

Navigating the Compliance Landscape

如何做好合规性

MATHIAS POSCH

I A P C O  
EDUCATION

BESPOKE  
EDGE  
SUZHOU MICE

# Corporate Compliance 公司合规



## Definition:

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The act or process of complying to a proposal or regimen; conformity in fulfilling official requirements, such as specifications, policy, standard, or law.

A close-up photograph of a person's hands filling out a form. The person is using a silver pen to write in a field. The form has several columns and rows, with some fields already filled with blue ink. A green semi-transparent box is overlaid on the top right of the image, containing the title text. In the background, a blue mobile phone is visible on the left, and a black circular object, possibly a pen holder, is on the bottom left.

# Compliance and PCOs 合规与PCOS

More and more PCOs when organising corporate events need to act on behalf of the client according to certain accepted standards.

# The PCO's role PCO 所扮演的角色

## Meetings Management

## Industry Support for meetings

Understand the regulations within the company or industry that impact what you can do and how

Understand and educate yourself about the regulations of the industry that supports the meeting/should support. There are company and industry-specific regulations

# Risks 风险

Risks associated to non-compliance have grown dramatically and we as PCOs must take all measures to strictly comply with the relevant laws and legislations of our clients.

# Non compliance is not an option

## 不合规已不再是一个选择

- 490m USD fine by China
- Jail time for Executives
- GSK Drug Sales dropped by 61% in China





# Questions 问题

- What does the corporate compliance involve when organising events?
- How do we know that the code and its application for the event are understood by our team?
- Are there adequate and effective information and communication controls in place in our team?
- Have we established internal management methods to follow the compliance procedures?

# Compliance and Events

## 合规与会议

- Budget management
- Contract management
- Financial and General reporting
- Supplier management
- Closure of accounts and invoicing
- Data privacy
- Survey, administration and reporting

**In fulfilling these obligations the PCO should not take any discretionary power or judgement.**



# Governmental Meetings and Conferences 政府会议 和大会

- Strict guidelines and “codes” on various levels
  - National
  - European Union
  - International (WHO, UN,...)
- These guidelines can pertain to
  - Environment
  - Ethical Business Practice
  - Protocol
  - Spending Limitations
  - Often political (\$ 4 Dollar/shrimp spending)



## **The Daily Show with Jon Stewart**

**Roasts Obama GSA Officials for Wasteful Spending,  
Refusing to Be Held Accountable for Vegas Bash**

Comedy Central  
April 18, 2012

# Non Pharma Associations/ Industry Conferences 非药 学协会 / 行业会议

- More scrutiny also in other industries
- Conflict of Interest is a huge concern and should be considered by the PCO when working on Sponsorship, etc.
- Other industries include: Legal, Financial, Business, etc.
- Ethical Practices and Environment
- Cater to the Conference and embrace the topic
  - E.g. Conference on Quality Management: You better have your QM in place and apply it at every step
  - Conference for International Auditors: Make sure all books are audited by a reputable company
- Question: Can a law firm sponsor a judge's conference?
- Don't assume, have frank but respectful conversations
- Don't show any kind of opinion

# Corporate Meetings 公司会议

- In addition to industry standards and codes, company specific regulations come into play
- Be sure to ask and educate yourself as some companies do these meetings „on the fly“ and are not always forthcoming with information
- → Have a compliance check list of questions including environmental and ethical guideline questions as well as questions about spending limits and guidelines (Hotel categories, travel,...)
- No 2 companies are the same – discretion is key!



