Introduction of ICH China Research WG

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Background

- **Birth:** Jul 30, 2009
- **Leader:** Dep. of Drug Registration, SFDA
- **Parties involved:** SFDA, NICPBP, ChPC, CDE, CCD, CDR, Peking University, CQAP, RDPAC
- **Coverage:** Quality, Safety, Efficacy, Multidisciplinary

**Abbreviations:**
- CCD: Center for Drug Certification
- CDE: Center for Drug Evaluation
- CDR: Center for Drug Reevaluation
- ChPC: Chinese Pharmacopoeia Commission
- CQAP: China Quality Association for Pharmaceuticals Association Committee
- NICPBP: National Institute for the Control of Pharmaceutical and Biological Products
- RDPAC: R&D based Pharmaceutical
Sub-group responsibility

Core Committee
Determine working directions, approve and monitor budget.

WG - Q/S/E/M
According to each group’s working plan and other tasks assigned by Core Committee, Q/S/E/M WG carry out the translation, discussion and study and comparison of ICH guidelines, formulate the working reports.

Secretary Group
Responsible for meeting preparations, documents drafting, and coordinate with each groups.
Objectives

- Translate ICH guidelines to Chinese and publish as official version of ICH in Chinese
- Study and compare with China guidelines
- Revise, establish, improve China’s guidelines system adaptive to local situation and condition
- Training of ICH guidelines towards large number of audiences.
- Transform, disseminate WG study outcomes
- Tighten contact with ICH, strengthen exchange and cooperation with relative parties of ICH
Work Progress

- ICH China WG Meeting: 2~3 times / year
- ICH China WG Quarterly Newsletter: Mar, Jun, Sep 2010…
- ICH China WG e-room: in construction
# Work Schedule

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Participants</th>
<th>Outcome</th>
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| Jul 30 2009| ICH China WG Preparatory Meeting | 17 persons   | • ICH China WG establishment  
• WG structure and key members determination  
• Working direction determination |
| Dec 23 2009| ICH China WG 1<sup>st</sup> Meeting | 29 persons   | • WG members determination  
• Working plan determination  
• Preliminary Operating rules determination |
| Apr 2 2010 | ICH China WG 2<sup>nd</sup> Meeting | 36 persons   | • Missions and Responsibilities determination  
• Q/S/E/M/Secretary leaders reported study progress and next plan, discussed faced issues, solutions and further improving approaches  
• Financial policy and Operating rules determination |
| Sep 2010   | ICH China WG 3<sup>rd</sup> Meeting |              |                                                                         |
# Working task division

<table>
<thead>
<tr>
<th>ICH China WG Working Objective in 2010</th>
<th>Secretary Group</th>
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<tbody>
<tr>
<td>1. Translate and publish ICH guidelines</td>
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<td>2. Selected topic study</td>
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<td>3. Transformation of study outcome</td>
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<td>4. Training / dissemination</td>
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<tr>
<td>1. Coordinate ICH guidelines translation and publication in ICH China WG</td>
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<td>2. Edit Quarterly Newsletter: issued 1\textsuperscript{st} version of Mar 2010, next version June 2010</td>
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<td>3. Organize Working Meeting and coordinate Q/S/E/M WG seminar</td>
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<td>4. Coordinate training and dissemination: at least once a year</td>
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<td>5. Establish ICH China WG eroom</td>
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<td>6. Establish contact with ICH</td>
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<th>Quality WG</th>
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<td>1. Follow up and pay attention to Q11 progress</td>
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<td>2. Comparative study Q4B Annex and ChP, formulate final report to Core Committee by Q4 2010</td>
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<td>3. In-depth understanding of step 5 ICH guidelines: Q3A, Q3B, Q3C, Q1D, organize a seminar in Q4 2010.</td>
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<td>4. Introduction of Q8, Q9, Q10 and the implementation in ICH countries, study how to apply in R&amp;D and how to evaluate the registration dossier including QbD elements in China</td>
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<td>5. Training</td>
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## Task division

| **Safety WG** | 1. Translate ICH S1, S2, S3, S6, S9, M3: completion by Q3 2010  
2. Carcinogenicity Studies Guidelines Seminar: conducted in May 2010  
3. Summarize investigation feedback and formulate final report to Core Committee by Q4 2010  
4. Training |
| **Clinical WG** | 1. Comparative study of clinical guidelines of China and ICH  
2. E9: comparative study with China Biostat Guideline completion, formulate final report to Core Committee in Q3 2010  
3. E11: formulate final report to Core Committee in Q4 2010  
4. E2: start exploratory development in Q4 2010  
5. Training |
| **Multidisciplinary WG** | 1. Translate ICH M2, M5: complete by Q3 2010  
2. M1: introduce the application in ADR in 3rd working meeting  
3. M5: translation completion, formulate final report to Core Committee in Q4 2010  
4. Harmonize terminology, electronics code and vocabulary within each WG: complete glossary collection by Q4 2010  
5. Training |
Message from China ICH WG

- Official Chinese version of ICH Guidelines authorization from ICH
- Welcome involvement and participation of ICH EWG/IWG/GCG/MedDRA to the work progress of China ICH study WG.
- Welcome workshop being carried out in China brand-named as ICH
- Hope experts from China ICH study WG in the field of Q, E, S could be invited to attend ICH discussion, not only in GCG, but broader areas.
- The most interested area, Q11 right now.
THANK YOU!