*** MFDS Cell & Gene Therapy Products Guidelines (25.7.)**

Number	Title	revision date	Scheduled revision date	Language	URL
1	Considerations on Evaluating Dendritic Cell Therapy Products for Cancer Treatment	2005		Korean	https://www.mfds.go.kr/brd/m_1060/view.do?seq=1247&searchFr=&searchKw=&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
2	Guideline on the Quality evaluation of Gene Therapy Products	2022		Korean	https://www.mfds.go.kr/brd/m_1060/view.do?seq=1515&searchFr=&searchKw=%EC%9C%A0%E2%2C%20%EB%8F%8C%20%EB%9D%BC%20%EB%8F%8C%EC%A0%9C%C+%EC%9E%E5%EC%A7%8B%20%EB%8F%8C%20%EB%9D%BC%20%EB%8F%8C%20%EB%8F%8C%20%EB%8F%8C&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
3	Considerations for Immunogenicity Assessment of Allogenic Stem Cell Therapy Product	2025		Korean	https://www.mfds.go.kr/brd/m_1060/view.do?seq=1587&searchFr=&searchKw=%EB%8F%9F%EC%A7%8E%C%A4%8F%C%A4%8F%C%A4%8F%8B%5D%EC%A4%8F%C%EC%8B%9B%EB%A3%8E%C%EC%A0%9C%20%EC%A0%9C%20%EC%A0%9C&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
4	Considerations in Tumorigenicity Assessment of Stem Cell Therapy Product	2022		Korean	https://www.mfds.go.kr/brd/m_1060/view.do?seq=1495&searchFr=&searchKw=%EC%A4%8F%EA%B0%9C%C%A4%8F%EC%8F%A7%EC%9F%8F%EB%A3%8E%C%EC%A0%9C+%EC%A7%5E%EB%97%EC%9E%8D%EC%B4%8F&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
5	Considerations in Biodistribution Assessment of Stem Cell Therapy Product	2024		Korean	https://www.mfds.go.kr/brd/m_1060/view.do?seq=1547&searchFr=&searchKw=%EC%A4%8F%EA%B0%9C%C%A4%8F%EC%8F%A7%EC%9F%8F%EB%A3%8E%C%EC%A0%9C+%EC%B2%8F%EB%8F%8F%EB%8F%8F%20%EB%A3%8E%C%EC%A0%9C&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
6	Guideline for evaluation of cell therapy products containing scaffolds	2020		Korean	https://www.mfds.go.kr/brd/m_1060/view.do?seq=1524&searchFr=&searchKw=%EC%A7%8D%EC%A7%8D%EB%A3%8E%C+%EC%8F%A7%EC%9D%8D%EB%A3%8E%C%20%EC%A0%9C%20%EC%A0%9C&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
7	Guideline on Release Tests for Cell Therapy Products	2023		Korean	https://www.mfds.go.kr/brd/m_1060/view.do?seq=1521&searchFr=&searchKw=%EC%A4%8F%EB%7C%EC%B5%9B%EB%A3%8E%C%EC%A0%9C+%EC%9D%8F%EC%A7%8B%EA%B0%9B%EB%A3%8E%C&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
8	Guideline on Quality, Non-clinical and Clinical Assessment of Stem Cell Therapy Product	2024		Korean	https://www.mfds.go.kr/brd/m_1059/view.do?seq=1509&searchFr=&searchKw=%EC%A4%8F%EA%B0%9C%C%A4%8F%EC%8F%A7%EC%9F%8F%EB%A3%8E%C%EC%A0%9C+%EC%A7%8F%EC%A7%8B&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
9	Guideline on the Design of Early-Phase Clinical Trials of Cell Therapy and Gene Therapy Products	2015		Korean	https://www.mfds.go.kr/brd/m_1060/view.do?seq=1292&searchFr=&searchKw=%EC%A4%8F%EA%B0%9C+%EC%B4%9C%EC%B4%7B%EC%B0%8C%EC%B7%7B+%EB%B4%9C%EC%B0%8C%EC%B0%8C%EB%B0%9C&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
10	Guideline on the Quality and Nonclinical Evaluation of Plasmid DNA based Gene Therapy Products	2023		Korean	https://www.mfds.go.kr/brd/m_1059/view.do?seq=1539&searchFr=&searchKw=%EC%A4%8F%EC%B9%8C%EC%A4%8F%EC%B9%8F%EC%B9%8F+%20%20%20+&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
11	Guideline on Eligibility Determination for Donors of Cell Therapy Products	2021		Korean	https://www.mfds.go.kr/brd/m_1060/view.do?seq=1480&searchFr=&searchKw=%EC%A4%8F%EB%7D%EC%B0%9C%EB%A3%8E%C+%EC%A4%8F%EB%7C%EA%B0%9C%EC%B0%9C+%EC%A4%8F%EC%B0%9C+%EC%A4%8F%EC%B0%9C&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
