

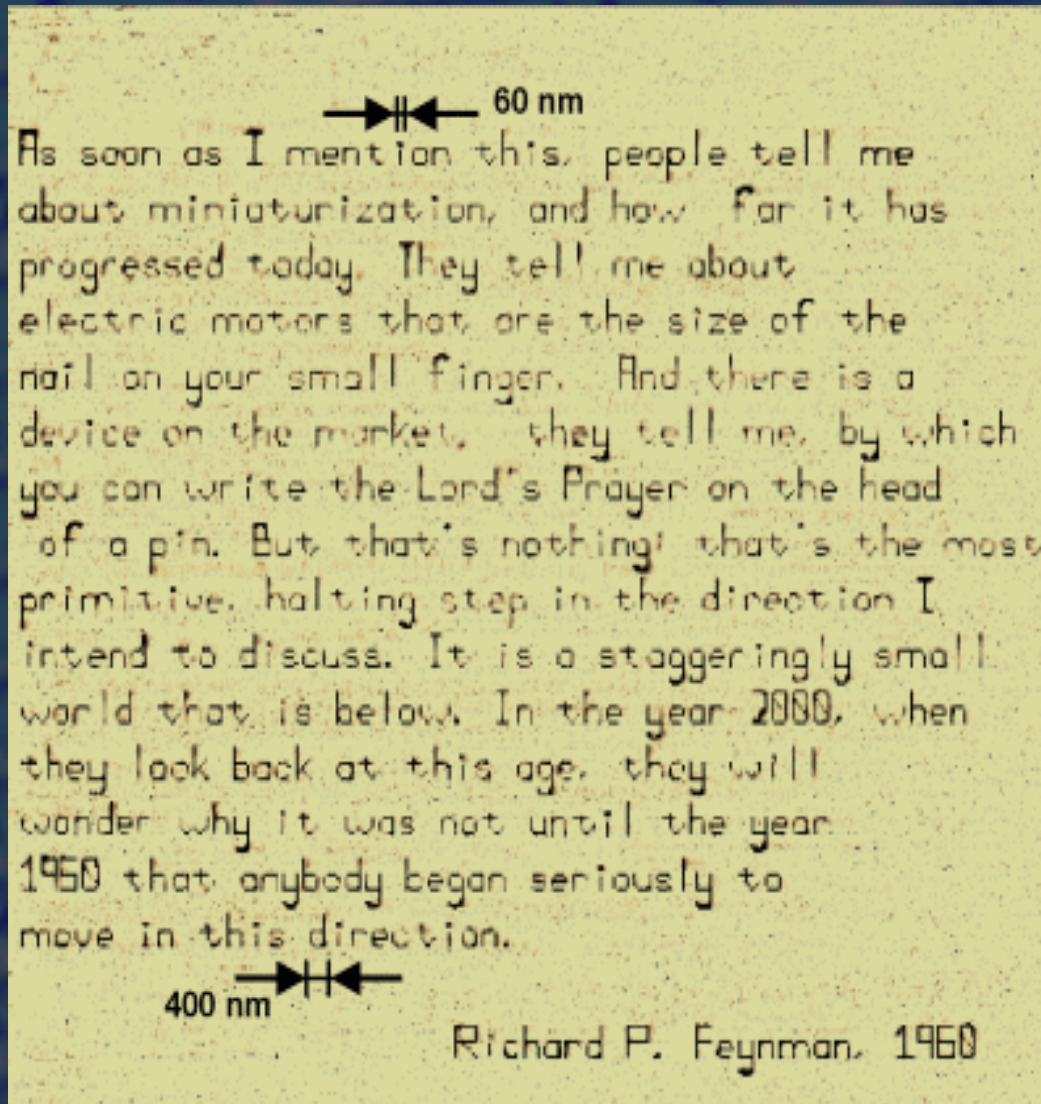
Medical nanotechnology

- a new challenge for standardization?

Richard Moore
Scientific Director, Eucomed

What is nanotechnology?

