AdvaMed
Advanced Medical Technology Association

How to Secure CFDA Pre-Market Approval and Post-Market Compliance

December 11-12, 2018

801 Pennsylvania Ave NW | Conference Center | Washington, DC

December 11, 2018

9:00 – 10:30 am **The Law and Regulations**

- The regulatory framework and evolution
- Pre-requisites for CFDA submission as a foreign medical device
- Different types of submissions
  - New submission for registration
  - Submission for change of registration (re-submission)
  - Submission for renewal without change
  - Filing for Class I device
- General process and requirements for CFDA registration
- How to do filing for Class I device

10:30 – 10:45 am **Break**

10:45 – 12:15 pm **Strategy and Planning**

- How to determine when re-submission for change is needed, and if re-submission rather than a new submission is acceptable
- How to determine if a new submission rather than re-submission is necessary
- How to determine if clinical trial in China is needed, and when clinical evaluation through predicate equivalency is acceptable
- Acceptance of foreign clinical trials data
  - When the applicant can be benefited
  - Criteria for acceptance
  - How to determine the acceptability: an internal assessment proposed
- When the clinical data on Chinese population is necessary and how to decide

12:15 – 1:30 pm **Lunch**

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1:30 – 2:30 pm **Strategy and Planning – Part 2**

- Taking advantage of CFDA special process for expedite approval
- Special process for innovative medical device
  - Criteria for eligibility and process for application
  - Who would be more benefited
- Preferential process for review & approval
  - Qualifications

2:30 – 4:00 pm **Clinical Trial or Evaluation Requirement**

- How to conduct clinical evaluation through predicate equivalency
  - Selection of a predicate(s)
  - Proving equivalency with predicate
  - Searching and collecting clinical data/literature
  - Data (META) analysis
  - Clinical evaluation report
- Steps to conduct clinical trial in China
- Quality requirement (GCP) and inspection for clinical trial
- Pre-approval for clinical trial with high risk devices

4:00 – 5:30 pm **Reception**

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9:00 – 10:30 am **Type Testing Requirement**

- The legal basis for type testing (political basis for why type testing needs to be done by CFDA test lab)
  - Type test of registration
  - Entrusted-commercial test
- How to determine what specifications shall be tested and can be accepted
  - Standards mandatory or recommended for use;
  - Guidance
  - Functionality/performance claimed
- Role of test laboratory accredited
- Potential acceptance of test report done by manufacturer's in-house test lab or third party.

10:30 – 10:45 am **Break**

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10:45 – 12:00 pm **CMDE/CFDA Review Process**

- Organization, roles and workflow
- Acceptance of submission dossier
- Interacting with CFDA before and during review process
- How to fulfill the supplementary request (deficiency) during review
- Consequence if it's failed to satisfy the supplementary request, and major causes for failure
    - GCP audit
    - Insufficient clinical data
    - Mandatory standard requirement
    - GMP audit
    - Others…

12:00 – 1:15 pm **Lunch**

1:15 – 2:30 pm **Restructure of the Administration**

- Overview of Restructure of Government since Mar 2018
- Establishment of State Administration for Market Regulation (SAMR)
- Changed roles and focus of National Medical Product Administration (NMPA)
- Impact of the changes on medical device industry
- Draft amendment for State Council's regulations for medical device

2:30 – 2:45 pm **Networking Break**

2:45 – 4:30 pm **Post-Market Compliance**

- Legal responsibilities of local agent in China and the manufacturer
- Custom clearance for importation
- Distribution license and the requirement
- Product/packaging labeling, IFU requirement
- Requirement for advertisement & promotional material
- Post-market Surveillance and recall requirements
- Quality requirement for medical equipment in use

4:30 pm **Adjourn**