



Future of Drug Development

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THESIS

Multiple Forces Are Driving the Shape of the Future

- International regulatory convergence
- Advanced manufacturing
- Rise of biosimilars
- New science and technology
- Digital revolution
- Drug costs

THE GENERIC INDUSTRY AND ITS REGULATORS
NEED TO BE AHEAD OF THESE TRENDS

International Regulatory Convergence

- This is a good thing
- Too many repetitive submissions in too many regions, too many inspection visits—leads to errors, increase costs
- Convergence of regulators:
 - Mutual reliance initiative between EU and US
 - At the end, only EU inspectors inspect in Europe and only US inspectors in USA
 - Must go through a process, currently just for surveillance inspections, but making progress
 - Other regulators could join
 - FDA interacts closely with other regulators via foreign offices

International Regulatory Convergence: Convergence of Standards

- ICH
 - Revitalized
 - Hope for and expect substantive industry participation
 - Continue to harmonize technical requirements
- Inspection reports
 - Need to be able to read each other's reports (e.g., different languages, formats)
 - US: piloting NIP (“new inspection protocol”), procedures and standardized, quantified assessment
 - Ultimate goal—regulators use same tool, understandable work product worldwide, industry understands standards

Advanced Manufacturing

- I believe that continuous production will be revolutionary for solid oral dosage forms over the long run
- Firms will be able to use various platform technologies to easily and rapidly switch among strengths and APIs.
- Reduced costs, reduced or no off-line laboratory testing, reduced space and environmental footprint, better control of attributes, continuous 24 hr production when needed

Advanced Manufacturing

- Likely brand companies will adopt first, but ideal for manufacture of multiple different products that are similar
- It will be a number of years before the equipment, technology and know-how will be available commercially, but these will come
- This advance should decrease any regulatory problems significantly, due to ability to control attributes

Rise of Biosimilars

- Biologics are highest-priced medicines right now
- Biosimilars not generics—but greatly streamlined pathway
- Robust program taking place at FDA and industry—but still early times
- Any new scientific/technical program takes years to fully develop
- Cost pressure—rapid uptake once approved in US

New Science and Technology

- Some rapid uptake by generics—e.g., abuse deterrent opioid formulations
- Combination products
 - Advanced delivery systems
 - Inhalers
 - Auto-injectors
 - Future—into CNS, other spaces
 - Other drug-device combos

New Science and Technology

- Precision medicine/specialty pharma
 - Revolution coming in the treatment of many diseases
 - Large number or small/orphan subgroups
 - May be large number of related drugs using a “platform technology” i.e., small modifications needed to address different mutations within the same gene
 - Bottom line: increased number of different drugs needed

Digital Revolution: How Much Can We Automate?

- We are still in the pre-Henry Ford era of automation in drug development
- Ford's lesson: standardization needed to get efficiency in a process
- We are getting electronic submissions, but the more we standardize, the fewer mistakes everyone will make and the more efficient the process will become
- Can't make this too burdensome on your end, need to be congruent with business processes

Drug Costs

- Will be an ongoing theme
- Generic industry (most) seen as good guys, but issues with single source products
- Clearly will be a continued focus in US and elsewhere
- Various types of pressures on regulators
- We will continue to be asked ways to mitigate drug cost issues

GENERIC INDUSTRY AND ITS REGULATORS NEED TO BE AHEAD OF THESE TRENDS

GDUFA 2: Is it Forward-Looking?

- Not just about current efficiency/timeframes
- Prepares for the future, for example
 - Focused research to enable approval or more streamlined development of non-oral dosage forms
 - Complex drugs program: get advice upfront on development program
 - Interaction and guidance

CDER is Planning for the Future

- Lifecycle management
 - Awareness of lifecycle across center
 - Building in awareness at time of new drug approval
- Consistent, documented, automated procedures that are scalable: establishing QMS
- Continue to improve e-submission to streamline process and reduce cycling: hope to markedly reduce cycles so that CDER and industry can concentrate on getting work out and preparing for the future

Facility Assessment: An area of ongoing improvement efforts

- We understand the frustration about the timelines and relative lack of transparency of current process
- Area of high focus and intense effort
 - High priority for me personally
 - We will roll out new process with timelines and much more transparency
 - ORA reorganization in the spring, at that time our partners in facility assessment will be organized in a manner that will enable a much better process that reduces duplication

Summary

- Bold future for the affordable pharmaceuticals industry!
- Pace of change will be rapid
- Need to work with regulators to enable
- GDUFA 2 (and BSUFA 2) are next steps
- Industry undoubtedly will expand its role as major source of pharmaceutical care for the world's population