



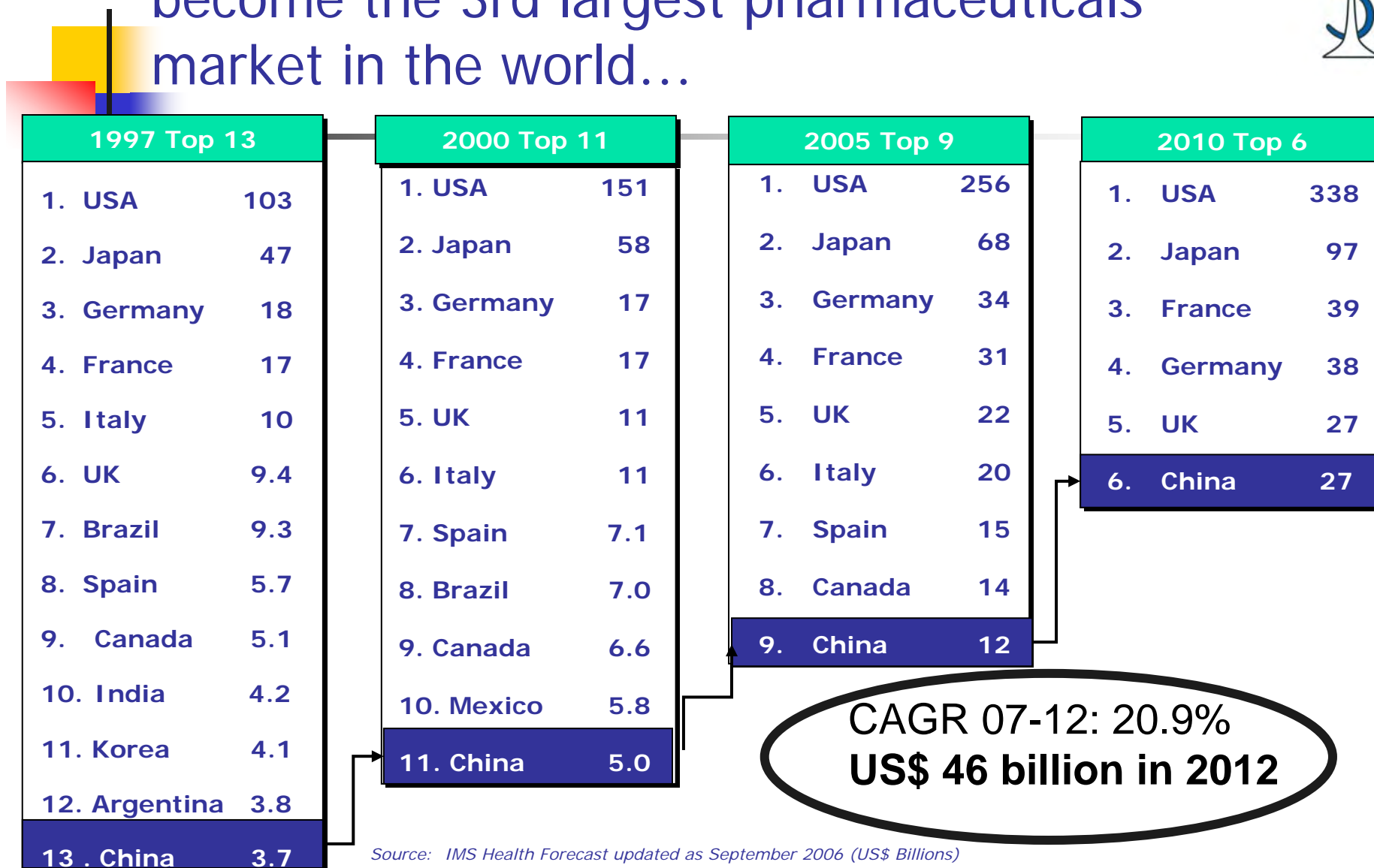
General information, drug development requirements for a new marketing authorization application for new chemical entities and new biological entities in China

Doktorantenkolloquium im Rahmen der
Dissertation im Fachbereich Drug Regulatory
Affairs an der Uni Bonn am 29.05.2010

