



Choosing a Country Compliance Officer in Central Eastern Europe

Tomasz Kruk, LLM, MBA, Director Global Ethics & Compliance

6th International Pharmaceutical, Regulatory and Compliance Congress
Budapest, May 15th 2012

Elements of effective compliance program



Sources:

1. The US Sentencing Commission - Guidelines Manual, Chapter 8 Sentencing of Organizations, Part B Remedying Harm from Criminal Conduct, and Effective Compliance and Ethics Program
2. Compliance Program Guidance for Pharmaceutical Manufacturers developed by the Office of Inspector General (OIG).
3. Good Practice Guidance on Internal Controls, Ethics, and Compliance Adopted 18 February 2010 by the OECD Council
4. CORPORATE COMPLIANCE PROGRAM is a part of the Nov. 2010 PROSECUTION AGREEMENTS: United States vs. Panalpina Inc.: Plea Agreement or United States vs. Shell: Deferred Prosecution Agreement
5. Consultation on guidance about commercial organizations preventing bribery (section 9 of the Bribery Act 2010) Consultation Paper CP11/10 This consultation begins on 14 September 2010 This consultation ends on 8 November 2010

Central Eastern Europe and its pharmaceutical market



- Underfunded public healthcare systems.
- Low income of HCPs'.
- “Branded generics market” - generic drugs require solid sales forces.
- Generic medicines represent approx ½ of the total CEE pharmaceutical market in value and almost ¾ in volume.
- CEE pharmaceutical market worth over USD 60 billion (and by 2016 is expected up to over USD 100 billion).

Importance of a Country Compliance Officer



- Required local element of an effective corporate compliance program.
- Accountable for day-to-day compliance at the country level.
- Particularly important in case of countries with:
 - large, diverse sales forces,
 - a difficult regulatory environment,
 - a history of non-compliance within country operations,
 - high corruption in the country (real or perceived).

The ideal candidate?

Q's

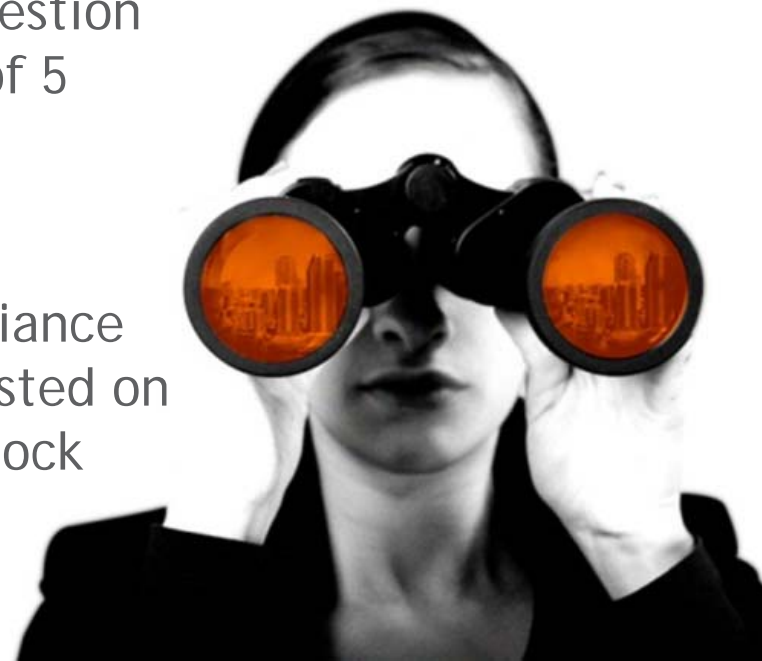
- Education:
- Previous industry:
- Previous employer:
- Years of professional experience:
- Soft skills:
- Most important area of responsibility:

