

# **Life Molecular Imaging Global Compliance Program**

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## 1. Purpose

As a subsidiary of the Life Healthcare Group, an international, diversified healthcare organization that operates in a diverse, complex and changing healthcare landscape, Life Molecular Imaging (“LMI” or the “Company”)) believes that good business always begins with **COMPLIANCE FIRST**.

It is the policy of LMI to comply with all laws, rules and regulations (“Laws”) affecting the Company and to maintain the highest ethical standards in its business practices.

The LMI Compliance Program applies to all LMI subsidiaries, directors, employees, agents, and contractors of LMI. In addition, the Compliance Program applies to all arrangements between LMI and other parties, including without limitation, customers, contract manufacturers, distributors, marketing companies, researchers, vendors, and other persons or entities.

The scope of the Compliance Program encompasses compliance with all applicable Laws, as well as compliance with LMI’s Code of Conduct and other LMI policies and procedures. The Code of Conduct mandates a Compliance Program. The Compliance Program seeks to prevent non-compliance as well as enable early detection and correction of potential non-compliance with Laws, the LMI Code of Conduct, and other LMI policies and procedures.

An effective compliance program provides a mechanism that enables a company to comply with applicable Laws and internal codes, policies and procedures, and addresses the public and private sectors' mutual goals of reducing fraud, waste and abuse. In addition to fulfilling its legal duty to lawfully operate in applicable jurisdictions, a pharmaceutical company gains important additional benefits by implementing an effective compliance program which include:

- Demonstrating the company’s commitment to honest and responsible corporate conduct to employees, business partners, and the community.
- Increased feasibility of identifying, preventing and correcting potentially unlawful or unethical behavior at an early stage.
- A structured process to encourage employees and third parties to report potential non-compliance and allow for appropriate internal investigation and corrective action.

The value and effectiveness of a compliance program is determined by the company's successful implementation of the program and further development of compliance best practices which contribute to overall continuous improvement and success of the company.



This Compliance Program should be read in conjunction with the Life Healthcare Global Code of Conduct

## 2. Tone at the Top

LMI is committed to the success of its Compliance Program. A culture of compliance starts at the top of the organization. An effective compliance program has support from top level executives who support, endorse, and allocate resources to achieve the compliance program's objectives.

## 3. Compliance Program Structure

### Compliance Committee

LMI has appointed a standing Compliance Committee operating under its own charter to assist the LMI Board in providing oversight and guidance of LMI's Compliance Program.

### Compliance-Responsible Manager

The most senior LMI Compliance manager or executive ("LMI Compliance Responsible Manager") shall chair the Compliance Committee. In the event that such position is vacant, the LMI Board, upon recommendation of the Compliance Committee, shall appoint another person to serve in such capacity until the Compliance position is filled.

- The LMI Compliance Responsible Manager is responsible for the day-to-day management of the Compliance Program and supporting management and Accountable Executives in discharging their compliance obligations.
- The LMI Compliance Responsible Manager shall be assured direct access to LMI's Regional CEO, Board of Directors, Head of Legal, local Human Resources managers, and Group Compliance and Risk resources for the purpose of conducting investigations, making reports and providing recommendations on Compliance matters.
- The LMI Compliance Responsible Manager shall have all of the duties and responsibilities that are ordinarily performed by and attendant to a company's senior compliance responsible person. As part of these duties and responsibilities, the LMI Compliance Responsible Manager is responsible for the following Compliance activities on behalf of LMI:
  - Supporting Accountable Executives and management to;
    - identify all key Laws applicable to their operations and mitigate associated risks.

- Interaction and communications with Compliance responsible persons in LMI's parent companies.
- Establishing methods – such as conducting periodic audits, developing effective lines of communication on Compliance issues, and preparing, and assisting the departments with preparing, written standards and procedures.
- Periodically revising the Compliance Program, or recommending such revisions to the Compliance Committee, in light of changes in the needs of the Company or changes in Laws or standards.
- Overseeing the development, coordination and execution of Compliance Program training activities for all LMI staff.
- Ensuring that the applicable and appropriate compliance related background checks and due diligence are performed on all employees, staff, independent contractors and third parties.
- Investigating and acting on any report or allegation of unethical or improper conduct or business practices, reporting on the results of such investigations to the local Human Resources Manager and Head of Legal, and where appropriate, the Compliance Committee, and implementing and monitoring appropriate corrective action and/or subsequent compliance.
- Reporting on a regular basis to the Head of Legal and Regional CEO on the progress of the Compliance Program's implementation.
- Continuing the momentum of the Compliance Program and the accomplishment of its objectives after its implementation.