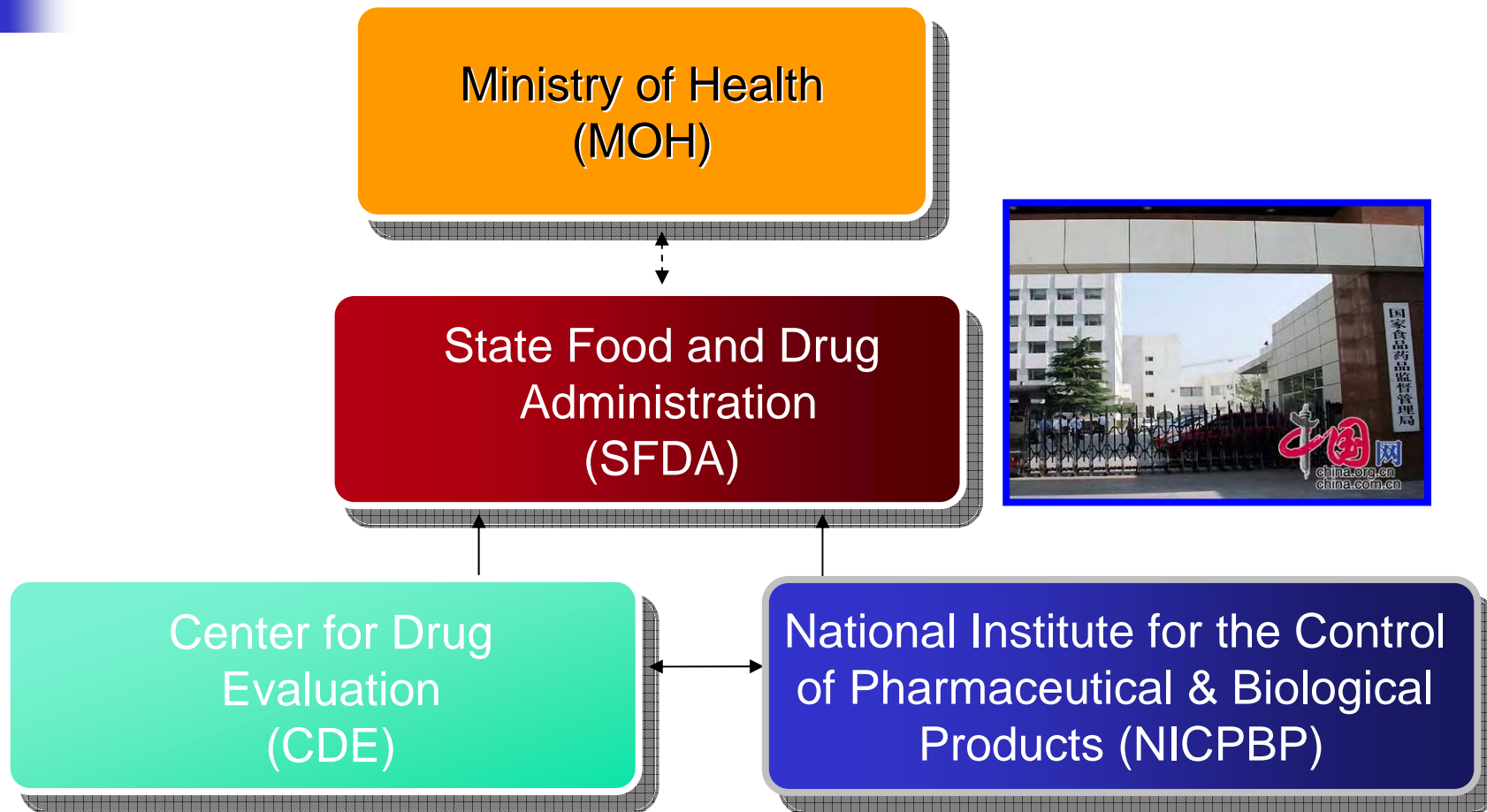
Andrea Herrmann, MDRA



By 2011, IMS China forecasts China may become the 3rd largest pharmaceuticals market in the world...



