

## **Flowonix Medical - Compliance Program**

### **I. Introduction: A Culture of Compliance**

Flowonix Medical and its employees take our responsibility to the community seriously and strive for the highest standards of corporate conduct. We are committed to establishing and maintaining an effective and comprehensive corporate compliance program to prevent and detect violations of law or company policy. Our mission as a healthcare company is to create products and market innovative solutions of high quality for unmet medical needs, thus enhancing people's health and quality of life. We do this in a responsible and ethical manner and with a commitment to sustainable development, respecting the needs of the individual, the society and the environment.

As a part of this effort, we have adopted a compliance program that addresses the matters covered by the Federal Register May 2003 publication "*Compliance Program Guidance for Pharmaceutical Manufacturers*" ("OIG Guidance"), which was developed by the United States Department of Health and Human Services Office of Inspector General ("HHS-OIG") and is also applicable to medical device manufacturers.

Our Compliance Program's purpose is to assist Flowonix Medical in maintaining compliance with the laws, regulations and company directives and guidance that apply to the commercialization of our products, to train our employees on these matters and to prevent, detect, and correct instances of non-compliance.

Flowonix Medical has described below the fundamental elements of our Compliance Program. In accordance with the voluntary standards established by the HHS-OIG Guidance and as explicitly recognized in the OIG Guidance, we have tailored our Compliance Program to fit the unique environment and size of Flowonix Medical as a medical device manufacturer.

This document is meant to serve as an introduction to Flowonix Medical's Compliance Program and is not intended as a comprehensive presentation of the entire Program. The Compliance Program is dynamic and incorporates guidance from multiple legal, regulatory and industry sources. We regularly review and enhance the Compliance Program to meet Flowonix Medical's evolving compliance needs.

### **II. Overview of the Compliance Program**

#### **1. Leadership and Structure:**

Chief Compliance Officer – Flowonix Medical has designated George Peters, Vice President of Quality Systems, as its Compliance Officer. As the Chief Compliance Officer, Mr. Peters has overall responsibility for oversight of Flowonix Medical's Compliance Program. This includes oversight of the development and operation of the Program including developing and implementing policies, procedures, and practices designed to ensure compliance with federal and state healthcare laws.

Compliance Committee - Flowonix Medical has established a Compliance Committee comprised of key stakeholders. The Compliance Committee meets regularly, assists the Chief Compliance Officer in the implementation of the Compliance Program, and provides compliance oversight within the day-to-day operations of the company.

#### **2. Written Policies and Procedures:**

At the core of our Compliance Program are ethical standards and compliance principles that guide our daily conduct, stated in our Business Ethics and Conduct section included in our Employee Handbook (the "Code"). The Code sets forth Flowonix Medical's expectation and requirement that management, employees and agents of Flowonix act in accordance with all

laws, regulations and applicable Company policies and uphold Flowonix Medical's high standards of business ethics. Our Code reflects our consideration of the Advanced Medical Technology Association (AdvaMed) "*Code of Ethics on Interactions with Health Care Professionals*," and OIG Guidance.

Policies and procedures have been generated to address the potential risk areas for manufacturers as identified in the HHS-OIG Guidance.

Flowonix Medical has also established guidance regarding appropriate interactions with health care professionals which includes limits on gifts, meals and other activities to comply with the AdvaMed "Code of Ethics on Interactions with Health Care Professionals."

3. Education and Training of Employees:

A critical element of our Compliance Program is education and training. Flowonix Medical is committed to implementing programs to effectively and timely communicate our directives and guidance to affected personnel. New personnel will receive such training as part of their initial training and existing personnel are expected to receive compliance training on at least an annual basis. Moreover, Flowonix Medical will review and update its training programs periodically, as well as identify additional areas of training on an ongoing basis.

4. Effective Lines of Communication:

Flowonix Medical is committed to fostering dialogue between management and employees. Our goal is that all employees, when seeking answers to questions or reporting potential instances of improper behavior, should know who to turn to for a meaningful response and should be able to do so without fear of retribution. To that end, we adhere to an "Open Door Policy", and encourage colleagues to discuss all issues, concerns, problems and suggestions with their immediate supervisor or other managers without fear of retaliation and with the assurance that the matter will be kept as confidential as possible.

Flowonix Medical has also established a Compliance Helpline, available 24 hours a day, 7 days a week, for anonymous reporting for potential violations.

5. Internal Auditing and Monitoring:

Flowonix Medical's Compliance Program includes efforts to monitor, audit and evaluate compliance with the company's policies and procedures. We note that in accordance with the OIG Guidance, the nature of our reviews as well as the extent and frequency of our compliance monitoring and auditing varies according to a variety of factors, including new regulatory requirements, changes in business practices, and other considerations. These monitoring activities are intended to identify potential or existing problem areas and to take corrective measures in an effort to prevent the recurrence of non-compliance.

6. Responding to Potential Violations:

An additional role of the Chief Compliance Officer, or designee, is to oversee the review of non-compliance reports and determine whether further investigation is necessary. When deemed necessary, the Chief Compliance Officer, or designee, will conduct an investigation into potentially non-compliant activity to determine whether a violation has occurred. Flowonix Medical's Compliance Program includes policies which address disciplinary actions or consequences for violation of the law or company policy.

7. Corrective Action Procedures:

A Compliance Program increases the likelihood of preventing, or at least identifying unlawful and unethical behavior. However, HHS-OIG recognizes that even an effective compliance program may not prevent all violations. As such, our Compliance Program requires the company to respond promptly to potential violations of law or company policy, take appropriate disciplinary action, assess the root cause of the violation, and take appropriate corrective measures.

**Flowonix Medical’s DECLARATION OF COMPLIANCE – 2015**

As stated in its Code of Conduct (the “Code”), Flowonix Medical is committed to ethical and legal conduct that is compliant with all relevant laws and regulations and to correcting misconduct wherever it may occur in the organization. As part of our continued efforts in the area of compliance, Flowonix Medical has developed a Comprehensive Compliance Program that is reasonably designed to prevent and detect violations.

Consistent with the Department of Health and Human Services Office of the Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers (“HHS-OIG Guidance”), Flowonix Medical has tailored its Compliance Program to the nature of its business as a medical device manufacturer. Flowonix Medical’s Compliance Program is consistent with the AdvaMed Code of Ethics on Interactions with Healthcare Professionals (“AdvaMed Code”) which, although substantially similar to the Pharmaceutical Research and Manufacturers of America’s Code on Interactions with Healthcare Professionals (“PhRMA Code”), recognizes significant differences applicable to the medical device industry including unique interactions between medical device manufacturers and health care professionals.

Government guidance on compliance programs, including the U.S. Sentencing Guidelines and the HHS-OIG Guidance, recognize that no program can completely prevent individual employees from improper conduct. Therefore, Flowonix Medical cannot completely eliminate the possibility that an employee will violate these standards; however, Flowonix Medical has established policies and procedures to both prevent and identify potential violations and discipline employees as necessary. Recognizing that compliance is a dynamic concept that must be adapted to the characteristics of a particular company, Flowonix Medical continuously reviews and enhances its Comprehensive Compliance Program.

To the best of our knowledge and belief, and based upon a good faith understanding of the statutory requirements, Flowonix Medical hereby declares that it has established and is, in all material respects, operating in compliance with a Comprehensive Compliance Program that satisfies the requirements of applicable law.

To obtain a copy of Flowonix Medical’s Declaration of Compliance, please call 1-973-426-9229.

Last updated: April 22, 2015

Signed:   
George Peters, VP, Quality Systems & Chief Compliance Officer