A's

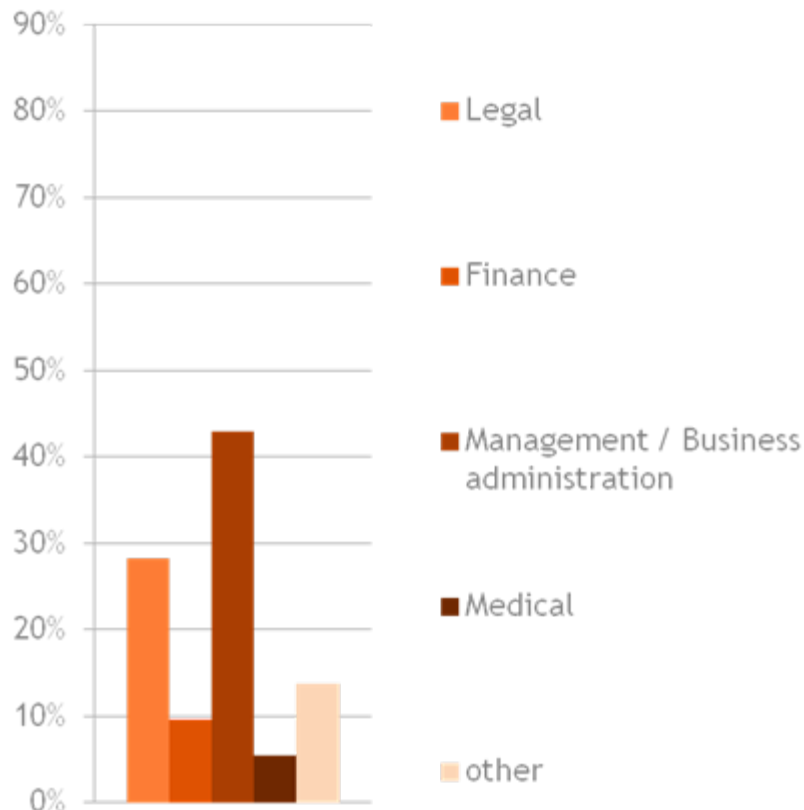
- Legal
- Pharmaceutical
- Multinational company
- 5+ years
- Self-starter
- Enforcing the country compliance program

Survey

- Key objective:
 - To define characteristics of the ideal country compliance officer (or manager, director, liaison) in CEE region.
- Methodology:
 - Structured questions – i.e. for every question respondents were offered a closed set of 5 responses from which to choose.
- Respondents:
 - 6 compliance VP's and 6 regional compliance directors for multinational companies listed on NYSE, NASDAQ, EURONEXT, Frankfurt Stock Exchange, Tokyo Stock Exchange.



Education



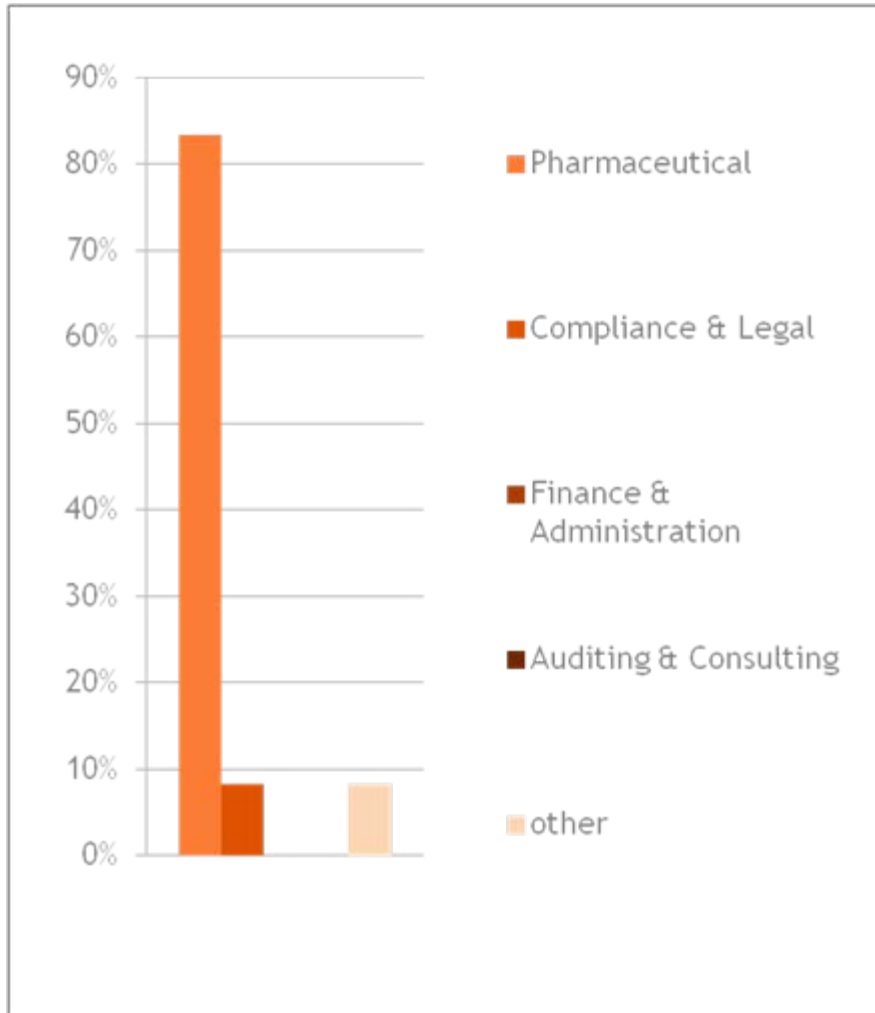
Interesting comments:

