NATIONAL MEDICAL PRODUCTS NEWSLETTER

NMPA Holds Meeting to Review Vaccine Regulation and Quality Management System

On May 4, the National Medical Products Administration (NMPA) held a review meeting on the vaccine regulation and quality management system in 2022, to summarize its construction and operation of the system, evaluate its appropriateness, effectiveness and adequacy, and make arrangements for the key tasks in the next stage.

NMPA Commissioner Jia Hong attended the meeting. Deputy Commissioner Huang Gao presided over the meeting.

The establishment of a vaccine regulation and quality management system is a basic element of the National Medical Products Administration (NMPA) and other regulatory authorities at all levels in China.

The NMPA has been implementing the vaccine regulation and quality management system and has significantly improved the safety and quality of vaccines, effectively regulating the vaccine industry and ensuring the safety and quality of vaccines.

At the meeting, the NMPA's Office of Vaccine Regulation and Quality Management System reported on the overall situation in the construction and operation of the system in 2022. The Department of Comprehensive Affairs, Planning, and Finance Affairs, the Department of Policies and Regulations, the Department of Drug Registration, the Department of Drug Regulation and the Department of Human Resource Affairs respectively reported on the operation of the system in each department.

In 2022, the NMPA advanced the quality management system based on the vaccine NRA assessment, formulated and updated procedural documents to standardize the regulatory process, improved its work through research and studies, elevated the operating efficiency and quality of the system via internal reviews, and enhanced the quality management capability of related personnel by strengthening training.

Remarkable progress has been made in the construction of the vaccine regulation and quality management system.

The meeting fully affirmed the outcomes in the construction of the vaccine regulation and quality management system. The NMPA has been building the system in line with China's national conditions and improving the overall quality and effectiveness of vaccine regulatory work, which has played a positive role in ensuring China's vaccine safety, as long as the vaccine regulation and quality management system has been operating steadily and effectively, and the regulatory work has been carried out orderly and in accordance with regulations.

The meeting stressed that the construction of the vaccine regulation and quality management system should be carried out in a profound and solid manner. First, efforts should be made to complete the vaccine NRA Institutional Development Plan (IDP) and rectify problems found during the internal review within the time limit and in line with quality requirements. Second, it is important to make further improvements by integrating quality management with regulatory work to improve the efficiency of the system. Third, mutual cooperation and coordination should be strengthened with other regulatory bodies.

NATIONAL MEDICAL PRODUCTS

2023 National Popular Science Week for Cosmetic Safety Kicks Off in Beijing

On May 22, the opening ceremony of the 2023 National Popular Science Week for Cosmetic Safety was held in Beijing. The opening ceremony is guided by China NMPA and jointly organized by Beijing, Tianjin, and Hebei Medical Products Administration, Lei Ping, member of NMPA Leadership Party Group and Deputy Commissioner, and Chen Bei, Deputy Secretary General of the People's Government of Beijing Municipality, attended and addressed the ceremony.

The National Popular Science Week for Cosmetic Safety is a brand activity for promoting popular science on cosmetics created by the NMPA, which has been held for 5 consecutive years. The theme of this cosmetic week is "Safe Use of Cosmetics, Co-governance and Sharing," aiming at promoting and implementing relevant regulations and provisions on the entity responsibility of cosmetics enterprises for cosmetic quality and safety, strengthening industry self-discipline, and enhancing social co-governance of cosmetic safety by taking the opportunity of implementing the rules on supervision and administration of enterprises taking entity responsibility of cosmetic quality and safety. More than 350 representatives from relevant industry associations, enterprises and media attended the ceremony.
Xu Jinghe Attended GWHC TC Open Workshop

On June 14, 2023, the Technical Committee of the Global Harmonization Working Party (GWHC TC) held an open workshop in Shenzhen, Guangdong Province. Xu Jinghe, the deputy commissioner of China’s National Medical Products Administration (NMPA) and Chairman of GWHC, attended the workshop and delivered a speech.