# Union Conferences 工会会议

- Similar to government: Can have very strict guidelines
- Follow all guidelines and clarify
- Be aware of sensitivities of the group (labour laws, use of unionized property,...)
- Often not very organized internally or up to date (Questionnaire is helpful)
- Don't assume and be too independent in your decisions (Ex: Missing chair person)

# Helpful Tips 提示

- Understand the client's compliance and needs
- Read the contract and regulations carefully
- Summarise the main points and give it to your team members
- Brief your team and continuously brief new staff
- Prepare checklists
- Work strictly with your accounting department
- Do not hide mistakes, be sure to inform the client

“Compliance starts with understanding  
and understanding starts with cultural  
awareness and competence”



# The Pharmaceutical Industry 制药业



# Development of a New Pharmaceutical Product

## 新药品的开发



*No. of molecules / No. of patients*

# Other Hurdles 其他的障碍

**receiving  
reimbursement**  
= economic price

**negative press**  
= industry &  
product

**price fall**  
= generics /  
health care  
savings

**Preclinical Research**  
(5-8 years)

**Phase I**  
(1-2 years)

**Phase II**  
(2-3 years)

**Phase III**  
(3-4 years)

**Post-  
Marketing**

# Why Compliance 为何要合规

## Acceptable

- In line with your values
- Legal
- Legitimate business need
- Modest
- Appropriate
- Fair market value
- Patient benefit
- Perceived to be acceptable

## Questionable

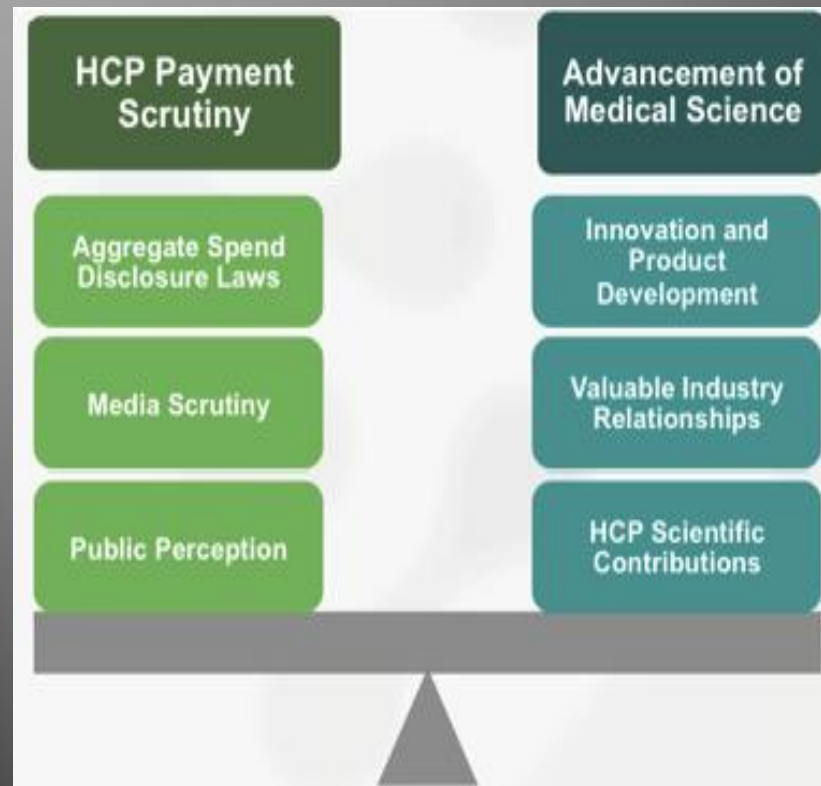
- What you can't explain
- What you can't defend
- What is not or poorly regulated
- Common practice, not in line with values or codes
- Common practice due to lack of enforcement
- Complex activity with all of the above

## Beyond

- What puts the patient at risk
- Wrong intent
- Illegal
- Against your values
- Not in line with industry code or regulations
- Extravagant