- Essentially... the science and technology of manipulating things at the atomic or molecular level
- In one sense, the nano- level is nothing new but our ability to work at that level to produce useful machines, materials or products in a multidisciplinary way is now coming of age
- The prefix “nano” is derived from the Greek word for “midget” and nanotechnology is usually taken to mean work at the scale of around several to 100 nm. There are one billion nanometres to a metre
- The background to these slides is, in fact, binary code represented by individual atoms – an example of nanoengineering

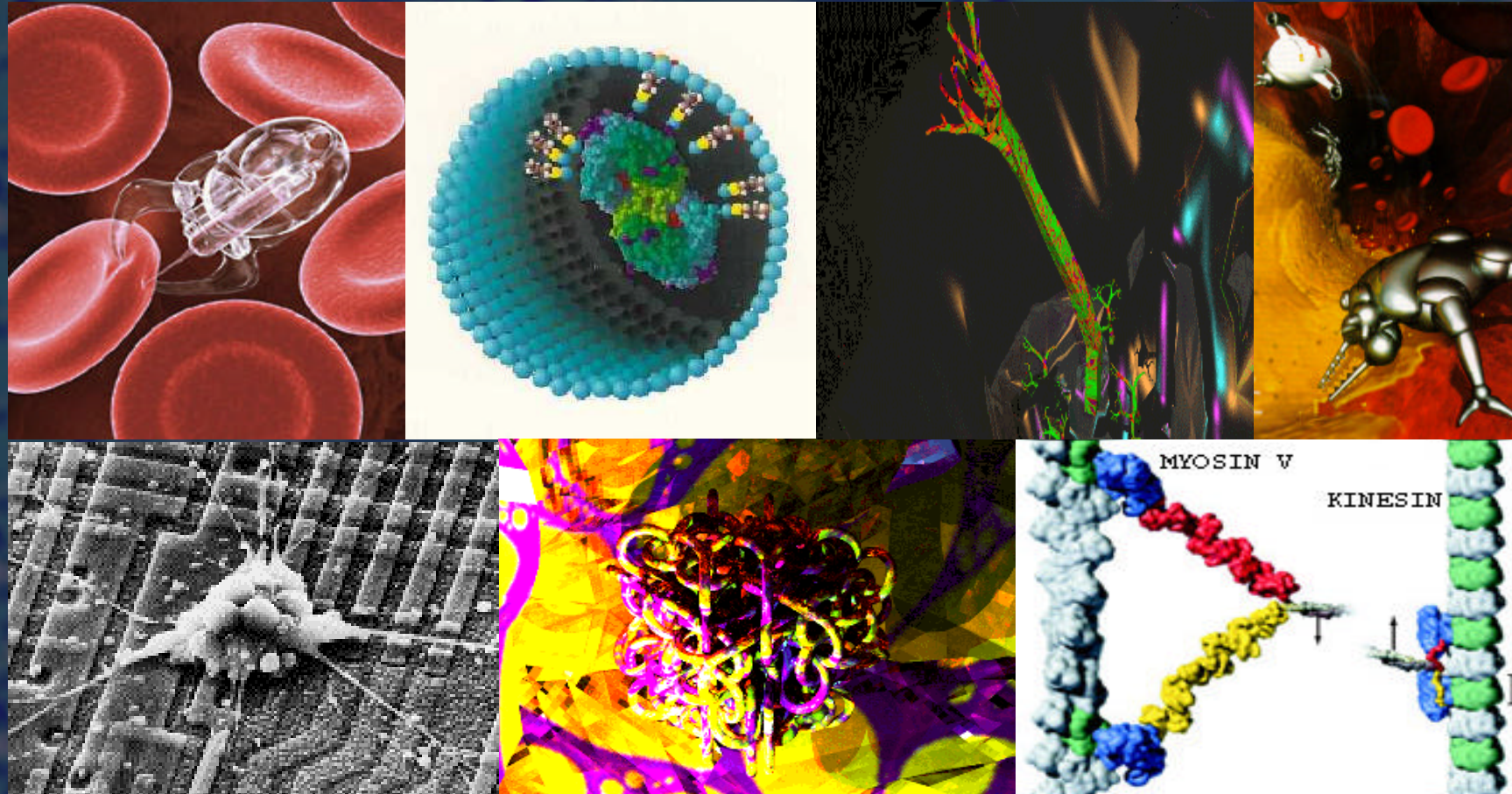


American Nobel Prize winning physicist Richard Feynman wrote this visionary passage back in 1960.

This representation of his words was created by an automated nano-plotter. The words were typed into the system's computer and then automatically output onto a gold substrate. In this example, the letters are written with an 'ink' of mercaptohexadecanoic acid, and the lines are 60 nanometers wide and one molecule thick. They are surrounded by a one-molecule-thick layer of octadecanethiol.

It took only 10 minutes to generate the nanostructured paragraph!

