ORDINE DEI DOTTORI COMMERCIALISTI E DEGLI ESPERTI CONTABILI
MILANO

FONDAZIONE COMMERCIALISTI ODCEC di MILANO

SCUOLA SUPERIORE SANT'ANNA PISA

LA RESPONSABILITÀ AMMINISTRATIVA DEGLI ENTI NELLA DIMENSIONE TRANSNAZIONALE. LA COMPLIANCE, EX D.LGS. 231/2001, TRA OBBLIGO E OPPORTUNITÀ

Individuazione, Gestione e Monitoraggio dei Rischi di Compliance

A glance from the company

Avv. Giovanna Lionetti
Senior Director Ethics&Compliance, Italy, Hungary, Bulgaria, Romania, Greece

23 febbraio 2024

COMPANY FOOTPRINT

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ASTELLAS: A GLOBAL COMPANY WITH A VISION TO BENEFIT PATIENTS

CORPORATE VISION:

On the forefront of healthcare change to turn innovative science into proven value for patients

QUICK FACTS:

Formed in **2005** from the merger of Yamanouchi and Fujisawa; **headquartered in Tokyo, Japan**, with locations in **more than 70 countries worldwide**

We have a culture of **doing good** for others, putting **patients at the heart** of everything we do

Our **'Focus Area'** approach means that we approach our **drug discovery, research and development** from **multiple perspectives**

Growing expertise in **emerging areas of discovery research**, including Primary Focus areas: blindness and regeneration, genetic regulation, immuno-oncology, mitochondria biology and targeted protein degradation

Broad pipeline including focuses on oncology, women's health, infectious diseases, overactive bladder, sensorineural hearing loss, and more

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OUR ASTELLAS FOOTPRINT*

TOP 30 GLOBAL BIOPHARMA COMPANY BASED ON GLOBAL REVENUES

MORE THAN 14,500 EMPLOYEES

OPERATING IN 70 COUNTRIES WORLDWIDE

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

¥ 1,296.2 BILLION ($11.3 BILLION USD**) TOTAL SALES REVENUE FOR FISCAL YEAR ENDING 31 MARCH 2022

TARGET OF ~19% GLOBAL ANNUAL SALES REINVESTED IN R&D

* Based on Full-Year Fiscal 2021 Earnings Report
** Exchange rate: ¥ 115 to $1 USD

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PROVIDING VALUE TO STAKEHOLDERS

1. Public Administration

- Improving people's quality of life and enhancing community healthcare by creating innovative new medicines
- Improving technology level, development of healthcare industry
- Recommendations for better healthcare policy
- Participating in economic and industry associations and various external initiatives

2. Local Communities

- Social contribution activities and donations
- Environmental conservation
- Job creation
- Increasing awareness and understanding of diseases and medical care

3. Employees

- Opportunities and places for self-development
- Places, co-workers, and resources for solving social issues and contributing to the health of people around the world
- Job satisfaction
- Good working environment (work style reforms, promotion of remote work, etc.)
- Compensation

4. Business Partners

- Driving innovation and creating new value through collaborations with Astellas and integration of capabilities

5. Shareholders and Investors

- Sustainable enhancement of enterprise value
- Stable shareholder dividends
- Timely and appropriate information disclosure

6. Health Professionals

- Providing information on safety and efficacy (including promotional materials)
- Ensuring a stable and resilient supply of investigational drugs and commercialised products

7. Patients and their families

- Fulfilling unmet medical needs by creating innovative medicines and medical solutions
- Providing information on safety and efficacy
- Improving Access to Health (ATH)
- Ensuring a continuous stable supply of investigational drugs and commercialised products
- Engagement with patient organisations
- Reducing the burden on families and the entire healthcare system

8. Academia, research institutions

- Find new knowledge from research data to create scientific innovation
- Applying cutting-edge research findings to medical care
- Training researchers

