List of Regulatory Notifications and Administrative Notice

as of 2025/10/10

Primary Category	Secondary Category	Tertiary Category	Title of Regulatory Document	Types of Regulatory Documents	Number	Date of Issue
Pharmaceuticals and Medical Devices Act			Act on Ensuring Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, etc. (Enacted on November 25, 2014)	Act	Showa35year law no.145issue	2025/6/1
			Enforcement Order of the Act on Ensuring Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, etc.	Cabinet Order	Showa36Cabinet Order No.11issue	2024/12/12
			Enforcement Regulations of the Law Concerning Ensuring Quality, Effectiveness, and Safety of Pharmaceuticals, Medical Devices, etc.	Ministerial Ordinance	Showa36Ministry of Health and Welfare Ordinance No.1issue	2025/6/1
	Business license related	Manufacturing related	Regarding handling of the manufacturing industry of medical devices and in vitro diagnostic drugs	Nofitication	Pharmaceutical and Food Agency1003No.1issue	2014/10/3
			Q&A regarding the handling of medical device and in vitro diagnostic drug manufacturing businesses	Nofitication	Pharmaceutical and Food Agency1020No.4issue	2014/10/20
			Q&A regarding licenses for medical device manufacturing and sales businesses	Administrative Notice		2013/1/11
		Sales and rental related businesses/ Repair industry related	Regarding the sale and rental of medical equipment	Nofitication	Pharmaceutical and Food Agency0410No.1issue	2015/4/10
			Questions and Answers (Q&A) regarding the handling of medical equipment rental business	Nofitication	Pharmaceutical and Food Agency1121No.51issue	2014/11/21
			Questions and Answers (Q&A) regarding the handling of medical equipment sales and repair businesses	Administrative Notice		2018/3/30
			Providing information on "Questions and Answers on Medical Equipment Sales, Rental and Repair Businesses"	Administrative Notice		2020/12/25□
			Processing notifications regarding the sale or rental of used goods by manufacturers and distributors	Nofitication	Drug, Food and Drug Administration1018No.1issue	2013/10/18
			Regarding the provision of information from the Japan Medical Device Association on "Questions and Answers on the Sales, Rental and Repair of Medical Equipment"	Administrative Notice		2012/11/28
			Q&A regarding the handling of sales and rental businesses of medical equipment (part 2)	Administrative Notice		2006/6/28
			Q&A regarding the handling of sales and rental businesses of medical equipment (Part 1)	Administrative Notice		2005/3/31□
			About the "Guidelines for Compliance with Laws and Regulations for Medical Equipment Retailers, Rental Companies, and Repairers"	Nofitication	Pharmaceutical Sciences0601No.1issue	2021/6/1
			Regarding the typographical error in the administrative notice dated December 25, 2020, "Provision of information on the 'Questions and Answers on the Sales, Rental and Repair of Medical Equipment'"	Administrative Notice		2021/3/12
			Providing information on "Questions and Answers on Medical Equipment Sales, Rental and Repair Businesses"	Administrative Notice		2020/12/25
			Questions and Answers (Q&A) regarding the handling of medical equipment sales and repair businesses	Administrative Notice		2018/3/30
			Q&A regarding the handling of medical equipment repair businesses (part 2)	Administrative Notice		2013/2/28
			Regarding the provision of information from the Japan Medical Device Association on "Questions and Answers on the Sales, Rental and Repair of Medical Equipment"	Other		2012/11/28□
			Q&A regarding the handling of medical equipment repair businesses	Administrative Notice		2005/4/1
			Regarding the operation of medical equipment repair businesses following the enforcement of the Act amending the Pharmaceutical Affairs Act and the Blood Collection and Donation Services Control Act	Nofitication	Drug and Food Machinery0331004issue	2005/3/31
			Applicability of medical equipment repair classification	Nofitication	Pharmaceutical and Food Safety0331008issue	2005/3/31
		Pharmaceutical Affairs and Medical Devices	Revision of the "Pharmaceutical Affairs Surveillance Guidance Guidelines" and the "Guidelines for Surveillance and Guidance of Pharmacies, Pharmaceutical Sales Businesses, etc."	Nofitication	Pharmaceutical and Food Agency1217No.3issue	2014/12/17
	QMSMinisterial Ordinance-related	QMSMinisterial Ordinance-related	Ministerial Ordinance on Standards for Systems for Carrying Out Operations Related to Manufacturing Control or Quality Control of Medical Devices or In Vitro Diagnostics (QMS System Ordinance)	Ministerial Ordinance	Ministerial Order No.94issue	2014/8/6
			Ministerial Ordinance on the Standards for Systems for Manufacturing and Quality Control of Medical Devices and In Vitro Diagnostics	Nofitication	Drug, Food and Drug Administration0911No.1issue	2014/9/11

			Partial amendment of the Ministerial Ordinance on the Standards for Systems for Manufacturing and Quality Control of Medical Devices and In Vitro Diagnostics	Nofitication	Pharmaceutical and Narcotics Agency0326No.8issue	2021/3/26
			Partial amendment of the evaluation criteria of the Ministerial Ordinance on the standards for systems for the manufacture and quality control of medical devices and in vitro diagnostics	Nofitication	Pharmaceutical and Narcotics Agency0713No.4issue	2021/7/13
	GVPMinisterial Ordinance	GVPMinisterial Ordinance	Ministerial Ordinance on Standards for Post-Marketing Safety Management of Drugs, Quasi-drugs, Cosmetics, Medical Devices, and Regenerative Medicine Products	Ministerial Ordinance	Ministerial Order No.135issue	2004/9/22
			Enforcement of the "Ministerial Ordinance Partially Revising the Enforcement Regulations of the Act on Ensuring Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, etc.," "Ministerial Ordinance Partially Revising the Ministerial Ordinance on Standards for Post-Marketing Safety Management of Pharmaceuticals, Quasi-drugs, Cosmetics, Medical Devices, and Regenerative Medicine Products, etc." and "Ministerial Ordinance Partially Revising the Ministerial Ordinance on Standards for Post-Marketing Surveillance and Testing of Medical Devices"	Nofitication	Pharmaceutical Sciences0731No.4issue	2017/7/31
			Enforcement of the Ministerial Ordinance on Standards for Post-Marketing Safety Management	Nofitication	Pharmaceutical and Food Agency0812No.4issue	2014/8/12
			Conformity assessment of standards for post-marketing safety management of pharmaceuticals, quasi-drugs, cosmetics, medical devices, and regenerative medicine products	Nofitication	Pharmaceutical and Food Safety Agency0930No.2issue	2014/9/30
	QMSMinisterial Ordinances	QMSMinisterial Ordinance	Ministerial Ordinance on Standards for Manufacturing Management and Quality Control of Medical Devices and In Vitro Diagnostics (Enforced November 25, 2014) (New QMS Ordinance)	Ministerial Ordinance	Ministry of Health, Labour and Welfare Ordinance No.169issue	2004/12/17
			Amendments to the QMS Ministerial Ordinance and enactment, amendment, and abolition of related ministerial ordinances and notices in accordance with the enforcement of the revised Pharmaceutical Affairs Law	Nofitication	Pharmaceutical and Food Agency0812No.1issue	2014/8/12
			Revision of the QMS Ministerial Ordinance in line with the enforcement of the revised Pharmaceutical Affairs Law	Nofitication	Drug, Food and Drug Administration0827No.4issue	2014/8/27
			Q&A on standards for manufacturing and quality control of medical devices and in vitro diagnostics	Nofitication	Drug, Food and Drug Administration1121No.twenty fiveissue	2014/11/21
			Questions and Answers (Q&A) on Standards for Manufacturing and Quality Control of Medical Devices and In Vitro Diagnostic Reagents (Part 2)	Nofitication	Drug, Food and Drug Administration0313No.8issue	2015/3/13
			Questions and Answers (Q&A) on Standards for Manufacturing and Quality Control of Medical Devices and In Vitro Diagnostics (Part 3)	Nofitication	Drug, Food and Drug Administration0901No.5issue	2015/9/1
			Revision of the Notification Concerning the Ministerial Ordinance on Standards for Manufacturing Management and Quality Control of Medical Devices and In Vitro Diagnostic Reagents	Nofitication	Drug, Food and Drug Administration0901No.1issue	2015/9/1
			Revision of the Ministerial Ordinance on Standards for Manufacturing and Quality Control of Medical Devices and In Vitro Diagnostic Reagents Related to Remanufactured Single-Use Medical Devices	Nofitication	Pharmaceutical and Narcotics Agency0731No.12issue	2017/7/31
			Partial amendment of the Ministerial Ordinance on Standards for Manufacturing and Quality Control of Medical Devices and In Vitro Diagnostic Reagents	Nofitication	Pharmaceutical and Narcotics Agency0326No.4issue	2021/3/26
			Revision of the Ministerial Ordinance on Standards for Manufacturing and Quality Control of Medical Devices and In Vitro Diagnostic Reagents and Revision of Related Ministerial Ordinances and Notifications	Nofitication	Pharmaceutical Sciences0326No.10issue	2021/3/26
			Partial amendment of the Ministerial Ordinance on Standards for Manufacturing and Quality Control of Pharmaceuticals and Quasi-drugs (Excerpt)	Nofitication	Pharmaceutical and Narcotics Agency0428No.2issue	2021/4/28
			Questions and Answers on Standards for Manufacturing and Quality Control of Medical Devices and In Vitro Diagnostics (Part 4)	Administrative Notice		2022/3/4
			Regarding partial revision of the "Partial revision of the Ministerial Ordinance on Standards for Manufacturing Management and Quality Control of Medical Devices and In Vitro Diagnostic Reagents"	Nofitication	Pharmaceutical and Narcotics Affairs0131No.1issue	2025/1/31
		QMSConformity Survey Related	Q&A regarding QMS conformity inspections for medical devices and in vitro diagnostics	Administrative Notice		2009/10/21

