

COMPLIANCE AND LEGAL: DEFINING THE BOUNDARIES

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GRIFOLS IS A WORLD-LEADING HEALTHCARE COMPANY



Grifols employs 13,200 people, who share the mission of improving people's health and well-being through the research, development, manufacture and distribution of plasma-derived biological medicines, clinical diagnostics systems and pharmaceutical preparations for hospital use.

SINCE 1940 GRIFOLS HAS CONTRIBUTED TO IMPROVING PEOPLE'S HEALTH



Grifols is one of the leading companies in the world in the production of plasma proteins, with a global market share of approximately 20%. Following the acquisition of the Novartis diagnostics unit in January 2014, Grifols completed its range of immunological diagnostics and is a world-leading company in transfusion medicine.

A LEADER IN THE MANUFACTURE OF PLASMA-DERIVED BIOLOGICAL MEDICINES AND IN TRANSFUSION MEDICINE



Grifols business model is one of vertical integration, enabling it to control the entire production cycle, starting with the collection of raw material in the form of plasma through an extensive network of donor centers in the United States, and ending with the finished product. In the area of diagnostics Grifols offers comprehensive solutions that contribute to transfusion safety for clinical laboratories, blood banks and transfusion services.

SALES REVENUE OF 2,741.7 MILLION EUROS IN 2013

- 92.4% OF INCOME IS GENERATED IN INTERNATIONAL MARKETS
- A STRONG PRESENCE IN THE USA AND CANADA, WHICH ACCOUNTS FOR OVER 63% OF SALES; 21% GENERATED IN EUROPE AND MORE THAN 15% IN OTHER REGIONS

GLOBAL DISTRIBUTION WITH PRODUCT SALES IN MORE THAN 100 COUNTRIES

DIRECT GEOGRAPHIC PRESENCE IN 25 COUNTRIES THROUGH WHOLLY OWNED SUBSIDIARIES

MANUFACTURING FACILITIES IN THE UNITED STATES, SPAIN, AUSTRALIA AND SWITZERLAND

150 PLASMA DONOR CENTERS IN THE USA

13,200 EMPLOYEES IN THE WORLD

- 73% OF THE WORKFORCE BASED IN THE UNITED STATES

LISTED IN THE TOP 100 MOST INNOVATIVE COMPANIES IN THE WORLD

ONGOING COMMITMENT TO R&D, WITH AN ALLOCATION OF 4.5% - 5% OF ANNUAL INCOME

FUNDING OF PORTFOLIO COMPANY R&D PROJECTS IN AREAS SUCH AS ALZHEIMER'S AND IN THE FIELD OF PERSONALIZED MEDICINE

EXPERTS IN THE MANUFACTURE OF LIFESAVING BIOLOGICAL MEDICINES, INCLUDING:

- IMMUNOGLOBULINS, PARTICULARLY INTRAVENOUS IMMUNOGLOBULIN (IVIG), TO TREAT IMMUNOLOGICAL DISORDERS
- ALBUMIN, TO RE-ESTABLISH AND MAINTAIN BLOOD VOLUME
- FACTOR VIII, FOR THE TREATMENT AND PROPHYLAXIS OF HEMOPHILIA
- ALPHA-1-ANTITRYPSIN, TO PROTECT AGAINST THE DETERIORATION OF LUNG TISSUES (PULMONARY EMPHYSEMA)

SPECIALISTS IN CLINICAL DIAGNOSTICS

- A WORLD LEADER IN TRANSFUSION MEDICINE
- LEADING MANUFACTURER OF INSTRUMENTS AND REAGENTS FOR IMMUNOLOGY AND HEMOSTASIS

HAVE YOU EVER HEARD THESE STATEMENTS?

- *‘Compliance clearance needed? I’ve already talked to Legal.’*
- *‘Lawyers are better able to run compliance than non-lawyers.’*
- *‘Legal and Compliance contradict each other.’*
- *‘Don’t worry, I’m a lawyer. This is under legal privilege.’*
- *‘Compliance must be separate from Legal.’*
- *‘Compliance must report to Legal.’*
- *‘How can Legal and Compliance better interact?’*