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PHARMACEUTICAL LANDSCAPE AND RISKS AREAS

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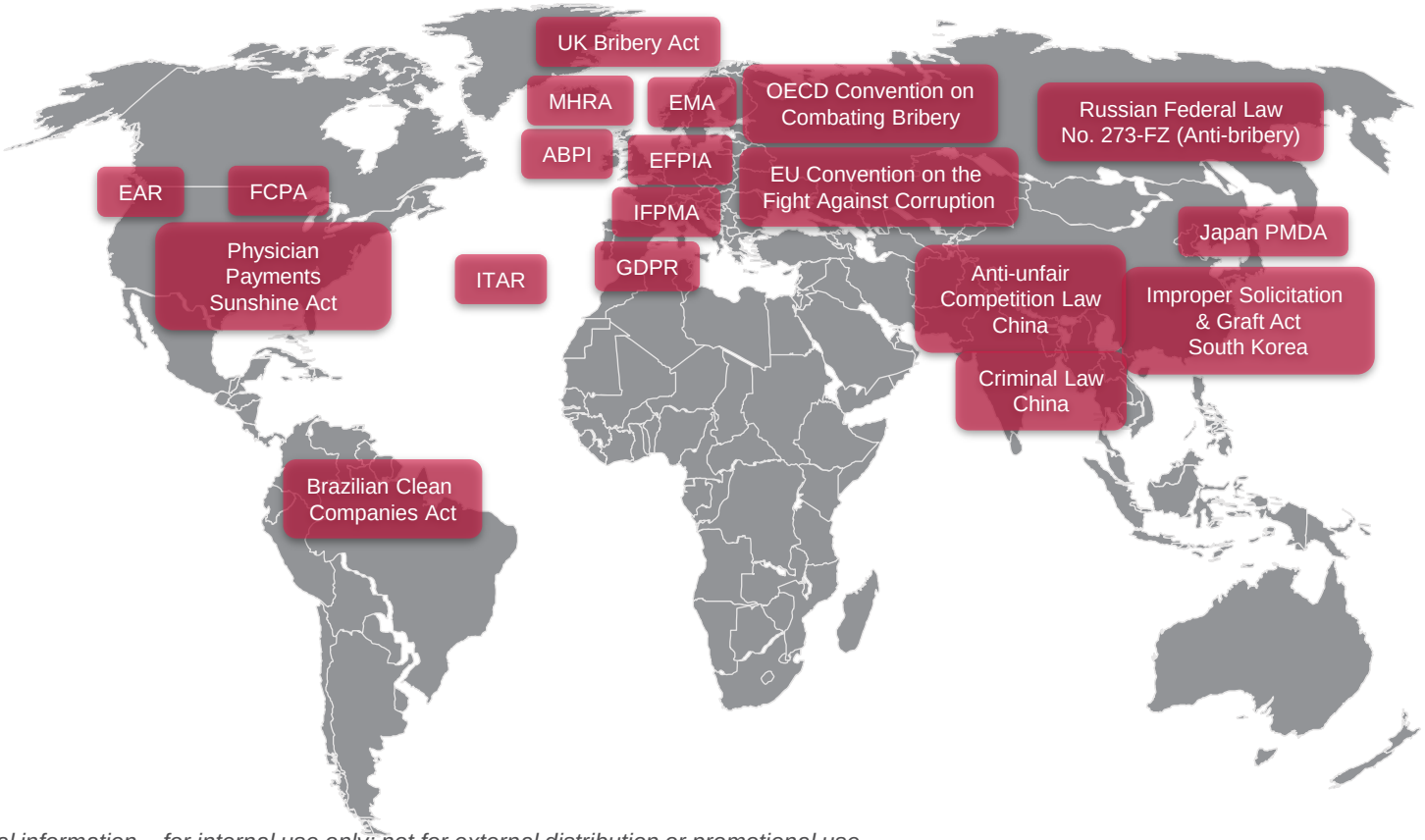
PHARMACEUTICAL REGULATIONS LANDSCAPE



