

Think Global, Act Local – Lessons Learned in a Global Compliance Experience

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Global Code of Business Conduct



Respect for People – Open Communication is Key

Translate materials into the local language

- translated the Code into 13 different languages
- toll free phone numbers for the Helpline for every major country

Language

Please confirm the language you wish to use when taking this CBT:

- 浏览(浏览站汉语版)
- Prohlédnout si tuto stránku pro školení v češtině
- Bekijk deze cursussite van _____ in het Nederlands
- View this training site in English
- Visualiser le site de formation de _____ en français
- Diese Training-Site auf Deutsch anzeigen
- Visualizza questo sito di addestramento di _____ in italiano
- このガイダントレーニングサイトを日本語で見る
- 이 교육 사이트를 한국어로 보기
- Visite esse site de treinamento da _____ em português (Brasil)
- Visualizar este sitio de formação _____ em português (Europa)
- Ver este sitio de formación _____ en español (Europa)
- Ver este sitio de formación _____ en español (Puerto Rico)
- ขอดูเว็บไซต์การอบรมของไกแดนท์ (_____) เป็นภาษาไทย

The language you have chosen will appear like this:

View this _____ training site in English

Exit OK

International Dialing Instructions

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Argentina	0800-555-4288
Australia	1-800-551-155
Austria	0800-200-288
Belgium	0-800-100-10
Brazil	0800-890-0288
Canada	1-800-225-5288
China	10811
Denmark	8001-0010
France	0800-99-00-11
Germany	0800-2255-288
Hong Kong	800-96-1111
India	000-117
Ireland	1-800-550-000
Italy	800-172-444
Japan	005-39-111
The Netherlands	0-800-022-9111
New Zealand	000-911
Singapore	800-0111-111
Spain	900-99-00-11
Sweden	020-799-111

1. Obtain an outside line.
2. From this list, enter the access number for your country.
3. When asked, dial 800-988-2471.
4. You will be connected with the _____ Helpline. Simultaneous interpreter service is available.

CODE OF BUSINESS CONDUCT

Topic 9:
Summary & Certification

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➤ Translation of “complaint” in a complaint handling training

Lesson 1: Recognizing Product Experiences

Screen 3 of 13

Product Experience Handling

Regulators worldwide require manufacturers to implement programs to monitor the performance of their products once released for distribution. These regulations are known by many different names, but we refer to this program as Product Experience Handling.

Many of you will be familiar with this program, but may recognize it as Complaint Handling or Complaint Vigilance. The name has recently changed to convey the message that to be in compliance with all relevant post-market monitoring regulations, we are required to capture more than just situations where a person actively complains about a product.



Click Next to continue.

Product Experience Handling

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Lesson 5: The Regulatory Environment

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Regulatory Reporting Requirements

Many regulatory authorities require reports of product experiences that occur within their borders. Some of the geographies include:

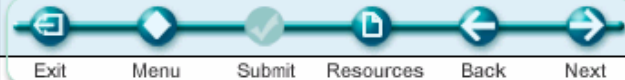
- Australia
- Canada
- China
- European Economic Area Countries
- Israel
- Japan
- United States

The regulatory environment constantly changes as more countries adopt reporting systems such as these.



Click Next to continue.

Product Experience Handling



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Respect for People – Open Communication is Key

- How you present information; can also have different cultural reactions



Respect for People – Open Communication is Key

- Power of live conversations and personal relationships
- Boston Scientific met with people locally or traveled to their location
 - Live summit meetings
 - Monthly phone calls
- These live connections opened doors for Boston Scientific in terms of finding out what the local issues were, and allowed us to connect people or raise awareness of different compliance issues



Keep current on changing requirements

- Participation in GHTF
- International legal team and compliance teams are watching for new or evolving requirements and standards
- Local “eyes and ears” are the compliance/quality connections within the geography



Separate International Customer Relationship Policy
to meet the global needs



International Customer Relationship Policy



U.S. Customer Relationship Policy

Legal/Compliance Obligations

- BSC provides procedures and a Toolkit customized to local requirements to ensure compliance with local laws and regulations



SPONSORSHIP TOOLKIT FOR SWITZERLAND

[previous page](#)

By clicking on the icons hereunder, the system will take you directly to the appropriate toolkit.