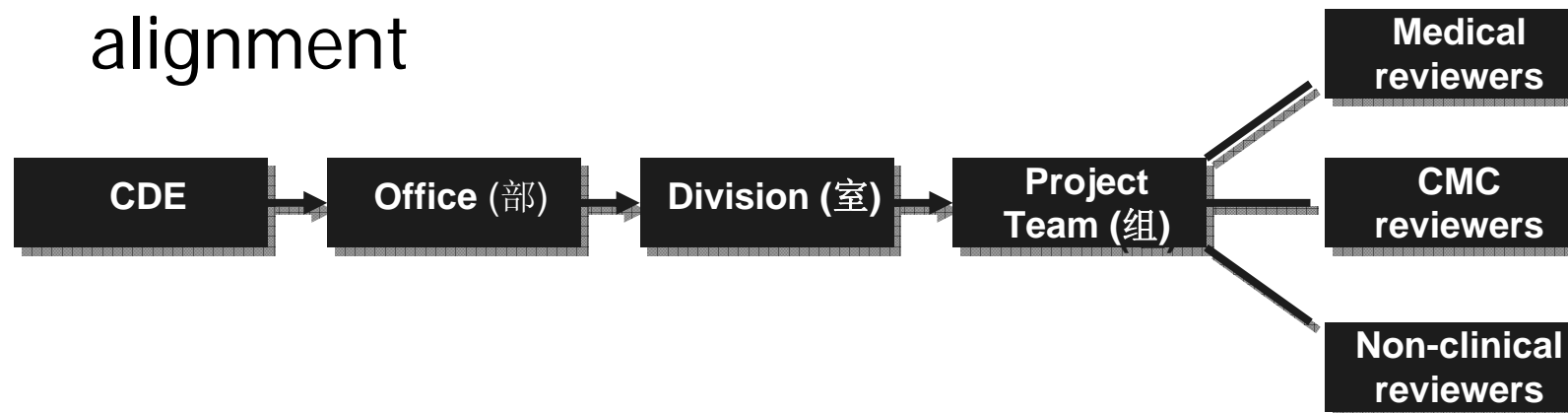
Key Regulatory Players in China



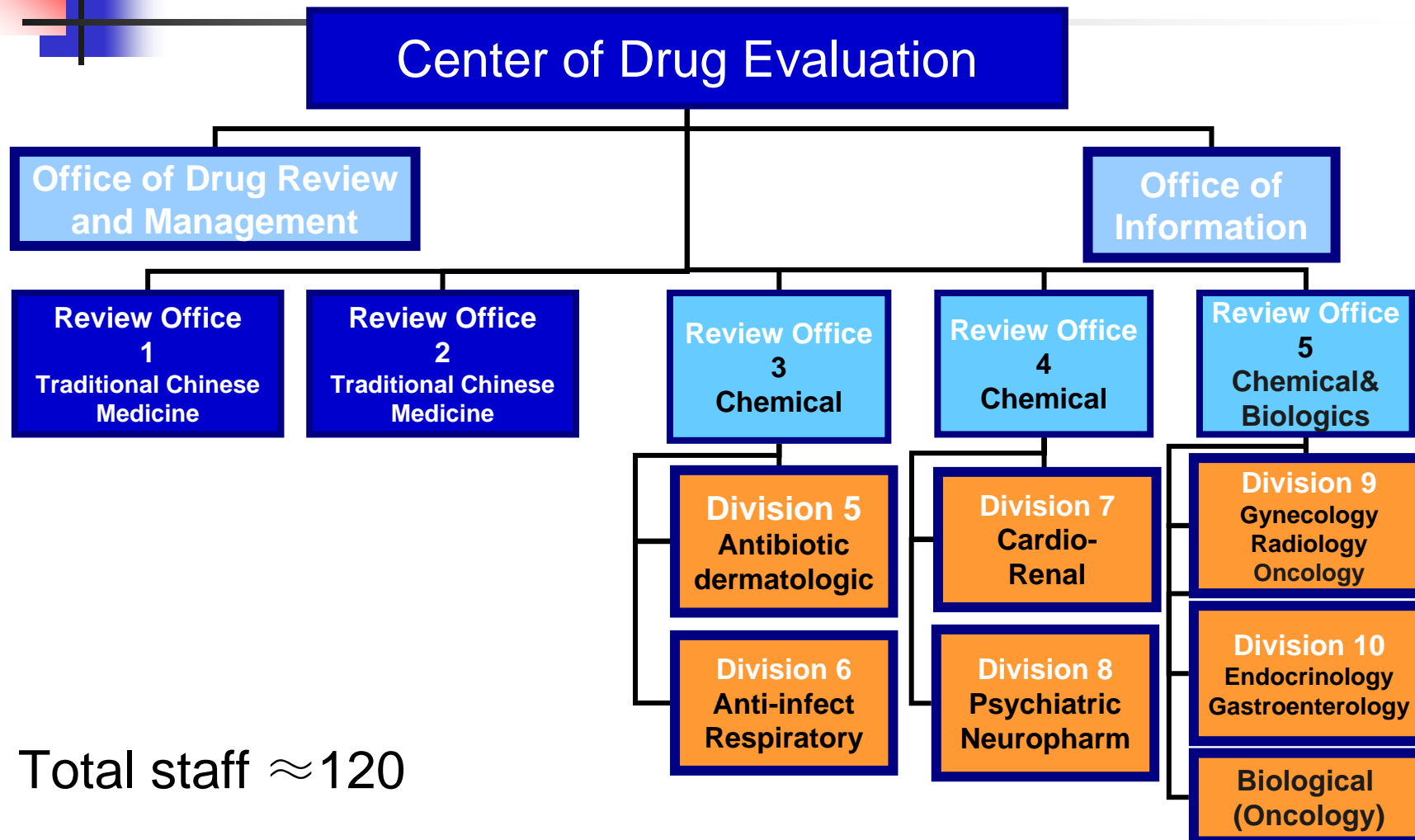


Center for Drug Evaluation (CDE)

- Responsible for technical review for CTA and IND/NDA applications
- US FDA CDER equivalent, similar structure and review scheme to CDER