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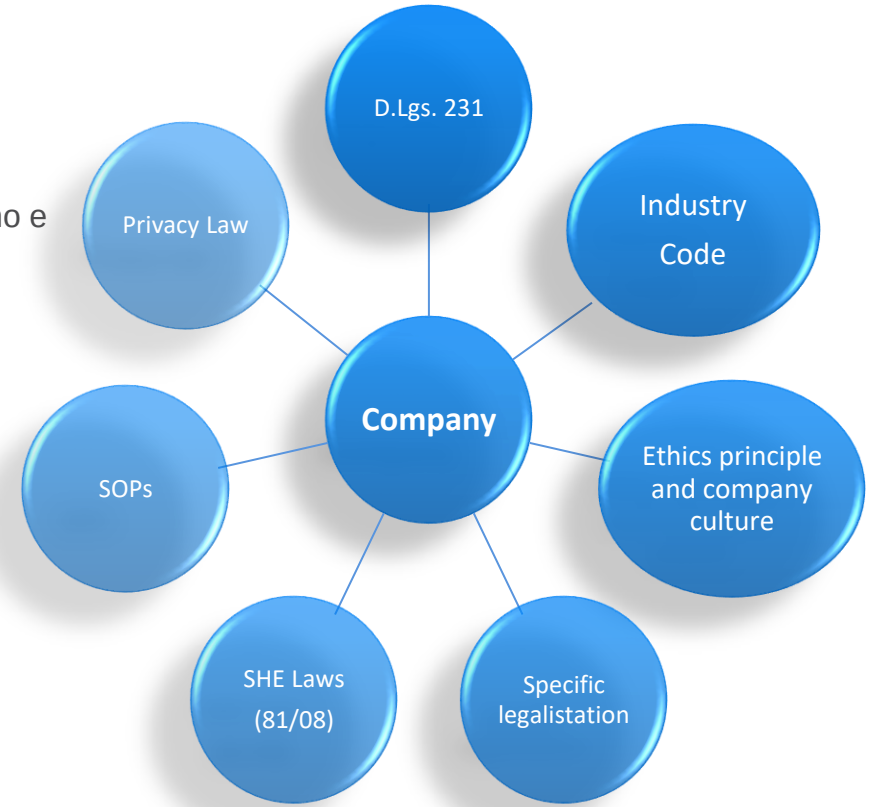
PHARMACEUTICAL REGULATIONS LANDSCAPE 2/2

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



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Date of preparation: April 2020 NON_2020_0031_APE

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UNDERSTANDING ETHICAL & COMPLIANCE RISKS

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INTEGRATED ANALYSIS OF RISKS

Business Continuity Risk	Operational Risk	Financial or Economic Risk	Reputational Risk
Supply chain disruptions Natural disasters A pandemic	Payment delays Equipment breakdowns Burdensome processes	Purchasing/Building a new plant Acquiring a company Issuing debt	Disclosure of patient information Product safety issues Labor problems

COMPANY MATURITY CURVE
KNOW YOUR HISTORY

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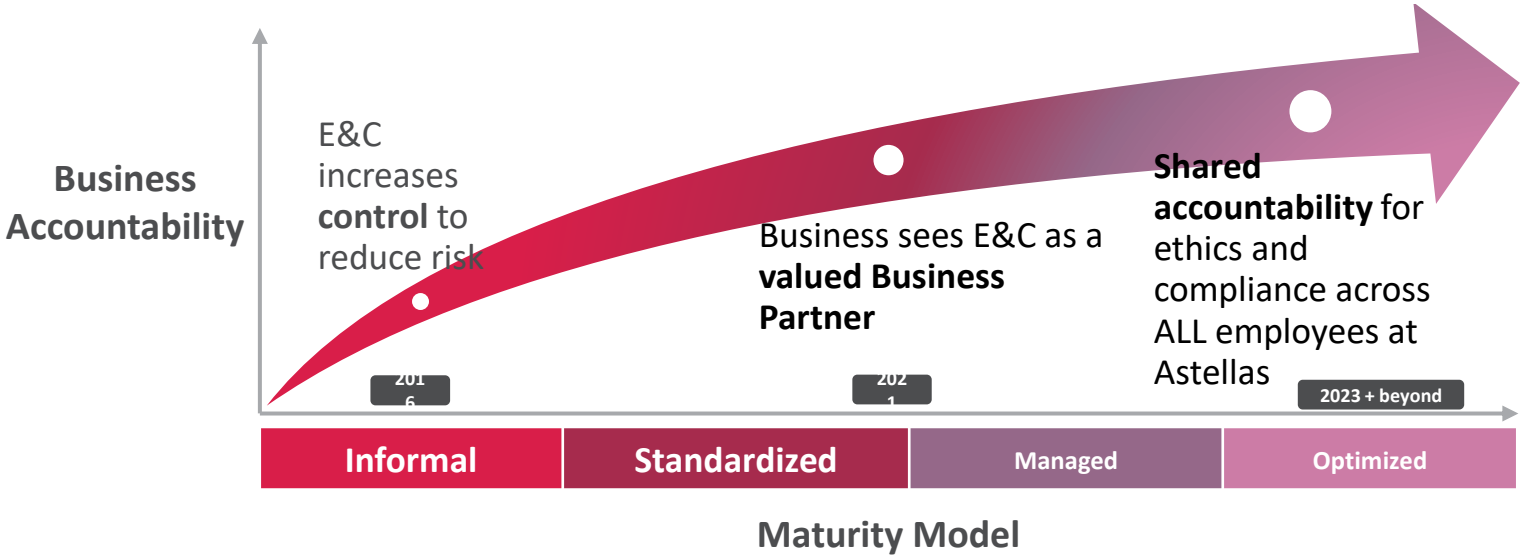
SIGNALS