"People ask me all the time what classes they should take to be a CCO. CCO is the one job where on the job training is the best path."

"... some of my better compliance officers have come up through the company in sales or even medical secretaries!"

"Education in legal, finance, medical, or management are all appropriate; professional experience in the pharma industry and knowledge of the laws and regulation is key."

Previous industry

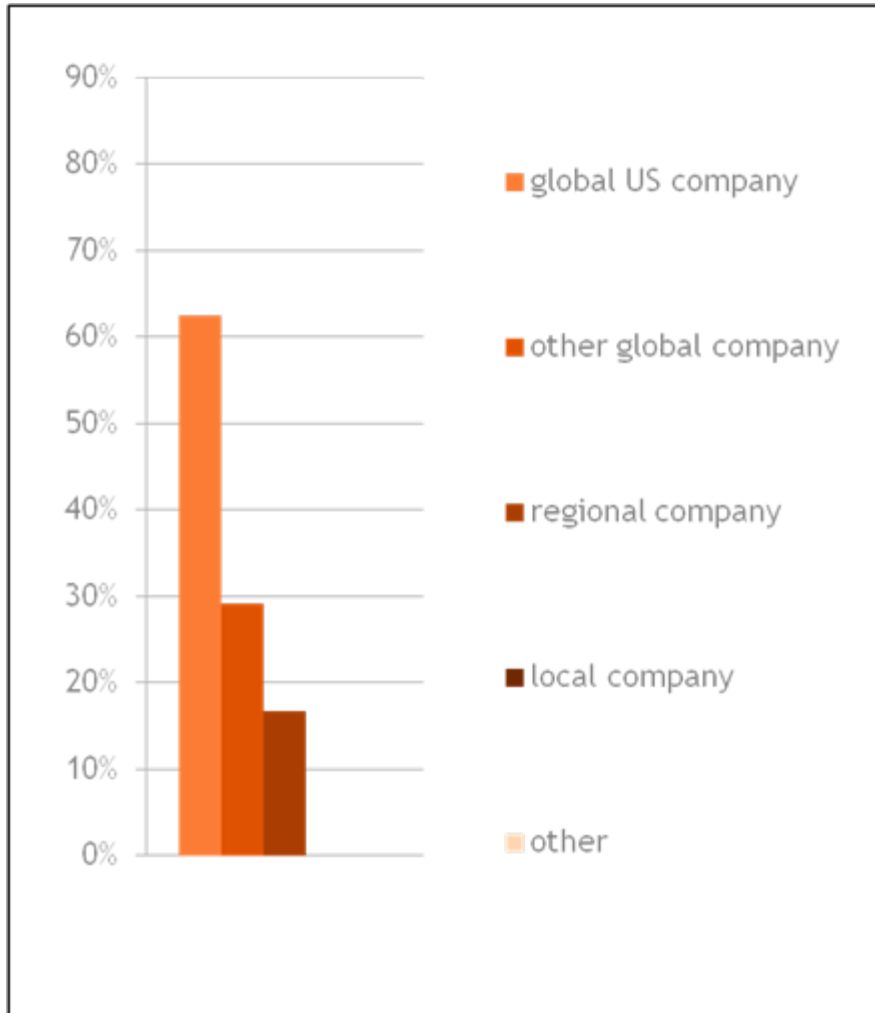


Interesting comments:

"Pls avoid Legal as they have different legal approach and attitude than real compliance officers"

"sales and marketing experience is also beneficial"

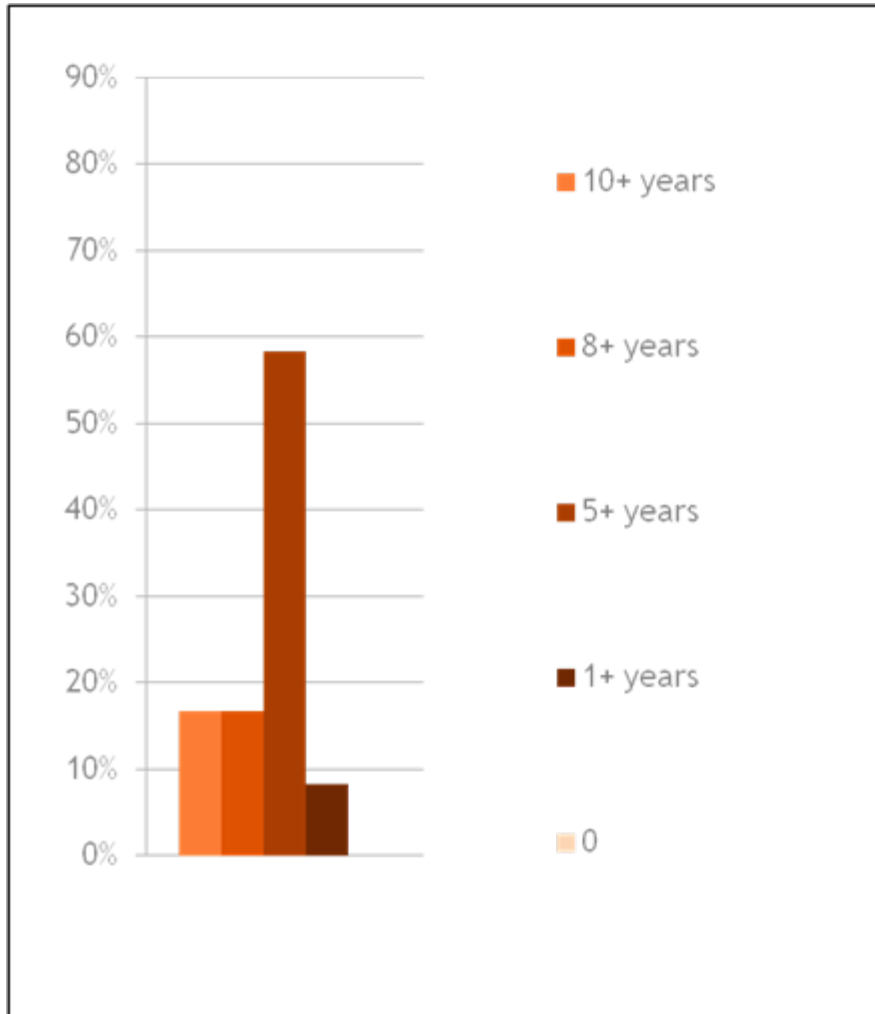
Previous employer



Interesting comments:

"Generally, I look for folks who have experience with a multinational Pharma (I see no difference between Pfizer and Novartis)."

