ODCEC m@ster

ORDINE DEI DOTTORI COMMERCIALISTI E DEGLI ESPERTI CONTABILI
MILANO

FONDAZIONE COMMERCIALISTI ODCEC di MILANO

Odcec M@ster La responsabilità amministrativa degli enti ex D. Lgs. 231/2001

Il sistema di compliance integrata

A company perspective

Avv. Giovanna Lionetti
Senior Director Ethics&Compliance Italy, Greece, Cyprus & Malta

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Astellas Pharma

GLOBAL STATISTICS

ASTELLAS IS A PHARMACEUTICAL COMPANY COMMITTED TO TURNING INNOVATIVE SCIENCE INTO VALUE FOR PATIENTS.

TOP 25 GLOBAL BIOPHARMA COMPANY BASED ON PRESCRIPTION SALES ACCORDING TO PHARMA EXEC[1]

MORE THAN 16,000 EMPLOYEES

OVER 40 OFFICES WORLDWIDE

HERITAGE OF THERAPEUTIC EXPERTISE
in oncology, urology, anti-infectives and transplantation

¥1,256,000 MILLION IN GLOBAL REVENUE, BASED ON FY2019 FORECAST RESULTS

17% GLOBAL ANNUAL SALES REINVESTED IN R&D, BASED ON FY2019 FORECAST RESULTS

1.Astellas placed 23rd in the Pharma Exec top 50 for 2019. Last accessed: March 2020.

RISULTATI 2021

*1 Japanese GAAP *2 IFRS *3 Figure for fiscal year ended March 31, 2021 is core operating profit

OUR CURRENT AREAS OF FOCUS

ACROSS OUR DIVERSE THERAPEUTIC EXPERIENCE WE AIM TO TRANSFORM INNOVATIVE SCIENCE INTO VALUE FOR PEOPLE WITH DISEASES AROUND THE WORLD, AND THE MANY HEALTHCARE PROFESSIONALS AND CAREGIVERS WHO SUPPORT THEM.

Oncology

We are committed to the fight against cancer. Over the last decade, we have built a leadership position and a substantial oncology pipeline. We are focused on discovering new cancer treatments and novel pathways, particularly in hard-to-treat cancers where few therapies exist.

Urology

We have introduced treatments that have helped address the unmet needs of patients and are are continuing to expand our urology portfolio through developing next-generation therapies.

Transplant

We are proud to have been involved in transplant for more than 20 years and continue to invest in this area, supporting multiple transplant organisations around the world. Our portfolio provides treatment options for people receiving kidney, liver and heart transplants.

Nephrology

We hope to build on our expertise supporting kidney transplant patients and have an ongoing programme of collaboration and outreach with the nephrology community to continue research in this area.

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April 2020 NON_2020_0031_APE

Date of preparation:

Contesto e scenario

THE CHANGING LANDSCAPE 1/2

ABPI: Association of the British Pharmaceutical Industry
EFPIA: European Federation of Pharmaceutical Industries and Association
EMA: European Medicines Agency
FCPA: Foreign Corrupt Practices Act
GDPR: General Data Protection Regulation
IFPMA: International Federation of Pharmaceutical Manufacturers & Associations
MHRA: Medicines and Healthcare Products Regulatory Agency
OECD: The Organisation for Economic Co-operation and Development

GxP:
Good Clinical Practice
Good Distribution Practice
Good Documentation Practice
Good Laboratory Practice
Good Manufacturing Practice

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THE CHANGING LANDSCAPE 2/2

- ✓ Complessità sistema legale e regolatorio
- ✓ Ambiente esterno e stakeholders
- ✓ Contesto politico e socio economico
- ✓ Cultura società multinazionali
- ✓ Necessità di approccio sinergico ed integrato

PRINCIPI COMPLIANCE INTEGRATA

- ✓ **Holistic approach to compliance program** and **procedures**
- ✓ **Cross-functional connections** and **flows** (internal functions, external functions i.e. Supervisory Board, local/HQ functions)
- ✓ Program consistent with **applicable laws and regulations** (i.e. localization of multinational program)
- ✓ A **common language** and **shared principles**
- ✓ **Consistency** with roles and responsibilities
- ✓ **Personal accountability**
- ✓ **Segregation** of duties and clear **roles, responsibilities**, activities and controls fully formalized
- ✓ **Delegation of authority**
- ✓ Transparency and **tracking** of all the activities
- ✓ Trending of **data** for spreading lessons learned