- Political and social environment
- Local Regulation
- Trade Association Trend
- Financial history and growth evolution
- Policy and Procedures
- System Integration and Application of Technology
- Management and Leadership
- Company risk profile and assessment

COMPANY MATURITY CURVE

Ethical Decision-Making Continuum	E&C	Fully Accountable	Leads & Sets Standards	Partners & Facilitates	Consults & Advises
	Business	Consults & Advises	Partners & Facilitates	Leads & Sets Standards	Fully Accountable
Business Risk-Based Decision-Making Continuum		Reactive	Informal	Structured	Intelligent



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THE ROLE OF COMPLIANCE

- Inspire a **culture and mindset of accountability for compliance and integrity** across all employees
- Enable a culture of **bold, innovative, informed and balanced risk taking**
- Enhance a **culture of ethics, compliance and integrity** to sustain high performance
- Be the engine that helps the business to **drive to the right results**
- The **custodian of reputation** and compliance for the affiliate to ensure sustainability of the business
- Leader both in name to model **ethical behaviour**, **informed risk-taking, agility, and innovation**

FUNDAMENTALS OF A COMPLIANCE PROGRAM

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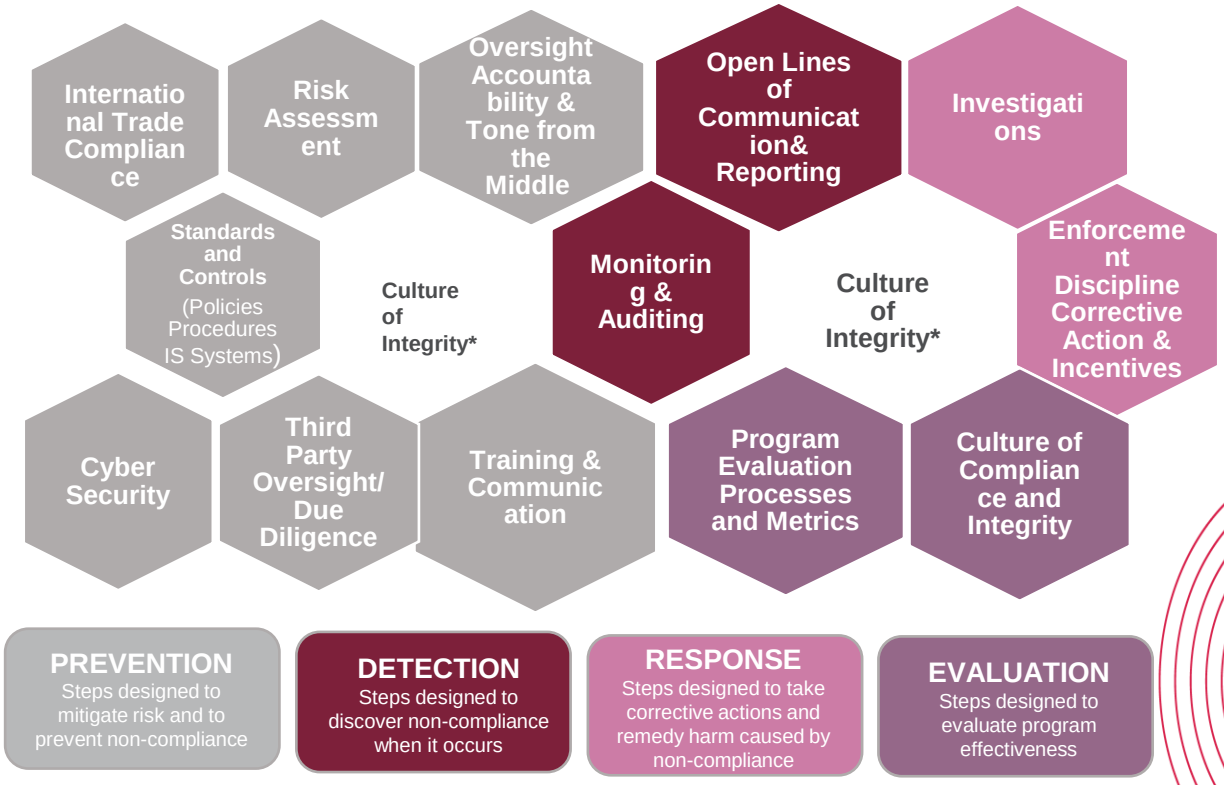
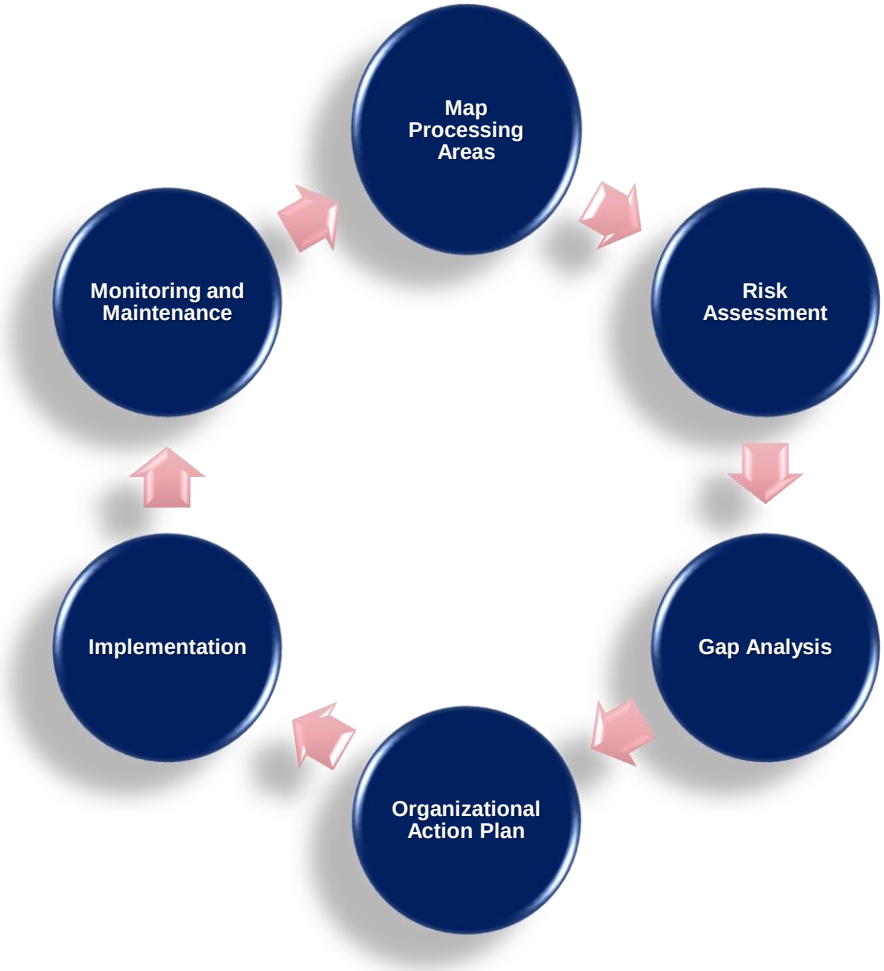
ELEMENTS OF GLOBAL ETHICS & COMPLIANCE PROGRAM



* A Culture of Integrity runs through and is interdependent with an effective Ethics & Compliance Program

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

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WHAT ABOUT CONTROLS

Funzioni interne

- Internal Audit
- Comitati aziendali
- Ethics&Compliance
- Legal/Regulatory/Quality
- Line Manager

Funzioni esterne

- Associazione di categoria
- Collegio Sindacale
- External Auditors
- Organismo di Vigilanza
- Autorità Esterne (Antitrust, Privacy, Public Contracts)