- Organizational structure – therapeutic alignment



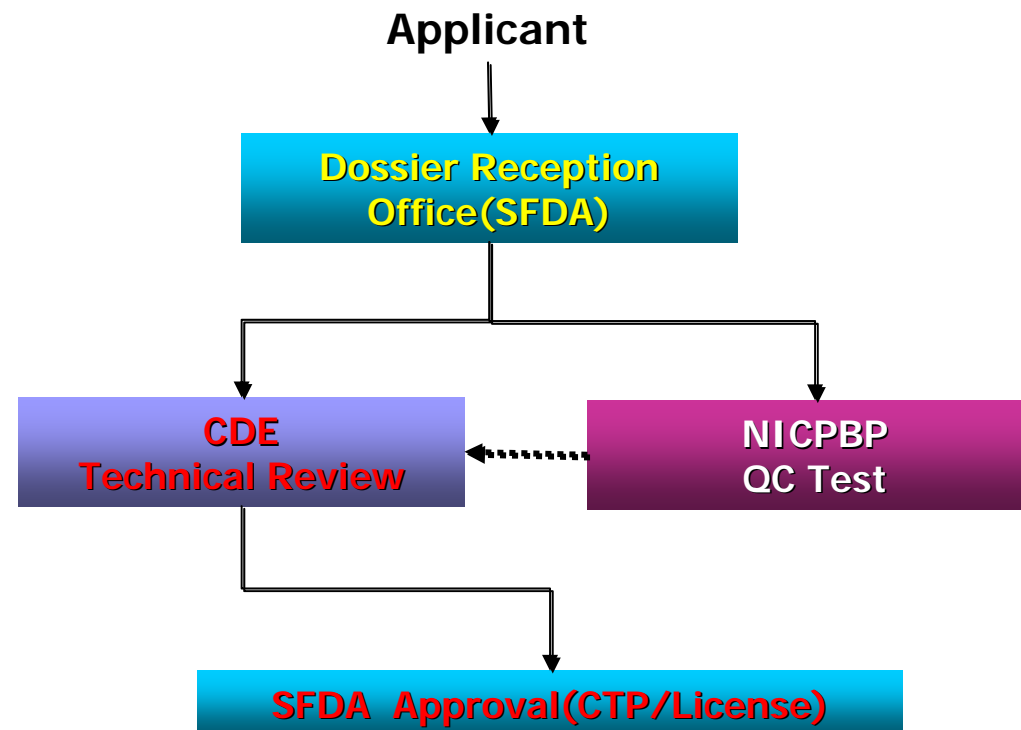
CDE Organization Chart



Total staff \approx 120



Regulatory Flow Chart



SFDA: State Food & Drug Administration

CDE: Center for Drug Evaluation

NICPBP: National Institute for the Control of Pharmaceutical & Biological Products