Years of professional experience

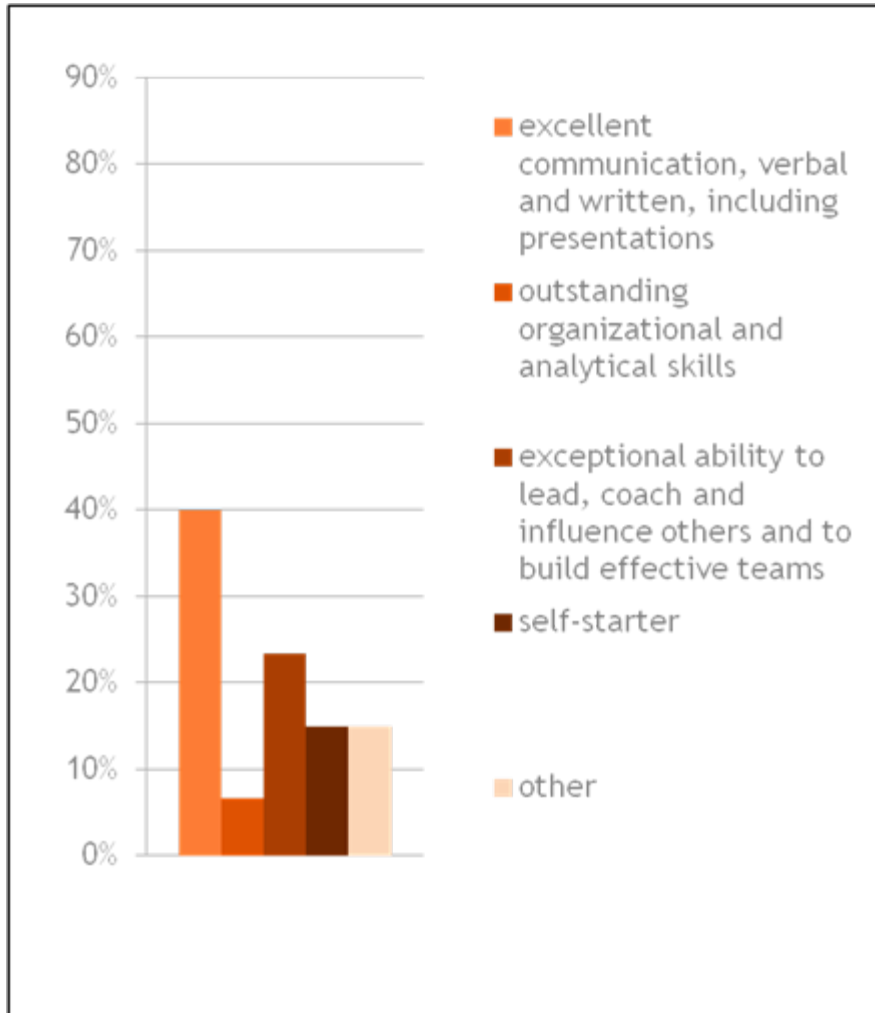


Interesting comments:

"5+ years for a leadership position in compliance"

"8+ years (years in pharma not years in compliance)"