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GOVERNANCE AND COMMITTEE

Espressione del modello di business dell'azienda

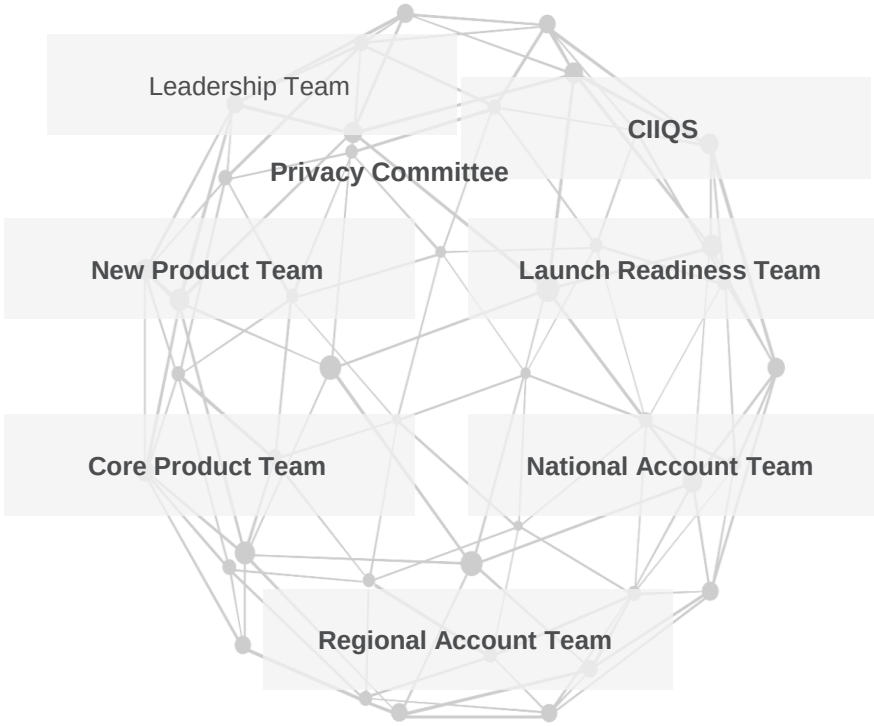
Strumento strategico di gestione delle decisioni in un contesto segregato

Funzione di indirizzo, coordinamento e controllo sotto un profilo di compliance e espressione di cross-funzionalità

Supporto alla gestione dei modelli (i.e. modello 231, modello Privacy, modello SHE)

Deleghe formalizzate

Inter-Connected Committees



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The Astellas E&C **Decision-Making Framework**

Our decision making framework to enable all Astellas employees to become accountable for making ethical and risk-based decisions and generate value for patients

Our Ethics and Compliance mindset means we:

- are curious and ask questions
- listen and confirm understanding
- are solutions-orientated
- have a positive can-do attitude
- assume good intent
- build trust, be transparent and act with integrity

PROCEED

START

E ETHICS

YES

- Does the activity align with expectations of **ETHICAL** business practices
- What is the **INTENT** behind the activity?
- What is the **PURPOSE** of the activity?
- What are we trying to **ACHIEVE**?
- What does **SUCCESS** look like?

V VALUE

YES

- How can **VALUE** to the patient be achieved in an ethical and compliant way?
- Does it bring **VALUE** and comply with local laws and regulations, our Code of Conduct and company policy?
- Is this activity aligned with the Astellas Way?

R RISK

- **IDENTIFY RISK** by considering the SPOC* questions first
- Can the risk be appropriately **MITIGATED**?
- Can we **ACCEPT** the risk?
- Are the risks significant which require further **ADVICE**?
- If risk cannot be mitigated nor accepted, or further advice is required, speak to a subject matter expert, peer group, or **ESCALATE** for advice

If circumstances change refer back to this framework

*see Risk Identification Model (SPOC)

SPOC – Key Questions to Consider

Astellas adhere to all relevant laws, regulations and Codes – we do not compromise on this!

S – SAFETY - PATIENT

- Will any of our activities adversely impact the safety of patients taking our medicines?
- Are there any concerns regarding unsubstantiated claims?
- Are there any concerns regarding the planned activities in terms of engagement with patients / POs?

P – PRIVACY - DATA

- Are we collecting and using the minimum amount of personal information, and will it be properly stored?
- Have we provided notice or collected consent (where required) from the impacted individuals?
- Will this involve sensitive, personal information or will personal information be transferred outside its country of origin?

P – PERCEPTION

- Does this activity pass the 'red face' test? If the details were made public, could it bring into question the company's reputation?
- Are activities communicated internally and externally, ensuring intent is transparent and clear?
- Are there any Conflicts of Interest (perceived/actual?)

