strong, collaborative relationships with our business partners is important, but we must use good judgment, discretion, and moderation when providing meals, or entertainment to ensure that we never engage in any situation where it appears we are trying to gain an unfair business advantage or where our ethical judgment might be compromised. Also, we should make sure that our offer does not violate the recipient's own policies. While it is customary in many parts of the world to give gifts to individuals that have a business relationship with the Company, we should never give gifts to government or public officials or HCPs.

## **Responding to Legal & Regulatory Inquiries**

We may be asked to provide information to both internal and external parties related to an audit or investigation. For us to be able to respond promptly, we must immediately notify our Chief Quality and Regulatory Officer if a regulatory agency contacts us requesting records or an audit. Likewise, any legal matters or subpoenas should be directed to our General Counsel immediately.

## **International Trade Compliance**

Simtra is committed to compliance with all applicable international trade sanctions and embargoes. This means that we are prohibited from conducting business in or with certain governments, individuals, and entities. We must carefully track sanctions and embargoes and maintain careful compliance with applicable laws controlling imports, exports, diversion, denied party lists, and anti-boycott regulations.

## **Records Management**

We need to maintain, manage, and ultimately destroy Company records consistent with our internal document retention policies. Retention requirements sometimes vary depending on the type of record or information or based on overlapping legal or regulatory requirements. Even then, some requests by government agencies, regulatory bodies or in litigation create an obligation for us to retain records beyond the normal retention period. We all need to be aware of, stay up to date on, and follow Company policy regarding preservation of records.



## OUR COMMITMENT TO RAISING ISSUES & CONCERNS

If you are aware of activities that are not consistent with our Code, policies or any law or regulation, you are encouraged to report your concerns to:

- Your Manager
- Our Chief Compliance Officer at:
  - Via email at **[compliance@simtra.com](mailto:compliance@simtra.com)**
  - Via direct email at: **[jagarrett@simtra.com](mailto:jagarrett@simtra.com)**
  - In the United States: +1.973.765.4127
- Human Resources
- Simtra's Ethics Hotline, which allows employees to report concerns anonymously:
  - In the United States: +1 833.221.2651
  - In Germany: 0800 1824463
  - From outside of Germany: +49 0800 1824463
  - Via the web: **<http://www.simtra.ethicspoint.com>**





The background of the entire image is a dark blue gradient. Scattered across this background are numerous 3D molecular models of proteins, rendered in a vibrant purple color. These models vary in size and complexity, with some appearing as large, intricate clusters and others as smaller, more compact structures. The lighting on the models creates highlights and shadows, giving them a three-dimensional appearance.

# Simtra

BioPharma Solutions