# Why Compliance 为何要合规

## Balancing the interests





# Pharma Compliance 药业合规

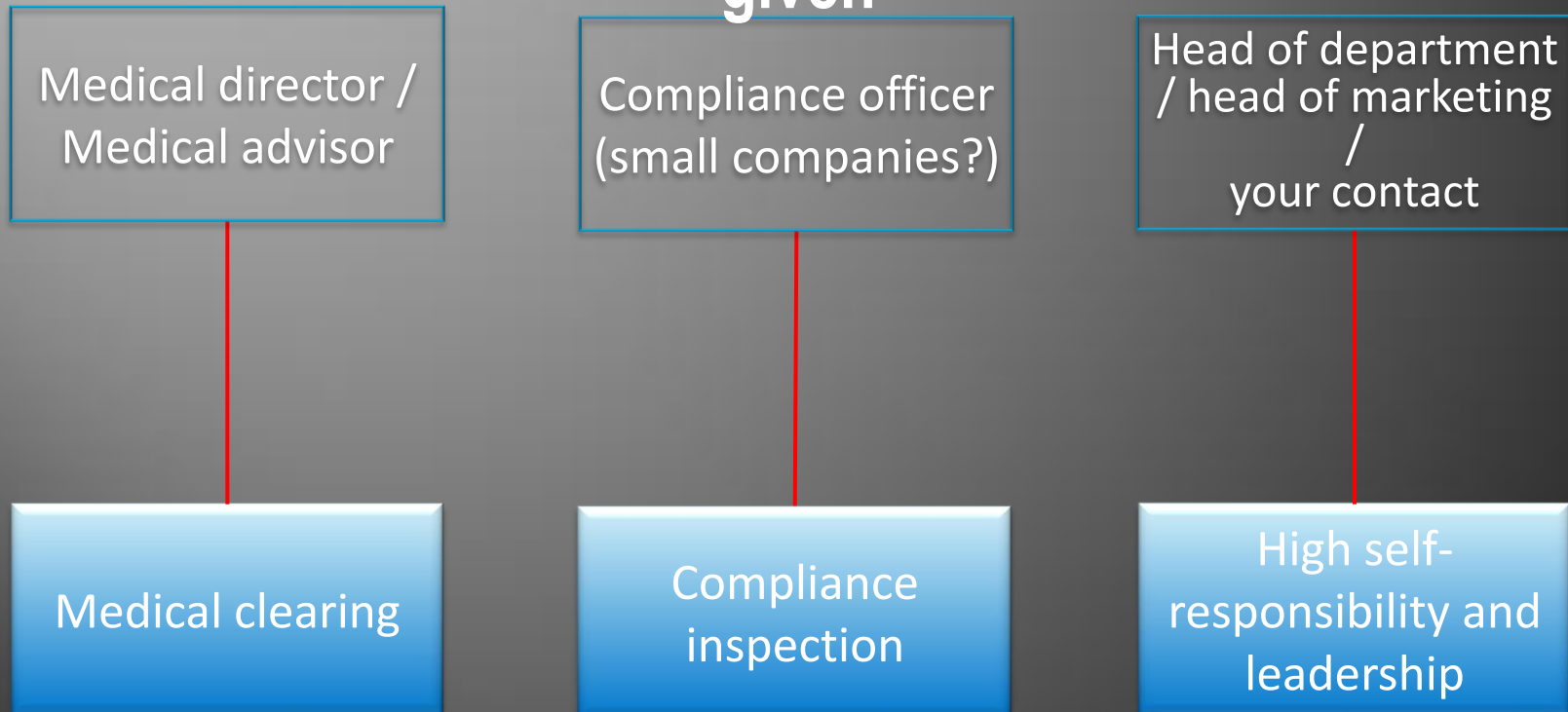
## Local Situation 当地的具体情况



# Pharma Compliance 药业合规

## Local Stakeholders 当地利益相关者

double-check if customer-internal approvals have all been  
given



Compliance

=

Rules

+

Adheren  
ce

# Rules 规则



**Law**

**Codes  
(Industry Codes)**

**Company  
regulations**

■ **International  
(e.g. FCPA)**

■ **International  
(e.g. IFPMA,  
EFPIA)**

**Might impose  
more stringent  
requirements**

■ **National**

■ **National**

**Pharmaceutical and  
Device Industry**

*Codes  
Sponsorship  
Funding*





# Adherence 遵守



David Brennan,  
then CEO of  
ASTRAZENECA  
"we will no  
longer pay for  
doctors to  
attend  
international  
scientific and  
medical  
congresses"

# Adherence 遵守



2013:  
Glaxo Smith  
Kline (GSK)  
announces to no  
longer sponsor  
doctors for any  
medical  
conferences (no  
flight, hotel or  
registration)

# Compliant Support 合规支持

- Is “Sponsorship” a dirty word?
- What Sponsorship/Exhibition Items are compliant and which ones aren't?