Positive Change & Trend of Agency

- SFDA is committed to promote drug innovation. The core is to build a quality review system based on GRP (Good Review Practice)
 - Regulatory review is transforming from a generic-dominated model to a model that promotes drug innovation.
 - Clinical-led, protocol-centered review model – Risk/benefit analysis
 - Special Review Procedure has been developed
 - Provision for reviewer-sponsor communication
 - A signal to establish a regulatory framework that separates IND from NDA (different sets of data/technical requirements, recognizing the global innovative drug development paradigm)
 - A high quality review system will eventually lead to a sustained reduction in clinical trial application review timeline



Special Review Procedure (e.g. Chemical Drug) (1)

	Standard Review Procedure	Special Review Procedure (SFDA issued in Jan. 2009)
Scope	Most applications go through this Standard Review Procedure	<ol style="list-style-type: none">1. NCE or New Bio-product which are not yet approved in any market2. New Drugs which are used for treatment of AIDS, malignant tumor and/or rare diseases and have obvious clinical therapeutic advantages3. New Drugs which treat diseases for which there is no effective therapy



Special Review Procedure (e.g. Chemical Drug) (2)

	Standard Review Procedure	Special Review Procedure (SFDA issued in Jan. 2009)
Timeline (Chemical Drug)	IND: 10.5 months NDA: 13.5 months	IND/CTA: 8-9 months NDA: 12 months
Rolling Submission	Not permitted	Permitted (e.g., safety, stability, CMC development, etc.)
CDE Consultation	No	Pre- & In process consultation is permitted

Advantage of Special Review Procedure will be lost once the drug is approved in any country.

Getting more harmonization with international regulatory standard and practice



- SFDA became ICH-GCG (Global Cooperation Group) member in 2007
- A memorandum of understanding (MOU) was signed in 2007 among Japan, Korea and China to promote Clinical Drug Developments in East Asia
- NCPBP became a member of United States Pharmacopoeia Convention (USP) in Feb.2008
- China Pharmacopoeia Commission (CPC) and USP sign a MOU in March 2008 with the purpose of working together to strengthen the quality of medicines and food in the States and China



Drug Development Model in China

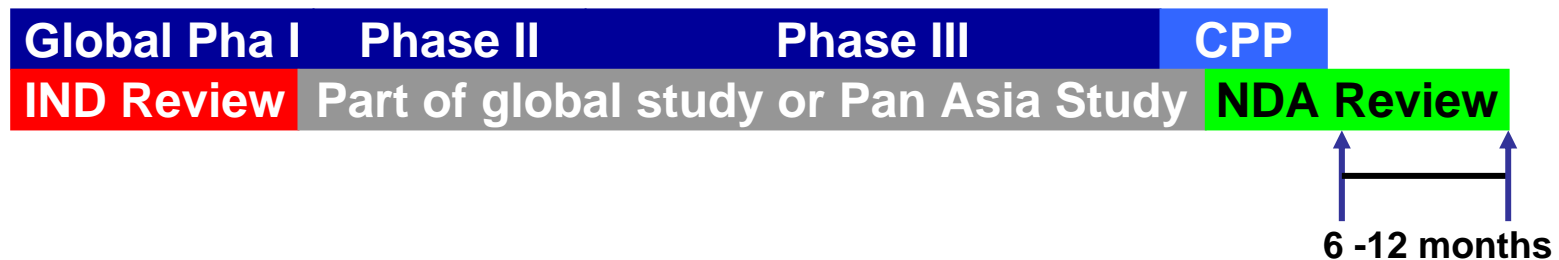
Yesterday

A Sequential development model - Delay the time to market



Today

A Parallel development model - Simultaneously launch



Tomorrow

An Independence development model- Regional Label for local Disease



Additional requirements for a MAA in China



- Detailed information about quality part requested, even very confidential information
- Administrative documents, e.g.
 - Application Forms
 - CPP
 - GMP certificates
 - Letter of authorizations (Power of Attorneys)
 - Labeling documents
 - SOPs for test methods
 - CoAs of DS and DP
- Only one manufacturer can be registered for DS and DP



Conclusion

- China is getting more and more important for pharmaceutical businesses
- A lot of global companies establish global functions (HUBs) in China for drug development
- China should be included quite early into the global regulatory strategy
- There are special requirements which needs to be considered before submission of MAA to the authority – otherwise a rejection of the application or a deficiency letter may be obtained
- Be proactive
- Talk to the agencies as a partner