June 23rd, 2022

Medical Devices Regulatory Developments in China - Classification, Distribution, Manufacturing, and Clinical Trial

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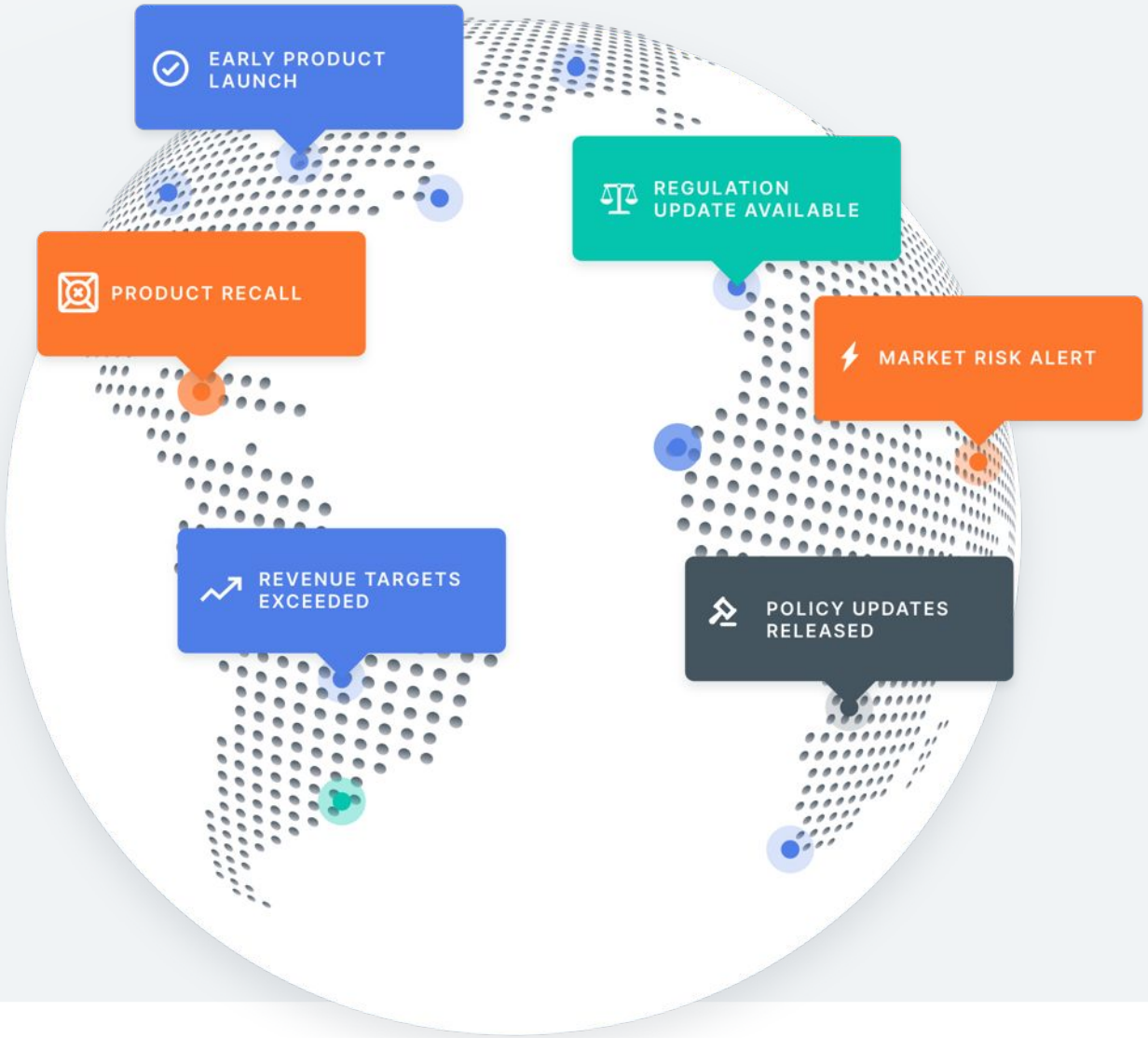
Amy specializes in consumer products compliance, focusing on China, Japan, South Korea, and other Asian countries.

She helps product manufacturers to identify and understand the regulations in place in the markets to which they sell by helping them to map their obligations with regard to product safety (chemicals, EMC, radio frequency), labeling, energy efficiency, waste and packaging.

WHAT WE DO

Unlocking Market Access

Keep on top of regulatory changes and their impact worldwide. Early warning alerts, impact probability, productivity workflow tools and so much more.



