

**KEDRION BIOPHARMA INC. & BIO PRODUCTS LABORATORY USA INC.  
HEALTHCARE COMPLIANCE PROGRAM SUMMARY**

Kedrion Biopharma Inc. (“KBI”) and Bio Products Laboratory USA Inc. (“BPL”) (collectively, the “Company”) are committed to conducting its business in accordance with the highest ethical standards and in accordance with applicable laws and regulations.

**Overview**

The Company has established a comprehensive U.S. healthcare compliance program (“Healthcare Compliance Program” or “HCCP”) in accordance with the U.S. Department of Health & Human Services, Office of Inspector General’s (“OIG”) Compliance Program Guidance for Pharmaceutical Manufacturers (“OIG Compliance Guidance”). Such HCCP is designed to promote compliance with applicable laws, the OIG Compliance Guidance, and the PhRMA Code on Interactions with Health Care Professionals.

This document summarizes the key elements of the Company’s HCCP.

**Compliance Officer**

The Company has a Compliance Officer responsible for: (i) the HCCP’s day-to-day operations; (ii) developing and implementing policies, procedures and guidance to administer the HCCP; (iii) assessing, developing and implementing HCCP training activities; (iv) monitoring the Company Confidential Disclosure Line; (v) investigating HCCP matters, including recommending corrective actions and disciplinary measures; and (vi) establishing and executing risk-based auditing and monitoring.

**Written Policies and Procedures**

The HCCP includes policies, procedures and guidance to Company representatives regarding interactions with healthcare professionals and healthcare entities, including, but not limited to, advisory boards, speaker programs, business courtesies, grants, healthcare professional consulting and advisory engagements, and Company promotional materials.

**Training and Education**

At onboarding, all US personnel are required to review and certify their understanding and intention to comply with the US Healthcare Compliance Policies. The Compliance Officer provides live training to US Sales team personnel during the New Hire Sales Onboarding process. Thereafter, all US personnel are required to annually review and acknowledge compliance with the US Healthcare Compliance Policies. The Compliance Officer facilitates training for all US Sales team personnel regarding the HCCP, using examples from internal and external events that have taken place during the past year. The Company issues periodic communications and conducts periodic training on specific topics. These communications and trainings are intended to respond to specific items that are identified as areas of expressed need, or through monitoring, audits, investigations, or external events.

**Communication Channels**

The Company is committed to promoting an open dialogue between management and employees. Our goal is that all employees with questions or concerns will know who to turn to for a meaningful response, without fear of retaliation.

The Company requires its employees to report any actual or suspected violations of law or policy. Employees can report actual or suspected violations or raise their concerns in a number of ways,

including to their manager, another Company manager, the Compliance Officer, or the Company Confidential Disclosure Line at:

- English-speaking USA and Canada: 844-880-0003
- Spanish-speaking USA and Canada: 800-216-1288 (not available from Mexico)
- [Online form](http://www.lighthouse-services.com/kedrion) at [www.lighthouse-services.com/kedrion](http://www.lighthouse-services.com/kedrion)
- Email to: [reports@lighthouse-services.com](mailto:reports@lighthouse-services.com) (must include company name).

Reporters to the Confidential Disclosure Line may elect to remain anonymous. Reports of suspected violations of Company policy or the law are promptly investigated.

### **Auditing and Monitoring**

The Company monitors, audits, and evaluates compliance with its policies and the law. Our approach includes targeted monitoring and auditing based on identified and prioritized risk areas in accordance with the OIG Compliance Guidance.

### **Disciplinary Guidelines: Investigations and Corrective Actions**

The Compliance Officer and Human Resources Department oversee investigations of compliance-related issues. The Company is committed to promptly responding to non-compliance with the HCCP and taking appropriate corrective action. Disciplinary actions, ranging from verbal reprimand, written warning, suspension and termination, are determined on a case-by-case basis.

### **California Annual Spend Limit**

California law requires pharmaceutical companies to adopt an annual limit on gifts, promotional materials, or items or activities that the pharmaceutical company and its employees and representatives may give or otherwise provide to an individual medical or healthcare professional in California. The limit does not include amounts attributable to drug samples, financial support for continuing medical education, or payment for legitimate professional services. The Company has adopted an annual spend limit of \$1,000 per California medical/healthcare professional. This annual limit may be revised from time to time.