Tuesday, December 3, 2019
9:00 am – 10:15 am  The Law and Regulations
- The regulatory framework and evolution
- Pre-requisites for NMPA 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 NMPA registration

10:15 am – 10:30 am  Networking Break

10:30 am – 11:30 am  Strategy for Submission and Clinical Evaluation
- 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
- Alternative forms of clinical evidence as opposed to a clinical trial

11:30 am – 12:30 pm  Submission with Foreign Clinical Trial Data without in-China Trial
- Background of the new policy
- What are the benefits from this new policy, and who should pursue?
- Principles and requirements for acceptance of foreign clinical trial data
- How to predicate the acceptability of foreign clinical trial – introduction of an internal assessment worksheet
- When the clinical data on Chinese population is necessary and how to fulfill
- Best practice sharing on demonstration of no difference on the patient population

12:30 pm – 2:00 pm  Lunch
2:00 pm – 3:15 pm  Special Process to Expedite Premarket Approval
- Taking advantage of NMPA green-channels for expedite approval
- Special process for innovative medical device
  o Criteria of eligibility and process of application
  o Who would benefit more?
- Preferential review & approval for products in urgent need
  o Eligibility and what products are qualified
  o Product for rare diseases
- Special policy in Hainan province for medical device without need of NMPA’s registration
  o Humanitarian Devices Exemption

3:15 pm – 4:30 pm  Clinical Trial or Evaluation Requirement
- How to conduct clinical evaluation through predicate equivalency
  o Selection of a predicate(s)
  o How to determine equivalency with predicate, or justify for non-significance if there is any difference
  o Searching and collecting clinical data/literature
  o Data (META) analysis, when data subset is required
  o Clinical evaluation report
- Steps and specialty of conducting clinical trial in China
- Quality requirement (GCP) and inspection for clinical trial
- NMPA pre-approval for clinical trial with high risk devices
- MOST’s pre-approval for clinical study using human genetic resource

4:30 pm – 6:00 pm  Reception

Wednesday, December 4, 2019
9:00 am – 10:00 am  Type Testing Requirement
- The legal basis for type testing (political basis for why type testing needs to be done by NMPA test lab)
  o Type test of registration
  o Entrusted-commercial test
- How to determine what specifications shall be tested and can be accepted and composite Product Technical Requirement (PTR)
  o Standards mandatory or recommended for use;
  o Technical guidance
  o Functionality/performance claimed
  o Special requirement for AI device and medical software
- Role of test laboratory NMPA-accredited
- Potential acceptance of test report done by manufacturer’s in-house test lab or third party
10:00 am – 10:15 am  Networking Break

10:15 am – 11:30 am  CMDE/NMPA Review Process
- Organization, roles and workflow
- Acceptance of submission dossier
  - Electronic submission
- Interacting with NMPA before and during review process
- 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
  - GMP audit
  - Others...
- Overseas manufacture site inspection during review or post-market

11:30 am – 12:30 pm  Lunch

12:30 pm – 1:30 pm  Regulatory Updates in 2019 and Foreseeing Future Development
- Expanding Market Authorization Holder (MAH) program
- Implementing UDI system for the key products as 1st batch
- Launching Hainan pilot program for Real World Clinical Evidence
- Facilitating registration for rare diseases medical devices
- Releasing particular provision for customized medical device
- Participating international safety information exchange (National Competent Authorities Report, NCAR)
- Regulatory Amendment and future development
  - More legal responsibility of entity and personnel;
  - Clinical trial exemption expansion;
  - Manufacturer’s in-house test report;
  - Exemption of COO’s approval for innovative product;
  - Clinical trial extension to benefit more patients in urgent need;
  - Recognition of single QMS audit;
  - Facilitation of AI and medical robotic devices;
  - MAH expansion to overseas device manufacturer/developer.

1:30 pm – 1:45 pm  Networking Break
1:45 pm – 3:30 pm

Postmarket Compliance
- Joint responsibilities of local legal agent and the manufacturer
- Post-market Surveillance: AE reporting and recall requirements
- Product/packaging labeling, IFU requirement and
- Product import inspection
- Post-market product inspection against PTR
- Distribution license, and product promotion/advertising

3:30 pm

Closing Remarks
Ralph Ives, Executive Vice President, Global Strategy and Analysis, AdvaMed

3:35pm

Adjournment