# Gala Dinner? 庆祝晚宴?





# Coffee Breaks? 茶歇？



# Conference Bags? 会议袋?





# Abstract USB Stick? 放摘要的U盘?



# Virtual Meeting? 虚拟会议?

International Association for the Study of Lung Cancer

# IASLC

15th World Conference on Lung Cancer  
October 27 - October 30, 2013  
Sydney, Australia  
WCLC.IASLC.ORG

Create account Username Password Login Forgot Password?

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Sessions by DaySessions by TypeTitlesTopicsAuthors

Click on "Add" to add session or abstract to your itinerary. Items added will show in the itinerary tab to the right.

## All days

Sunday | Monday | Tuesday | Wednesday | All Days

☐ [C | Inaugural Cochrane Workshop](#)  
Other Sessions: Sunday, October 27, 7:30 AM - 12:00 PM, Bayside 204 A+B, Level 2

☐ [CALC | Chinese Alliance Against Lung Cancer Session](#)  
Other Sessions: Sunday, October 27, 7:30 AM - 12:00 PM, Parkside Auditorium, Level 1

☐ [Y | Young Investigator & First Time Attendee Session](#)  
Other Sessions: Sunday, October 27, 8:00 AM - 11:30 AM, Parkside Ballroom A+B, Level 1

☐ [Addiction Incorporated \(Documentary Screening\)](#)  
Other Sessions: Sunday, October 27, 10:00 AM - 12:00 PM, Bayside Auditorium B, Level 1

☐ [Abbott Hands On Training Session: Molecular Diagnosis of Gene Fusions by FISH for Targeted Therapy](#)

Itinerary

All  
None When/Where

Titles/Authors

Remove selected

# Luggage Tags? 行李标签?



# Exhibit Booths? 展位?





# Satellite Symposia?

## 卫星专题讨论会?



CME/Non  
CME?

# What to do now? 现在该如何做呢？

## 1. Analysis – what do we know?

- Companies need access to doctors and medical professionals
- Conferences, Ad Boards, Meetings,... are an excellent way to foster relationships in a PROFESSIONAL atmosphere
- Doctors will need the support from Pharma to start and continue research projects
- Conferences can't survive without financial support from sponsors



# What to do now? 现在该如何做呢?

## 2. Analysis: what are the issues?

- Public and official scrutiny on Pharma spending and doctors receiving funds (directly or indirectly) has never been stronger
- As a result there are more (self-imposed) regulations than ever
- The medical education and research system is built on strong support by companies and can't sustain itself in the current form without these funds

# What to do now? 现在该如何做呢?

## 3. Evaluate and plan: What must be done?

- The Pharmaceutical industry needs to find a proper new marketing strategy or fix the “old one” instead of just acting reactive
- Conference Organizer need to be aware of the new reality and find new finance models
- Keep education and research in the focus of everything you do when it comes to conferences/meetings, etc

# What to do now? 现在该如何做呢？

## 4. Practical tips

- Have a very open dialogue with your contacts at Pharmaceutical companies on what can/should be done
- Be aware of the decision processes and who you should be in touch with and who/when not (legal, grant application reviews,...)
- Take nothing for granted and be flexible/open
- Adjust budgets to allow for cuts in case funding is reduced

# Final “wise words” 最后的“经验之谈”

- In order to be successful in today's conference market we need to finally leave the idea that we are “logistics providers” behind us and be AWARE of the market and its developments at all times. The Key to success is to
  - Educate
  - Communicate
  - Innovate