Xu Jinghe pointed out that GWHC is an important platform for regulatory cooperation among member countries and regions. At present, GWHC has formulated more than 40 technical guidelines, effectively facilitating the regulatory capacity improvement in member countries and regions. In the following years, GWHC will implement the GWHC Structural Framework toward 2026, in earnest, put more efforts in regulation publicity and enforcement, continue to carry out regulatory capacity development, bolster the convergence, harmonization and reliance in regulation, and actively contribute to global public health.

This open workshop introduced the GWHC Strategic Framework towards 2026, work achievements and future prospects of GWHC, TC review requirements for IVD and medical device software, etc. More than 300 representatives from GWHC member countries and regions attended the workshop onsite. The live streaming of the workshop was accessible to 33 member countries and regions. The representatives highly appreciated the workshop, regarding it as a good channel for global medical device enterprises and stakeholders to better understand international regulatory rules.

(Jun. 14, 2023)

Xu Jinghe Attends GWHC Technical Committee Leaders Meeting

The Technical Committee (TC) Leaders Meeting of the Global Harmonization Working Party (GWHC) was held on June 14 and 15 in Shenzhen, South China’s Guangdong province. The GWHC leadership, TC committees, groups, consultants and relevant experts participated in the event. The meeting focused on the work plan for formulating and revising regulations and recent key work arrangements. Xu Jinghe, deputy commissioner of China’s National Medical Products Administration (NMPA), attended and addressed the issue of member countries and regions.

(Jun. 16, 2023)

Zubretamab Injection Approved for Marketing

Recently, the Zubretamab injection (Chinese trade name: 小分子) of Zhejiang BioRay Biopharmaceutical Co., Ltd. is approved for marketing by China NMPA. This drug is indicated for the treatment of CDDO positive diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) for adult patients, and should be combined with standard chemotherapy (cyclophosphamide, doxorubicin, vincristine, prednisone).

(Zubretamab Injection is a human-mouse chimeric monoclonal antibody targeting the CDDO antigen on the surface of B cells. It can specifically bind to the CD95 antigen on the surface of B cells, thereby initiating the immune response of B cells to cytolytic and exerting anti-tumor effects. The marketing of this drug provides more treatment options for patients.

(May 27, 2023)

Xu Jinghe and GWHC TC Leaders Meeting

On May 14, 2023, at 8:30 a.m., the National Medical Products Administration held a meeting (GWHC TC Leaders Meeting) in Shenzhen, South China’s Guangdong province. Xu Jinghe, deputy commissioner of China’s National Medical Products Administration (NMPA), attended and addressed the issue of member countries and regions.

Xu said that health is the issue of greatest concern, the most eternal pursuit, and the most precious wealth of humanity. The GWHC TC working groups should conscientiously fulfill their mission, actively adapt to the new needs of innovative development in the global medical device industry, formulate and regulate regulatory coordination plans in a timely manner, and accelerate the regulatory convergence, harmonization and reliance of member countries and regions.

In order to enhance the publicity, training and application of regulations and to continue to improve regulatory systems and capabilities of member countries and regions, Xu added. He also underscored the efforts to adhere to the principles of openness, cooperation, and consensus. He further emphasized the importance of leveraging the advantages of the GWHC and strengthening communication and cooperation with relevant international organizations, in a bid to protect and promote global public health.

(Jun. 16, 2023)

Afosbuvir Tablets Approved for Marketing

Recently, the Class-I innovative drug Afosbuvir Tablets (Chinese trade name: 乐可菲) of Nanning SanPharmaceutical Co., Ltd. is approved for marketing by China NMPA. It is an innovative drug independently developed in China with independent intellectual property rights. Used in combination with dacomitinib hydrochloride, it is indicated for the treatment of chronic hepatitis C virus (HCV) of genotype 2, 1 and 6 infection for adults who are initially treated or have been treated with interferon, combined with or without compensatory cirrhosis.