			Regarding the Q&A on "Handling QMS Conformity Inspection Applications"	Administrative Notice		2011/4/1
			Mutual use of survey results from QMS inspections and surveillance inspections	Nofitication	Drug, Food and Drug Administration0401No.12No. Yakushokuki0401No.7issue	2011/4/1
			Q&A regarding the relationship between the QMS Ministerial Ordinance and ISO13485:2003	Administrative Notice		2011/5/30
			How to handle the revision of ISO13485 in QMS surveys	Administrative Notice		2016/7/29
			Examples of issues raised in QMS conformity inspections and guidance on how to achieve conformity	Administrative Notice		2017/4/3
			Handling of Standards Conformity Certificates and QMS Conformity Inspection Applications	Nofitication	Pharmaceutical and Narcotics Agency0831No.1No.0831No.16issue	2020/8/31
			Procedures for using MDSAP reports in QMS conformity inspections	Nofitication	Pharmaceutical Machinery1118022issue	2021/11/18
			Regarding handling of simultaneous applications for approval, etc. and QMS inspection applications	Administrative Notice		2023/2/7
			QMS Inspection Guidelines	Nofitication	Pharmaceutical and Narcotics Affairs0612No.2issue	2024/6/12
			Regarding partial revision of "QMS Inspection Guidelines"	Nofitication	Pharmaceutical and Narcotics Affairs 0708No. 7	2024/7/8
			Regarding documents to be attached to simple consultation regarding QMS inspection (Revised parts: Form 1, Form 2 (2015/1/30))	Administrative Notice		2014/12/3
			Documents to be submitted when applying for a QMS conformity inspection	Administrative Notice		2025/10/1
		Product group	Ministerial Ordinance on the classification of medical devices or in vitro diagnostics prescribed in Article 23-2-5, Paragraph 7, Item 1 of the Law on Ensuring Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, etc. (Product Group Ordinance)	Ministerial Ordinance	Ministry of Health, Labour and Welfare Ordinance No.95issue	2020/9/1
			Medical devices or in vitro diagnostics designated by the Minister of Health, Labour and Welfare as those for which an investigation should be conducted for each item pursuant to the provisions of Article 2, Paragraph 1 of the Ministerial Ordinance on the Classification of Medical Devices or In Vitro Diagnostics as stipulated in Article 23-2-5, Paragraph 8, Item 1 of the Law on Ensuring Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, etc.	Nofitication	Ministry of Health, Labor and Welfare Notification No.317issue	2014/8/6
			Partial amendment of the medical devices or in vitro diagnostics designated by the Minister of Health, Labour and Welfare as those for which an investigation should be conducted for each item pursuant to the provisions of Article 2, Paragraph 1 of the Ministerial Ordinance on the Classification of Medical Devices or In Vitro Diagnostics as Provided in Article 23-2-5, Paragraph 8, Item 1 of the Law on Ensuring Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, etc.	Nofitication	Ministry of Health, Labor and Welfare Notification No.196issue	2021/5/14
			Applicability of medical devices and in vitro diagnostic products	Nofitication	Drug, Food and Drug Administration0911No.5issue	2014/9/11
			Selection of multiple product group categories in QMS conformity inspection applications	Nofitication	Drug, Food and Drug Administration1121No.twenty oneissue	2014/11/21
			Q&A on standards for manufacturing and quality control of medical devices and in vitro diagnostics	Nofitication	Drug, Food and Drug Administration1121No.twenty fiveissue	2014/11/21
			Handling of Standards Conformity Certificates and QMS Conformity Inspection Applications	Nofitication	Pharmaceutical and Narcotics Agency0831No.1No.0831No.16issue	2017/7/31
	Medical device manufacturing and sales approval/Certification Application/Notification related	Manufacturing and sales approval application related	Application for approval to manufacture and sell medical devices	Nofitication	Pharmaceutical and Food Agency1120No.5issue	2014/11/20
			Points to note when applying for manufacturing and sales approval for medical devices	Nofitication	Pharmaceutical and Food Agency1120No.1issue	2014/11/20
			Points to note when preparing attachments for medical device manufacturing and sales approval applications	Nofitication	Drug and food machine0120No.9issue	2015/1/20

			Questions and Answers (Q&A) regarding medical device manufacturing and sales approval applications and attached documents	Nofitication	Pharmaceutical and Food Agency0601No.1issue	2015/6/1
			Questions and Answers (Q&A) regarding medical device manufacturing and sales approval applications and attached documents (Part 2)	Nofitication	Yakusei Machinery0301No.1issue	2016/3/1
			Regarding partial revision of "Points to note when preparing attached documents for medical device manufacturing and sales approval applications"	Nofitication	Pharmaceuticals and Medical Devices Agency0228No.7issue	2018/2/28
			Revision of Good Review Practice for Medical Devices	Administrative Notice		2016/6/3
			Regarding confirmation of generic medical device approval application documents	Administrative Notice		2015/3/11
		Manufacturing and sales certification application related	Application for certification to manufacture and sell medical devices	Nofitication	Pharmaceutical and Food Agency1120No.8issue	2014/11/20
			Points to note when applying for certification to manufacture and sell medical devices	Nofitication	Pharmaceutical and Food Agency1120No.4issue	2014/11/20
			Regarding the handling of documents concerning the reliability of documents to be attached to the application for certification of highly-regulated medical devices	Nofitication	Pharmaceutical and Food Agency1120No.8issue	2014/11/20
			Points to note when preparing attachments for medical device manufacturing and sales certification applications	Nofitication	Pharmaceutical and Food Agency0210No.1issue	2015/2/10
		Designated highly-regulated medical device	Regarding the handling of certification standards for highly-regulated medical devices	Nofitication	Pharmaceutical and Food Agency1105No.2issue	2014/11/5
			Regarding the handling of certification standards for highly-regulated medical devices (2)	Nofitication	Pharmaceutical and Food Agency0325No.1issue	2015/3/25
			Regarding the handling of certification standards for highly-regulated medical devices (part 3)	Nofitication	Pharmaceutical and Food Agency0930No.2issue	2015/9/30
			Regarding the handling of certification standards for highly-regulated medical devices (part 4)	Nofitication	Pharmaceutical Sciences1118No.1issue	2015/11/18
			Regarding the handling of certification standards for highly-regulated medical devices (part 5)	Nofitication	Pharmaceutical Sciences1224No.4issue	2015/12/24
			Regarding the handling of certification standards for highly-regulated medical devices (part 6)	Nofitication	Pharmaceutical Sciences0330No.1issue	2016/3/30
			Regarding the handling of certification standards for highly-regulated medical devices (part 7)	Nofitication	Pharmaceutical Sciences0407No.6issue	2017/4/7
			Regarding the handling of certification standards for highly-regulated medical devices (part 8)	Nofitication	Pharmaceutical Sciences0307No.1issue	2023/3/7
			Conformity checklist for designated highly-controlled medical devices, etc.	Nofitication	Pharmaceutical and Food Agency0325No.1issue	2015/3/25
			Partial amendments to the handling of certification standards for highly-regulated medical devices	Nofitication	Pharmaceutical Sciences0225No.1issue	2020/6/26
			Partial amendments to the handling of certification standards for highly-regulated medical devices	Nofitication	Pharmaceutical Sciences0626No.1issue	2020/2/25
			Regarding the handling of documents concerning the reliability of documents to be attached to the application for certification of highly-regulated medical devices	Nofitication	Pharmaceutical and Food Agency1120No.8issue	2014/11/20
		Manufacturing and sales notification related	Points to note when submitting a manufacturing and sales notification for medical devices	Nofitication	Pharmaceutical and Food Agency1121No.41issue	2014/11/21
			Q&A Regarding Notification of Manufacture and Sale of Medical Devices (Instruments Used in Orthopedic and Dental Implant Surgery, etc.)	Administrative Notice		2025/10/10
		Approval etc.Q&A	Q&A regarding approval applications for medical devices and in vitro diagnostics	Nofitication	Pharmaceutical and Food Agency1125No.twenty twoissue	2014/11/25
			Questions and Answers (Q&A) regarding approval applications for medical devices and in vitro diagnostics (part 2)	Nofitication	Pharmaceuticals and Medical Devices Agency0201No.1issue	2019/2/1
			Q&A regarding approval applications for medical devices and in vitro diagnostics	Administrative Notice		2006/11/27
			Questions and Answers (Q&A) regarding approval applications for medical devices and in vitro diagnostics, Part 2	Administrative Notice		2007/3/8
			Questions and Answers (Q&A) regarding approval applications for medical devices and in vitro diagnostics, Part 3	Administrative Notice		2008/6/16
		New basic requirements standards	Basic Requirements Standards (effective from November 25, 2014)	Nofitication	Notification No.122issue	2005/3/29

