

APRIL 23-27  
TAMPA, FLORIDA, USA  
WWW.ACRP2010.ORG

GLOBAL CONFERENCE & EXHIBITION  
**ACRP2010**  
WITH THE APPI PHYSICIANS PROGRAM



# **Clinical Research in the EU: A Device Perspective**

Presented by:

Regina Freunsch  
Accovion GmbH  
Germany

APRIL 23-27  
TAMPA, FLORIDA, USA  
WWW.ACRP2010.ORG

GLOBAL CONFERENCE & EXHIBITION  
**ACRP2010**  
WITH THE APPI PHYSICIANS PROGRAM



*EU Medical Device Business  
in the Past:*

**Uniform marketing platform**

*To date:*

**Harmonization of the EU market  
meets**

**Patient Safety**

***“Nothing is more constant than the change”***

---

## EU definition on Medical Devices

- Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings. Devices are to be used for:
    - Diagnosis, prevention, monitoring, treatment or alleviation of disease
    - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
    - Investigation, replacement or modification of the anatomy or of a physiological process
    - Control of conception
  - This includes devices that do not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means
  - Medical devices must not be mistaken with medicinal products
  - All marketed medical devices must be identified with the CE mark
-

**ISO 14155**

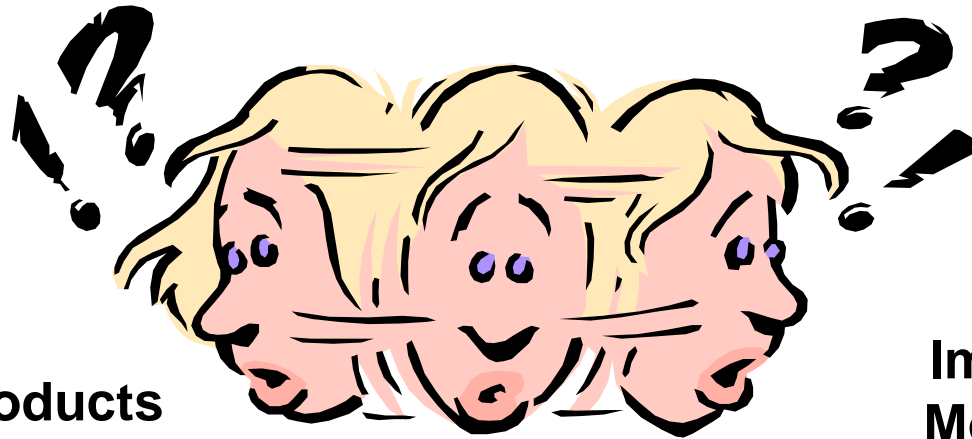
**Declaration of Helsinki**

**Borderline products**

**Directive 90/385/EEC**

**active / passive  
implantable**

**RISK**



**Class I,II, III**

**Data Protection**

**CE Mark**

**Combination products**

**Importation and  
Movement in EU**

**Directive 2007/47/EC**

**Device or Drug**

**Safety Reporting**

**Directive 93/42/EEC**

APRIL 23-27  
TAMPA, FLORIDA, USA  
WWW.ACRP2010.ORG

GLOBAL CONFERENCE & EXHIBITION  
**ACRP2010**  
WITH THE APPI PHYSICIANS PROGRAM



# Thank you !

## Regina Freunscht

Director Marketing and Communication  
Accovion GmbH  
Helfmann-Park 10  
65760 Eschborn  
Germany

Phone: +49 6196 7709 442  
Mobile: +49 172 696 4772

[regina.freunscht@accovion.com](mailto:regina.freunscht@accovion.com)  
[www.accovion.com](http://www.accovion.com)