



**business solutions in regulatory
affairs and quality assurance**

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Regulatory Approval: The icing on the cake

Rod Ruston

Priory Analysts

Regulatory approval

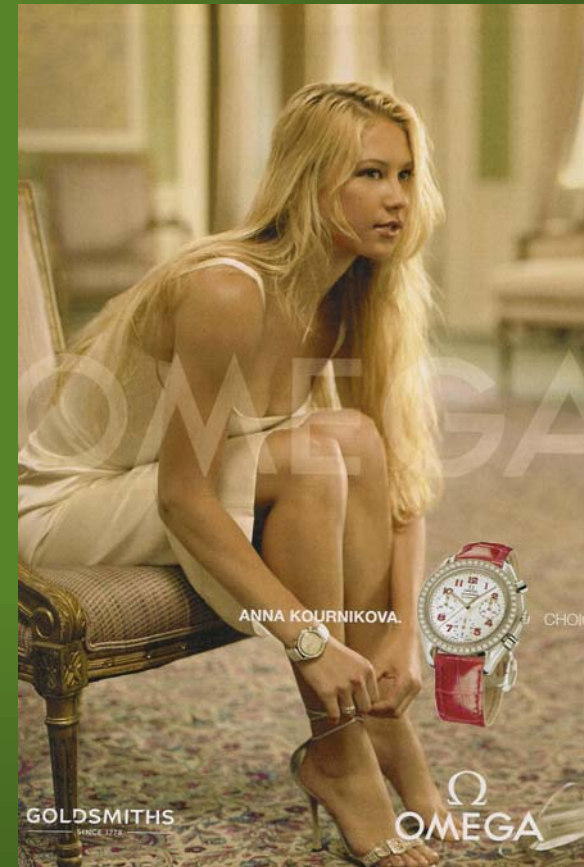
Icing on the
cake?

Or basic
ingredient?

For a consumer product...

It could be commercial suicide...

...to launch a product without an eye-catching advertisement



(Thank you, Omega watches & Goldsmiths)


For a medical product...

It is commercial suicide...

...to develop a product without regulatory input at all stages.



Rule 1:



**In this business,
regulatory approval
is king**

Rule 2: define the product

- **What do you claim the product does?**
- **Medical equipment must:**
 - diagnose a medical condition
 - prevent illness
 - promote healing
 - prevent conception
 - replace anatomy or physiological process
 - alleviate incapacity

medical device means:

any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- 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,

and which does 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;

The Medical Devices Directive

Is your product?

- **Medical equipment**
- **Medicinal product**
- **Cosmetic**
- **Personal protective equipment**
- **Toy**
- **Biocide, recreational craft...**