			Regarding the handling of standards for medical devices and in vitro diagnostics stipulated by the Minister of Health, Labour and Welfare pursuant to Article 41, Paragraph 3 of the Pharmaceuticals and Medical Devices Act	Nofitication	Pharmaceutical and Food Agency1105No.5issue	2014/11/5
		raw materials	Regarding the handling of registration master records for pharmaceutical ingredients, etc. for medical device raw materials	Nofitication	Pharmaceuticals and Medical Devices Agency0530No.1issue	2029/5/30
			Questions and Answers (Q&A) regarding procedures for changing raw materials for medical devices	Nofitication	Drug and food machine0529No.4issue	2013/5/29
			Procedures for changing raw materials for medical devices	Nofitication	Drug and food machine0329No.7issue	2013/3/29
			Q&A regarding the description of ingredients in medical device manufacturing and sales approval applications	Administrative Notice		2007/8/15
			Regarding the submission of the report on the international harmonization study on the efficacy and safety evaluation methods of medical devices, "Description of ingredients in application forms for approval of manufacture (import) of medical devices"	Administrative Notice	Administrative Notice Medical Device ReviewNo.19	2004/11/15
		biological safety	Regarding the complete revision of "Amendment of the basic principles of biological safety assessment required for manufacturing and sales approval applications for medical devices"	Nofitication	Pharmaceuticals and Medical Devices Agency0311No.1issue	2025/3/11
			Questions and Answers (Q&A) on the Basic Principles of Biological Safety Assessment Required for Medical Device Manufacturing and Sales Approval Applications	Administrative Notice		2025/3/11□
			Questions and Answers (Q&A) on the Basic Principles of Biological Safety Assessment Required for Medical Device Manufacturing and Sales Approval Applications (Part 2)	Nofitication	Pharmaceuticals and Medical Devices Agency0106No.4issue	2020/1/6
		Cybersecurity	Application of Article 12, Paragraph 3 of the Basic Requirements for Medical Devices	Nofitication	Pharmaceuticals and Medical Devices Agency0331No.8issue	2023/3/31
			Regarding confirmation of conformity with Article 12, Paragraph 3 of the Basic Requirements for Medical Devices	Nofitication	Pharmaceuticals and Medical Devices Agency0523No.1issue	2023/3/31
			Questions and Answers (Q&A) regarding the application of Article 12, Paragraph 3 of the Essential Requirements for Medical Devices	Administrative Notice		2023/7/20
			Provision of information related to cybersecurity measures for medical devices	Nofitication	Pharmaceuticals and Medical Devices Agency0417No.1No. Pharmaceutical and Medical Devices Safety and Health0417No.1issue	2025/4/17
			Handling of minor change procedures due to partial changes related to cybersecurity measures for medical devices	Nofitication	Pharmaceuticals and Medical Devices Agency0423No.1issue	2024/4/23
			Vulnerability management to ensure cybersecurity of medical devices	Nofitication	Pharmaceuticals and Medical Devices Agency0328No.1No. Pharmaceutical and Medical Devices Safety and Health0328No.3issue	2024/3/28
			Questions and Answers (Q&A) on Cybersecurity of Medical Devices	Administrative Notice		2024/1/31
			Basic principles for reporting defects in medical device cybersecurity	Nofitication	Pharmaceutical Safety and Health0115No.2issue	2024/1/15
			Revision of the Guide for Introducing Cybersecurity to Medical Devices	Nofitication	Pharmaceuticals and Medical Devices Agency0331No.11No. Yakusho Anhatsu0331No.4issue	2023/3/31
			Guide for ensuring and enforcing cybersecurity for medical devices	Nofitication	Pharmaceuticals and Medical Devices Agency1224No.1No. Yakusho Anhatsu1224No.1issue	2021/12/24
			IMDRF publishes guidance on medical device cybersecurity principles and practices	Nofitication	Pharmaceuticals and Medical Devices Agency0513No.1No. Yakusho Anhatsu0513No.1issue	2020/5/13
			Guidance on ensuring cybersecurity of medical devices	Nofitication	Pharmaceuticals and Medical Devices Agency0724No.1No. Yakusho Anhatsu0724No.1issue	2018/7/24
			Ensuring Cybersecurity for Medical Devices	Nofitication	Pharmaceutical and Food Agency0428No.1No.0428No.1issue	2015/4/28
		Usability	Handling of amendments to the Japanese Industrial Standards on requirements for usability engineering of medical devices	Nofitication	Pharmaceuticals and Medical Devices Agency0930No.1No.0930No.1issue	2022/9/30
			Questions and Answers (Q&A) on the Application of Basic Requirements for Usability Engineering of Medical Devices	Administrative Notice		2023/8/10
		Software Life Cycle Process	Application of Article 12, Paragraph 2 of the Basic Requirements for Medical Devices	Nofitication	Pharmaceuticals and Medical Devices Agency0517No.1issue	2017/5/17

