

AIMS

- To unearth possible flaws in the ToV control system
- To define refinements in order to improve SOPs and operational practices
- To suggest the best methods of data collection for Transparency purposes

DURATION

3-4 weeks

EFFORT

3 sessions

HOW IT WORKS

1 STANDARDIZATION

We have defined a standard in cataloging the types of activities performed by a company, the questions asked during the audit phase and the mandatory regulatory obligations that we use to cross-check the company's procedures; we also rely on a standard matrix for the evaluation of the Audit. This makes the Sunshine Assessment reproducible and not subject to forgetfulness or errors.



2 COMPLIANCE DATABASE

The 150 mandatory regulatory obligations extracted from around 20 laws, decrees and ethical codes make up a database that allows us to be always up to date and to integrate company SOPs with agile regulatory checklists to support the approval phases.



3 REPORT

The Assessment Report is a volume of about 30 pages containing an introduction to the legislation and to the project, the analysis of SOPs, the results of Audit and the conclusions and final suggestions.



ROADMAP

KICK OFF MEETING

- Project presentation
- Briefing about methods and tools
- Setting up the work team

1

ACTIVITIES SELECTION

- Cataloging of business activities that involve transfers of value
- Collection of SOPs concerning Healthcare Compliance

2

3

FACE TO FACE AUDIT

Different company positions are interviewed using 50 guiding questions with the objective of assessing the level of data sharing and availability as well as the degree of compliance-assurance within the different roles in the company

4

5

SOP ANALYSIS

Conformity check of procedures by cross-checking with more than 150 mandatory obligations extracted from more than 20 applicable Italian laws, decrees and ethical codes

TOV MANAGEMENT

- Analysis of data management systems (CRM, ERP, Expense Report,...)
- Definition of tools and methods for collecting transparency data

6

7

SUNSHINE REPORT

The Sunshine Report is a snapshot of both the company's ability of being capable of tracking transfers of value and the adherence to legal requirements of its procedures and its operational standards; the report also expresses recommendations useful to achieve Sunshine Readiness whenever gaps are detected

POSSIBLE FOLLOW-UP: SOPs REVIEW ROUNDTABLE

- Standardization of existing SOPs
- Workflow and Compliance Checklist
- Drafting of new SOPs
- Training