Some future nanotechnology medical product ideas



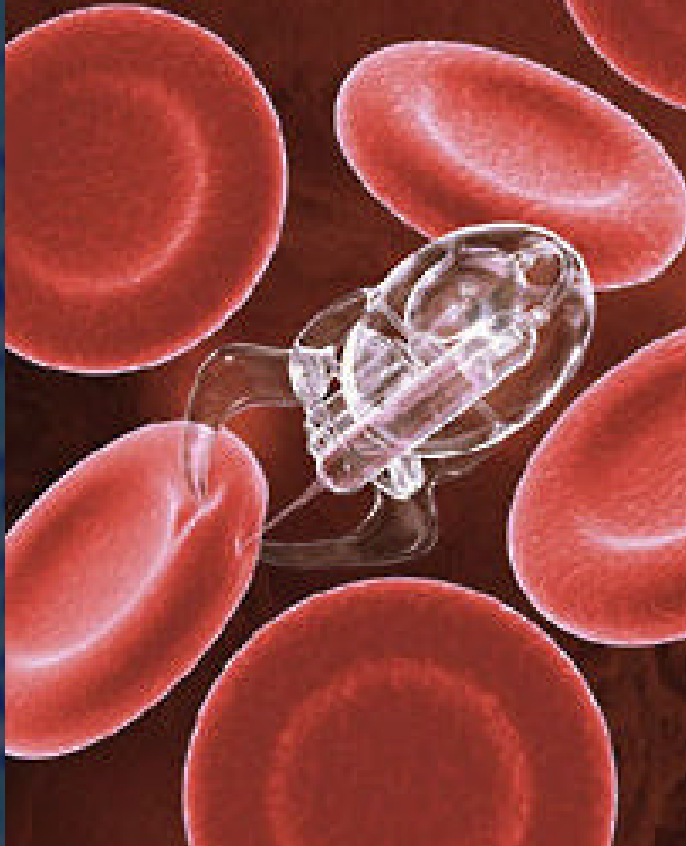
Some future nanotechnology medical product ideas



Lab-on-a-chip devices like the one pictured here are already under active development and are likely to benefit from far greater miniaturization as nanotechnology know-how develops.

These nanodevices will eventually be able to carry out many simultaneous analyses, could possibly be implanted *in-vivo* and be able to provide active real-time feedback to other active implantable medical devices. This may replace the need for external lab analyses in many cases.

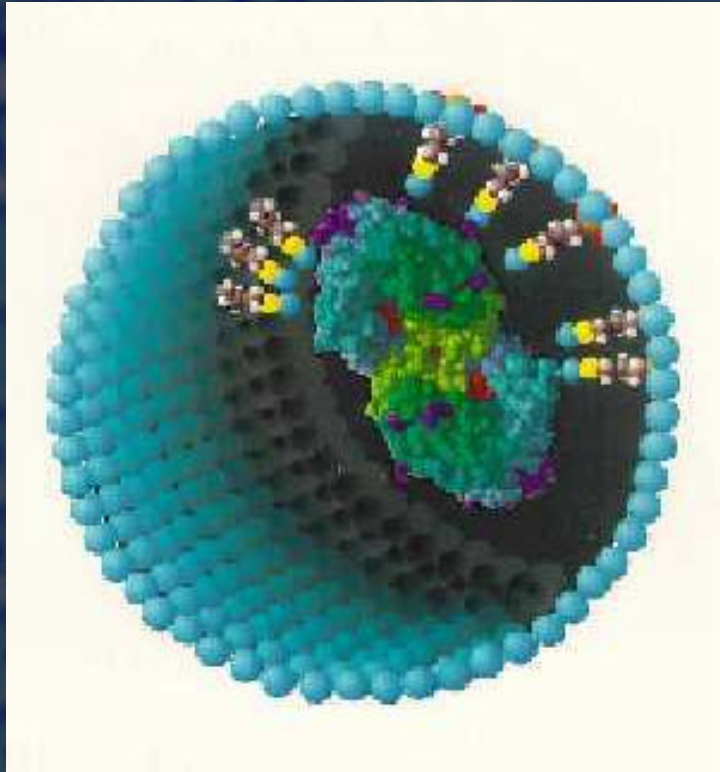
Some future nanotechnology medical product ideas



Vastly reduced component sizes resulting from nanoengineering could enable complete surgical robots or miniature medical devices to be constructed.

The picture on the left is, for now, just an artists representation of a drug delivery nanodevice but it is expected within the nanotech community that this level of miniaturization will become possible.