ENHANCED PROMINENCE OF COMPLIANCE

Traditional Challenges

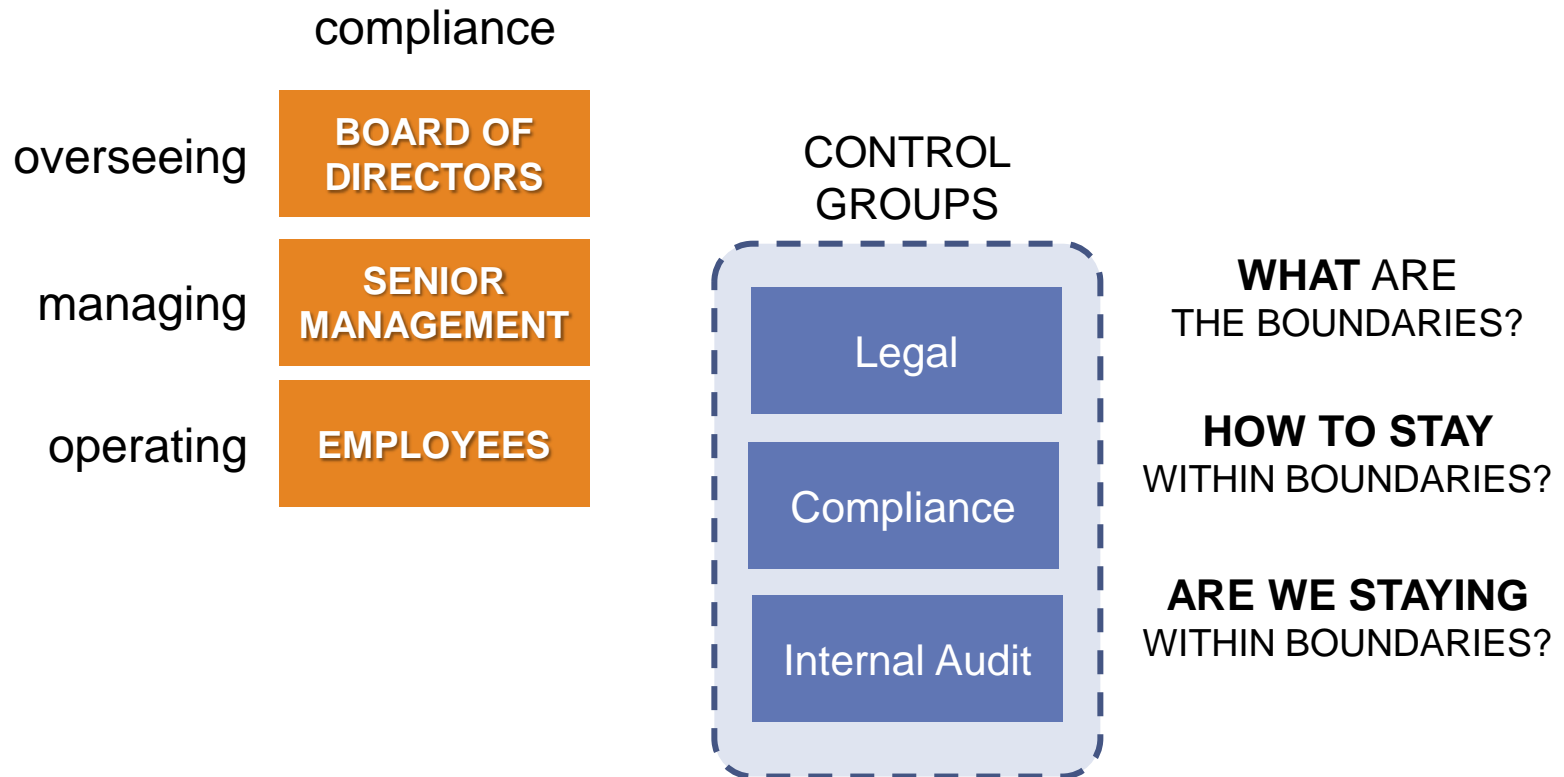
- **Unclear regulations. Evolutionary nature of the function**
- **Risk of multiple and sometimes inconsistent responsibilities**
- **Relationship with other control units**

New Expectations and Demands

- **Assignment of increased responsibilities**
- **Closer involvement with day-to-day business operations**
- **Increased interdependence with other control units**

Source: 'White Paper: The Evolving Role of Compliance', SIFMA, March 2013

COMPLIANCE GOVERNANCE PRINCIPLES



COMPLIANCE FUNCTIONAL PRINCIPLES

- **Independence, i.e.:**
 1. **Formal status;**
 2. **Compliance officer / head of compliance;**
 3. **Avoiding of conflicts of interest;** and
 4. **Unrestricted access to information and personnel.**
- **Resources, both sufficient and appropriate.**
- **Responsibilities, clearly defined.**
- **Periodic and independent review (e.g. by internal audit).**

Source: 'Compliance and the compliance function in banks', Basel Committee on Banking Supervision, April 2005

COMPLIANCE-LEGAL INTERACTIONS

- **Interpreting rules and regulations, and assessing applicability**
- **Advising on the regulatory requirements**
- **Drafting policies and procedures**
- **Conducting internal investigations**
- **Responding to regulatory examinations and inquiries**
- **Handling customer complaints**
- **Drafting disclosures and filings**

Legal privilege can be compromised; a formal protocol is advisable

Source: 'White Paper: The Evolving Role of Compliance', SIFMA, March 2013