		Clinical evaluation	Handling of clinical trial data for medical devices conducted overseas	Nofitication	Pharmaceutical479issue	1997/3/31
			Important points regarding "Handling of clinical trial results for medical devices conducted overseas"	Administrative Notice		2006/3/31
			Regarding the handling of results of clinical trials on medical devices conducted overseas	Nofitication	Drug and Food Machinery0331006issue	2006/3/31
			Q&A regarding "Handling of clinical trial results for medical devices conducted overseas"	Administrative Notice		2006/6/23
			Necessary scope of clinical trial data for medical devices	Nofitication	Drug and Food Machinery0804001issue	2008/8/4
			Clarification of handling of clinical trial data on rare disease medical devices, etc.	Nofitication	Drug and food machine0329No.1issue	2013/3/29
			Regarding the handling of the scope of medical device "clinical trial test results" that must be submitted (response based on pre-market and post-market initiatives)	Nofitication	Pharmaceuticals and Medical Devices Agency1117No.1No. Yakusho Anhatsu1117No.1issue	2017/11/17
			Regarding the handling of performance evaluation tests of diagnostic medical devices using existing medical image data that does not involve additional invasiveness or intervention	Nofitication	Pharmaceuticals and Medical Devices Agency0929No.1issue	2021/9/29
			Questions and Answers (Q&A) regarding the handling of performance evaluation tests of diagnostic medical devices using existing medical image data that do not involve additional invasiveness or intervention	Administrative Notice		2022/12/8
			Examples of Considerations and Approaches for Using Test Results Obtained from Designated Clinical Research in Approval Applications for Medical Devices and Regenerative Medicine Products	Administrative Notice		2024/6/5
			Partial amendment of the "Questions and Answers (Q&A) on the handling of performance evaluation tests of diagnostic medical devices using existing medical imaging data that do not involve additional invasiveness or intervention"	Administrative Notice		2025/3/17
			Partial amendment of "Handling of performance evaluation tests of diagnostic medical devices using existing medical image data, etc. that do not involve additional invasiveness or intervention"	Nofitication	Pharmaceuticals and Medical Devices Agency0317No.6issue	2025/3/17
		Sterilization validation related	Regarding corrections to "Establishment of Sterilization Validation Standards"	Nofitication	Pharmaceutical and Narcotics Agency1021No.5issue	2022/10/21
			Establishment of sterilization validation standards	Nofitication	Pharmaceutical and Narcotics Agency1017No.1issue	2022/10/17
		Publication of next-generation medical device evaluation indicators	Publication of Next-Generation Medical Device Evaluation Indicators (Next-Generation High-Performance Artificial Heart/DNA Chip Genetic Diagnostic Agent)	Nofitication	Drug and Food Machinery0404002issue	2008/4/4
			Publication of Next-Generation Medical Device Evaluation Indicators (Fracture Reduction Assist Devices / Joint Surgery Assist Devices / Cell Sheets for Cell Therapy of Severe Heart Failure / Corneal Epithelial Cell Sheets)	Nofitication	Medicine and food machine0118No.1issue	2010/1/18
			Publication of Next-Generation Medical Device Evaluation Indicators (Corneal Endothelial Cell Sheet/Computer-Assisted Surgery Device for Soft Tissue Application)	Nofitication	Medicine and food machine0528No.1issue	2010/5/28
			Publication of Next-Generation Medical Device Evaluation Indicators (Articular Cartilage Regeneration/Nerve Function Modification Devices/Custom-Made Orthopedic Bone-Synthesizing Implants)	Nofitication	Medicine and food machine1215No.1issue	2010/12/15
			Publication of Next-Generation Medical Device Evaluation Indicators (Cell Sheets for Periodontal Tissue Treatment / Custom-Made Artificial Hip Joints for Orthopedic Surgery / Computer-Assisted Diagnostic Devices)	Nofitication	Yakushokuki-hatatsu 1207 No. 1	2011/12/7
			Publication of Next-Generation Medical Device Evaluation Indicators (Custom-Made Orthopedic Knee Prosthesis/Diagnostic Device Based on RNA Profiling)	Nofitication	Yakushokuki-hattsu 1120 No. 5	2012/11/20
			Publication of Next-Generation Medical Device Evaluation Indicators (Autologous iPS cell-derived retinal pigment epithelial cells / Functional recovery device / Medical device for treating severe limb ischemia)	Nofitication	Yakushokuki-hatatsu 0529 No. 1	2013/5/29

			Publication of evaluation indicators for next-generation medical devices and regenerative medicine products (Allogeneic iPS(-like) cell-derived retinal pigment epithelial cells / Spinal implants that maintain mobility and stability / Orthopedic implants using two-dimensional stacking technology)	Nofitication	Pharmaceutical and Food Safety Officer Notification 0912 No. 2	2014/9/12
			Publication of evaluation indicators for next-generation medical devices and regenerative medicine products (nasal cartilage regeneration / cardiac catheter ablation devices using 3D mapping devices / custom-made orthopedic implants using 3D additive manufacturing technology using patient image data, etc.)	Nofitication	Pharmaceutical and Food Safety Officer Notification 0925 No. 1	2015/9/25
			Publication of evaluation indicators for next-generation medical devices and regenerative medicine products (articular cartilage regeneration using human chondrocytes or somatic stem cell processed products / articular cartilage regeneration using human (allogeneic) iPS(-like) cell processed products / bioabsorbable vascular stents)	Nofitication	Pharmaceutical and Medical Devices Agency Notification No. 0630-1	2016/6/30
			Publication of Next-Generation Medical Device and Regenerative Medicine Product Evaluation Indicators (Human (Allogeneic) Epidermal (Skin) Regeneration)	Nofitication	Pharmaceutical and Medical Devices Agency Notification No. 0725-1	2018/7/25
			Publication of Next-Generation Medical Device Evaluation Indicators (Diagnostic devices using microfluidic chips / Medical devices with new functions using biomaterials / Blood flow simulation software / Medical image diagnostic support systems using artificial intelligence technology / Accelerator-based neutron irradiation equipment systems for boron neutron capture therapy)	Nofitication	Pharmaceutical and Medical Devices Agency Notification No. 0523-2	2019/5/23
			Publication of Next-Generation Medical Device Evaluation Indicators (Home Medical Devices/Devices for Treating Intractable Wounds)	Nofitication	Notification No. 0925-1 from the Pharmaceutical and Medical Devices Agency	2020/9/25
			Publication of Next-Generation Medical Device Evaluation Indicators (Medical Support Devices with Closed-Loop Control Systems)	Nofitication	Pharmaceutical and Medical Devices Agency Notification No. 0630-4	2021/6/30
			Publication of Next-Generation Medical Device Evaluation Indicators (Breast Cancer Diagnostic Support Devices/Medical Device Programs Inducing Behavior Change)	Nofitication	Pharmaceutical and Medical Devices Agency Notification No. 0609-1	2022/6/9
			Publication of Next-Generation Medical Device Evaluation Indicators (Implantable Ventricular Assist Devices)	Nofitication	Pharmaceutical and Medical Devices Agency Notification No. 0331-5	2023/3/31
			Publication of Next-Generation Medical Device Evaluation Indicators (Devices Using Decellularized Tissue/Medical Devices for Meniscus Repair and Reconstruction)	Nofitication	Pharmaceutical and Medical Devices Agency Notification No. 1129-2	2024/11/29
			Publication of Next-Generation Medical Device Evaluation Indicators (Medical Devices for Comprehensive Treatment of Severe Chronic Lower Limb Ischemia)	Nofitication	Pharmaceutical and Medical Devices Agency Notification No. 0609-1	2025/6/9
			Publication of Next-Generation Medical Device Evaluation Indicators (Home-Use Programmed Medical Devices for Disease Treatment)	Nofitication	Pharmaceutical and Medical Devices Agency Notification No. 0808-1	2025/8/8
	Program medical equipment	Program medical equipment	Handling of medical device programs	Nofitication	Pharmaceutical and Food Agency1121No.33No.1121No.1No. Yakushokukan Narcotics Division1121No.29issue	2014/11/21
			Q&A regarding handling of medical device programs	Administrative Notice		2014/11/25
			Q&A regarding the handling of medical device programs (part 2)	Administrative Notice		
		Program medical device applicability	Basic principles regarding whether a program is a medical device	Nofitication	Drug, Food and Drug Administration1114No.5issue	2014/11/14
			Regarding the partial revision of the "Basic principles regarding applicability of programs to medical devices"	Nofitication	Pharmaceutical and Narcotics Agency1228No.2issue	2018/12/28
			Guidelines for the Program on Medical Device Applicability	Nofitication	Pharmaceuticals and Medical Devices Agency0331No.1No.0331No.15issue	2021/3/31
			Partial Revision of Guidelines for Programs Regarding Medical Device Applicability	Nofitication	Pharmaceuticals and Medical Devices Agency0331No.1No.0331No.4issue	2023/3/31
			Case studies on whether a program is a medical device	Administrative Notice		2023/3/31
			About the website explaining the medical device applicability of the program	Administrative Notice		2024/8/8
			Regarding medical device applicability of dental programs	Nofitication	Pharmaceuticals and Medical Devices Agency1228No.4No.1228No.6issue	2018/12/28
		Application for approval of program medical devices	Handling applications for medical device programs	Nofitication	Pharmaceutical and Food Agency0331No.4issue	2015/3/31