Soft skills



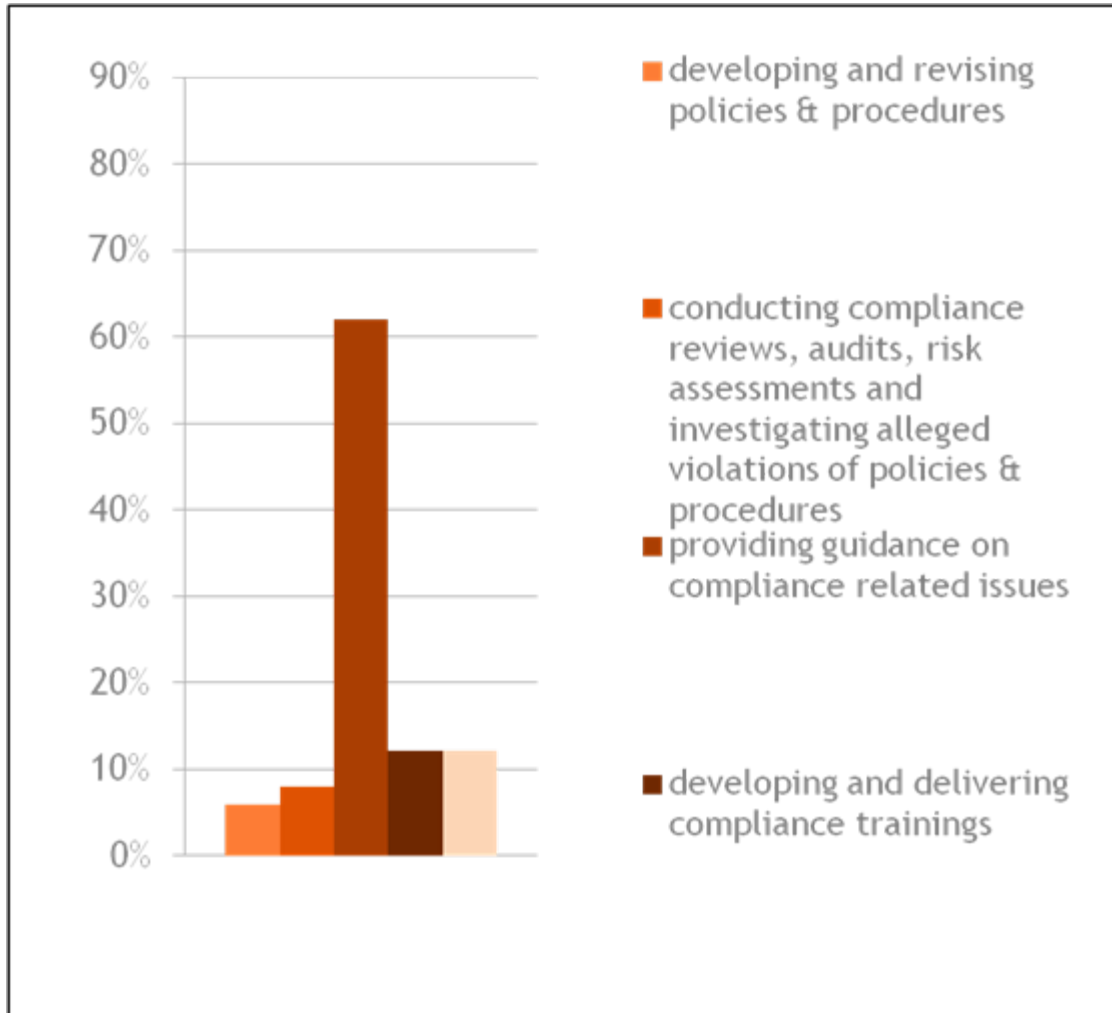
Interesting comments:

"All of the above. A good compliance officer needs to be well rounded and know the business very well."

"Sense of humor"

"... along with problem-solving and listening skills."

Most important area of responsibility



Interesting comments:

"I want the business to ask lots of questions and seek guidance from compliance, so I selected providing guidance."

Summary:

Q's

- Education:
- Previous industry:
- Previous employer:
- Years of professional experience:
- Soft skills:
- Most important area of responsibility:

A's

- Management / Business Administration (43%)
- Pharmaceutical (83%)
- Global US company (63%)
- 5+ years (58%)
- Excellent communication, verbal & written incl. presentations (40%)
- Providing guidance on compliance related issues (62%)

The ideal Country Compliance Officer*



- Mature, positive, energetic, self-starter, practical who can solve problems (if challenged by hard issues - doesn't run away), a role model in business ethics, able to work in a team.
- Understands legal and financial implications of business decisions and help simplify business process.
- Has the respect of country senior management but be able to say "no" when necessary.
- Knowledgeable of the culture of the country / countries in scope of responsibility.

** This definition is the combination of responders' responses describing their ideal candidate for a country compliance officer.*

Questions?



Thank you!

