

CHINA ENFORCEMENT: ANTICIPATING 2011

A. GMP: The Crouching Tiger

- Major Rewrite Finalized
- Not Translated
- Huge Additions to Special Annexes
- Indirect API Qualification Measure
- More Specific Sterility
- Inspectors Being Trained in ICH Mode
 - Varying standards understood
 - Watch for stricter CAPA focus on sterility

Yang Chen, Beijing

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B. Confirmed AIC Focus On:

- CME
- KOL's
- Distribution Agreements

C. Clinical Trials: Increased Exposure of Western Companies

- Patient compensation
- Policy concerns

D. More Contentious IP Interface

- Ongoing litigation
- Possible pressure and market access issues

SINGAPORE 2011

I. Medical Device Rewrite

- Increased scrutiny, especially design controls/manufacturing
- Recent recalls

II. Internet Sales

- Including approved products
- Part of Interpol crackdown [“Operation Pangea III”]
- 30% of internet drugs found adulterated

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