			Publication of Guidance on Submissions for Medical Device Programs	Administrative Notice		2016/3/31
			Publication of guidance for appropriate and prompt approval and development of program medical devices based on their characteristics	Administrative Notice		2023/5/29
			Publication of the Guidance for Appropriate and Rapid Approval and Development of Program Medical Devices Based on Their Characteristics (Second Edition)	Administrative Notice		2024/6/5
			Regarding the handling of two-stage approval based on the characteristics of program medical devices	Nofitication	Pharmaceuticals and Medical Devices Agency1116No.2issue	2023/11/16
			Questions and Answers on "Handling of Two-Step Approval Based on the Characteristics of Programmed Medical Devices"	Administrative Notice		2024/6/12
			Examples of application forms and attached documents for manufacturing and sales approval (certification) of medical device programs	Administrative Notice		2015/2/10
			Regarding handling of applications for manufacturing and sales certification of medical device programs	Nofitication	Pharmaceutical and Food Agency1125No.6issue	2014/11/25
			Regarding partial revision of "Regarding points to note when applying for approval of home medical devices that detect symptoms of illness and encourage medical examination"	Nofitication	Pharmaceuticals and Medical Devices Agency0621No.1No. Pharmaceutical and Medical Devices Safety and Health0621No.1issue	2024/6/21
			Results of the Public Comment Solicitation Regarding the "Evaluation Criteria (Draft) for Home-Use Programmed Medical Devices for Disease Treatment"	Other		2025/8/8
			Publication of Next-Generation Medical Device Evaluation Indicators (Home-Use Programmed Medical Devices for Disease Treatment)	Nofitication	Pharmaceutical and Medical Devices Agency Notification No. 0808-1	2025/8/8
	Biologically-derived	Biologically-derived	Regarding the partial revision of the Biological Raw Materials Standards	Nofitication	Pharmaceutical and Food Agency1002No.27issue	2014/10/2
			About the implementation of the Biological Raw Materials Standards	Nofitication	Pharmaceutical and Food Safety Agency1002No.1No. Pharmacy Foods Agency1002No.5issue	2014/10/2
			Regarding the designation of biological products, specified biological products, and designated regenerative medicine products	Nofitication	Pharmaceutical and Food Safety Agency1105No.1No. Pharmacy Foods Agency1105No.2issue	2014/11/5
			Q&A on the implementation of the Biological Raw Materials Standards	Administrative Notice		2015/6/30
			Survey contents and reporting methods for periodic reports on infectious diseases of regenerative medicine products and biological products	Nofitication	Pharmaceutical Safety and Health Agency0428No.1issue	2017/4/28
			Regarding the regular reporting system for infectious diseases related to regenerative medicine products and biological products	Nofitication	Pharmaceutical Sciences0428No.1issue	2017/4/28
			Q&A regarding regular reporting of infectious diseases in regenerative medicine products and biological products	Administrative Notice		2017/7/28
			Regarding the enforcement of the partial revision of the Biological Raw Materials Standards	Nofitication	Pharmaceutical and Medical Devices Agency0228No.1No.0228No.1issue	2018/2/28
			Regarding the partial revision of the Biological Raw Materials Standards	Nofitication	Pharmaceutical Sciences0228No.1issue	2018/2/28
			Partial revision of the standards for biological raw materials	Nofitication	Ministry of Health, Labor and Welfare Notification No.37issue	2018/2/28
			Partial amendment to the "Periodic reporting system for infectious diseases related to regenerative medicine products and biological products"	Nofitication	Pharmaceutical Sciences0730No.5issue	2021/7/30
			Partial revision of the "Q&A regarding periodic reporting of infectious diseases in regenerative medicine products and biological products"	Administrative Notice		2024/3/29
			Important points regarding periodic reporting of infectious diseases in regenerative medicine products and biological products	Nofitication	Pharmaceutical Safety and Health Agency6No. 1, Pharmaceutical and Medical Device Safety Agency3No. 2 of the Pharmaceutical and Medical Devices Agency's Security Affairs Division2issue	2024/3/29

			Partial revision of the "Implementation of Standards for Biological Raw Materials"	Nofitication	Pharmaceuticals and Medical Devices Evaluation and Disclosure Division0117No.6No.0117No.7issue	2025/1/17
	Heparin-containing medical devices		Regarding the handling of medical devices that use heparin	Nofitication	Pharmaceutical and Food Agency0224No.1issue	2015/2/24
	Multiple generic name products, combination medical devices	Multiple sales name related	Handling of manufacturing and sales certification applications for medical devices that fall under multiple generic names	Nofitication	Yakushokuki-Hatsu 0207 No. 1	2013/2/7
			Regarding the handling of manufacturing and sales approval (certification) for medical devices with multiple sales names	Nofitication	Pharmaceutical and Food Agency1121No.47issue	2014/11/21
		Combination medical devices, multiple generic names	Handling of manufacturing and sales approval applications, manufacturing and sales certification applications, and manufacturing and sales notifications for combination medical devices	Nofitication	Drug and Food Machinery0331002issue	2009/3/31
			Questions and Answers (Q&A) regarding combination medical devices and items with multiple generic names (part 1)	Administrative Notice		2009/7/1
			Questions and Answers (Q&A) regarding combination medical devices and items with multiple generic names (part 2)	Nofitication	Drug and food machine1111No.1issue	2013/11/11□
	Combination Products		Handling of combination product approval applications	Nofitication	Pharmaceutical and Food Safety Agency1024No.2No. Pharmacy Foods Agency1024No.1No.1024No.9No. Yakushokukan Narcotics Division1024No.15issue	2014/10/24
			Regarding partial revision of "Handling of Approval Applications for Combination Products"	Nofitication	Pharmaceutical and Medical Devices Agency0915No.1No.0915No.1No. Yakusho Anhatsu0915No.3No.0915No.3issue	2016/9/15
			Q&A regarding the handling of combination product approval applications	Administrative Notice		2016/11/22□
			Revision of "Handling of Approval Applications for Combination Products"	Nofitication	Pharmaceutical and Medical Devices Agency1122No.4No.1122No.10No. Yakusho Anhatsu1122No.7No.1122No.4issue	2016/11/22
	Partial and minor changes		Procedures for partial changes to medical equipment	Nofitication	Drug and Food Machinery1023001issue	2008/10/23
			Handling of applications for partial changes to approved items related to medical devices and in vitro diagnostic drugs	Nofitication	Drug and food machine0713No.3issue	2009/7/13
			Scope of information to be included in application forms for medical device manufacturing and sales approval and procedures for partial changes to medical devices (orthopedic implant products)	Nofitication	Drug and food machine0701No.10issue	2013/7/1
			Regarding the handling of minor change procedures for partial changes to medical equipment	Nofitication	Pharmaceuticals and Medical Devices Agency0731No.5issue	2017/7/31
			Regarding the handling of minor change procedures etc. due to partial changes to medical device programs	Nofitication	Pharmaceuticals and Medical Devices Agency1020No.1issue	2017/10/20
			Handling of minor change procedures due to partial changes related to cybersecurity measures for medical devices	Nofitication	Pharmaceuticals and Medical Devices Agency0423No.1issue	2024/4/23
			Procedures for changing raw materials for medical devices	Nofitication	Drug and food machine0329No.7issue	2013/3/29
			Questions and Answers (Q&A) regarding procedures for changing raw materials for medical devices	Nofitication	Drug and food machine0529No.4issue	2013/5/29
			Expediting procedures for changing or adding manufacturing sites for medical devices and in vitro diagnostics	Nofitication	Pharmaceutical and Food Agency1119No.7No. Yakushokukan Narcotics Division1119No.12issue	2014/11/19
			Regarding speeding up procedures for changing or adding manufacturing sites for pharmaceuticals, etc.	Nofitication	Pharmaceutical and Food Safety Evaluation and Notification No.0306001No. Yakushokukan Narcotics Division0306001issue	2008/3/6
			Partial amendment of "Accelerating procedures for changes and additions to manufacturing sites for medical devices and in vitro diagnostics"	Nofitication	Pharmaceutical and Food Safety Evaluation and Notification No.1210003No. Yakushokukan Narcotics Division1210007issue	2007/12/10
			Extension of deadline for fax transmission and application for manufacturing site change expedited review	Administrative Notice		2007/5/15
			Q&A regarding the rapid review of manufacturing site changes	Administrative Notice		2007/4/27
			Extension of the period for expediting procedures for specific changes to medical devices	Nofitication	Drug and food machine0328No.1issue	2014/3/28
			Extension of the period for expediting procedures for specific changes to medical devices	Nofitication	Drug and food machine1112No.6issue	2010/11/12

