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Detailed Program

Medical Device Market China

- Chinese Market for Medical Technology, Market Dynamics and Market Potential
- Health Care Reform and Government Programs
- Private Healthcare Facilities in China and Access to Private and Public Hospitals
- Challenges for Foreign Medical Technology Companies in China
- Tender Procedure in Chinese Healthcare Market
- Megatrends - Digitalization of China's Health Care and Medical Self Care
- Latest NMPA Report about Product Registration in China

Medical Device Authorization in the People's Republic of China

- New Market Regulation Administration SMAR
- Evolution of NMPA
- Regulatory Framework
- New Classification Catalog for Medical Devices and IVD in China
- NMPA Registration Types and Processes
- NMPA Legal Agent
- Application Checking List
- Comparison Test Standards CH vs EU and Type Test Requirements
- Clinical Trials
- Official fees
- Labeling Requirements for Medical Devices in China
- Unauthorized Claims and Penalties
- NMPA Confidentiality Code
- Certificate of Database

Latest Chinese Medical Device Regulatory Changes

- Role of NMPA Legal Agent and Handling of Adverse Events
- New Classification Catalogue
- Determination of Registration Units
- Type Test Options
- Acceptance of Overseas Clinical Data for Clinical Evaluation Report (CER) in China
- Company Name in Chinese
- Electronic Regulated Product Submission
- Amendment to <Regulations for the Supervision and Administration of Medical Devices>
- Special Requirement for Cyber Security
- Overseas Factory Inspections
- Unique Device Identification (UDI)

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About the Speakers

Anna Fischer attained degrees in Natural Sciences (BSc) and China Business (MSc) in England and Hong Kong and has been working for Cisema group since 2013. She has been advising companies on China certification as business consultant of Cisema in Munich, Beijing and Hong Kong. Anna Fischer currently resides in Hong Kong and has specialized in NMPA (National Medical Products Administration) registration of medical devices. She has written scientific work on topics of regulatory affairs in China.

Stefan Fischer is electrical engineer and, since 2002, managing director of Cisema group with offices in Munich, Vienna, Coventry, Chicago, Tokyo, Seoul, Hong Kong, Beijing, Hangzhou, Qingdao and Shenzhen. Prior to founding Cisema, he spent 17 years working for Siemens and relocated to Siemens Beijing in 1992. Stefan Fischer currently resides in Hong Kong. He focuses on NMPA registration of medical devices in China and regularly publishes specialist articles and consults companies on China certification.

About the company

Cisema was founded in 2002 as the first consulting firm for China Compulsory Certification (CCC). Today, the company has about 100 employees located at eleven locations all over the world. Cisema's guiding principle is transparency and, therefore, provides free information material to clients and holds in-house workshops, as well as public seminars.

Cisema supports a large number of companies with the NMPA (National Medical Products Administration, former CFDA) registration of their medical products in China. With help of the Instruction for Use (IFU) Cisema performs classification according to the Chinese Classification Catalog and issues quotations for the registration of medical devices and IVDs in China by providing full-cost calculations and milestone plans. As a full-service provider, Cisema supports the complete registration process until the certificate is issued. This includes type tests in China, preparation of the Clinical Evaluation Report (CER), submission of the application dossier, handling the Supplementary Notice and more. For many of their clients, Cisema also assumes the role of the local legal representative as NMPA Legal Agent. As a Clinical Research Organization (CRO), Cisema also conducts clinical trials in China.