1 SPONSORSHIP STANDARD OPERATING PROCEDURE (SOP)

Title	Version	Type	Size	Nature
Local Sponsorship Standard Operating Procedure	 English		313ko	Guidelines

2 GIFT & ENTERTAINMENT

Title	Version	Type	Size	Nature
Gifts, Meals, and Entertainment Guidelines	 English		263ko	Policy

3 INTERNAL APPROVAL DOCUMENTS

3.1 INTERNAL REQUEST FORM (IRF)

Title	Version	Type	Size	Nature
Request form / e-version	 English		303ko	Form
Request form / handwritten	 English		293ko	Form

3.2 INTERNAL APPROVAL REQUIREMENTS

Title	Version	Type	Size	Nature
Internal Approval Chart	 English		269ko	Table

Sometimes conflicting expectations

- Different regulators have different expectations for notification of key events
 - SEC
 - FDA
 - International government authorities



Lesson 5: The Regulatory Environment

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Global Information Sharing

It is becoming increasingly common for regulatory authorities from different geographies to share information.

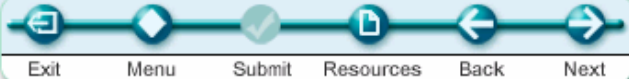
- Countries that are members of the Global Harmonization Task Force (GHTF) have instituted a mandatory report exchange program.
- Regulatory authorities frequently post advisory notices on their Web sites.

It is important that the regulatory authorities do not receive information solely from other sources without an associated communication from our company. Your commitment to submitting appropriate experiences will allow us to provide regulators the best possible information regarding product performance.



Click Next to continue.

Product Experience Handling



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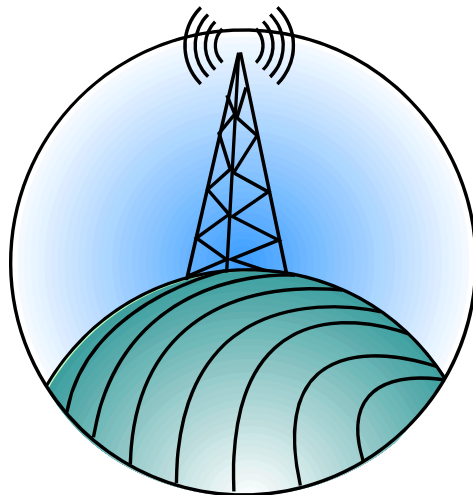
Next

- Transparency in one geography may be perceived differently in another
 - SEC requirements
- Product Performance Report information – may be viewed differently

Respect all local laws and regulations...not just the medical device approval requirements

For example:

- Privacy
- Radio Frequency
- Environmental Health and Safety



1. Key Privacy Differences Between US and EU
2. Data governance

Medical device approvals are pan-European, however, privacy, security and post-market requirements are established by each country

Country Specific Regulations

Each country may have additional data protection regulations which need to be followed