			Q&A on Expedited Procedures for Certain Changes to Medical Devices	Administrative Notice		2009/3/4
			Expediting procedures for specific changes to medical devices	Nofitication	Drug and Food Machinery1110001issue	2008/11/10
	Medical device modification plan		Handling of confirmation applications for change plans for medical devices	Nofitication	Pharmaceuticals and Medical Devices Agency0831No.14issue	2020/8/31
			Questions and Answers (Q&A) regarding confirmation applications for changes to medical devices, medical devices using artificial intelligence-related technology, and program medical devices	Administrative Notice		2023/12/22
			Examples of application forms and attached documents for confirmation of change plans for program medical devices	Administrative Notice		2023/12/22
	Package insert related	Instructions for filling out	Revision of the Guidelines for Attached Documents for Medical Devices	Nofitication	Pharmaceutical and Food Agency1002No.8issue	2014/10/2
			Items that should be included in the package insert for biological products	Nofitication	Pharmaceutical Development0515005 issue	2003/5/15
			Regarding instructions for package inserts for biological products	Nofitication	Pharmaceuticals and Medical Devices Safety Division0520004issue	2003/5/20
			Q&A regarding the instructions for medical device package inserts and instructions for use	Administrative Notice		2012/10/26
			Instructions for writing precautions for use of medical devices	Nofitication	Pharmaceutical and Food Safety Agency1002No.5issue	2014/10/2
			Guidelines for medical device package inserts (details)	Nofitication	Pharmaceutical and Food Safety Agency1002No.1issue	2014/10/2
			Q&A regarding instructions for medical device package inserts	Administrative Notice		2014/10/31
			Revision of the Guidelines for Package Inserts and Other Information Concerning Conditional Approval of Pharmaceuticals, etc.	Nofitication	Pharmaceutical Sciences0831No.17issue	2020/8/31
			Regarding handling of conditional approval etc. in package inserts etc.	Nofitication	Pharmaceutical Safety and Health Agency0831No.4issue	2020/8/31
			Guidelines for electronic package inserts for medical devices	Nofitication	Pharmaceutical Sciences0611No.9issue	2021/6/11
		Electronic package inserts	Provision of information on precautions for pharmaceuticals, etc.	Nofitication	Pharmaceutical Safety and Health Agency0219No.1issue	2021/2/19
			About the Q&A regarding "Provision of Information on Precautions for Pharmaceuticals, etc."	Administrative Notice		2021/2/19
			Regarding the provision of information on precautions for medical devices (Request for public awareness)	Administrative Notice		2021/4/19
			Partial revision of the Q&A regarding "Provision of Information on Precautions for Pharmaceuticals, etc."	Administrative Notice		2021/6/11
			Partial revision of the Q&A regarding "Provision of Information on Precautions for Pharmaceuticals, etc."	Administrative Notice		2021/7/14
			Partial revision of the Q&A regarding "Provision of Information on Precautions for Pharmaceuticals, etc."	Administrative Notice		2022/9/13
			Regarding partial revision of "Provision of information on precautions for pharmaceuticals, etc."	Nofitication	Pharmaceutical Safety and Health Agency0913No.5issue	2022/9/13
		Notification of package insert information	Q&A regarding notification of package insert information, etc.	Administrative Notice		2014/9/1
			Important points regarding the notification and publication of information, etc.	Nofitication	Pharmaceutical Safety and Health Agency0219001No. 1, Pharmaceutical and Medical Device Safety Agency0219001No. 2 of the Pharmaceutical and Medical Devices Agency's Security Affairs Division0219001No. Pharmaceuticals and Medical Devices Agency0219001issue	2021/2/19
			Important points to note when submitting information, etc.	Nofitication	Pharmaceutical Safety and Health Agency0219No.2issue	2021/2/19
			Regarding partial revision of "Points to note regarding the notification and publication of important information"	Nofitication	Pharmaceutical Safety and Health Agency1No. 1, Pharmaceutical and Medical Device Safety Agency1No. 2 of the Pharmaceutical and Medical Devices Agency's Security Affairs Division1No. Pharmaceutical Safety and Health Agency1issue	2024/7/9

			Regarding partial revision of "Notes on matters to be noted when submitting information, etc."	Nofitication	Pharmaceutical Safety and Health Agency0709No.1issue	2024/7/9
		Consultation related	Regarding partial revision of "Points to note regarding consultations following revisions to package inserts, etc."	Nofitication	Pharmaceutical Safety and Health Agency0507001No. 1, Pharmaceutical and Medical Device Safety Agency0507001No. 2 of the Pharmaceutical and Medical Devices Agency's Security Affairs Division0507001No. Pharmaceuticals and Medical Devices Agency0507001issue	2019/5/7
			Important points regarding consultations regarding revisions to package inserts, etc.	Administrative Notice	Administrative communication (Reiwa5year2month17Japan Pharmaceuticals and Medical Devices Agency60issue)	2023/2/20
		Omission of information on package inserts, etc.	Points to note when omitting information from package inserts for in vitro diagnostic medicines and medical devices	Nofitication	Pharmaceutical and Food Safety Agency0901No.04issue	2014/9/1
			Q&A regarding the omission of information contained in package inserts for in vitro diagnostic medicines and medical devices	Administrative Notice		2014/9/1
	Clinical TrialsGCPconnection		Partial amendment of "Guidelines for the implementation of document-based conformity inspections of medical device standards and on-site inspections of medical device GCP" and "Procedures for the implementation of document-based conformity inspections of approval application documents for non-clinical trials of medical devices"	Nofitication	Drug and food machine1112No.1issue	2012/11/12
			Procedures for document-based compliance inspections and on-site GCP inspections of clinical trials of medical devices	Nofitication	Pharmaceutical Machinery1227102issue	2018/12/27
			Partial amendment of "Procedures for Written Compliance Inspections of Approval Application Documents and GCP On-site Inspections for Clinical Trials of Medical Devices"	Nofitication	Pharmaceutical Machinery1225006issue	2020/12/25
			Partial amendment of "Procedures for Written Compliance Inspections and GCP On-site Inspections of Approval Documents for Clinical Trials of Medical Devices"	Nofitication	Pharmaceutical Machinery0630009issue	2022/6/30
			Partial amendment of the "Guidelines for medical device conformity document inspections and medical device GCP on-site inspections"	Nofitication	Pharmaceuticals and Medical Devices Agency0808No.4issue	2022/8/8
			Procedures for document-based compliance inspections and on-site GCP inspections of clinical trials of medical devices	Nofitication	Pharmaceutical Machinery0824032 issue	2022/8/24
	Non-clinical trialsGLPconnection	Document-based compliance inspection for non-clinical trials	Important points to note for smooth implementation of medical device document-based compliance inspections (non-clinical trials)	Administrative Notice		2018/2/9
			Checklist for reliability of clinical trials of medical devices and examples of detailed catalogue of materials	Administrative Notice		2018/11/13
			Partial amendment of "Procedures for implementing document-based conformity inspections of approval application documents for non-clinical trials of medical devices"	Nofitication	Pharmaceuticals and Medical Devices Agency0808No.1issue	2022/8/8
			Regarding "Q&A on the Procedures for Conducting Written Compliance Inspections of Application Documents for Nonclinical Trials of Medical Devices"	Nofitication	Notification by the Chief of the Pharmaceuticals and Medical Devices Agency1228001issue	2022/12/28
			Procedures for conducting document-based compliance inspections of approval application documents for non-clinical trials of medical devices	Nofitication	Pharmaceutical Machinery1228001issue	2022/12/28
		Non-clinical trials for safety (GLP)	Ministerial Ordinance on Standards for Conducting Nonclinical Trials on the Safety of Medical Devices (GLP Ordinance)	Ministerial Ordinance	Ministry of Health, Labour and Welfare Ordinance No.37issue	2022/5/20
			Q&A on the Standards for Conducting Nonclinical Trials on the Safety of Medical Devices	Administrative Notice		2007/1/22
			Regarding the handling of the revised Ministerial Ordinance on Standards for the Conduct of Nonclinical Trials on the Safety of Medical Devices by the Ministerial Ordinance Partially Amending the Ministerial Ordinance on Standards for the Conduct of Nonclinical Trials on the Safety of Medical Devices	Nofitication	Pharmaceutical and Food Safety0613010issue	2008/6/13