12	Guideline for Nomenclature of Drug Substance of Cell Therapy Products	2017		Korean	https://www.mfds.go.kr/brd/m_1060/view.do?seq=1292&searchFr=&searchKw=%EC%A4%8F%EB%7D%EB%7D%EC%B0%9C%EB%A3%8E%C%EC%A0%9C+%EC%B0%9C%EB%A3%8E%C%EC%B0%8B%EC%B0%8B%EB%7D+&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
13	Guideline on Nonclinical Evaluation of Gene Therapy Products	2023		Korean	https://www.mfds.go.kr/brd/m_1060/view.do?seq=1532&searchFr=&searchKw=%EC%A4%8F%EC%A7%8D%EC%B5%9B%EB%A3%8E%C%EC%A0%9C+%EB%B5%9B%EC%B5%9B%EC%B7%7B%EC%B8%8C%EB%B7%7B&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
14	Advanced biological products regulatory science consultation casebook	2023		Korean	https://www.mfds.go.kr/brd/m_1060/view.do?seq=1508&searchFr=&searchKw=%EC%B2%A4%EB%B1%A8%EB%B5%9C%EC%B7%8E%EC%B4%A4%EC%B5%9B%EC%B5%9B%EC%B7%8E%EC%B7%8E+%EA%B7%8C%EC%A0%9C%EA%C%B7%8E%EC%B5%9B%20+%EC%B7%8E%EC%B4%A4&searchFr=&searchKw=%EC%B2%A4%EB%B1%A8%EB%B5%9C%EC%B7%8E%EC%B5%9B%20+%EC%B7%8E%EC%B4%A4&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
15	Guideline on Quality, Non-clinical and Clinical Assessment of Extracellular Vesicles Therapy Products	2023		Korean	https://www.mfds.go.kr/brd/m_1060/view.do?seq=1542&searchFr=&searchKw=%EC%A4%8F%EC%B8%8C%EC%A4%8F%EC%B8%8C%EC%B0%9C%EB%A3%8E%C%EC%A0%9C+%EC%B0%9C%EB%A3%8E%C&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
		2024		English	https://www.mfds.go.kr/brd/m_1061/view.do?seq=1541&searchFr=&searchKw=%EC%A4%8F%EC%B8%8C%EC%A4%8F%EC%B8%8C%EC%B0%9C%EB%A3%8E%C%EC%A0%9C+%EC%B0%9C%EB%A3%8E%C&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
16	Guideline on Quality Assessment for Gene-Editing Based Advanced Therapy Medicinal Products	2024		Korean	https://www.mfds.go.kr/brd/m_1060/view.do?seq=1556&searchFr=&searchKw=%EC%A7%8C%EC%A4%8F%EC%B5%9D%EC%B8%8C%EC%A7%8D%EC%B8%8C%EB%B0%9C%EB%B0%9C%EB%A3%8E%C%EC%A0%9C+%EC%B0%9C%EC%A0%9C&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
17	Classification manual for advanced biological products	2020		Korean	https://www.mfds.go.kr/brd/m_1060/view.do?seq=1526&searchFr=&searchKw=%EC%B2%A4%EB%B1%A8%EB%B5%9C%EC%B7%8E%EC%B4%A4%EC%B5%9B%EC%B5%9B%EC%B7%8E+%EC%A0%9C%EC%A0%9C%EB%B7%8E&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
18	Guideline on Long-term Follow-up of Advanced Biopharmaceutical Products: Products subject to Long-term Follow-up and Observing Subjects	2020		Korean	https://www.mfds.go.kr/brd/m_1526/view.do?seq=1526&searchFr=&searchKw=%EC%B2%A4%EB%B1%A8%EB%B5%9C%EC%B7%8E%EC%B4%A4%EC%B5%9B%EC%B5%9B%EC%B7%8E+%EC%B5%A5%EB%B0%9C%EB%B0%9C+%EC%B5%A5%EB%B0%9C%EC%A0%9C&searchFr=&searchKw=%EC%A0%9C%EC%A0%9C%EB%B7%8E&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
19	Guideline for Cell Bank Evaluation of Cell Therapy Products	2023		Korean	https://www.mfds.go.kr/brd/m_1537/view.do?seq=1537&searchFr=&searchKw=%EC%A4%8F%EC%B7%8E%EC%A4%8F%EC%B7%8E%EC%A0%9C+%EC%B4%8F%EC%B7%8E%EC%B7%8E%EC%B0%8D%EC%B0%8D+%EC%B5%9E%EA%B0%8D+%EA%B0%8D%EC%B0%8D%EB%B7%7D+&searchFr=&searchKw=%EC%B2%A4%EB%B1%A8%EB%B5%9C%EC%B7%8E%EC%B5%9B%EC%B7%8E%EC%B7%8E%EC%B7%8E&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
