CAMP

Quality by Design: A Challenge to the Pharma Industry

CAMP Member Companies March 2002

The Changing Healthcare Scene & Impact on the Pharmaceutical Industry

Ageing population → urgent need for new medicines & greater use of pharmaceuticals

BUT

Increasing healthcare costs → pressure to reduce use (and price) of pharmaceuticals

More informed payers & consumers → greater need to demonstrate health and economic value

Pressure comes in many forms…

- External pressures
  - diseases
  - shareholders
  - special interest groups
  - governmental agencies
- Internal pressures
  - pipeline
  - speed to market
  - cost of goods
  - consolidation & merger savings
  - continuity of supply

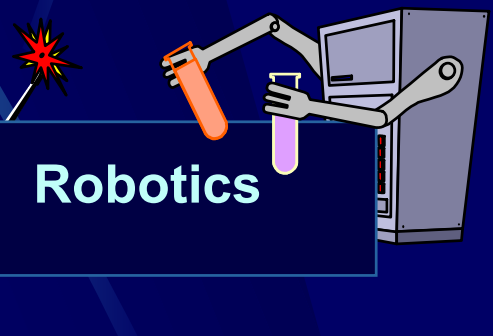
These pressures have driven innovation …

Supercompression of Drug Discovery

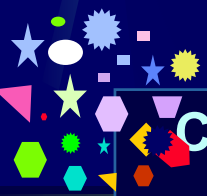
Cell & Molecular Sciences

Biotechnology

Genetics

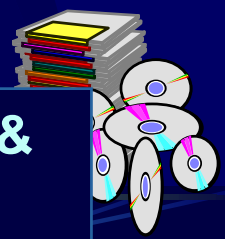


Robotics



Combinatorial Chemistry

Computer & Inform. Technology



Informatics & Databases

The typical pharmaceutical business model

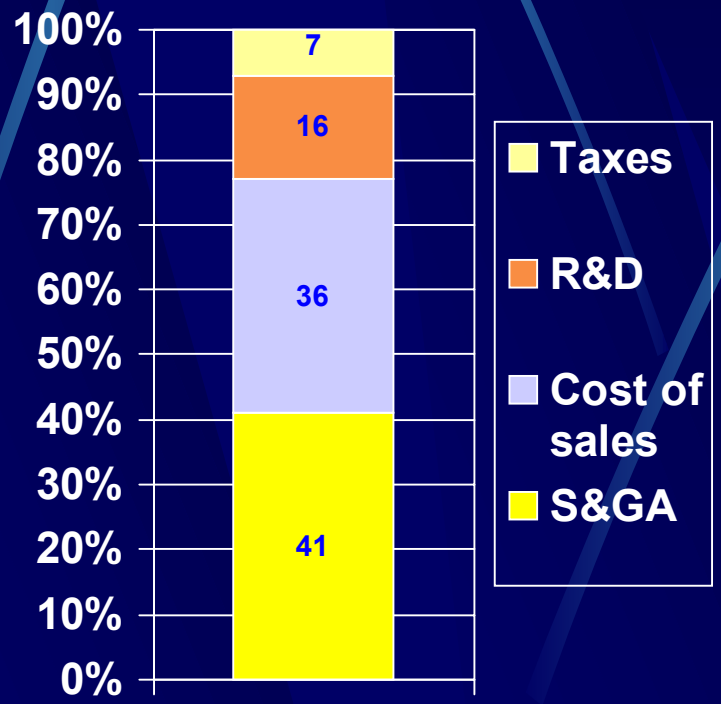
V Blenders

Slant Cone Blenders

Granulators

Are manufacturing costs significant?

