

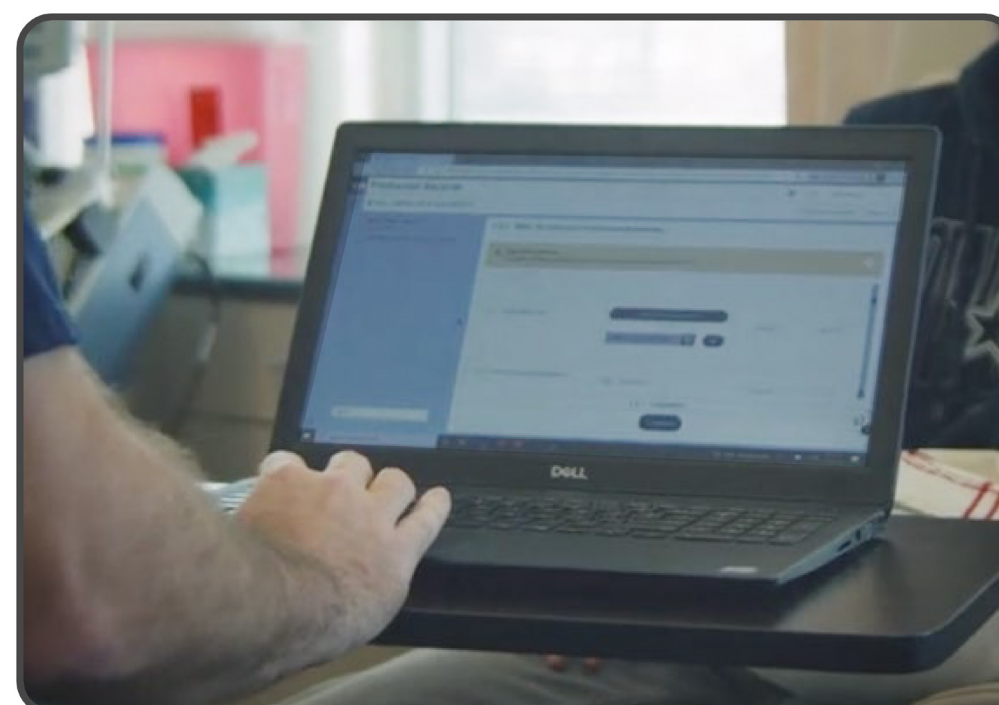
Background:

Cell and gene therapy development requires standardization of data input in documentation to ensure traceability throughout a product's manufacturing and its supporting processes including cell and tissue collections, testing, and distribution. **Data inputs must be concurrent, legible, accurate, and representative of the process at hand.**

Handwritten entries using paper contend with proper ink types, misspelling, illegible entries, etc. As organizations implement digital or automated solutions, including electronic documentation systems, the issues with handwritten entries can be greatly reduced. Electronic Batch Records (eBR) were implemented at our organization to provide documentation support, reduce Good Documentation Practices (GDP) errors, improve cycle time and enhance traceability.

Study Design/Methods:

An eBR template was implemented using our unified electronic Quality Management System (eQMS), MasterControl. Each record is designed and implemented in collaboration with clients, operational entities, and Quality. The electronic record uses eQMS to verify user identity and maintain **21 CFR part 11 compliance. Templates are designed with required entries and entry types including predecessors, binary option choices, multiple choices, attachments, numerical entries, automatic calculation, etc.** Operator entries are time-stamped and signed upon submission. This allows collection of large amounts of data with fewer errors related to Good Documentation Practices (GDP). Here, we compare performance using paper batch records to electronic batch records.



Results/Findings:

Table 1: Documentation errors in comparable sized, paper and electronic batch record.

	ERRORS		
Batch Record	Paper	Electronic	% Reduction
1	114	48	58%
2	151	63	58%
3	92	44	52%
4	81	34	58%
5	79	16	80%
Total	517	205	60%
Average	103	41	60%

When comparing similar sized paper batch records to electronic, we consistently see improvement in documentation errors (Table 1)—on average, 60% reduction (range, 52-80%; 517 vs. 205) on comparable records.

Conclusion:

Implementation of the eBR led to a **60% average reduction of documentation errors**. This decrease in errors, along with other automation benefits of an eBR, allows resource re-allocation to additional quality initiatives and results in faster record review and batch release times. As use of the eBR expands and matures, we expect to see further error reduction and increased efficiency.