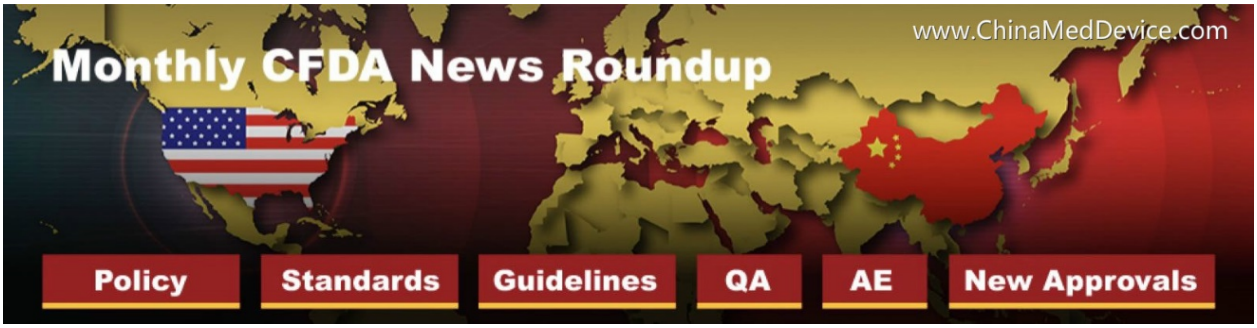


Monthly CFDA News Roundup covers policies, government reports, standards, guidelines, QA/recall/AE, and new approvals in medical device and IVD in China. It is edited by China Med Device, LLC (www.ChinaMedDevice.com) a consulting firm specializing in China CFDA regulatory, CRO and market access services.

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**Highlights:**

1. Second round UDI feedback has been requested by CFDA, to adequately identify medical devices through their distribution and use in China.
2. CFDA accelerates its effort in post-market surveillance, following the vaccine scandal with the demotion of major CFDA leadership.
3. Registration Holder system newly-initiated in two provinces, after successful piloting in Shanghai.
4. IVDs stand for 25% CFDA new approvals, and 3 IVD guidelines issued.

**Policy**

1. CFDA announced Unique Device Identification (**UDI**) draft plan on August 22. Feedbacks need to be submitted by September 21, 2018. This is the second round of UDI feedback requested by CFDA.
   When fully implemented, the label of all devices in China will include a unique device identifier in human- and machine-readable form. Within 60-day grace period, the license holder of the medical device shall upload the product identification and related data to CFDA UDI database.

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For English version of UDI draft plan, please email info@ChinaMedDevice.com.

2. CFDA issued Decree No.1 for Medical Device **Adverse Event Reporting** on August 31. More control, strictness and timely post-market surveillance will be enforced. The major changes from previous regulation include:
    - Provincial CFDA offices will take major responsibility for surveillance, instead of National Test Center as in the past. It means more staff and quicker action for "fly-inspection".
    - Overseas adverse events are required to be reported, and the report must be conducted by local legal agent.
    - Adverse event records shall be kept 2 years after the expiration date; 5 years if no expiration date provided; Implantable device registration holders shall keep the records permanently.
    - Yearly Risk Analysis becomes mandatory.
    - Penalties, such as stopping production, suspension of importation and fines, are specified for the first time.

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    For English version of the Decree, please email info@ChinaMedDevice.com.

3. CFDA published 2018 Medical Device Industry **Standard Revision Plan** on August 7th. Industry standard of 99 devices, IVDs and their quality system will be available by end of this year, some of which have already been issued so far.
    The standards also specify the modifications, effective dates, and give recommendations for registration application. CFDA will issue standards in 20 days after adoption, for the betterment of transparency of regulatory operation.

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4. CFDA announced Initiation for **Registration Holder system** in Guangdong and Tianjin, after Shanghai's piloting program started in early January. Registration holder in the three provinces can now be independent of the manufacturer.

5. CFDA issued Modified Requirement for Medical Device **Renewal Registration**. Issues including registration material, legal agent and multi-center trial have been addressed.

    For official CFDA link of above documents, please email info@ChinaMedDevice.com.

**Government Announcement**

3 CFDA national chiefs and 7 provincial leaders have been demoted on August 16, as result of the recent **vaccine scandal**. Public awareness and government alertness over QMS system have been elevated to a new level.

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**Guideline**

CFDA issued 7 guidelines including 3 for **IVDs**:
Technical Review Guideline on Nasogastric Tube
Technical Review Guideline on Disposable Sterile Catheter
Technical Review Guideline on Custom Denture
Technical Review Guideline on Intrauterine Device
Technical Review Guideline on Methicillin-Resistant Staphylococcus Aureus (MRSA) Reagent
Technical Review Guideline on Chromosomal Abnormalities Detection Reagent
Performance Evaluation Guideline of Next Generation Sequencing (NGS) Based Cancer Biomarker

**QA/Recall/AE**

1. CFDA announced **Voluntary Registration Withdrawals** during December 15, 2017 to June 25, 2018. 139 medical devices and IVDs have been voluntarily withdrawn due to incorrect clinical data and noncompliance with clinical trial regulation. **Beckman Coulter, Roche, Boston Scientific, Smith & Nephew and St. Jude** are on the list.

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2. CFDA announced **recall notices** for 11 imported medical devices and IVDs**. Johnson & Johnson, Philips, GE, Medtronic** and 7 others are on the list:

   Johnson & Johnson: Contact lens
   Philips: Mobile digital x ray machine
   GE: Single-photon emission computed tomography
   Medtronic: Disposable cutterhead
   DePuy Orthopaedics: Artificial knee joint
   BioMérieux: Gram-positive bacteria flashcard (class I recall)
   Biomet Orthopedics: Knee joint
   Zimmer: Metal intramedullary nail
   Mako Surgical: Orthopedic surgery navigation system
   Arrow: Central venous catheter

Teleflex Medical: Disposable laryngeal tube

For the reasons of recall and the model numbers, please email info@ChinaMedDevice.com.

**New Approval**

1. CFDA published Approvals of Medical Devices for July 2018. 45 domestic class III, 17 imported class III and 23 imported class II medical devices and IVDs have been approved. **GE, Roche, Boston Scientific, Life Technologies (US), and Edwards Lifesciences** are on the list. Among them are 21 IVD manufactures, accounting for 25% of total approval.

2. CFDA granted **Innovation Approval** status to a domestic manufacturer.
   Aipute: Anchor Balloon Dilatation Catheter

For summary of innovation approval guideline, click HERE. For complete English version of the guideline, please email info@ChinaMedDevice.com.

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**About China Med Device, LLC**

China Med Device, LLC provides turn-key solutions for western medical device/IVD companies to enter China with regulation and commercialization services. Our CFDA regulatory services cover strategy, RA, clinical evaluation, CRO, QA and post market compliance. We are experienced in handling innovation approvals and priority reviews. Our commercial services cover market assessment research, reimbursement, partnership, distribution qualification and management. We have offices in Beijing, Suzhou and Boston. Our management team has 100+ years of combined experience in medical device and IVD and has been involved with 1,000+ CFDA certificates and 250+ companies' success.