China SFDA Updates
- New Structure and Responsibility

ICH St. Louis Meeting

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International Cooperation Dep.
State Food and Drug Administration, China
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History of SFDA

1998
- Establishment of SDA for Centralized drug supervision

2003
- Establishment of SFDA with additional function of comprehensive food supervision as well as administration of health food and cosmetics

2008
- Restructuring and functional adjustment

1998 2009
Functions of State Food and Drug Administration

SFDA

- Drug
- Medical Device
- Cosmetics
- Health Food
- Food Consumption
The Internal Structure of SFDA

Commissioner

- Deputy Commissioner
  - Deputy Commissioner
  - Deputy Commissioner
  - Deputy Commissioner

- General Office (Dept. of Planning & Finance)
- Dept. of Policy & Regulations
- Dept. of Food License
- Dept. of Food Safety Supervision
- Dept. of Drug Registration (Dept. of TCMs & Ethno-Medicines Supervision)
- Dept. of Medical Devices Supervision
- Dept. of Drug Safety & Inspection
- Bureau of Investigation & Enforcement
- Dept. of Personnel
- Dept. of International Cooperation
# Internal Structure of SFDA

<table>
<thead>
<tr>
<th>Department</th>
<th>Functions</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Office (Dept. of Planning &amp; Finance)</td>
<td>To assist commissioners, assist the formulation of policies, draft plans for development, allocate systematic resources, etc.</td>
</tr>
<tr>
<td>Dept. of Policy &amp; Regulations</td>
<td>To draft laws, regulations and provisions; law-enforcement monitoring; press release, etc.</td>
</tr>
<tr>
<td>Dept. of Food License</td>
<td>To issue license for food hygiene at consumption stage; registration of health food and cosmetics.</td>
</tr>
<tr>
<td>Dept. of Food Safety Supervision</td>
<td>To undertake daily inspection of food safety at consumption stage; supervise the production of health food and cosmetics.</td>
</tr>
<tr>
<td>Dept. of Drug Registration</td>
<td>To take charge of drug registration and supervise the implementation of GLP, GCP, etc.</td>
</tr>
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## Internal Structure of SFDA

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<tr>
<td>Dept. of Medical Devices Supervision</td>
<td>To take charge of clinical study, registration, production and distribution of medical devices.</td>
</tr>
<tr>
<td>Dept. of Drug Safety &amp; Inspection</td>
<td>To implement GAP, GMP, GSP; supervision of controlled drugs.</td>
</tr>
<tr>
<td>Bureau of Investigation &amp; Enforcement</td>
<td>To take charge of the market compliance of food safety at consumption stage, drugs, medical devices, health food and cosmetics; organize investigation and impose punishment on illegal activities.</td>
</tr>
<tr>
<td>Dept. of Personnel</td>
<td>To take charge of personnel affairs and registration of licensed pharmacists.</td>
</tr>
<tr>
<td>Dept. of International Cooperation</td>
<td>To carry out international exchanges and cooperation.</td>
</tr>
</tbody>
</table>
## Affiliated Organizations of SFDA

### State Food and Drug Administration

- National Institute for the control of Pharmaceuticals and Biological Products
- State Pharmacopoeia Commission
- Center for Drug Evaluation of SFDA
- Center for Drug Certification of SFDA
- National Committee on the Assessment of the Protected Traditional Chinese Medical Products (Center for Health Food Evaluation of SFDA)
- Center for Drug Reevaluation of SFDA (National Center for ADR Monitoring)
Affiliated Organizations of SFDA

- Center for Medical Device Evaluation of SFDA
- Information Center of SFDA
- Training Center of SFDA (Certification Center for Licensed Pharmacist of SFDA)
- China Pharmaceutical News paper
- China Medico-Pharmaceutical Science & Technology Publishing House
- China Center for Pharmaceutical International Exchange
- Southern Medicine Economic Research Institute of SFDA
## Affiliated Organizations of SFDA

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<tr>
<td>National Institute for the control of Pharmaceuticals and Biological Products</td>
<td>testing of drugs and medical devices, etc. as the top technical arbitration institute for drug quality in China</td>
</tr>
<tr>
<td>Center for Drug Evaluation of SFDA</td>
<td>technical evaluation for drug registration</td>
</tr>
<tr>
<td>Center for Drug Certification of SFDA</td>
<td>on-site inspection for GAP, GCP, GLP, GMP certification</td>
</tr>
<tr>
<td>National Committee on the Assessment of the Protected Traditional Chinese Medical Products (Center for Health Food Evaluation of SFDA)</td>
<td>technical assessment of the protected traditional Chinese medical products; technical evaluation for market authorization of health food</td>
</tr>
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### Affiliated Organizations of SFDA

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<tr>
<td>Center for Drug Reevaluation of SFDA (National Center for ADR Monitoring)</td>
<td>post-marketing surveillance through adverse reaction monitoring, re-evaluation and elimination of drugs</td>
</tr>
<tr>
<td>Center for Medical Device Evaluation of SFDA</td>
<td>technical evaluation for medical devices registration</td>
</tr>
<tr>
<td>Certification Center for Licensed Pharmacist of SFDA</td>
<td>Licensed pharmacist registration, further education, etc.</td>
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Local Food and Drug Administrations

SFDA

Provincial FDA: 31

Municipal & city-level FDA: 339

County-level FDA: 2344

People’s Government of Provinces, Autonomous Regions & Municipalities

Municipal & city-level People’s Government

County-level People’s Government
## Local Food and Drug Administrations

<table>
<thead>
<tr>
<th>Level</th>
<th>Administrative Organizations</th>
<th>Technical Organization</th>
<th>Staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>National level</td>
<td>1</td>
<td>16</td>
<td>205</td>
</tr>
<tr>
<td>Provincial level</td>
<td>31</td>
<td>167</td>
<td>2602</td>
</tr>
<tr>
<td>Municipal &amp; city level</td>
<td>339</td>
<td>362</td>
<td>11832</td>
</tr>
<tr>
<td>County level</td>
<td>2344</td>
<td>478</td>
<td>31580</td>
</tr>
<tr>
<td>Total</td>
<td>2715</td>
<td>1023</td>
<td>&gt;60000</td>
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SFDA ICH Related Activities

- Q8/Q9/Q10 Workshop Dec. 2008
- All ICH guidelines have translated to Chinese
- CDT legally used since Oct. 1, 2007, detailed Chinese version under way by CDE
- A training course established by SFDA training center on ICH
- Based on ICH 5, China-Korea-Japan, tri-party on CT will bring new inputs to GCG
- ICH study group established early 2009
- Officially representing to ICH GCG Oct, 2009
Suggestions

- Non ICH region do need training and fact-to-face communication with ICH experts
- Contribution from non-ICH expertise
- “Bring ICH to the Region” to “ICH in the Region” (physically presenting)
- Cooperation with DRA
- Cooperation among None-ICH RHI and DRA
- Relation with RHSC, APEC LISF
Thank you!