Afosbuvir is an inhibitor for HCV NS5B RNA-dependent polymerase (necessary for virus replication). It is a nucleoside precursor drug, metabolized into pharmacologically active metabolites (S12923M) in the cell, which can be encoded into HCV RNA by NS5B polymerase to terminate replication. The marketing of this drug provides a new treatment option for adult patients with chronic HCV infection.

(May 17, 2023)
The meeting also called for greater efforts to thoroughly implement the guiding principles of the 20th National Congress of the Communist Party of China, advance the development and operation of the regulation and quality management system, strengthen drug safety regulation, improve the efficiency of drug regulation, promote the modernization of the drug regulatory system and regulatory capacity through quality management, and to drive the high-quality development of the drug industry in a bid to contribute to the Chinese modernization of drug regulation.

(May 4, 2023)

Xu Jingle Attended GHWC TC Open Workshop

On June 14, 2023, the Technical Committee of the Global Harmonization Working Party (GHWC TC) held an open workshop in Shenzhen, Guangdong Province. Xu Jingle, the deputy commissioner of China’s National Medical Products Administration (NMPA) and Chairman of GHWC, attended the workshop and delivered a speech. Xu Jingle pointed out that GHWC is an critical platform for regulatory cooperation among member countries and regions. At present, GHWC has formulated more than 60 technical guidelines, effectively facilitating the regulatory capacity improvement in member countries and regions. In the following years, GHWC will implement the GHWC Strategic Framework towards NOC, earn more funds in regulation publicity and enforcement, continue to carry out regulatory capacity development, bolster the convergence, harmonization and reliability in regulation, and actively contribute to global public health.

This open workshop introduced the GHWC Strategic Framework towards 2026, key achievements and future prospects of GHWC, regulatory requirements for IVD and medical device software, etc. More than 300 representatives from GDWC member countries and regions attended the workshop on-site. The live streaming of the workshop was accessible to 33 member countries and regions. The representatives highly appreciated the workshop, regarding it as a good channel for global medical device enterprises and stakeholders to better understand international regulatory rules.

(June 14, 2023)

Duc Duong and Xu Jingle Attended Global Harmonization Working Party (GHWC) TC Open Workshop

Recently, the Zubetanatam injection (Chinese trade name: Zuzen) of Zhejiang BiyoBai Pharmaceutical Co., Ltd. is approved for marketing by China NMPA. This drug is indicated for the treatment of CD30 positive diffuse large B lymphoma, non-metastatic unspecified (CD30+), NOS for adults, and should be combined with standard CHOP therapies (cytosplastamid, doxorubicin, vincristine, prednisone).

Zubetanatam injection is a human-mouse chimera monoclonal antibody targeting the CD30 antigen on the surface of B cells. It can specifically bind to the CD30 antigen on the surface of B cells, thereby initiating the immune response of B cytolytic and exerting anti-tumor effects. The marketing of this drug provides more treatment options for patients.

(July 27, 2020)

Aflosbav Tablets Approved for Marketing

Recently, the Class 1: innovative drug Aflosbav Tablets (Chinese trade name: Zafed) of Nanjing Sathome Pharmaceutical Co., Ltd. is approved for marketing through the priority review and approval procedure of China NMPA. It is an innovative drug independently developed in China with independent intellectual property rights. Used in combination with dachau drug, it is indicated for the treatment of chronic hepatitis virus (HCV) of genotype 1, 2 and 6 infection for adults who are initially treated or have been treated with interferon, combined with or without compensatory cirrhosis.

Aflosbav is an inhibitor for HCV NS5B RNA-dependant polymerase (necessary for virus replication). It is a nucleoside precursor drug, metabolized into pharmacoologically active metabolites (SH292MS3) in the cell, which can be converted into HCV RNA by NS5B polymerase to terminate replication. The marketing of this drug provides a new treatment option for adult patients with chronic HCV infection.

