How to Secure NMPA Pre-market Approval and Post-Market Compliance

November 19-20, 2024

The Alexandria at Torrey Pines | 10996 Torreyana Rd, San Diego, CA 92121

**Schedule reflects Pacific Daylight Time*

Tuesday, Nov 19

11:30 am – 12:30 pm **Check in & Networking Lunch**

12:30 pm – 1:45 pm **The Law and Regulations and Evolution**

- The regulatory framework and evolution
- Classifications and administration
- Prerequisites for NMPA submission as a foreign medical device
- Overview of registration approvals and trend analysis
- General requirements and process for NMPA registration

1:45 pm – 2:45 pm **Different Types of Submission and Strategy**

- 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
  - Filing for IFU change
- 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

2:45 pm – 3:00 pm **Networking Break**

3:00 pm – 4:15 pm **Clinical Evaluation based on Data from Predicate Equivalent and Literature**

- Options and pathway for clinical evaluation
- Principles for clinical evaluation based on predicate equivalency

- Types and uses of clinical and non-clinical data
- Strength level of clinical data as evidence
  - Literature
  - Real world clinical data
  - Post market surveillance
  - Clinical trials
- When and what clinical database/raw data is required for submission
- How to determine the right strategy for clinical evaluation

4:15 pm – 5:30 pm **Special Process to Expedite Pre-market Approval**

- Taking advantage of NMPA green channels for expedited approval
- Special process for innovative medical devices
  - Criteria for eligibility and processing of application
  - Who would benefit more?
- Preferential review & approval for products with urgent need
  - Eligibility and what products are qualified
  - Products for rare diseases
- Special policy in Hainan province for medical device without need for NMPA registration
- New Policy for urgent medical needs in Great Bay Area

5:30 pm – 6:30 pm **Networking Reception**

Wednesday, Nov 20

8:15 am – 9:00 am **Networking Breakfast**

9:00 am – 10:00 am **Clinical Trials in China**

- How to determine if clinical trial is needed, and clinical evaluation through predicate equivalency could not be accepted
- Submission with foreign clinical trial data without in-China trial
- Steps of conducting clinical trials in China
- Quality requirement (GCP) and inspection for clinical trial
- NMPA pre-approval for clinical trial for high-risk devices

- MOST's pre-approval for clinical study using human genetic resource (*MOST stands for Ministry of Science and Technology)

10:00 am – 11:15 am **Type Testing and Requirement**

- The legal basis for type testing
  - Type test of registration
  - Entrusted-commercial test
- How to determine what specifications shall be tested and can be accepted
- Composite Product Technical Requirement (PTR)
  - Standards mandatory or recommended for use
  - Technical guidance
  - Functionality/performance claim
  - Special requirement for AI device and medical software
- Work with NMPA-accredited lab for obtaining test report
- Acceptance of test report conducted by manufacturer's in-house test lab or third party

11:15 am – 11:30 am **Networking Break**

11:30 am – 12:45 pm **NMPA/CMDE Review Process and Communication**

- Organization, roles and workflow
- Acceptance checklist of submission dossier
  - Electronic submission (eRPS)
- Communication process with NMPA/CMDE* before and during review (*Center for Medical Device Tech Evaluation)
- How to fulfill the supplementary request (deficiency) during review
- Consequence if it fails to satisfy the supplementary request, and major causes for failure
  - GCP audit
  - Insufficient clinical data or failure of predicate equivalency
  - Mandatory standard requirement
  - Biocompatibility and toxicology of raw materials
  - QMS inspection during submission and review
  - Others

12:45 pm – 1:45 pm **Networking Lunch**

1:45 pm – 2:45 pm **Regulatory Updates and Foreseeing Future Development**

- Medical Device Regulations Amendments 2021
- Expanding Market Authorization Holder (MAH) program
- Transferring import devices registered to be "made in China"
- Implementing UDI system and GSP requirement for distributors of medical devices
- Launching Hainan pilot program for Real World Clinical Evidence
- Participating international safety information exchange (National Competent Authorities Report, NCAR)
- Exemption of Approval of Country of Origin as prerequisite for innovative products
- Clinical trial extension to benefit more patients with urgent need
- Manufacturer's in-house test report
- Pilot program for LDT (Laboratory Developed Test) implemented
- Re-test on GB9706.1 (IEC60601-1) series standard 3rd edition
- New GB or YY product standards development or modification
- Temporary import and use of non-registered medical devices in urgent needs by medical institute

Future Regulatory Development

- More legal responsibility of local agent and personnel
- Clinical trial exemption expansion and Multiple Center Clinical Trial
- Recognition of single QMS audit
- Facilitation of AI and medical robotic devices
- MAH expansion to overseas manufacturer or developer

2:45 pm – 4:00 pm **Post-market Compliance**

- Legal responsibilities of local legal agent and the manufacturer
- Adverse event reporting and re-evaluation requirements:
  - Understanding definition of adverse event
  - When, how and who to report and re-evaluate?

- Annual Self-Inspection Report for Manufacturer's Quality Management System (QMS)
- Periodic Risk Evaluation Report for device registered
- Recall requirement: what, when and who shall it be reported and executed?
- Post-market product test against PTR
- Product labeling, advertising and distribution license
- Overseas manufacture online or on-site inspection

4:00 pm **Program Concludes**