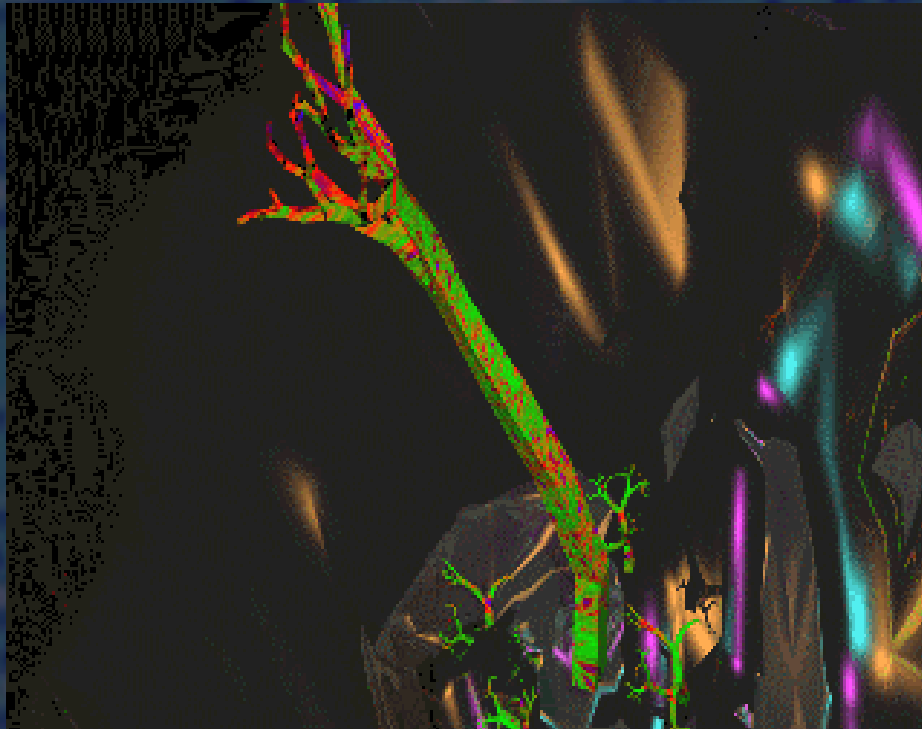
Some future nanotechnology medical product ideas



One major future application of nanotechnology may be the targeted delivery of drugs to specific organs or tissues e.g. for the treatment of cancers at their site rather than the use of systemic and often highly toxic chemotherapy.

Another possible application could be the delivery to specific sites of coated nanoparticles that could then be heated using intense light thereby destroying diseased tissue and cells.

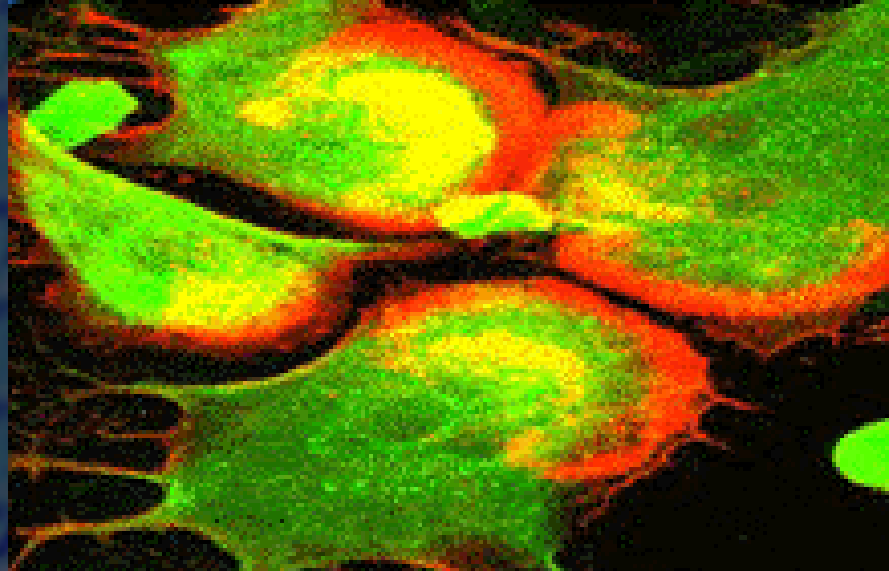
Some future nanotechnology medical product ideas



Nanotechnology also offers considerable promise in the rapidly-developing field of human tissue engineering.