(July 17, 2023)
Befotertinib Mesylate Capsules Approved for Marketing

Recently, the Class I innovative product Befotertinib Mesylate Capsules (Chinese trade name: 贝福替尼) of Betta Pharmaceuticals Co., Ltd. is approved by China NMPA. It is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that had progressed after prior EGFR tyrosine kinase inhibitor therapy, and with epidermal growth factor receptor (EGFR) T790M mutation. Befotertinib Mesylate is the third-generation EGFR tyrosine kinase inhibitor, which can selectively inhibit EGFR sensitive mutation and EGFR T790M drug-resistant mutation.

(Nov. 3, 2021)

Medical Devices

Magnetic Resonance Monitoring Semiconductor Laser Treatment Equipment Approved for Marketing

Recently, the innovative product Magnetic Resonance Monitoring Semiconductor Laser Treatment Equipment of Sinovation (Beijing) Medical Technology Co., Ltd. is approved by China NMPA. The core technology of magnetic resonance monitoring of this product has a national invention patent. During the laser treatment process, magnetic resonance temperature imaging technology is used to receive the gradient echo sequence of magnetic resonance equipment in real time, thereby calculating the temperature of the treatment area and realizing real-time monitoring during the treatment process. This product, together with disposable laser optical fiber kit, is used for laser treatment of local lesions (with a clear epidermopelagic area or a clear epilasitic pathway) for patients with drug unresponsive epilepsy. Due to shorter treatment time, smaller damage to healthy brain tissues and less postoperative complications, patients will recover quickly, and the treatment difficulty of intracranial lesions in neurosurgery is reduced. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Apr. 30, 2021)

Disposable Laser Optical Fiber Kit Approved for Marketing

Recently, the innovative product Disposable Laser Optical Fiber Kit of Sinovation (Beijing) Medical Technology Co., Ltd. is approved by China NMPA. The core technologies such as structures, materials, structure, and manufacturing process of this product have national invention patents. Under long-term working conditions, the optical fiber undergoes almost no deformation when heated, and therefore the intensity of laser scattering along the axis can relatively maintain consistency. This not only increases the treatment range, but also reduces the thermal power density, thus effectively improving the safety of surgery. This product, together with magnetic resonance monitoring semiconductor laser treatment equipment, achieves the minimally invasive treatment of intracranial lesions in neurosurgery and is used for laser treatment of local lesions (with a clear epiploctopelagic area or a clear epilasitic pathway) for patients with drug unresponsive epilepsy. Due to shorter treatment time, smaller damage to healthy brain tissues and less postoperative complications, patients will recover quickly, and the treatment difficulty of intracranial lesions in neurosurgery is reduced. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Apr. 14, 2023)

Coronary Function Measurement System Approved for Marketing

Recently, the innovative product Coronary Function Measurement System of Suzhou RainMed Medical Technology Co., Ltd. is approved by China NMPA. The product is composed of work station, transducer, IPD (heart and IBP signal input cable) and (optional), and only applied with the disposable invasive pressure transducer of Suzhou RainMed Medical Technology Co., Ltd. It is intended to assess Coronary Angiography Index of Microvascular Resistance (eIMR) by conducting vascular segmentation and three-dimensional reconstruction on coronary angiography images, and making hemodynamic analysis combing with the aortic pressure measured by disposable invasive pressure transducer, which assists clinicians to assess the function of coronary microcirculation for patients. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Apr. 20, 2023)

Coronary Function Measurement System Approved for Marketing

Recently, the innovative product Coronary Function Measurement System of Suzhou RainMed Medical Technology Co., Ltd. is approved by China NMPA. The product is composed of work station, transducer, IPD (heart and IBP signal input cable) and (optional), and only applied with the disposable invasive pressure transducer of Suzhou RainMed Medical Technology Co., Ltd. It is intended to assess Coronary Angiography Index of Microvascular Resistance (eIMR) by conducting vascular segmentation and three-dimensional reconstruction on coronary angiography images, and making hemodynamic analysis combing with the aortic pressure measured by disposable invasive pressure transducer, which assists clinicians to assess the function of coronary microcirculation for patients. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Apr. 20, 2023)
Befotertin Mesylate Capsules Approved for Marketing

Recently, the Class I innovative product Befotertin Mesylate Capsules (Chinese trade name: 贝福替尼胶囊) of Berta Pharmaceutical Co., Ltd. is approved by China NMPA. It is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that had progressed after prior EGFR tyrosine kinase inhibitor therapy, and with epidermal growth factor receptor (EGFR) T790M-mutated.

