



EVERSANA™

Donor eligibility determination has historically been one of the areas in the tissue industry to receive the most scrutiny by the FDA. There is a significant amount of data that can be difficult to collect and many changing variables go into the decision-making process that ultimately determine the acceptance of a donor. Incorrect donor eligibility determinations can result in tremendous liability risk and loss of revenue.

EVERSANA and ReproTech teamed up to develop an automated, web-accessible system to assist in the donor eligibility determination process. This system is specifically designed to provide tissue organizations with the ability to fully automate the donor eligibility process in a way that is not only compliant with FDA 21 CFR 1271 but also speeds up eligibility determination and saves money.

Primary Services

THE SYSTEM TAKES INPUT FROM NUMEROUS SOURCES AND MANAGES THE FOLLOWING AREAS:



SCREENING:

An electronic questionnaire is utilized to comply with FDA screening requirements. Companies with supplementary requirements for donor eligibility can add in customized questionnaires. The donor answers questions based on the type of tissue being donated.



PHYSICAL EXAM:

Results are input into the system either during the exam or at the conclusion by appropriate personnel. Additional questions may be added as the client sees fit.



TESTING:

Testing panel results are entered into the system by assigned personnel. The system ensures all required tests are reported appropriately.



RELEVANT MEDICAL HISTORY AND RECORDS:

These additional records may be added to the file as attachments in their native document type or scanned into the system and added to the donor file. The information could include any relevant information about the donor.

Based on inputs at each step of the donor eligibility process, the system utilizes validated logic to identify high-risk areas and noncompliances in the donor information and helps you make the correct eligibility determination. Based on this determination, a compliant summary of records is created by the system according to the requirements of 21 CFR 1271.55(b).

Built to support geographically diverse organizations through our web portal, the status of your donors may be easily monitored and the system supports electronic approvals compliant with 21 CFR Part 11.

For more information about EVERSANA's Donor Eligibility Outsourcing Services, call: 303.832.8200 or email: des@eversana.com.

About EVERSANA™



EVERSANA is the leading independent provider of global services to the life science industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product lifecycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers. The company serves more than 500 organizations, including innovative start-ups and established pharmaceutical companies to advance life science solutions for a healthier world. To learn more about EVERSANA, visit EVERSANA.COM or connect through [LinkedIn](#) and [Twitter](#).