			Regarding the handling of documents related to non-clinical trials on the safety of pharmaceuticals, medical devices, and regenerative medicine products that must be attached when applying for manufacturing and marketing approval for pharmaceuticals, medical devices, and regenerative medicine products	Nofitication	Pharmaceutical and Food Safety Agency1121No.9issuePharmaceutical and Food Agency1121No.13issue	2014/11/21
			Partial amendment of the implementation guidelines for on-site inspections of pharmaceutical GLP, medical device GLP, and regenerative medicine products GLP	Nofitication	Pharmaceutical Machinery8876issue	2024/12/27
	Usage evaluation/GPSP	Usage evaluation	Handling of performance evaluations related to manufacturing and marketing approval of medical devices and in vitro diagnostic drugs	Nofitication	Pharmaceutical and Food Agency1121No.44issue	2014/11/21
			Basic principles regarding the subject of usage evaluation at the time of manufacturing and marketing approval of medical devices and in vitro diagnostics	Nofitication	Pharmaceutical and Food Agency1226No.3issue	2014/12/26
			Regarding partial correction of "Handling of performance evaluation related to manufacturing and marketing approval of medical devices and in vitro diagnostic drugs"	Administrative Notice		2015/12/28
			Questions and Answers (Q&A) regarding performance evaluation	Administrative Notice		2015/12/28□
			Regarding the necessity of designating performance evaluation of medical devices, procedures related to the investigation period, and specific operations	Nofitication	Yakusei Machinery1228No.1issue	2015/12/28
			Handling of medical devices for which performance evaluation has been completed	Nofitication	Pharmaceutical Sciences0805No.1issue	2019/8/5
			Publication of the results evaluation report for medical devices, etc.	Nofitication	Pharmaceuticals and Medical Devices Agency0806No.1issue	2019/8/6

			Questions and Answers (Q&A) on points to note regarding ensuring reliability when using data from registries or medical information databases in applications for approval of medical devices and applications for performance evaluation	Administrative Notice		2024/5/29
		GPSP	Ministerial Ordinance on Standards for Post-Marketing Surveillance and Testing of Medical Devices (GPSP Ordinance)	Ministerial Ordinance	Ministry of Health, Labour and Welfare Ordinance No.38issue	2023/12/26
			Partial amendment of "Procedures for Written Compliance Inspections of Medical Device Reexamination and Reevaluation Application Documents and GPSP On-site Inspections" (Part 4)	Nofitication	Pharmaceutical Machinery0630011issue	2022/6/30
			Partial revision of the "Guidelines for GPSP On-site Inspections of Medical Devices"	Nofitication	Pharmaceuticals and Medical Devices Agency0808No.7issue	2022/8/8
	Post-marketing related	Side effect report related	Reporting adverse drug reactions, etc.	Nofitication	Pharmaceutical and Food Agency1002No.20issue	2014/10/2
			Revision of "Q&A regarding reporting of adverse reactions, etc. of combination products"	Administrative Notice		2017/6/9
			Partial revision of "Reporting adverse reactions to medicines, etc."	Nofitication	Pharmaceutical Sciences0730No.8issue	2021/7/30
		Collection related	Recall of medicines, medical devices, etc.	Nofitication	Pharmaceutical and Food Agency1121No.10issue	2014/11/21
			Q&A regarding "Recall of pharmaceuticals, medical devices, etc."	Nofitication	Drug, Food and Drug Administration1121No.5issue	2014/11/21
			Partial amendment of "Regarding the recall of pharmaceuticals, medical devices, etc."	Nofitication	Pharmaceutical Sciences0208No.1issue	2018/2/8
	PMDAConsulting services	Face-to-face advice, etc.	Guidelines for face-to-face consultations and certification verification surveys conducted by PMDA		Pharmaceutical Machinery0302070issue	2012/3/2
			Regarding partial revision of the "Implementation guidelines for face-to-face advice, certification verification surveys, etc. conducted by the Pharmaceuticals and Medical Devices Agency"	Nofitication	Pharmaceutical Machinery970No. (Pharmaceutical Machinery and Equipment No.968issue)	2025/5/8
		Pharmaceutical Strategy Consulting	Regarding the implementation of pharmaceutical strategy consultation services for pharmaceuticals and medical devices	Nofitication	Pharmaceutical Machinery0701001issue	2013/7/1
			Partial amendment of the Special Zone Medical Device Pharmaceutical Strategy Consultation Implementation Guidelines	Nofitication	Pharmaceutical Machinery0316002issue	2017/3/16
			Partial amendments to the implementation guidelines for pharmaceutical strategy consultations	Nofitication	Pharmaceutical Machinery0316001issue	2017/3/16
	others	Certification succession	Procedures for succession of certification for medical devices and in vitro diagnostic drugs	Nofitication	Pharmaceutical and Food Agency0925No.1issue	2014/9/25
		Approval certification number related	Regarding the method of granting approval numbers and certification numbers	Nofitication	Pharmaceutical and Food Agency0925No.5issue	2014/9/25
	Import-related		Revision of the "Guidelines for Confirming Imports of Pharmaceuticals, etc."	Nofitication	Pharmaceutical and Narcotics Affairs0630No. 1	2025/6/30
			Q&A on pharmaceutical import procedures	Administrative Notice		2025/6/30
			Partial amendment of the Import Monitoring Guidelines for Pharmaceuticals, etc. and Poisonous and Deleterious Substances	Nofitication	Pharmaceutical Sciences0318No.1 issue(Pharmaceutical Sciences0318No.2issue)	2020/3/18
			Partial amendment of the Import Monitoring Guidelines for Pharmaceuticals, etc. and Poisonous and Deleterious Substances	Nofitication	Pharmaceutical Sciences1126No.4issue	2018/11/26
			Import notification and notification of import of pharmaceuticals, etc. through the NACCS system	Administrative Notice		2015/11/30
			Revision of the Guidelines for Handling Import Notifications of Pharmaceuticals, etc.	Nofitication	Pharmaceutical and Food Agency0422No.2issue	2014/11/21
	Export Notification		Regarding the operation of GMP certification under the Mutual Recognition Agreement on the issuance of certificates for pharmaceuticals for export, etc.	Nofitication	Drug, Food and Drug Administration0628No.4issue	2013/6/28
			Regarding the implementation of GMP, QMS, and GCTP inspection procedures for issuing certificates for export drugs and medical devices, etc.	Nofitication	Pharmaceutical and Food Agency1125No. 5	2014/11/25
			Implementation of GMP, QMS, and GCTP inspections related to the issuance of certificates for export pharmaceuticals and medical devices, etc.	Nofitication	Pharmaceutical and Food Agency1125No.9issue	2014/11/25
			Regarding the format for issuing certificates for export drugs, medical devices, etc. due to organizational restructuring, etc.	Administrative Notice		2016/6/21

			Issuance of certificates for export medicines, medical devices, etc.	Nofitication	Pharmaceutical Sciences0802No.4issue	2021/8/2
			Regarding the format for issuing certificates for export drugs, medical devices, etc. due to organizational restructuring, etc.	Other		2023/9/1
	Approval for manufacturing and selling in vitro diagnostic drugs/Certification Application/Notification related	In Vitro Diagnostics	Notification of marketing or manufacturing of in vitro diagnostic reagents	Nofitication	Pharmaceutical and Food Agency0821No.1No.0821No.1issue	2014/8/21

