FDA/CBER

SUCCESS STORY

FDA/CBER moves to electronic document submission to streamline review and processing of biologics research information

Food and Drug Administration/Center for Biologics Evaluation and Research

- The FDA Center for Biologics Evaluation and Research (CBER) regulates biological products.
- Employees: 1,028
- Headquarters: Rockville, Maryland

www.fda.gov/cber

Industry
Federal Government

Solution
Electronic Document Submission

Products Used

- Adobe® Acrobat®
- Documentum 4 Enterprise Content Management Platform
- Oracle8i Database

In Partnership with
Booz Allen Hamilton

Organization Profile

The FDA Center for Biologics Evaluation and Research (CBER) has a crucial charter that includes everything from keeping the nation's blood supply safe to reviewing and approving childhood vaccines.

CBER evaluates large volumes of scientific and clinical data from manufacturers to determine whether biological products meet the agency's standards for approval. To facilitate information access and better serve companies developing critical treatments, CBER is moving from paper-based review processes to more efficient electronic review of materials.

Challenges Faced

Improve service for sponsors

Hundreds of "sponsors," including pharmaceutical and biopharmaceutical companies, academia, and individual investigators, submit materials to CBER for regulatory review each year. Materials include Investigational New Drug (IND) applications, Biologics License Applications (BLAs), promotional labeling and advertisements, and safety data. These submissions vary in size from a license application with 1,000 volumes to a one-page IND amendment.

The costs and subsequent delays of routing and tracking paper submissions challenge CBER's resources. Explains Michael Fauntleroy, director of electronic submissions for CBER, "The clinical development of an investigational entity subject to an IND typically takes place over several years. During this time, a tremendous amount of material is collected. A major goal for CBER's electronic submissions program is to facilitate the review process using electronic submissions while ensuring that sponsors' materials are tracked and managed reliably."

Lower costs and streamline material processing and review

For sponsors, submitting materials on paper can be time-consuming and expensive, including copying and shipping boxes of documents to CBER. Sending a hard-copy of an original licensing application can take a week or more from when the application is mailed to the time it arrives on the CBER reviewers' desks. Given the revenue-generating opportunities for some treatments—frequently prescribed treatments can generate more than a million dollars daily in sales—fast delivery and reliable receipt of applications are critical.

Success Strategy

CBER's IT staff worked with the consulting firm Booz Allen Hamilton and the CBER review community to implement an operational system for managing and reviewing electronic submissions. The system is built around a Documentum content management application, an Oracle database, and Adobe Acrobat software.

Adobe

"Electronic submissions enable our agency to handle more information faster, streamline internal operations, and improve our service to stakeholders."

Michael Fauntleroy, Director of electronic submissions, FDA, Center for Biologics Evaluation and Research

The electronic workflow offers sponsors the option of sending BLAs, IND applications, amendments, and other regulatory communications to CBER as Portable Document Format (PDF) files on CD or via secure e-mail featuring a digital electronic signature. As BLA and IND amendments are received via e-mail they are automatically processed and loaded into the Electronic Document Room (EDR), with load notifications sent to the affected reviewers. CBER utilizes electronic forms to facilitate the routing of electronic submissions to reviewers. These forms import data directly into a database, saving time and minimizing errors by eliminating the need to rekey information.

CBER reviewers can use the electronic annotation tools in Acrobat software during reviews of guidance-compliant electronic submissions. Final reviews and regulatory materials are stored in CBER's searchable archive, the EDR.

"A major advantage is that we can access the EDR, execute a search, and retrieve sponsor- or CBER-generated documentation online in minutes, thus promoting the efficient review and processing of regulatory submissions," says Fauntleroy.

Business Benefits

• Efficient review and handling of regulatory documentation

• Improved services for sponsors

• Lowered administrative time and costs for the FDA and sponsors

The electronic submission of BLAs and IND applications offers secure and easy options for enhancing information sharing between sponsors and CBER review teams. To ensure document integrity for regulatory purposes, the files look exactly like the original documents. And, by accessing a searchable archive of PDF documents and commenting electronically on files, CBER staff can streamline the regulatory review process.

"Electronic submissions enable our agency to handle more information faster, streamline internal operations, and improve our service to stakeholders," explains Fauntleroy. "Sponsors can save considerable time and money as well, ultimately improving revenue and time-to-market for products." For instance, electronic regulatory amending submissions sent via secure e-mail can arrive on reviewers' desks in eight to twelve minutes compared to three days to a week if delivered on paper.

Adds Fauntleroy, "We do not mandate electronic submissions, but the new process results in such impressive time-savings and efficient information access that companies can see clear benefits in opting to send materials electronically."

By moving to an electronic workflow for routing, reviewing, and archiving, everyone wins: consumers benefit from introduction of potentially lifesaving treatments, companies can more quickly recoup their R&D investment in leading drugs by speeding time-to-market for treatments, and taxpayers fund a more efficient government agency.

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