

Workshop for the Reproductive HCT/P Industry FDA Resources Quick Links

- FDA Website
 - <https://www.fda.gov/>
- Tissue Guidance Documents
 - <https://www.fda.gov/vaccines-blood-biologics/biologics-guidances/tissue-guidances>
- Tissue and Tissue products main page on fda.gov
 - <https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products>
- Tissue Establishment Registration information webpage
 - <https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/tissue-establishment-registration>
- CBER On-Line: Establishment Registration
 - <https://www.accessdata.fda.gov/scripts/cber/CFApps/Login/Index.cfm?CFID=14371273&CFTOKEN=3bf68105249a55d0-A85D0D0F-1372-5AE1-674338933A9DF71D>
- Compliance Program Guidance Manual Inspection of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)
 - <https://www.fda.gov/media/73949/download>
- Electronic Code of Federal Regulations
 - https://www.ecfr.gov/cgi-bin/text-idx?SID=3ee286332416f26a91d9e6d786a604ab&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl
- Division of Manufacturers Assistance and Training, Office of Communications, Outreach, and Development
 - industry.biologics@fda.hhs.gov
 - Use this email address for industry questions outside of an inspection.
- 483 Responses Email
 - orabioinspectionalcorrespondence@fda.hhs.gov
 - Use this email address for responses to 483 observations after an inspection.
- Webpage for FDA Workshop for the Reproductive Tissue Industry
 - <https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/fda-workshop-reproductive-tissue-industry-sept-29-and-oct-1-2020-09292020-10012020>
 - This is where questions asked during the workshop will be posted with answers.