Befotertin Mesylate is the third-generation EGFR tyrosine kinase inhibitor, which can selectively inhibit EGFR sensitive mutation and EGFR T790M drug-resistant mutation.

NMPA Holds Training on NRA for Vaccines in Beijing

The National Medical Products Administration (NMPA) held a special training session in Beijing from June 6 to 7, where experts from the World Health Organization (WHO) introduced the National Regulatory Authority (NRA) for vaccines, and the NMPA Deputy Commissioner Huang Guo addressed and attended the event.

Six experts, including Rodrigo Gaspar, Director of Regulation and Prequalification Department of the WHO, expounded on the development of related cutting-edge technologies, international experience in the construction of the NRA, Good Regulatory Practices for regulatory authorities, the development of the quality management system, as well as drug vigilance and pre-qualification based on the assessment of the NRA for vaccines.

The event was organized by the NMPA’s Institute of Executive Development. Officials from related departments of the NMPA, affiliated institutions, the Chinese Center for Disease Control and Prevention, and provincial-level medical products administrations participated in the training.

Disposable Laser Optical Fiber Kit Approved for Marketing

Recently, the innovative product Disposable Laser Optical Fiber Kit of Sinovation (Beijing) Medical Technology Co., Ltd. is approved by China NMPA.

The core technologies such as materials, structure, and manufacturing process of this product have national invention patents. Under long-term working conditions, the optical fiber undergoes almost no deformation when heated, and therefore the intensity of laser scattering along the axis can relatively maintain consistency. This not only increases the treatment range, but also reduces the laser power density, thus effectively improving the treatment effect.

This product, together with magnetic resonance imaging, is used to conduct minimally invasive treatment of intracranial lesions in neurosurgery, and is used for laser treatment of local lesions (with a clear epileptic focus area or a clear epileptic pathway) for patients with drug non-responsive epilepsy due to shorter treatment time, smaller damage to healthy brain tissues and less postoperative complications, patients will recover quickly, and the treatment difficulty of intracranial lesions in neurosurgery is reduced. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

Coronary Function Measurement System Approved for Marketing

Recently, the innovative product Coronary Function Measurement System of Suzhou RainMed Medical Technology Co., Ltd. is approved by China NMPA.

The product is composed of work station, transmitter, IOP (intraocular pressure) signal input cable (optional), and only applied with the disposable invasive pressure transducer of Suzhou RainMed Medical Technology Co., Ltd.

It is intended to assess Coronary Angiography Index of Microvascular Resistance (mIMR) by conducting vascular segmentation and three-dimensional reconstruction images, and making hemodynamic analysis combining with the aortic pressure measured by disposable invasive pressure transducer, which assists clinicians to assess the function of coronary microcirculation for patients. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.
Metal Additive Manufacturing Thoracolumbar Fusion Matching Prosthesis System Approved for Marketing

Recently, the innovative product Metal Additive Manufacturing Thoracolumbar Fusion Matching Prosthesis System of Beijing AK Medical Co., Ltd. is approved by China NMPA. This product is composed of thoracolumbar fusion matching prostheses and matching components such as buckles and screws. This product innovatively adopts polyethylene buckles as a flexible connection device, combined with the posterior screw-cement system, to achieve a “true” structural joint of fixation of the anterior and posterior approach. For patients who require multi-segment thoracolumbar resection and reconstruction, this product adopts a porous structure and can realize matching design for patients (designed and manufactured based on patient CT data) and implant fixation, which can improve the comprehensive quality of life and survival rate of patients to a certain extent. This product is intended for structural reconstruction from upper thoracic vertebrae to lower lumbar vertebrae (T1-L5) after three or more consecutive vertebral resections due to tumors or other lesions. It needs to be matched with the spinal interconnective system and achieve permanent implantation. The marketing of this product will provide a new treatment option for patients. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Apr 21, 2023)

