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Device Validation Forum: Issues with Medical Device Part 11 Electronic Records; Electronic Signatures

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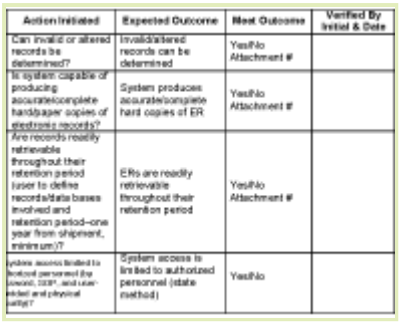

Action Initiated	Expected Outcome	Met Outcome	Verified By Initial & Date
Can invalid or altered records be determined?	Invalid/altered records can be determined	Yes/No Attachment #	
Is system capable of producing accurate/complete hard/paper copies of electronic records?	System produces accurate/complete hard copies of ER	Yes/No Attachment #	
Are records readily retrievable throughout their retention period (user to define records/data bases involved and retention period–one year from shipment, minimum)?	ERs are readily retrievable throughout their retention period	Yes/No Attachment #	
[illegible]	System access is limited to authorized personnel (state method)	Yes/No	

Subpart 11.10: Verify Records Input and Retention.

INTRODUCTION As the medical device industry moves toward electronic records (ER) and signatures by in-house systems and/or cloud/web-based systems, and away from paper documentation, 21 Code of Federal Regulations (CFR) Part 11, Electronic Records; Electronic Signatures (ES) verification and validation (V&V) activities and documentation become mandatory. These issues are not only a regulatory/Part 11 concern but also a user/customer concern. These requirements should not be viewed as unnecessary bureaucratic red tape. All industries, not just US Food and Drug Administration-regulated ones,...