20	Guideline on Non-clinical Assessment of Bio-convergence Product using Decorcellized 3D bioscaffold	2021		Korean	https://www.mfds.go.kr/brd/m_1495/view.do?seq=1495&searchFr=&searchKw=%EC%A7%8D%EC%B8%7D%EB%B7%8D+%EB%A7%8E%EC%B8%7D%EC%A4%8F%EB%B5%9C&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
21	Guideline on The Requirements for Quality Dossier of Cell and Gene Therapy Products	2022		Korean	https://www.mfds.go.kr/brd/m_1504/view.do?seq=1504&searchFr=&searchKw=%EC%A4%8F%EC%B8%8C%EC%B7%8E%EC%A0%9C+%EC%B4%8F%EC%B7%8E%EC%B7%8E+%EC%B8%7D&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
22	Guideline on Quality and Non-clinical Assessment of Live Biotherapeutic Product for Clinical trial	2023		Korean	https://www.mfds.go.kr/brd/m_1531/view.do?seq=1531&searchFr=&searchKw=%EC%B5%9C%EA%B7%8E%EC%B5%9B%EC%B5%9B%EC%B7%8E%EC%A0%9C+%EC%B0%9C%EC%B7%8E+%EC%B0%9C%EC%B7%8E+%EC%B0%9C&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
23	Guideline on the Quality Control of mRNA-based Gene Therapy Products	2022		Korean	https://www.mfds.go.kr/brd/m_1506/view.do?seq=1506&searchFr=&searchKw=mRNA+%EA%B7%8C%EC%B5%9B%EC%B5%9B&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
24	Guideline for evaluation of replication-competent retroviruses	2022		Korean	https://www.mfds.go.kr/brd/m_1508/view.do?seq=1508&searchFr=&searchKw=%EB%B5%9C%A5%8C%EA%B0%9C%EB%B5%A5+%EB%A0%8B%EB%B8%8A%EB%B5%A5+%EB%A0%8B%EB%B8%8A%EB%B5%A5%20%EB%B4%9F%EC%B0%8B%EB%B5%9C%EC%B0%8B&searchFr=&searchKw=%EB%B5%A5%20%EB%B4%9F%EC%B0%8B%EB%B5%9C%EC%B0%8B&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
25	Guideline on Quality, Non-clinical and Clinical Assessment of Xenotransplantation	2024		Korean	https://www.mfds.go.kr/brd/m_1560/view.do?seq=1560&searchFr=&searchKw=%EC%B5%8F%EC%A2%5B%EC%B0%8F%EC%B8%8C%EC%A0%9C+%EC%B2%8F%EC%A7%8B&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
26	Considerations on the Development of Personalized Neoantigen Coded Therapy Products	2023		Korean	https://www.mfds.go.kr/brd/m_1538/view.do?seq=1538&searchFr=&searchKw=%EA%B8%8C%EC%B0%8B+%EB%A7%8D%EC%B8%A4%EC%B8%8C+%EC%B5%A9%EC%B7%8D%EC%B5%9C%EC%B0%8B&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
		2024		English	https://www.mfds.go.kr/brd/m_1551/view.do?seq=1551&searchFr=&searchKw=%EA%B8%8C%EC%B0%8B+%EB%A7%8D%EC%B8%A4%EC%B8%8C+%EC%B5%A9%EC%B7%8D%EC%B5%9C%EC%B0%8B&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
27	Guideline on Nonclinical Biodistribution Considerations for Gene Therapy Products	2024		Korean	https://www.mfds.go.kr/brd/m_1550/view.do?seq=1550&searchFr=&searchKw=%EC%9C%A5%EC%A9%8A%EC%B7%8E%EC%B9%8F%EB%A3%8E%C%EC%A0%9C+%EB%B9%8A%EC%B4%A4%EC%B1%B1+%EC%B1%9C%EC%B7%8E&searchFr=&searchKw=%EC%B1%9C%EC%B7%8E&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
28	Considerations in Developing CAR(Chimeric Antigen Receptor)-T Cell Products	2024		Korean	https://www.mfds.go.kr/brd/m_1559/view.do?seq=1559&searchFr=&searchKw=%EC%B2%A4%EB%A5%B4%EB%B0%9C+%EC%B5%A0%EC%B9%B0+%EC%B8%8B%EC%B0%A8%EB%C%B2%B4&searchFr=&searchKw=%EC%B2%A4%EB%A5%B4&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1
30	Considerations on the Potency Test for Cell and Gene Therapy Products	2025		Korean	https://www.mfds.go.kr/brd/m_1569/view.do?seq=1569&searchFr=&searchKw=%EC%B7%A2%EA%B0%8D%EC%B0%9C%EC%B7%7B+%EC%B4%A4%EC%A0%9C+%EC%B8%9C&searchTy=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1