P – PROMOTION

- Does the promotion meet the high standards required by the relevant regulations, Codes and laws including internal approval processes?
- Could this activity imply or create a perception around promotion to the public?
- Do the planned activities fit with all relevant Astellas policies?

O – OFF LABEL / PRE-LICENSE PROMOTION

- Have you looked at all activities in their entirety to ensure there is not a negative perception?
- Has sufficient consideration to other activities taken place in parallel?

C – CORRUPTION

- Have we taken all appropriate actions to ensure that there are no concerns?
- Have you completed the Due Diligence, when needed?
- Have we applied Fair Market Value? Do we have robust documentation?
- Are there considerations from an ABAC perspective that should be addressed?
- Transfer of Value Considerations – are they appropriate and have we met regulatory / transparency requirements?

C – COMPETITION

- Does the activity involve any other pharmaceutical companies ? If so, what are we doing to safe guard sensitive and/or confidential information?
- Are there any considerations regarding anti-competition law that we need to apply?
- Is there are any history/information suggesting this activity could generate a potential Code complaint?

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SPEAK-UP CULTURE

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When something doesn't feel right, Speak Up

A guide on how to raise concerns

Speaking up is not about getting other people into trouble. If something does not feel right, even if it's just a suspicion, report it. It might be that no compliance violation has taken place – but we'd rather be aware and able to look into it – then at least we know for sure.

You can raise concerns about anything in good faith, regardless of whether it happened to you personally, you observed it or were only told about it. Astellas strictly prohibits retaliation or retribution against anyone who, in good faith, raises a concern about compliance issues or cooperates in an investigation, even if such concerns or allegations are ultimately found to be mistaken or unsubstantiated.

We can all play our part

It's important we are all ready to call out non-compliant or unethical behaviour or business practices. This includes anything that goes against:

- the Astellas Group Code of Conduct
- any of Astellas's policies and procedures
- any applicable laws, regulations or industry codes

Don't leave it to others to report concerns. Even if you think someone else might have raised an issue, your information may help us gain a more complete picture of what happened. We'd rather hear multiple reports of the same issue, than never hear anything at all.

And if what you tell us needs to be dealt with elsewhere, we'll pass it on to the right team.

How to raise a Speak Up concern

1 Arrange to talk to someone

Your manager is there to listen to your concerns. They'll find a safe, quiet space for you to talk.

Here's some ways to structure your conversation:

- "Can we set up some time to speak privately about something I'm worried about?"
- "I would like to share something that doesn't feel right. Do you have time to speak with me in private?"
- "I'm concerned about something that I need to share with you."

If you're worried about speaking to them, speak to a more senior manager. You can contact the Ethics & Compliance or HR Team or use the Astellas Hotline – EthicsPoint. Calls are not recorded and Astellas cannot identify the reporter if you choose to remain anonymous.

2 Explain your concern

You don't need to know everything about the issue before you report it. Just share the information you do know. Explain what "feels wrong" or what you have heard or seen.

Here's some ways to structure your conversation:

- "This happened on…and has been going on for…I became aware of this when…"
- "This occurred at…" and "…was a witness to this"
- "I heard something that does not feel right."

Your manager will ask if you are comfortable speaking to Ethics & Compliance directly, and if you are not, then they can report the matter on your behalf. Alternatively, you can also share your concern through the Astellas Hotline – EthicsPoint, where you will receive a key code to receive updates on your report.

While there is always the option to report your concerns anonymously (where local law permits), we encourage you to provide your details, and your identity will be kept confidential on a need-to-know basis.

3 How your concerns will be handled

Your report will be treated confidentially. Once you've raised your concerns, you shouldn't discuss it with anyone else. This allows E&C to look into the issue in a fair and objective way.

If you've provided your details, the E&C team might get in touch to ask further questions. The team is multi-lingual, but if necessary, they can also provide an interpreter to support you.

E&C will review the matter and will investigate or take other appropriate action to resolve the problem. That can be anything from a bit of extra training, changes to processes, or coaching. It's not just about formal action.

Why it matters

Speaking up is one of the most important things you can do to help maintain our ethical and compliant culture.

You are in a unique position to make Astellas aware of potential issues at the earliest opportunity. When you do that, we can take appropriate steps to prevent misconduct or stop it as soon as possible. So, if you think something is happening that isn't right, say something straight away.

For more information, refer to the Astellas Group Code of Conduct. You can find other important information on the Ethics & Compliance Global Site.

Integrity in Action

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