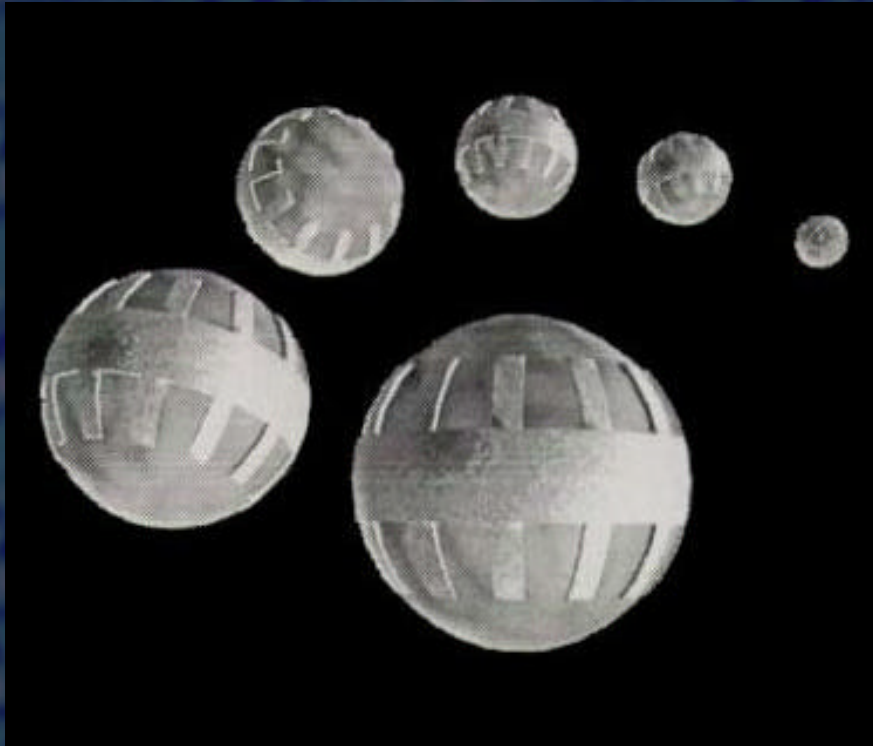
This is an artist's representation of an engineered human nerve cell utilizing a matrix formed of a nanoengineered biodegradable biopolymer

Some future nanotechnology medical product ideas



Nanotechnology offers great promise for genetic therapy – by facilitating the sorting of cells outside the body for re-injection or by enabling the building of cell-assisting micro-machines at the cell or sub-cell size scale

Some future nanotechnology medical product ideas



For example, it has been suggested that “respirocytes” like those depicted here could augment oxygen supply to poorly vascularized tissues.

Measuring 1 micron it has been suggested that these could pump 236 times more oxygen to tissue than a red blood cell. They could also include an onboard nanocomputer and chemical and pressure sensors.

So these are some of the ideas ...where are the problems?

- In the field of nanotechnology, science is progressing much more quickly than the regulatory environment can evolve
- In some cases, there is a complete regulatory vacuum as the science is completely novel
- In other areas, nanotechnology products may fall under the scope of existing Directives such as the Medical Device Directive but the Directive itself was never conceived with such products in mind
- In yet other areas, nanotechnology products may completely blur the usual “demarcation boundaries” between different regulations

So these are some of the ideas ...where are the problems?

- A further, but potentially more difficult challenge, may be that of poor public perception and acceptance of nanotechnology
- Unfortunately, poor handling of previous “new technology” issues such as GM food have left a legacy of public distrust of scientists and industry
- For certain aspects of nanotechnology, hazards, risks and risk/benefit are, as yet, not fully evaluated. Effective risk communication will be an important tool in gaining acceptance of nanotechnology in medicine
- There are, therefore, regulatory, risk management and public perception issues to be addressed prior to the widespread implementation of nanotechnology medical products and thereafter also issues of take up and reimbursement by healthcare providers

How can standardization help?

- While this presentation has concentrated on medical applications, nanotechnology is like to impact many areas of technology and production
- There is, therefore, a very considerable potential role for standardization across a number of engineering and other sectors
- Given the nature of nanotechnology and the speed of innovation, it is likely that “traditional” engineering-type standards will no longer be sufficient
- There will probably be a number of different challenges for the standards organizations

How can standardization help?

- First, there will be an important exercise in “selling” the concept of standardization to a new constituency of stakeholders who may have little knowledge the process or even negative perceptions, e.g. timeliness
- If standards can be demonstrated to be useful to new, high-growth areas like nanotechnology, some important questions still remain:
- What can be standardized? The potential range of applications and products would appear to render “product specific” standards inappropriate. In the medical sector, a shift has already occurred towards safety and performance
- How can standardization best be achieved? There have been a number of new “standardization products” in recent years and these may have to be further adapted to the needs of nanotechnology and other innovative fields