		Manufacturing and sales approval application related	Regarding handling of attached documents for application for manufacturing and marketing approval of in vitro diagnostic medical products	Nofitication	Drug and Food Machinery0331005issue	2008/3/31
			Application for manufacturing and marketing approval of in vitro diagnostic medical products	Nofitication	Pharmaceutical and Food Agency1121No.15issue	2014/11/21
			Points to note when applying for approval to manufacture and sell in vitro diagnostic products	Nofitication	Pharmaceutical and Food Agency1121No.16issue	2014/11/21
			Partial amendment of "Points to Note When Applying for Manufacturing and Marketing Approval of In Vitro Diagnostics" and "Points to Note When Applying for Manufacturing and Marketing Certification of In Vitro Diagnostics"	Nofitication	medicineFood Machinery0120No. 5	2015/1/20
			Application for manufacturing and marketing approval of in vitro diagnostic medical products	Nofitication	Pharmaceutical Sciences 0222No. 5	2016/2/22
			Points to note regarding ensuring reliability in application documents for manufacturing and marketing approval of in vitro diagnostic drugs	Administrative Notice		2019/9/9
			Approval standards for in vitro diagnostic drugs	Nofitication	Pharmaceutical and Food Agency0120No.1issue	2015/1/20
		Manufacturing and sales certification application related	Application for certification to manufacture and sell in vitro diagnostic products	Nofitication	Pharmaceutical and Food Agency1121No.18issue	2014/11/21
			Points to note when applying for certification to manufacture and sell in vitro diagnostic products	Nofitication	Pharmaceutical and Food Agency1121No.19issue	2014/11/21
			Certification standards for in vitro diagnostic medical products	Nofitication	Pharmaceutical and Food Agency0120No.5issue	2015/1/20
		Manufacturing and sales notification related	Handling of manufacturing and sales notifications for in vitro diagnostic drugs	Nofitication	Pharmaceutical and Food Agency1121No.twenty threeissue	2014/11/21
		Basic requirements	Checklist for Compliance with Essential Requirements for In Vitro Diagnostic Medical Devices	Nofitication	Pharmaceutical and Food Agency0120No.1issue	2021/8/18
		Repurposing of general-purpose diagnostic drugs	Conversion of in vitro diagnostic drugs to over-the-counter testing agents	Nofitication	Pharmaceutical and Food Agency1225No.1issue	2014/12/25
			Improving the provision of information when selling over-the-counter test kits	Nofitication	Pharmaceutical and Food General Affairs1225No.1No. Pharmacy Foods Agency1225No.4issue	2014/12/25
Regenerative Medicine Act			Act on ensuring the safety of regenerative medicine, etc.	Act	Heiseitwenty fiveyear law no.85issue	2025/6/1
			Enforcement Order of the Act on Ensuring the Safety of Regenerative Medicine, etc.	Cabinet Order	Heisei26Cabinet Order No.278issue	2025/5/31
			Enforcement Regulations of the Act on Ensuring the Safety of Regenerative Medicine, etc.	Ministerial Ordinance	Ministry of Health, Labour and Welfare Ordinance No.110issue	2014/9/26
			Regarding the handling of the Regenerative Medicine Act, Enforcement Order and Enforcement Regulations	Nofitication	From Medical Research Institute1031No.1issue	2025/6/1
			Q&A (integrated version) regarding the Act on Ensuring the Safety of Regenerative Medicine, etc.	Administrative Notice		2025/2/18
	QMSConformity Survey Re	QMSconnection	Ministerial Ordinance on Standards for Manufacturing and Quality Control of Regenerative Medicine Products	Ministerial Ordinance	Ministry of Health, Labour and Welfare Ordinance No.93issue	2021/8/1
	Regenerative medicine provision plan		Revision of the Guidelines for Writing Regenerative Medicine Provision Plans, etc.	Administrative Notice		2023/2/20
	Regenerative medicine product manufacturing and sales approval application		Application for manufacturing and sales approval for regenerative medicine products	Nofitication	Pharmaceutical and Food Safety0812No.30issue	2014/8/12
			Points to note when applying for manufacturing and sales approval for regenerative medicine products	Nofitication	Pharmaceutical and Food Agency0812No.5issue	2014/8/12
			Guidelines for attaching documents and their outlines for approval applications for regenerative medicine products (March 26, 2025 edition)	Administrative Notice		2025/3/26版
	Infectious disease periodic reporting system		Regarding the regular reporting system for infectious diseases related to regenerative medicine products	Nofitication	Pharmaceutical and Food Safety0812No.7issue	2014/8/12
			Regarding the regular reporting system for infectious diseases related to regenerative medicine products	Nofitication	Pharmaceutical Sciences0428No.1issue	2017/4/28
			Attached form, attachments 1 to 7			

			Partial amendment to the "Periodic reporting system for infectious diseases related to regenerative medicine products and biological products"	Nofitication	Pharmaceutical Affairs Bureau No. 0730 No. 5	2021/7/30
	Package insert related	Instructions for filling out	Guidelines for electronic package inserts for regenerative medicine products	Nofitication	Pharmaceutical Development 0607No. 1	2024/6/7
			Guidelines (details) for electronic package inserts for regenerative medicine products	Nofitication	Pharmaceutical Safety and Health 0607No. 2	2024/6/7
			Regarding instructions for package inserts for regenerative medicine products	Nofitication	Pharmaceutical and Food Agency1002No.12issue	2014/10/2
			Regarding the detailed regulations for the description of package inserts for regenerative medicine products	Nofitication	Pharmaceutical and Food Safety Agency1002No.13issue	2014/10/2
			Instructions for writing precautions for use of regenerative medicine products	Nofitication	Pharmaceutical and Food Safety Agency1002No.9issue	2014/10/2
	Clinical TrialsGCPconnection	Clinical trial implementation related	Ministerial Ordinance on Standards for Conducting Clinical Trials of Regenerative Medicine Products	Nofitication	Heisei26Ministry of Health, Labour and Welfare Ordinance No.89issue	2025/4/1
			Enforcement of the Ministerial Ordinance Partially Revising the Ministerial Ordinance on Standards for Conducting Clinical Trials of Medical Devices and the Ministerial Ordinance Partially Revising the Ministerial Ordinance on Standards for Conducting Clinical Trials of Regenerative Medicine Products	Nofitication	Pharmaceutical Sciences0721No.1issue	2016/7/21
			Enforcement of the Ministerial Ordinance on Standards for Conducting Clinical Trials of Regenerative Medicine Products	Nofitication	Pharmaceutical and Food Safety0812No.16issue	2014/8/12
			Regarding the partial revision of the "Guidance for the Ministerial Ordinance on Standards for Conducting Clinical Trials of Regenerative Medicine Products"	Nofitication	Pharmaceuticals and Medical Devices Agency1226No. 2	2023/12/26
		Field survey	Guidelines for document-based compliance inspections of approval application documents for regenerative medicine products, on-site GCP inspections of regenerative medicine products, and on-site GPSP inspections of regenerative medicine products	Nofitication	Pharmaceuticals and Medical Devices Agency0703No. 1	2023/7/3
		Notification of clinical trial plans, etc.	Notification of clinical trial plans for processed cells, etc.	Nofitication	Pharmaceutical and Food Safety0812No.26issue	2014/8/12
			Regarding the handling of notifications of clinical trial plans etc. related to processed cells, etc.	Nofitication	Pharmaceutical and Food Agency0812No.1issue	2014/8/12
			Notification of clinical trial plans for processed cells, etc.	Nofitication	Pharmaceutical Sciences0831No. 7	2020/8/31
			Regarding the handling of notifications of clinical trial plans etc. related to processed cells, etc.	Nofitication	Pharmaceuticals and Medical Devices Agency0831Issue 9	2020/8/31
			Questions and Answers (Q&A) regarding the submission of clinical trial plans for devices, etc. and processed cells, etc.	Administrative Notice		2022/3/25
			"Questions and Answers (Q&A) regarding the submission of clinical trial plans for drugs, equipment, or processed cells, etc."	Administrative Notice		2023/3/30
			Regarding partial revision of "Handling of notifications of clinical trial plans, etc. related to processed cells, etc."	Nofitication	Pharmaceuticals and Medical Devices Agency 0329No. 6	2024/3/29
	Non-clinical trialsGLPconnection	Non-clinical trial related	Ministerial Ordinance on Standards for Conducting Non-Clinical Trials on the Safety of Regenerative Medicine Products	Ministerial Ordinance	Heisei26Ministry of Health, Labour and Welfare Ordinance No.88issue	2022/5/20
			Enforcement of the Ministerial Ordinance on Standards for Conducting Nonclinical Experiments on the Safety of Regenerative Medicine Products	Nofitication	Pharmaceutical and Food Safety0812No.20issue	2014/8/12
	After manufacturing and salesGPSPconnection		Ministerial Ordinance on Standards for Post-Marketing Surveillance and Testing of Regenerative Medicine Products	Ministerial Ordinance	Ministry of Health, Labour and Welfare Ordinance No. 90 of 2014	2023/12/26
			Enforcement of the Ministerial Ordinance on Standards for Post-Marketing Surveillance and Testing of Regenerative Medicine Products	Nofitication	Pharmaceutical and Food Safety0812No.twenty threeissue	2014/8/12
			Promulgation of the Ministerial Ordinance Partially Amending the Ministerial Ordinance on Standards for Post-Marketing Surveillance and Testing of Pharmaceuticals (Ministerial Ordinance on Standards for Post-Marketing Surveillance and Testing of Regenerative Medicine Products)	Nofitication	Pharmaceutical Sciences 1026No. 10issue	2017/10/26
			Guidelines for document-based compliance inspections of approval application documents for regenerative medicine products, on-site GCP inspections of regenerative medicine products, and on-site GPSP inspections of regenerative medicine products	Nofitication	Pharmaceuticals and Medical Devices Agency0703No. 1	2023/7/3