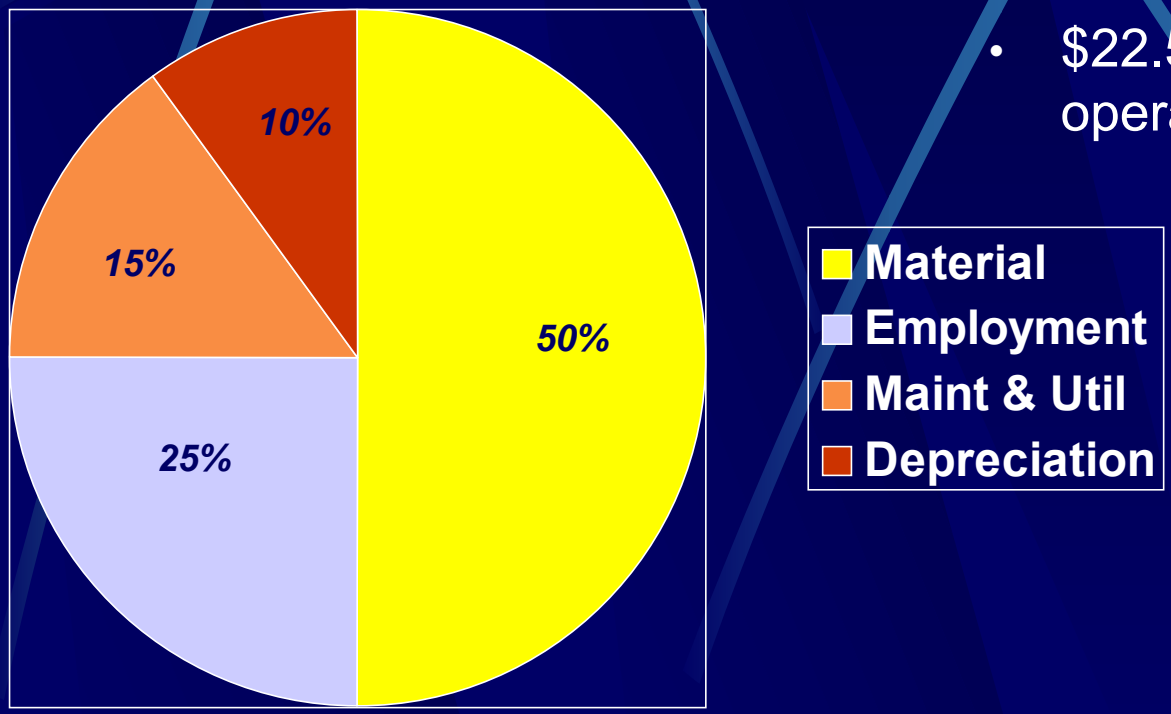
Cost Distribution: Big Pharma (16 Companies)



- Total sales > $ 300 Bn
- Total costs ~ $ 250 Bn
- COS > $ 90 Bn

Where are the Quality and Financial Opportunities?

Manufacturing Costs: Big Pharma



- $45 Bn in materials
- $22.5 Bn in personnel costs
- $22.5 Bn in dep and operating

The result of today's manufacturing processes:

- Large inefficient batch equipment
- Low utilization 30 - 40 % on average
- Capital and labor intensive
- High inventories and excessive warehouse space
- Elaborate HVAC and mechanical segregation
- High transportation costs
- High operating costs
- Low product yields
- Excessive amounts of product non-conformances
- Long lead-times due to stage and final product testing

Main points from this:

- High tech in R & D
- Relatively low tech in Manufacturing
- It matters
  - Big Pharma manufacturing costs are $ 90 Bn
  - Significantly more than R&D

How can we make a difference?

