



Drug Development & Formulation Challenges during 21st Century

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Drug Development & Formulation Challenges during 21st Century

- Pharmaceutical & Biotech industries are now addressing health problems on a global basis (result of ongoing efforts for global harmonization).
- Globalization has a major impact on drug development & manufacturing (especially generics).
- Competition from offshore companies is a growing challenge to the pharmaceutical companies in developed nations.



Drug Development & Formulation Challenges during 21st Century

Critical factors for profitable drug development:

- Speed / cycle time of drug development
- Cost controls (expected cost ~\$1.9 bn by 2013 for new molecules)
- Quality of drugs produced

eg., Ranbaxy, Dr. Reddy's are examples of success stories for two offshore companies for establishing businesses in Americas and Europe.



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Merck's Vioxx: Rise & Fall of product

- \$2.5 bn made in 2003.
- Block buster with 105 Million prescriptions written in US through August 2004.
- 18 months later (Early 2006) Vioxx withdrawn from the market due to ADRs.
- Very expensive return to market after corrections.



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Challenges ahead for both Innovators and Generics:

- Business pressures
- Innovators need to invent new molecules
- Generics need to compete and develop with a list of products with competition and seek approval and be one of the first players in the markets.



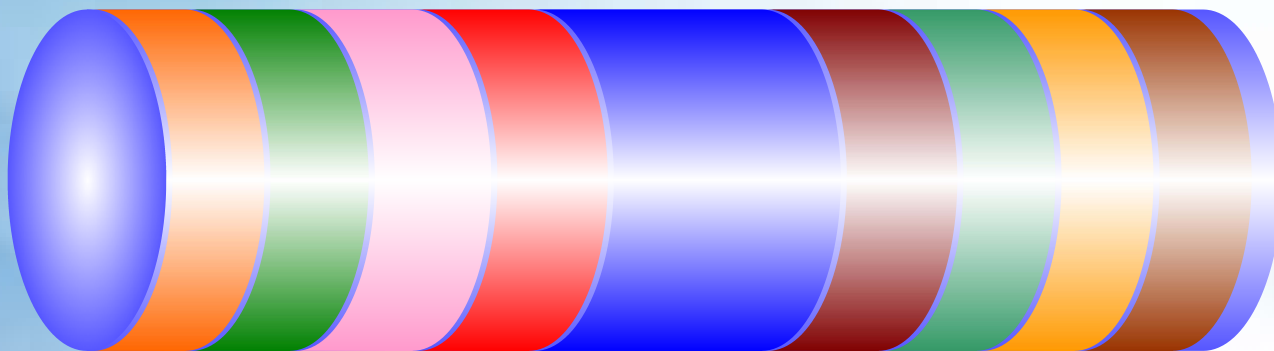
Drug Development & Formulation Challenges during 21st Century

**Various players are developing &
continuously evolving plans.**

- Maintain and exceed profitability of drug development processes (innovation, patents etc.)
- Orchestrate all drug development activities in a proactive, timely and orderly fashion.



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Drug development process involves:

- Innovation (new molecules/entities)
- Product development
- Clinical studies
- Regulatory approval
- Manufacturing & Quality
- Marketing



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Current expectations are:

- Shorter Developmental cycles
- Aggressive timelines for regulatory approvals
- Race to be first in the market
- High success rate of scale up manufacturing
- Low price / competitive edge
- Potential biological drug molecules and unique formulations



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Biopharmaceuticals

- 25 % of new drugs coming to the markets are biological in nature.
- Projected annual sales will surpass \$52 billion
- Biopharmaceuticals and protein based drugs are increasingly popular due to potency, high specificity.
- Less accumulation and low toxicity.



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Additional critical factors of Formulation Development

- Material Sourcing
- Special Delivery System Design
- Excipient/Packaging Compatibility
- Physical/Chemical Stability
- Scale Up



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Realities of Biopharmaceutical Formulation Development

- Sensitive/Unstable Molecule Structure
- Limited Administration Route (Mainly Parenteral)
- Poor Bioavailability
- High Cost/Low Yield Manufacturing Procedure



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How do we address these
issues and achieve
success???



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Team Work

- Product Development
- Clinical
- Regulatory
- Manufacturing
- Marketing



Operating Efficiency is Key to Success

- R&D Investment
- Human Resource status
- **Continuous evaluation and building core competence**



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Business challenges

- Innovators need to invent new molecules.
- Generics need to compete to develop products and seek approval and be one of the first players in the markets.



Drug Development & Formulation Challenges during 21st Century

**For continued success in maintaining and
expanding current market position**

- Coordinated Team Work is required from all departments of organization.
- Right Product selection, Development in a timely and cost effective manner.
- Stay with core competence and expand business through strategic partnership.
- Uniqueness of the product
- Product presentation in a novel / unique delivery system offering stability and ease of dosing.



The End

Critical factors for profitable drug development are:

- **Speed / cycle time**
- **Cost**
- **Quality**