- Italy
- Spain
- Germany
- Austria
- France
- Netherlands
- UK

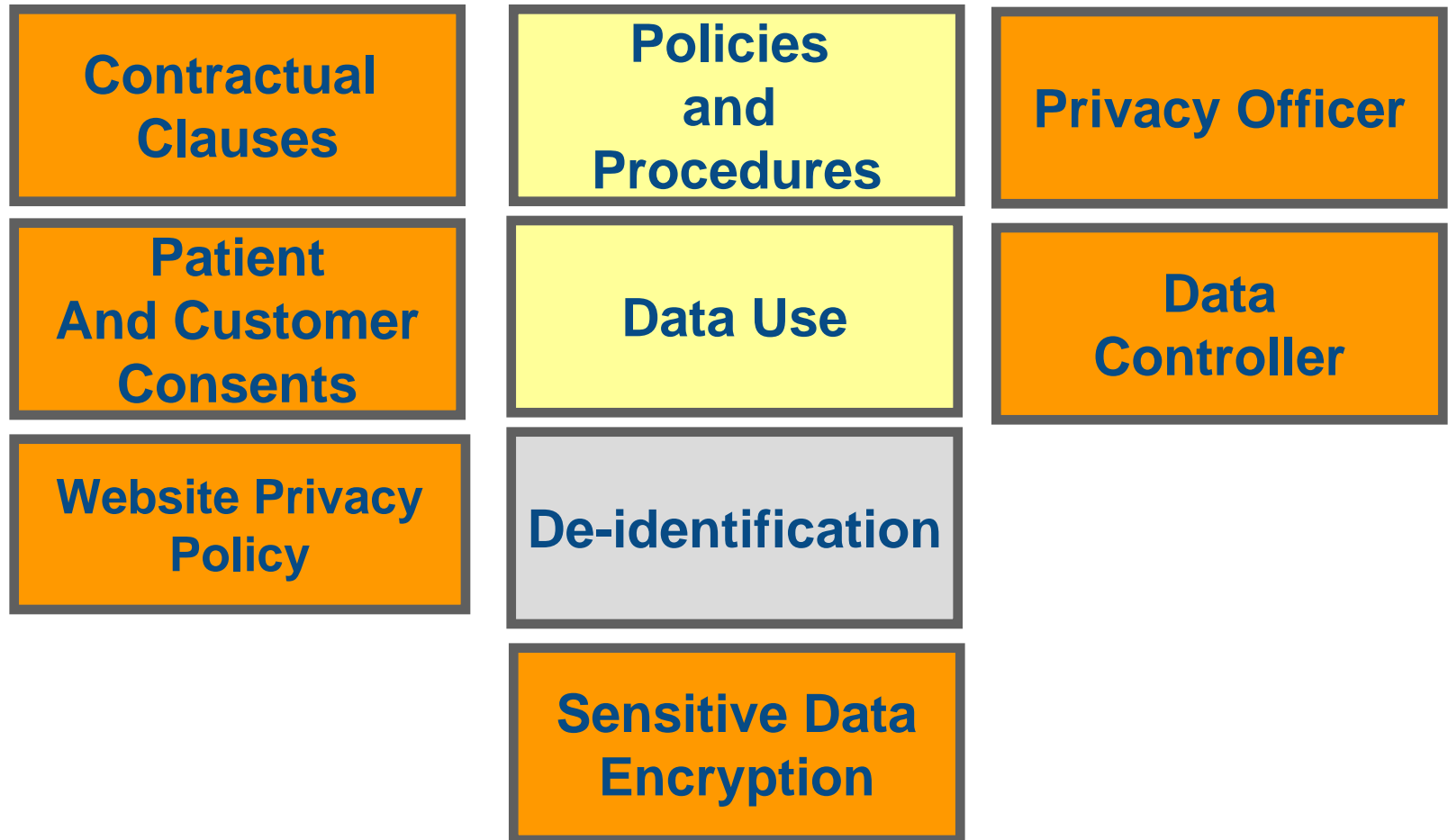
(Requirements confirmed via external legal opinion)



Additional controls applied to data depend on the structure of the data controller relationship

- Some countries require additional controls to any data that originate in that country (e.g. Italy)
- Other countries deem the data controller country rules to apply

Latitude EU Privacy – What's Required Boston Scientific



A Side by Side Comparison

US- HIPAA



EU - 95/46/EC



Protected Health Information (PHI)-

identifiable health information – 18 items.
PHI Can be written, electronic or oral.

Data Definitions

Personal Data – **any** information relating to an identifiable natural person (referred to as the *data subject*)



Je ne suis pas encore rangé des voitures

I am not giving up my wild lifestyle yet.

(literally: I am not yet parked away from the cars)