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 ...
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

![Pie chart showing material, employment, maintenance, and depreciation costs]

- Material: 50%
- Employment: 25%
- Maint & Util: 15%
- Depreciation: 10%
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

- R&D
- Manufacturing
- Marketing
Process for new products

- MOLECULE
- LABORATORY SCALE PROCESS
- MANUFACTURING SCALE PROCESS
- PROCESS DESIGN & ENGINEERING
- PILOT PLANT & C T MATERIAL
- EQUIPMENT SELECTION AND LAYOUT DESIGN
- GLOBAL SOPs and VALIDATION PROTOCOLS

- Commercial
- Devices
- Engineering and Operational Excellence
- Registration process

Roll out to sites with turnkey package
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???