Pharmaceutical Drug Development

Challenges from Concept to Commercialization

SCRI – NHIC Symposium
Conrad Hotel, Singapore

Stephen S. Hsu Ph.D.
Director APAC Commercial Quality
Teva Pharmaceuticals
29 August 2017

drstephenhsu@gmail.com

Agenda

- Costs of Healthcare Product Innovation
- GxP
- Regulations & Regulators
- Post-Approval
- Distribution
- Shelf-life and Stability

Personal Bio

Opinions expressed are solely my own and do not express the views or opinions of my employer

Innovation

Consumer Product Innovation

$2.50

$3.00

Healthcare Product Innovation

$2.50

$350.00

GxP (GLP, GCP, GMP, GDP, etc)

- GMP (Good Manufacturing Practice, or a.k.a…)
- SOPs, Work Instructions, Forms & Records
  - Quality systems
  - Incoming Material testing & release
  - Production
  - QC testing
- Document & Data Management costs
  - Creation
  - Review
  - Approval
  - Training
  - Revision
  - Archiving

Regulations & Regulators

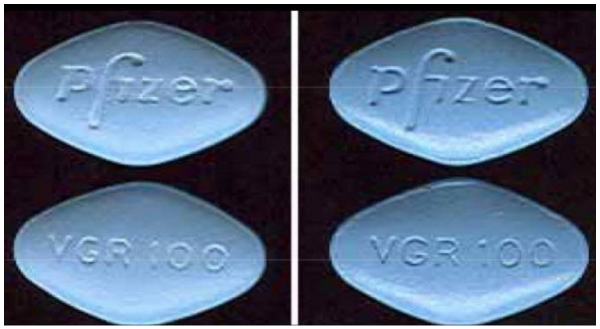
- Complexity of Value Chain
  - RM – API/DS – DP – 1 pack – 2 pack – Lab - Release
- Harmonization and Convergence
  - Population-specific clinical trials
  - Stability
  - Local artwork and PI/PIL
  - Market authorization
- Audits and Auditors
- Risk Appetite & Risk Management

Post – Approval

- Regulatory approaches to CMC changes
  - Pre-approval vs notification (timelines)
  - Multiple “effective” production process for same product
- Bridging stock vs remaining shelf-life vs an unpredictable tender market
- Multiple barcode requests by customers in a single market
- Local testing
  - Testing : Analytical Method Transfer (AMT)
  - Reference standards

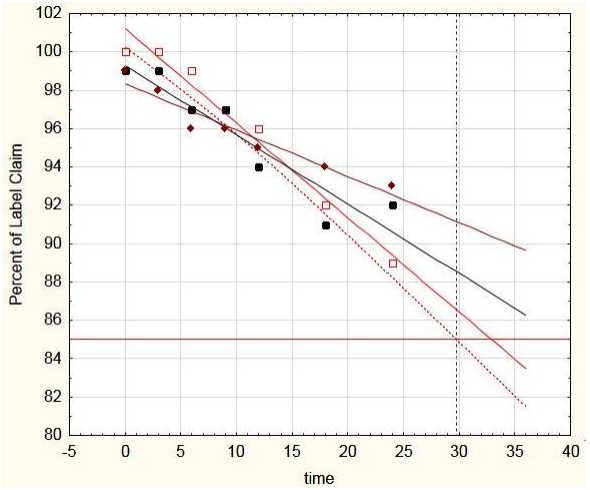
Distribution

- Good Distribution Practice not uniformly applied or enforced
  - E.g. Warehouse mapping
- Country dependent
- Anti-counterfeiting efforts
  - Supply chain integrity
  - RFID and 2-D barcodes
  - Serialization and Aggregation
  - Embedded security features



Shelf-Life and Stability

- Is a product usable after expiration date?
- Shelf-life (months): 0, 1, 3, 6, 9, 12, 18, 24, 36, 48
- Hold times (Production & Packaging)
- Tablet:
  - API -> Degradation products
  - Excipient
- Toxicology



Risk Management

$???

Q & A