STEPS TO COMPLY WITH THE FDA'S GUDID SUBMISSION REQUIREMENTS

1. PREPARATION

A - Determine the best method for your GUDID data submissions

B - Set up FDA GUDID account

C - Set up FDA Electronic Submissions Gateway (ESG) Account

There are four methods available;
1. FDA- GUDID Web Interface
2. Software
3. Online hosted software (SaaS)
4. Outsourced service

1. Identify the DUNS # and make necessary changes to D&B info
2. Identify the individuals for GUDID account management roles
3. Identify third-party submitters
4. Submit a GUDID new account inquiry
5. GUDID account request document

1. An ESG account is required for all submissions methods aside from the FDA's GUDID Web Interface.
2. Reed Tech provides an ESG account at no additional charge

2. DATA COLLECTION

A - Identify your GUDID data

B - Collect, verify and validate source GUDID data

1. Locate UDI data
2. Determine any gaps in data
3. Identify data formats
4. Remedy any issues from data discovery

1. Capture GUDID data; merge partial records as necessary
2. If necessary, capture data from label
3. If desired, collect additional data fields
4. Standardize data as needed
5. Verify and validate the data

3. SUBMISSION

A - FDA's GUDID submission method

B - For other submission methods

1. If using FDA's GUDID Web Interface, manually enter each data record

For bulk SPL submissions:
1. Create fully-validated SPL UDI submissions per FDA business rules
2. Submit SPL UDIs to FDA via ESG
3. Download and process three FDA acknowledgment messages for each SPL
4. Correct any files that do not pass FDA validation requirements

4. MAINTENANCE

A - Updates

B - Add new data

C - Update data for products no longer in commercial distribution

1. Update existing data records as needed

1. Add new data records for new products

1. Update data records for products no longer in commercial distribution