

# *CBER eSubmitter Training Session*



**August 2011**



# Training Agenda

- Getting Started with the eSubmitter Tool
- Creating an eSubmitter Submission
- Packaging an eSubmitter Submission
- Question & Answer Session



# What is eSubmitter?

- Software is currently used by various offices within the Center for Devices and Radiological Health (CDRH), the Center for Tobacco Products (CTP), and the Center for Veterinary Medicine (CVM)
- CBER has recently released templates into production for BLA/BLS submissions for Establishments that Collect Whole Blood and Blood Components, including Source Plasma



# How Does eSubmitter Work?

- Data capturing forms (question and answer, file attachment capability, etc.)
- Uses business rule logic (conditional statements) to require the submitter to complete applicable sections based on previous responses
- Walks users through the process of compiling a complete and structured submission

# The eSubmitter Process

  
**FDA Subject Matter Experts**

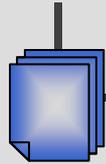
  
**Regulated Industry**

  
**FDA Systems**

**eReviewer**

  
**Review Documents**

**eDesigner**



**eSubmitter**

**Templates (Submission Forms)**

**Submission ZIP File**



**ESG**

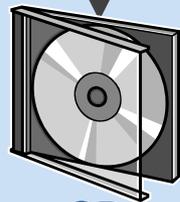


**Electronic Document Repository**

**Electronic Submission Tracking**

**Legend**

- = current process
- ..... = future process



**CD**



**eLoader**



# Desired Outcomes from the eSubmitter Initiative

eSubmitter provides:

- A straightforward and user friendly approach to compiling well-structured and complete electronic submissions
- More complete submissions which may improve the review process
- Transparency to promote clear understanding of what FDA is looking for in a complete submission



## Contact Information & Resources

Support Email for CBER eSubmitter Users:  
[CBER\\_eSubmitter\\_Program@fda.hhs.gov](mailto:CBER_eSubmitter_Program@fda.hhs.gov)

**FDA eSubmitter website:**

<http://www.fda.gov/ForIndustry/FDAeSubmitter/>