



<b>POLICY AND PROCEDURE</b> <i>Compliance Program</i>			
<b>Document No.</b> <b>Compliance 01</b>	<b>Revision</b> <b>001</b>	<b>Effective Date</b> <b>September 1, 2014</b>	<b>Page 1 of 4</b>

Keryx Biopharmaceuticals Inc. (“Keryx” or the “Company”) is committed to essential principles of good corporate conduct and integrity in all of its activities. To that end, Keryx has established and will maintain an effective Compliance Program to support the acquisition, development, and commercialization of medically important pharmaceutical products to address underserved needs.

The key components of the Compliance Program are described below, addressing each of the seven elements of an effective compliance program as outlined in the Compliance Program Guidance for Pharmaceutical Manufacturers issued in 2003 by the Office of the Inspector General of the Department of Health and Human Services (“OIG Guidance”), as well as consideration of the Pharmaceutical Research and Manufacturers of America Code on Interactions with Health Professionals as updated and made effective January 2009 (PhRMA Code), the Prescription Drug Marketing Act, relevant guidelines of the American Medical Association (AMA), the guidelines for the Accreditation Council for Continuing Medical Education (ACCME), and other guidance put issued by the US Food and Drug Administration (FDA) and other government agencies. As the OIG Guidance envisions, Keryx has designed its Compliance Program to fit the size, resources, market position, and other unique aspects of our Company. Keryx also recognizes that an effective compliance program must evolve and respond to the changing circumstances of the Company and the compliance, legal and regulatory environment. Keryx is committed to continuous quality improvement based on regular review, assessment, and development of the Compliance Program.

**1. Written Policies and Procedures**

Keryx’s Code of Conduct and Ethics establishes key ethical principles that all Keryx employees, officers and directors of the Company must follow, as well as standards to help ensure compliance with applicable laws and company policies. To emphasize the importance of the principles and guidelines contained in the Code of Conduct and Ethics, each Keryx employee must certify that he or she has read and agrees to abide by those policies.

In addition to the Code of Conduct and Ethics, Keryx has developed and implemented policies, procedures, guidelines, work instructions, and other directions to address potential risk areas for pharmaceutical manufacturers. In addition, although not a member of PhRMA, Keryx supports and has implemented policies and procedures with the requirements of the PhRMA Code.

**(a) California Health and Safety Code §§ 119400 – 119402 Declaration**

Keryx declares that:



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- (i) The Compliance Program is reasonably designed to prevent or detect and address misconduct that encompasses the compliance program requirement set forth in the California Marketing Practices Act (California Health and Safety Code §§ 119400-119402, or the “California Statute”);
- (ii) To the best of our knowledge, Keryx is in compliance with its Compliance Program and the requirements of the California Statute as of June 1, 2014. Keryx will evaluate and update our Compliance Program, as necessary and appropriate.

For purposes of complying with the California Statute, Keryx has established a maximum annual aggregate dollar limit of two thousand dollars (\$2,000) for gifts, promotional materials, and related activities provided to California healthcare professionals. This limit is an annual limit, not an average or targeted spending limit, and the amount spent per healthcare professional is anticipated to be substantially less than this maximum amount. For purposes of clarity, this annual spending limit does not include the value of: (1) drug samples given to physician and healthcare professional intended for free distribution to patients; (2) financial support of independent education including continuing medical education; (3) financial support for health education scholarships; and (4) payments made for legitimate professional services provided by a healthcare professional so long as the amount paid is based up the fair market value of the services provided.

## **2. Head of Compliance and Compliance Committee**

Keryx has designated a Senior Legal Counsel and Head of Compliance (“Head of Compliance”), who is responsible for developing, overseeing, and monitoring the operation the Compliance Program. The Head of Compliance has the authority to exercise appropriate professional judgment regarding the Compliance Program, and to develop and implement revisions and improvements as needed to maintain an effective Compliance Program. The Head of Compliance reports to the General Counsel.

Keryx has also established a Compliance Committee. The Compliance Committee is comprised of representatives from key Company departments and is charged with providing oversight regarding significant healthcare-related regulatory and compliance issues, and assisting and supporting the Head of Compliance in the development, implementation, monitoring and maintenance of Keryx’s Compliance Program.

## **3. Education and Training**

Education and training are essential to effectively communicating our standards and requirements to Keryx personnel, and enabling them to perform in accordance with them. Keryx personnel are provided training on Keryx’s Code of Conduct and Ethics and on the compliance-



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related policies, procedures, guidelines, and work instructions applicable to their job functions. Keryx maintains and monitors training records to help ensure all employees have received required training.

#### **4. Employee Communications and Reporting**

Keryx is committed to fostering an active and appropriate dialogue between management and employees regarding ethical and compliance-related matters. Keryx personnel are encouraged to seek answers to compliance-related questions or concerns from the Head of Compliance, the General Counsel, the Director of Human Resources or their manager, and are provided with guidance on how to access compliance-related information.

Keryx has also adopted policies and procedures that require personnel to report potential compliance violations. These policies and procedures include measures intended to ensure that appropriate reports will not subject the person making a good faith report of what they honestly believe to be an actual or suspected violation to retaliation by Keryx. As well, personnel may anonymously report potential compliance violations via an online tool or toll-free service.

#### **5. Auditing and Monitoring**

Keryx's Compliance Program includes compliance-related monitoring and auditing functions to help evaluate on-going adherence to our compliance-related policies and procedures. Consistent with OIG Guidance, Keryx takes a number of factors into consideration when determining the nature, extent, and frequency of our compliance monitoring and auditing activities. New regulatory requirements, developments in business practices, internal risk assessments, and similar considerations may result in new or revised compliance-related monitoring and auditing activities.

#### **6. Enforcement and Discipline**

Keryx maintains policies and procedures for addressing potential compliance-related violations. These policies and procedures are intended to ensure that relevant facts and circumstances are understood and considered in connection with all enforcement and disciplinary activities, and that appropriate and consistent action is taken to address inappropriate conduct and deter future violations.

#### **7. Corrective and Preventative Action**

Keryx believes that the Compliance Program increases the likelihood of preventing or identifying unlawful and unethical behavior. However, even an effective compliance program will not prevent all violations. Our Compliance Program therefore requires the Company to



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respond promptly to potential violations of law or Keryx policy, take appropriate disciplinary action, assess whether the violation may be due to gaps in our policies, practices, or internal controls, and take appropriate corrective action to prevent or limit future violations.

**8. Revision History**

Revision No.	Effective Date	Supersedes	Reason for Revision

**9. Sponsorship and Policy Management**

Senior Legal Counsel & Head of Compliance