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Il metodo

RISK BASED APPROACH 1/2

RISK BASED APPROACH 2/2

✓ **Map Processing Areas**

Identify where, why and how (e.g. procedures, policies guidance)

Internal interviews/Key internal stakeholders

✓ **Risk Assessment**

Determine potential threats and inherent risks

Analyze information acquired from mapping

✓ **Gap Analysis**

Identify technical and organizational measures

Evaluate effectiveness

Residual risk

✓ **Organizational Action Plan**

Define priorities

Approve compliance architecture (e.g. roles and responsibilities, Governance)

Increase awareness and accountabilities

Procedures

Training

Corporate communication campaigns

✓ **Implementation**

Action plans and CAPA

✓ **Monitoring and Maintenance**

Audit effectiveness

Discussion in compliance committee/Leadership Boards

INTEGRAZIONE DEI CONTROLLI

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Governance e Comitati

COMPLIANCE INTEGRATA E GOVERNANCE

- ✓ Espressione del modello di business dell'azienda
- ✓ Strumento strategico di gestione delle decisioni in un contesto segregato
- ✓ Funzione di indirizzo, coordinamento e controllo sotto un profilo di compliance e espressione di cross-funzionalità
- ✓ Supporto alla gestione dei modelli normativi (i.e. modello 231, modello Privacy, modello SHE)
- ✓ I cambiamenti organizzativi impattano sulla governance e sui modelli
- ✓ I Comitati posseggono deleghe formalizzate, si riuniscono con frequenza prestabilita e prevedono la verbalizzazione delle riunioni e la successiva diffusione dei verbali ai principali organismi aziendali

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Il ruolo della cultura

THE MATURITY CURVE

REACTIVE

- Tone from the top absent
- Ad hoc & informal structure
- Loosely applied resources
- Tactical, reactive execution
- Limited / local risk assessment
- Disjointed or no monitoring exists
- Fragmented reporting
- Incompatible systems / technology

INFORMAL

- Leadership acknowledges need
- Limited global policies
- Inconsistent reporting lines. Some local dedicated resource
- Limited backend monitoring and use of KRI*
- Some system integration at local level
- Limited application of technology

STANDARDISED

- Leadership sets clear expectations
- Global policy architecture
- Standardised reporting lines
- Business acumen and compliance/risk knowledge
- Standard taxonomy of risks
- Monitoring process / tools that are not uniform
- Standardised reports using KRI/KPI*
- Standard systems, interfaces & models

MANAGED

- Management actively involved
- Global policies/ limited transparency
- Proactive insightful analysis
- Aligned and consistent monitoring
- Standardised executive dashboards
- Standard data models, tools & applications

OPTIMISED

- Management demonstrates ownership
- Clear governance and risk transparency
- Clear functional roles
- Proactive value-add strategic partner
- Globally consistent & optimised process
- Continuous and consistent monitoring, including self-monitoring
- Global data analytics driving insightful reports
- Integrated systems and technology facilitate program

Based on informal benchmarking and review of websites

* KRI – Key Risk Indicator / KPI – Key Performance Indicator

BUILDING CAPABILITIES TO ENHANCE ETHICS &COMPLIANCE CULTURE

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PROACTIVELY DRIVE ETHICAL AND COMPLIANT CULTURE IN CLOSE PARTNERSHIP WITH BUSINESS

- **New, engaging way to build discussions around Compliance**
- **Encouraging dialogue through leadership to increase compliance maturity (i.e. Tone from the Top/Middle)**
- **Cultivate culture of innovation, growth, performance**
- **High Trust, Less Fear (Avoidable Failure)**

- **Appropriate risk taking and learning culture**
- **Psychological Safety**
- **Fearless Organization**
- **Compliance Leadership Skills**
- **Leading in Ambiguity**

Some pills

……in pills

- ✓ Analize market and **environment**
- ✓ Analize **company history**, «as is» and values
- ✓ Create a **compliance framework**
- ✓ Define a **compliance program** that considers all the risk phases
- ✓ Analyse and approach risk area with **same method** and **language**
- ✓ Structure a clear **map of processes**, roles and accountabilities
- ✓ Establish a connection between compliance program and **culture**
- ✓ **Communicate** well in the organization relying on a strong tone from the top
- ✓ Reinforce and implement **line monitoring**
- ✓ Working **across functions**, involving people in order to create trusthful and effective relationship
- ✓ Facilitate interfunctional communication and partnerhips

Integrity in Action

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