### **Department Heads**

The Department Heads play an important role in the Compliance Program. The Department Head shall:

- Work with the LMI Compliance Responsible Manager and the Compliance Committee as needed.
- Establish compliant departmental policies and procedures that comply with the Compliance Program, and hold staff within their departments accountable to abide by the Compliance Program and such policies and procedures.

- Ensure the education and training of staff within their departments on the most up-to-date policies and procedures impacting department and staff job functions.
- Participate in auditing and monitoring activities as requested by the LMI Compliance Responsible Manager.
- Promptly report suspected or known violations of the Compliance Program that have occurred within their departments and have come to their attention to the LMI Compliance Responsible Manager or through anonymous reporting channels; and
- Apprise staff members of the results of Compliance Program monitoring, auditing, and reporting activities.

#### 4. Compliance Program Elements

The LMI Compliance Program shall incorporate the following:

- **Designation of a Compliance Responsible Person**  
The LMI Compliance Responsible Manager is responsible for the operation and monitoring of the Compliance Program.
- **Policies and Procedures**  
Establish standards of conduct and written policies and procedures for staff that support adherence to all applicable Laws affecting LMI.
- **Conducting Effective Training and Education**  
Provide education, training, and communication to employees, contractors, vendors, and other relevant parties about the standards and the Compliance Program requirements.
- **Developing Effective and Open Lines of Communication**  
Development and maintenance of a process to receive compliance complaints, issues and concerns, and the adoption of procedures to protect the anonymity of complainants and prohibit retaliation against individuals making reports to the LMI Compliance Responsible Person.
- **Conducting Internal Monitoring and Auditing**  
Maintain a system for evaluating, monitoring, auditing, and reporting compliance matters proactively and/or in response to identified issues.
- **Disciplinary Guidelines**



In conjunction with Human Resources, maintain and enforce an appropriate disciplinary mechanism for the consistent enforcement of Compliance Program requirements.

- **Responding to problems and corrective actions.**  
Sustain an appropriate mechanism for responding promptly to problems and implementing corrective action.

## **5. Compliance Reporting**

LMI shall maintain mechanisms by which directors, employees, and external parties can report any concerns, issues or suspected non-compliance relating to the LMI's Compliance Program, governance, administration, or operation (including, but not limited to, its financial and clinical practices).

### **Anonymous Reporting**

LMI shall maintain and make available to all staff and third parties anonymous reporting channels (e.g., the Life Healthcare Group Tip Offs anonymous hotline managed by Deloitte Risk Services) and will ensure the anonymity of the LMI staff members and third parties who report a violation as is possible under the circumstances in the judgment of the LMI consistent with its obligations to investigate concerns and take necessary corrective action. There shall be no retaliation in the terms and conditions of employment as a result of such reporting.

## **6. Annual Work Plan**

At the beginning of each fiscal year, LMI's Compliance Responsible Person will develop a work plan outlining major Compliance activities or projects for the fiscal year. The work plan will be based upon prior findings and identified areas of risk, emerging compliance trends and regulatory advisory opinions. The work plan will be reviewed and adopted by the Compliance Committee no later than November 15<sup>th</sup> of the then current fiscal year.



## Annual Declaration of Compliance

### California Compliance Law Statement

Life Molecular Imaging "LMI" is committed to compliance laws and regulations that pertain to its business, sales, research, , and marketing practices in the countries in which LMI operates. LMI is in compliance with its Compliance Program (CCP) and Cal. Health & Safety Code §§ 119400-119402. Our Compliance Program contains the elements of an effective compliance program identified in the "Compliance Program Guidance for Pharmaceutical Manufacturers" published by the Office of the Inspector General, U.S. Department of Health and Human Services ("HHS-OIG Guidance"). In addition, LMI has adopted the "Code on Interactions with Healthcare Professionals" published by The Pharmaceutical Research and Manufacturers of America (the "PhRMA Code") and has policies, procedures and processes designed to help ensure compliance with the PhRMA Code.

In accordance with Chapter 8, Part 15, Division 104 of the California Health and Safety Code (§§ 119400-119402), LMI has established an annual aggregate dollar limit of \$2,000 per healthcare professional licensed in California for the following items: 1) meals provided in connection with informational presentations or scientific exchange; 2) educational items intended to enhance patient care (excluding items of minimal monetary value and/or of no independent value (e.g. printed advertising, reimbursement fact sheets)) and items for the benefit of and distribution to patients/care givers.

To obtain a copy of the Compliance Program Document, send an email to:  
[compliance@life-mi.com](mailto:compliance@life-mi.com)