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

Templates (Submission Forms)

eSubmitter

Submission ZIP File

ESG

Electronic Document Repository

Electronic Submission Tracking

CD

eLoader

Legend

= current process

= future process

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

FDA eSubmitter website:

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