Self-expanding Radioactive Seed-Carried Biliary Stent Approved for Marketing

On May 11, 2023, the innovative product Self-expanding Radioactive Seed-Carried Biliary Stent of Rongsheng (Nanjing) Medical Technology Co., Ltd. is approved by NMPA. By far 200 innovative medical devices have been approved by NMPA. The product consists of an internal and an external stent, each with a disposable introducer, and the external stent with a empty seed capsule. It combines radioactive therapy with stent technology for treatment of malignant biliary obstruction. The dual stent structure of the internal and external stent reduces the diameter of the external tube of the introducer, allowing for micro-invasive therapy and providing a vehicle for 3-dimensional intraoperative radiotherapy while expanding the stent. This product is indicated for the dilation and treatment of biliary stricture or obstruction caused by malignant tumours that are inoperable or not surgically removed due to unwillinngness. After implantation, the Self-expanding Radioactive Seed-Carried Biliary Stent can dilate the biliary stricture and allow the radioactive seeds carried on the stent can provide brachytherapy to the tumour tissue to inhibit tumour growth, which is expected to prolong the effective bile duct patency time and improve the survival time and life quality of patients. The marketing of this product will provide a new treatment option for patients.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Jun 21, 2023)

Intravascular Imaging Device Approved for Marketing

Recently, the innovative product Intravascular Imaging Device (Navisight Hybrid System) of Conavi Medical Inc is approved by China NMPA. This product is composed of a console and a patient interface module (PIM), and is used in conjunction with a single-use IVUS OCT catheter for intravascular imaging of coronary arteries during percutaneous coronary interventional operation. The imaging catheter of this product is equipped with IVUS and OCT probes at the far end, which can automatically obtain images and feedback them to the user, making the imaging procedure easier and achieving simultaneous registration of intravascular ultrasound and optical interference tomography imaging. This product is superior to similar marketed products and can achieve both types of imaging simultaneously, which meets doctors’ requirements for resolution and penetration, simplifies doctors’ operations, and improves accuracy and safety of imaging. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(May 16, 2023)

Radiotherapy Planning Software Approved for Marketing

Recently, the innovative product radiotherapy planning software of Shanghai United Imaging Healthcare Co. Ltd. is approved by China NMPA. This product is used to plan external radiotherapy treatments with photon and electron beams. Its core technology mainly includes automatic beam arrangement and automatic plan optimization algorithm. The former automatically designs the beam gantry...
Self-expanding Radioactive Seed-Carried Bilary Stent Approved for Marketing

On May 11, 2023, the innovative product "Self-expanding Radioactive Seed-Carried Bilary Stent of Rongbang (Jinan) Medical Technology Co., Ltd." approved by NMPA. By far 200 innovative medical devices have been approved by NMPA.

The product consists of an internal and an external stent, each with a disposable introducer, and the external stent with a empty seed capsule. It combines radioactive seeds therapy with stent technology for the treatment of malignant bilary obstruction. The dual stent structure of the internal and external stent reduces the diameter of the external tube of the introducer, allowing for micro-invasive therapy and providing a vehicle for 3-dimensional intra-organ radiotherapy while expanding the stent. This product is indicated for the dilation and treatment of bilary stricture or obstruction caused by malignant tumours that are inoperable or not surgically removed due to unwillingness. After implantation, the Self-expanding Radioactive Seed-Carried Bilary Stent can dilate the bilary stricture and the radioactive seeds carried on the stent can provide brachytherapy to the tumour tissue to inhibit tumour growth, which is expected to prolong the effective bile duct patency time and improve the survival time and life quality of patients. The marketing of this product will provide a new treatment option for patient.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients. (May 11, 2023)

Intravascular Imaging Device Approved for Marketing

Recently, the innovative product "Intravascular Imaging Device (Navisight Hybrid System) of Conavi Medical Inc." approved by China NMPA. This product is composed of a console and a patient interface module (PIM), and is used in conjunction with a single-use IVUS OCT catheter for intravascular imaging of coronary interventional operation.

