

## 1.0 COMPREHENSIVE COMPLIANCE PROGRAM

Soleno is committed to advancing scientific knowledge and patient well-being through ethical research and marketing of pharmaceutical products. In service of this mission, Soleno conducts activities in compliance with applicable laws, regulations, and industry codes. We commit to acting honestly, ethically, and fairly, and work to ensure that our conduct, and that of our third-party business partners, meets and exceeds all required standards.

We also declare that the structure of our Comprehensive Compliance Program (CCP) incorporates the principles articulated in the Program Guidance for Pharmaceutical Manufacturers published in April 2003 and the General Compliance Program Guidance (GCPG) published in November 2023 by the Office of the Inspector General of the United States Department of Health and Human Services (OIG-HHS). The CCP adopted by Soleno is intended to adhere to the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals (PhRMA Code).

Soleno's CCP is designed to prevent non-compliance with company policies and the laws and regulations applicable to the pharmaceutical industry as well as effectively detect and correct non-compliance. Soleno's CCP is flexible and evolving, incorporating periodic risk assessments and adjustments to policies and practices to ensure the program can address the changing needs and emerging compliance risks of our business.

Soleno's CCP includes the following:

- 1.1 **Implementing Written Policies and Procedures** – As part of Soleno's CCP, Soleno has established a *Code of Business Conduct and Ethics*. All employees interacting with Healthcare Professionals (HCPs) and other customers are required to follow additional policies and procedures governing appropriate and inappropriate actions. Soleno updates these policies and procedures on an ongoing basis and ensures they are available and provided to all employees and relevant third parties.
- 1.2 **Designating a Compliance Officer and Compliance Committee** – Soleno has designated a Compliance Officer and a Compliance Committee charged with operating and monitoring Soleno's CCP. Additionally, the Compliance Officer has the authority to report on its CCP directly to the Board of Directors.
- 1.3 **Conducting Regular, Effective Training and Education** – Soleno requires periodic compliance training for all personnel on the policies and procedures established as part of the CCP.
- 1.4 **Developing Effective Lines of Communication** – Soleno has established an open line of communication for employees to contact the Legal & Compliance Department or Compliance Committee and report compliance questions and concerns to management and the Board of Directors. Personnel have a mechanism to report questions and concerns anonymously.

- 1.5 **Conducting Internal Monitoring and Auditing** – Soleno reviews and assesses business activities for compliance with applicable laws, regulations, guidelines, and company policies and procedures. This includes evaluating and identifying potential risks on an ongoing basis. Once potential risks are analyzed, the company identifies how to address any high-priority item, including by conducting an audit or putting monitoring in place.
- 1.6 **Enforcing Standards Through Well-Publicized Disciplinary Guidelines and Incentivizing Compliance** – Soleno’s *Code of Business Conduct and Ethics* includes a clear description of disciplinary action for non-compliance. Disciplinary action may include warnings, suspension, termination, and other sanctions, as appropriate.
- 1.7 **Responding Promptly to Detected Problems and Undertaking Corrective Action** – Soleno develops corrective action plans to address identified concerns in a timely fashion. Appropriate corrective action may include disciplinary action, enhanced training, improvement of policies and procedures, or reporting obligations to governmental authorities.
- 1.8 It is Soleno’s expectation that all employees and contractors comply with its CCP and all policies that support this program. As part of Soleno’s continuing commitment to compliance, Soleno continually reviews and revises the elements of its CCP.

As required by California Health & Safety Code § 119400-119402, with specific reference to the provision of “gifts, promotional material, or items or activities” a pharmaceutical company may provide to an individual healthcare professional (HCP), Soleno has established an aggregate, annual dollar limit of \$2,500 on promotional items and/or meals directed to an individual HCP who resides or practices in California.

To obtain a written copy of Soleno’s Code of Business Conduct and Ethics and written Declaration of Compliance, contact us at [legal@soleno.life](mailto:legal@soleno.life) or 844-723-8334.

## 2.0 DECLARATION OF COMPLIANCE

Soleno declares that, to the best of our knowledge, and based on our good faith understanding of the statutory requirements of the California Health & Safety Code §§ 119400-119402, we are in compliance with our Comprehensive Compliance Program (CCP) for the prior calendar year.

Dated January 24, 2025.