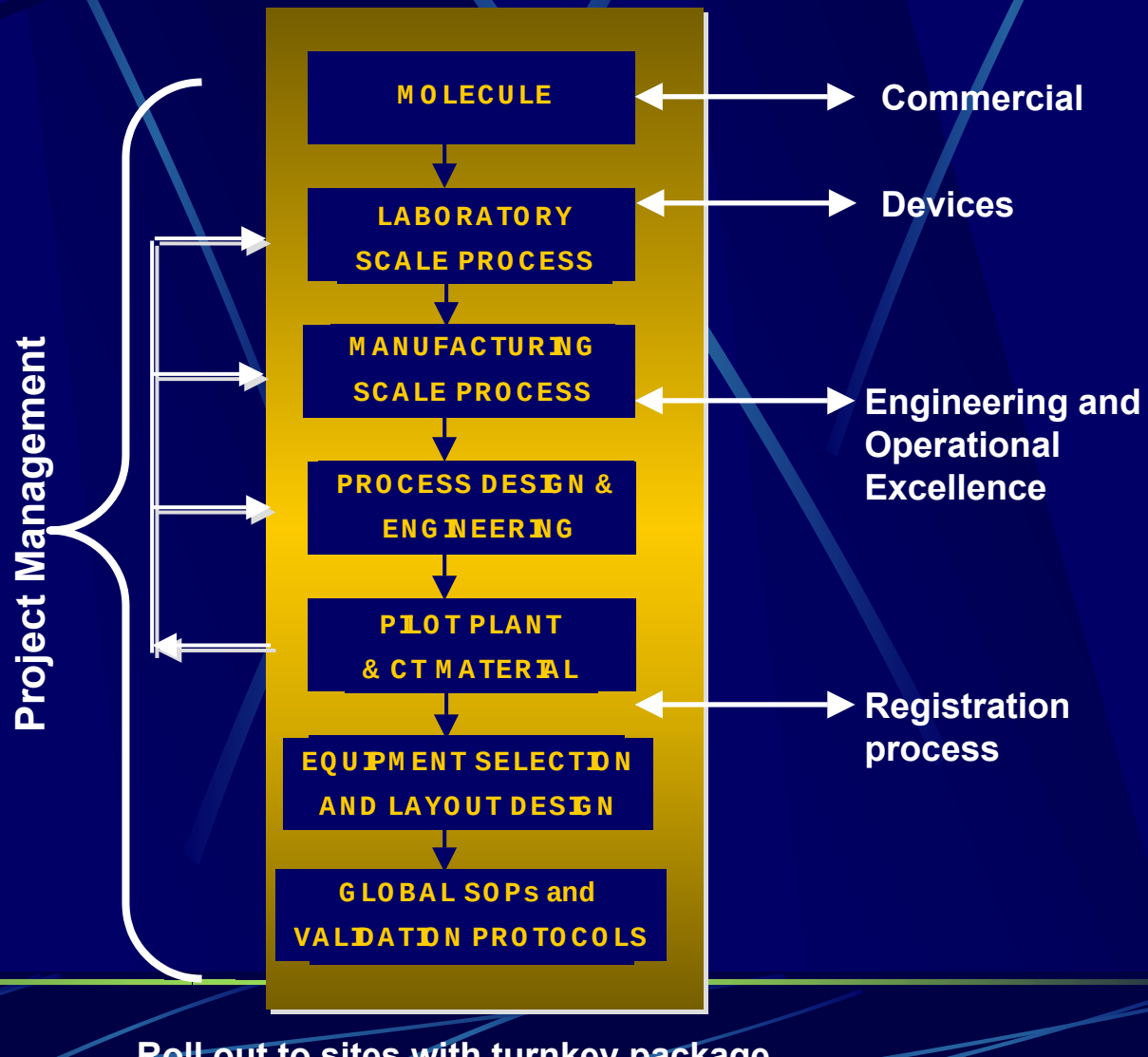
- Technology exists
  - Near infra-red
  - Laser induced fluorescence
  - Continuous processing
- On line monitoring and control to improve quality
  - Minimize troubleshooting and investigation systems
  - Prevent rather than repair
- Financial drivers are strong
  - 1% yield improvement = $400 million in savings
- There are significant barriers
  - Cultural
  - Organizational
  - Historical

Opportunities

- Closer links between R&D and Mfg.
- Develop and design manufacturing scale processes … before registration
- On line measurement and control
- Continuous processing
- Product plants … not component plants
- Small dedicated facilities

The future vision pharmaceutical business model

Process for new products



Today: A challenge

- Need a paradigm shift
- Barriers are challenging
- Environment is ready to improve quality, shorten time to market and reduce costs
- Will we take the step???