The imaging catheter of this product is equipped with IVUS and OCT probes at the far end and feedback them to each other simultaneously, achieving the synchronous imaging registration of intravascular ultrasound and optical fiber imaging technology. This product is superior to similar marketed products and can achieve both types of imaging simultaneously, which meets doctors’ requirements for resolution and penetration, simplifies doctors’ operations, and improves accuracy and safety of imaging. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients. (May 15, 2023)

Radiotherapy Planning Software Approved for Marketing

Recently, the innovative product "Radiotherapy planning software of Shanghai United Imaging Healthcare Co., Ltd." approved by China NMPA. This product is used to plan external radiotherapy treatments with photon and electron beams. Its core technology mainly includes automatic beam arrangement and automatic plan optimization algorithm. The former automatically designs the beam gantry identifying policies, further ensuring the quality of radiotherapy, reducing misdiagnosis, and improving the standardization of examination operations. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients. (May 12, 2023)
NATIONAL MEDICAL PRODUCTS NEWSLETTER

NMPA Holds Meeting to Review Vaccine Regulation and Quality Management System

On May 4, the National Medical Products Administration (NMPA) held a review meeting on the vaccine regulation and quality management system in 2022, to summarize the construction and operation of the system, evaluate its appropriateness, effectiveness and adequacy, and make arrangements for the key tasks in the next stage.

NMPA Commissioner Jin Hong attended the meeting. NMPA Deputy Commissioner Huang Gao presided over the meeting.

The establishment of a vaccine regulation and quality management system is a basic element in the World Health Organization (WHO) National Regulatory Authority (NRA) assessment of vaccines, and also an important demand to comprehensively improve China's vaccine regulatory capacity and promote the healthy development of China's vaccine industry. The NMPA attaches great significance to the construction, integrates the requirements of the WHO assessment and regulatory practices, and consistently advances the construction of the vaccine regulation and quality management system, which has greatly improved scientists-based and standardized vaccine regulation.

At the meeting, the NMPA's Office of Vaccine Regulation and Quality Management System reported the overall situation in the construction and operation of the system in 2022. The Department of Comprehensive Affairs, Planning, and Finance Affairs, the Department of Policies and Regulations, the Department of Drug Registration, the Department of Drug Regulation and the Department of Human Resources respectively reported the operation of the system in each department. In 2022, the NMPA advanced the quality management system based on the vaccine NRA assessment, formulated and updated procedural documents to standardize the regulatory process, improved its work through research and studies, elevated the operating efficiency and quality of the system via internal reviews, and enhanced the quality management capability of related personnel by strengthening training. Remarkable progress has been made in the construction of the vaccine regulation and quality management system.

The meeting fully affirmed the outcomes in the construction of the vaccine regulation and quality management system. The NMPA has been building the system in line with China's national conditions and improving the overall quality and effectiveness of vaccine regulatory work, which has played a positive role in enabling China to pass the lowest vaccine NRA assessment. The meeting noted that in the past year, the vaccine regulation and quality management system has been operating steadily and effectively, and the regulatory work has been carried out orderly and in accordance with regulations.

The meeting stressed that the construction of the vaccine regulation and quality management system should be carried out in a profound and solid manner. First, efforts should be made to complete the vaccine NRA Institutional Development Plan (IDP) and rectify problems found during the internal reviews within the time limit and in line with quality requirements. Second, it is important to make further improvements by integrating quality management with regulatory work to improve the efficiency of the system. Third, mutual...