

**2005 DataFax Users Group Meeting, Sun Valley, Idaho
Birds of a Feather Session on Electronic Data Capture, March 22, 2005**

Attendees

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Purpose

- To provide DataFax users with the opportunity to discuss electronic data capture.

Topics

- Available EDC Solutions
 - No one in the session had any significant experience with EDC solutions with the exception of the developers of DataFax-EDC.
 - The developers of DataFax-EDC intentionally avoided evaluating other EDC solutions in depth during development. This was to prevent inadvertent incorporation of proprietary features from other products in DataFax-EDC.
- Implementing EDC
 - Some attendees are being asked to explore implementing EDC within their organizations.
 - Discussion followed regarding the need to separate the infrastructure required to support EDC from the implementation of a specific EDC product. Generally, some kind of information technology infrastructure, including hardware technicians and end-user support staff, is necessary, regardless of the EDC product.
 - Other possible implementation options included an independent, third party service provider that could handle support and file/EDC management.
- 21 CFR Part 11
 - Regulations have been relaxed.
 - Goal is still to make electronic records as incontrovertible as paper records.
 - Biometric devices are an acceptable method for providing digital signatures.

Conclusions

- EDC is still a hot topic, but practical implementation has many unanswered questions.
- There is continued interest in an EDC solution for DataFax.