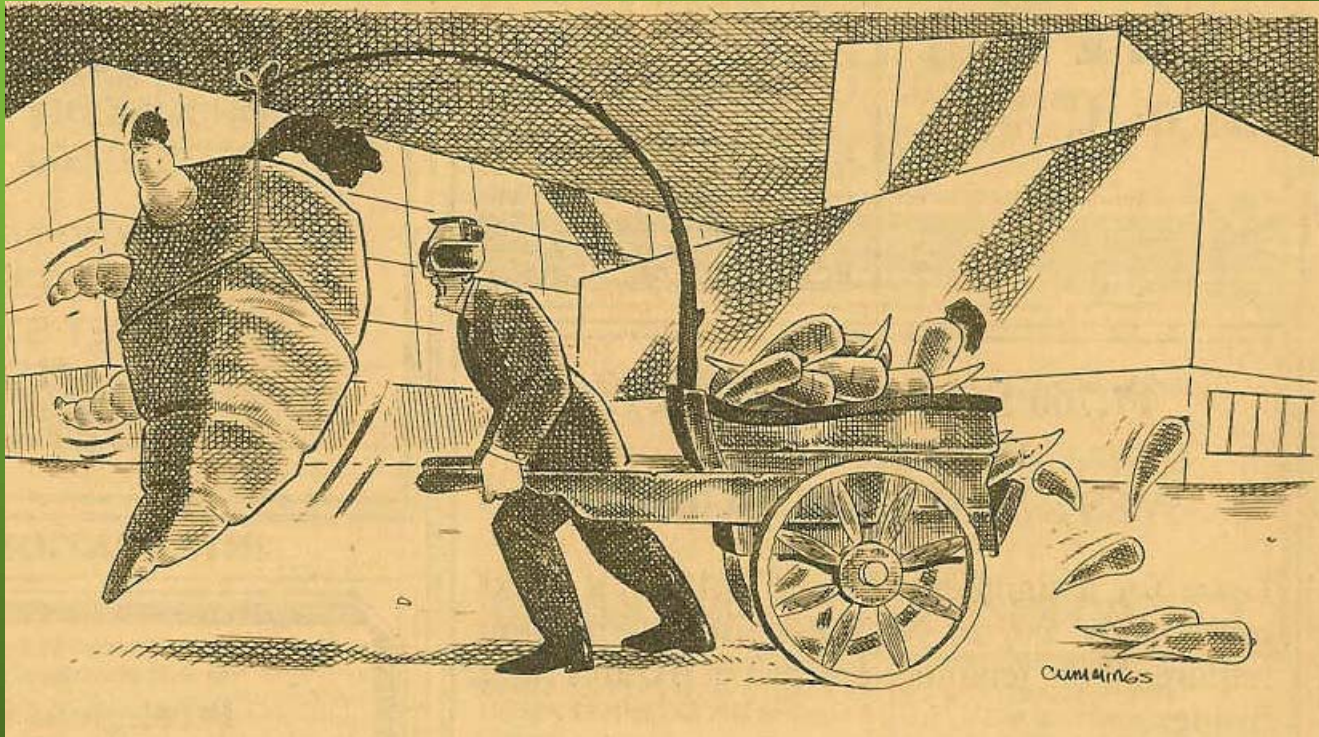
Rule 3: regulatory throughout

- Final release of completed product
- On completion of manufacturing
- During clinical trials
- In pre-clinical animal work
- Bench evaluation
- First models
- Initial concept

Rule 4: where to?

- **European Union**
- **USA**
- **Japan**
- **Canada**
- **Australia**
- **Other eg China, Russia, Middle East,**

Biggest is best?



(Thank you, Financial Times)

Rule 5: record

- **The purpose**
 - of any work, test, trial, or meeting
- **The results**
 - of any work, test, trial or meeting
- **The people involved and why**
- **The organisations involved and why**

Rule 6: science and regulatory

**All good regulatory = Good science
work**

**All good science Good regulatory
work**

Let's take a product through EU regulatory approval

Step 1: define the product

- Is it a medical device?
- Other possibilities:
 - Medicinal product
 - Cosmetic
 - Personal Protective Equipment
 - Toy
 - Food
 - Biocide

Step 2: know the law!

- EU is governed by Directives
- Directives are 'letters' from the EU to Member States
- Directives are written by Member States (our civil service)
- Directives do not 'come out of the blue' from Brussels!

