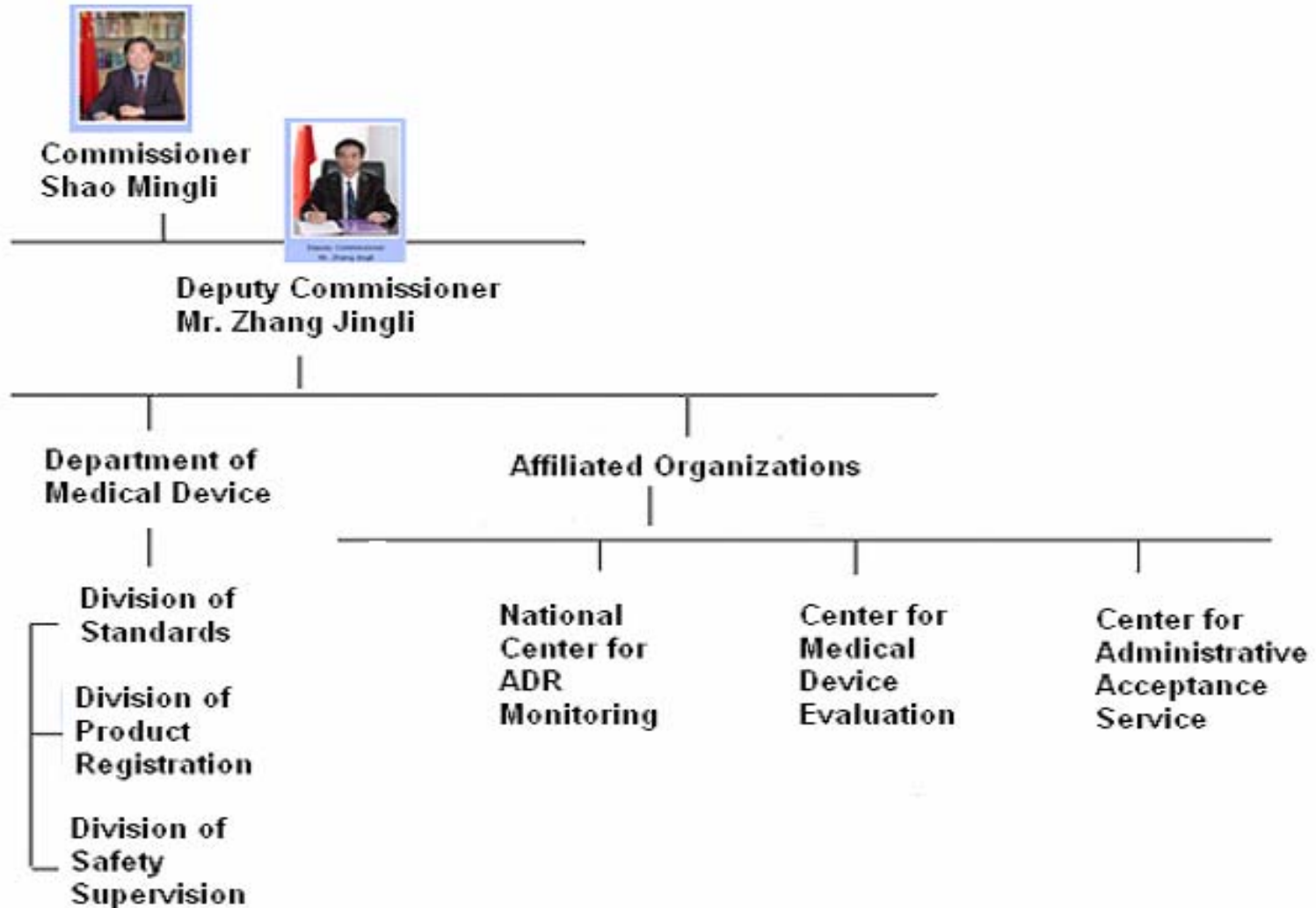


SFDA Organization Chart for Medical Devices



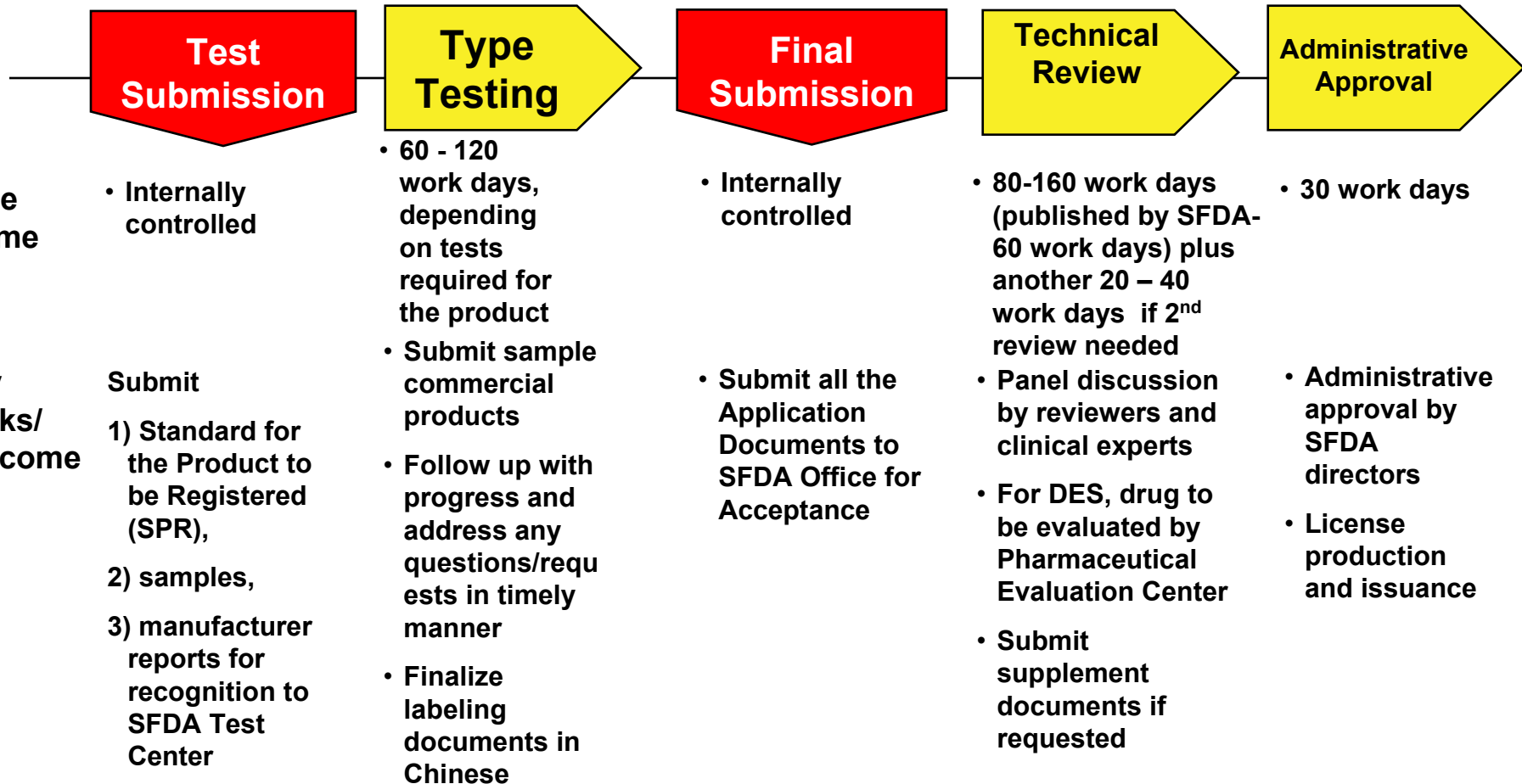
Regulatory Bodies for China Product Registration

- ❑ Center of Medical Device Evaluation (CMDE) is responsible for technical review of medical devices. CMDE is NOT under the Department of Medical Devices, but is one of the Affiliated organizations of SFDA.

- ❑ There are four divisions under CMDE, including:
 1. Division of Active Medical Devices
 2. Division of Non-Active Medical Devices, mainly includes implants for surgery, ophthalmic devices, and orthopedics devices.
 3. Division of In-Vitro Diagnostic Reagents
 4. Division of Non-Active Medical Devices, mainly includes injection / infusion medical devices

- ❑ There are only a total of 16 reviewers in CMDE, plus 4 heads of the 4 divisions, 2 co-directors, and 1 main director.

SFDA Product Registration Process



Whole process takes between 190 to 350 working days.



Medical Device Classification System

- The classification of medical devices should be determined by three aspects:
 - Structural characteristics
 - Form of operation
 - Conditions for use