

December 13, 2012

## Announcement of Organizational and Personnel Changes

Sysmex Corporation (HQ: Kobe, Japan; President and CEO: Hisashi Ietsugu) announced today its decision to implement organizational and personnel changes, effective January 1, 2013, as detailed below.

The aim of these changes is to strengthen the Group's pharmaceutical affairs and regulatory compliance structures, so as to improve compliance with the FDA (U.S. Food and Drug Administration)<sup>\*1</sup> and other national pharmaceutical regulatory systems, as well as to strengthen Sysmex's non-hematology<sup>\*2</sup> product lineup.

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### 1. Organizational changes

#### (1) Strengthening our pharmaceutical affairs and regulatory compliance structures

##### a) Establishment of an organization dedicated to pharmaceutical affairs and regulatory compliance

In addition to our mainstay hematology products, Sysmex is expanding our lineup of non-hematology products, such as those for hemostasis and urinalysis, and expanding sales of these products globally. We will expand this product lineup to include immunochemistry, clinical chemistry and other products so as to achieve further growth.

There has been a trend in recent years toward stricter examinations by administrative authorities over longer periods in the approval acquisition process for products in the IVD<sup>\*3</sup> industry overall. This trend is expected to continue.

Therefore, at this juncture Sysmex has elected to separate the Regulatory Affairs and Vigilance Department, which has functioned within the Regulatory Affairs and Quality Assurance Division to handle compliance with pharmaceutical laws and gather and manage product safety data in the marketplace, into the Regulatory Affairs Department and the Vigilance Department, thereby strengthening the specialized nature of each. This change is aimed at speeding up the Group's response to regulatory regimes and authorities so as to provide more efficient market entry for our expanding product lines and continue the strong growth of the Group.

\*1: FDA: This U.S. government agency is dedicated to the approval and regulation of food products, pharmaceuticals, cosmetics, medical instruments and other items. It evaluates product safety and efficacy, regulates clinical trials and performs other similar functions.

\*2: Non-hematology: *In vitro* diagnostics fields excluding hematology but including immunochemistry, clinical chemistry, hemostasis, urinalysis and others.

\*3: IVD: Abbreviation of "*in vitro* diagnostics"

## 2. Personnel Changes and Appointments

## (1) Personnel

Name	New position	Current position
Hiroshi Yamane	Vice President of Regulatory Affairs Dept.	Vice President of Regulatory Affairs and Vigilance Dept.
Shinichi Ogino	Vice President of Vigilance Dept.	Vice President of Quality Assurance Dept.
Yasuhiro Todoroki	Vice President of Quality Assurance Dept.	Director of Quality Assurance Dept.