Data Integrity Checklist

	Question	Comments
A Attributable	**Paper**	
	Does your company maintain a signature log for employees that work in GxP areas?	
	Are staff trained in Good Documentation Practices outlining that GxP records must be initialled and dated?	
	Is the use of scribes prevalent in your company?	
	Are digital images of a person's handwritten signature permitted at your company?	
	Electronic	
	Does the system use unique user logins with electronic signatures?	
	Are there audit trials in place recording the identity of operators entering, changing, confirming or deleting data?	
	Does the system identify and record the person releasing or certifying the batches? Is an electronic signature used?	
	Are staff trained on the fundamentals of data integrity which emphasises never to disclose their username or passwords with other staff?	

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L Legible	**Paper**	
	Are controls in place to ensure data is recorded using permanent, indelible ink?	
	Is the use of correction fluid, pencils and erasures prohibited?	
	Is there controlled issuance of bound, paginated notebooks for GMP activities?	
	Are archiving of paper records performed by an independent, designated archivist?	
	Are operators trained to use single-line cross outs accompanied by an initial and date when recording changes to a record?	
	Electronic	
	Is your stored data checked periodically for readability?	
	Are audit trails convertible to a generally intelligible form?	
	Can general users switch off the audit trail?	
	Is archived data checked periodically for readability?	
	Is data backed up in a manner permitting reconstruction of an activity?	

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	Question	Comments
C Contemporaneous	**Paper**	
	Are staff trained in Good Documentation Practices emphasizing the importance of recording data entries at the time of activity?	
	Are staff trained in Good Documentation Practices emphasizing that it is improper to back date or forward date a record?	
	Electronic	
	Does your system automatically generate a timestamp when data is entered?	
	Do electronic signatures contain an automatically generated timestamp?	
	Are users able to change the timestamps applied to records?	
	Are general users able to gain access and change the system clock or timezone settings?	
	Is data saved to unauthorised storage locations such as USB sticks?	
	Are there sufficient availability of user terminals at the location where a GxP activity takes place?	

PharmOut

Data Integrity Checklist

	Question	Comments
O Original	**Paper**	
	Are sticky notes or other unofficial notepads permitted in GMP areas of the facility?	
	Are qualification/validation activities performed on original pre-approved protocols?	
	Is there a controlled and secure area for archiving of records?	
	Are original records readily available for inspection?	
	Electronic	
	Is it possible to print out batch release records, showing any data that has been changed since the original entry?	
	Are your electronic signatures permanently linked to their respective record?	
	Does the person processing the data have the ability to influence what data is reported or how it is presented?	
	Does the system prevent deletion of original data?	
	Is it possible to take screenshots and use snipping tools to manipulate data?	
	Is metadata periodically reviewed?	

PharmOut

Data Integrity Checklist

	Question	Comments
A Accurate	**Paper**	
	Are forms, logbooks and notebooks formatted to easily allow for the entry of correct data?	
	Are procedures in place to independently review original paper records?	
	Are deviations and out-of-specification results investigated?	
	Are laboratory instruments calibrated and maintained?	
	Are secondary checks performed to check the accuracy of critical data?	
	Are staff pressured into meeting production targets, leading to compromised accuracy of records?	
	Electronic	
	Do interfaces contain built-in checks for the correct and secure entry and processing of data?	
	Does your system perform a check on the accuracy of critical data and configurations?	
	Are systems periodically reviewed?	
	Are interfaces validated to demonstrate security and no corruption of data?	
	Is archived data protected against unauthorised amendment?	