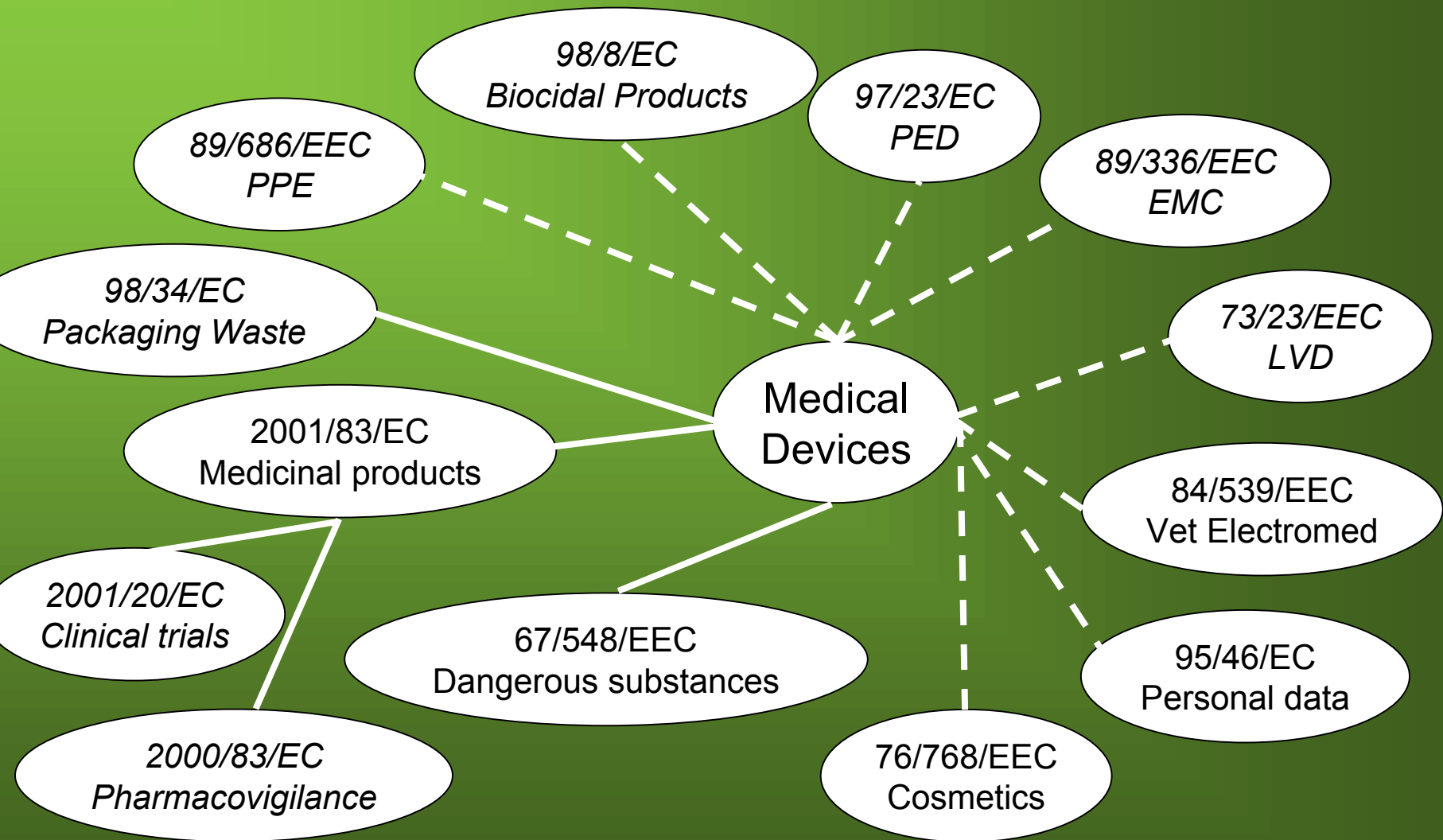
EU Directives

- 93/42/EEC medical devices
- 90/385/EEC active implantable...
- 98/79/EEC in vitro diagnostic...
- 2000/104/EC: stable blood derivatives
- 2003/12/EC: breast implants
- 2003/32/EC: animal tissue...

Don't' forget Rod Ruston's amendment!

- Four words from the Active Implantable Medical Device Directive:
 - *'of the design and'*
- JO L7 of 11/1/94, page 20
 - In AIMDD (90/385/EEC),
 - page 32,
 - Annex 5,
 - under point 3.2(b),
 - second indent,
 - second line

Other Directives related to medical devices



EU Directives in the UK

- **Appear as Regulations (Statutory Instruments, or SI)**
 - **Under the Consumer Protection Act, 1987**
 - **SI 2002 No 618: The Medical Devices Regulations**

The role of standards

- **Directive text:**
 - Concentrates on general principles
 - Realises it is difficult to change the text, which could create safety problems
 - Confers on certain European Standards ‘conformity with this is presumed to be conformity to the Directive’
 - These are ‘Harmonised Standards’

Harmonised Standards

60601-1	General requirements for safety
60601-1	Safety requirements for medical electrical systems
60601-1-2	Electromagnetic compatibility
60601-1-4	General requirements for programmable electrical medical systems

Harmonised Standards

13485	Medical devices. Quality systems management. Requirements for regulatory purposes
14971	Application of risk management to medical devices

Step 3: plan data requirements

- **Performance**
- **Safety**
- **Biocompatibility**
- **Bio-durability**
- **Labelling**
- **Sterilisation**
- **Clinical**

Step 4: create documentation

- **Technical file**
 - Data which confirms the device is safe
 - Data which confirms the device will perform to its intended purpose
- **Management system**
 - How the company operates (ISO 13485)

Step 5: assessment

- **Choose a Notified Body**
- **Go through assessment**
- **Write a Declaration of Conformity**
- **Sell throughout the EU 25 Member States, Norway, Iceland, Liechtenstein and Switzerland**

Timescale

Collect data through tests, clinicals and establish manufacture	
Write up data and compile quality system	3 months
Notified Body audit and corrections	3 months
Total time:	6 months + time to collect data/establish manufacture

Costs

- **Vary with size of company**
- **Complexity of device**
- **Novelty of device**
- **Novelty of materials used**
- **For straightforward device, no new materials, 20 people employed, count in terms of £10-20k**

The rules:

- **Rule 1: in this business, regulatory approval is king**
- **Rule 2: define the product**
- **Rule 3: regulatory throughout**
- **Rule 4: where to?**
- **Rule 5: record**
- **Rule 6: science and regulatory**

The Steps

- **Step 1: define the product**
- **Step 2: know the law!**
- **Step 3: plan data requirements**
- **Step 4: create documentation**
- **Step 5: assessment**

The End



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