UNLOCKING MARKET ACCESS

C2P - The Key to Unlocking Market Access

EVIDENCE	→	Procure & link evidence records to relevant requirements to prove compliance
REQUIREMENTS	→	Capture, analyze & manage in the platform “live” linked to regulations & standards. Build customized sets of requirements covering your products & countries
STANDARDS	→	Contextual linking to regulations & requirements Searchable versions & equivalences of standards
REGULATIONS	→	Stay in control of the evolving regulatory landscape with access to 70,000+ proposed & enacted regulations & documents


Compliance & Risks
70k+
Sources
195
Countries
20+
Industries
25
Languages
30
Global Network Partners
20k
Expert Queries answered in 2021

Overview

1. Overview of regulatory developments
2. Changes in the classification of medical device pursuant to Order No. 739
3. Amended Administrative Measures on Manufacturing Medical Devices and key changes
4. New restrictions on distribution of medical devices
5. Measures on clinical trial for medical device
6. Developments in mandatory standards for medical devices

01

Recent regulatory development

Key Regulations

- Announcement No. 21 and No. 30, 2022 amending Medical Device Classification Catalogue
- Administrative Measures on Manufacturing Medical Devices, Order No. 53, 2022
- Catalogue of Medical Device that are Prohibited from Delegated Manufacturing, Notice No. 17, 2022
- Administrative Measures on Operation of Medical Device, Order No. 54, 2022
- Administrative Measures on Clinical Trial Management of Medical Devices, Order No. 28, 2022
- Notice No. 21, 2022 on Implementing Administrative Measures on Clinical Trial Management of Medical Devices
- China Medical Device Standards Annual Report 2021 version

Classification of Medical Devices

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Medical Device Classification Catalogue

- The Catalogue was first issued in 2002 and repealed by 2017 version which contains 22 subcategories and 6609 sample products
- Announcement No. 147, 2020 adjusted the classification of 15 categories of medical devices and content of 13 classifications
- Announcement No. 25, 2022 adjusted the classification and content of 10 medical devices
- Announcement No. 30, 2020 adjusted the content of 27 categories of medical devices

Catalogue of Class I Medical Devices

- 90 pieces of product information and 538 product examples were added
- “List of Prohibited Ingredients for Certain Class I Medical Device Products” added
- In vitro diagnostic reagents or combination products are not included
- Notice No. 107, 2021 on Implementation of Catalogue of Class I Medical Devices

Administrative Measures on Manufacturing of Medical Device

03

Key Changes

- Implementing medical device registration holder system
- Improving medical device manufacturing monitoring measures
- More severe penalties
- Delegated manufacture – Catalogue of Products Prohibited from Delegated Manufacture
- New report system

Supplementary Document

- Guidance on Medical Device Quality Management System Annual Self-check Report
- Catalogue of Products Prohibited from Delegated Manufacturing
- Guidance on Medical Device Delegated Manufacturing Agreement

Administrative Measures on Distribution of Medical Devices

04

Key Changes

- Distributer responsibility and life circle approach on quality control
- Strengthening supervision of medical device distribution
  - annual inspection
  - extended inspection
  - product risk study conference
  - credit record system
- New requirements on Distribution License and Filing

Administrative Measures on Clinical Trial of Medical Devices

05

Key Changes

- Integrated IVD into the new clinical pathway
- Adjust safety report system
  - “double report” to “single report”
  - reporting scope changed to serious adverse events related to the investigational medical devices
  - changing time limit for report
- Simplify supervision procedure

Notice No. 21, 2022

- From 1 May 2022, clinical trials to be conducted according to the new requirements

- Issuance of list of documents for clinical trial

- Medical device clinical trial plan template
- Medical device clinical trial report template
- In-vitro diagnostic reagent clinical trial protocol template
- In-vitro diagnostic reagent clinical trial report template
- Template reporting form for serious adverse events in clinical trials of medical devices/in vitro diagnostic reagents
- Catalogue of documents for medical device clinical trials

Mandatory Standards for Medical Device

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Annual Report on Medical Device Standard Management in China of 2021

- A total of 41 mandatory standards for medical devices were released in 2021, including 17 national standards and 24 industry standards.
- As of 31 December 2021, there are a total of 1,849 medical device standards, including 91 mandatory national standards and 144 voluntary national standards.

Annual Report on Medical Device Standard Management in China of 2021

- This report contains 5 annexes:

- Annex 1 List of national standards for medical devices released in 2021;
- Annex 2 List of medical device industrial standards published in 2021;
- Annex 3 List of medical device industrial standards that are amended in 2021;
- Annex 4 List of published collateral safety standards for medical electrical equipment; and
- Annex 5 List of published safety standards specific to medical electrical equipment.

Thank You!

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