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Company Name	Date		Regulation	Note
Hospira	Mar 2013	483	211.180(d)	Data Integrity. The raw data generated from the semi-automated thickness tester used to measure the thickness of perimeter seals on bags used as container closure systems for injectable drugs can be overwritten with new data without explanation and the original data is erased from the computer's memory upon being overridden.
Gilead (CA, USA)	April 2013	483		Discrepancies with printed results. This data integrity issue is a repeated issue back from July 2012.
Puget Sound Blood Center and Program	Apr 2013	Warning Letter (WL)	211.68(b)	Lack of I/O Verification (Data Accuracy).
RPG Life Sciences Limited	May 2013	WL	211.68(b)	The computer system being used for HPLC did not have adequate controls to prevent unrecorded changes to data.
Fresenius Kabi AG	Jul 2013	WL	API[1]	Unacceptable practices in the management of electronic data.
Aarti Drug Limited	Jul 2013	WL	API	Failure to implement access controls and audit trails for laboratory computer systems.
Wockhardt Limited	Jul 2013	Statement of non-compliance with GMPs	2003/94/EC (EU GMPs)	Critical deficiency: Issues were identified which compromised the integrity of analytical data produced by the QC department. Evidence was seen of data falsification. A significant number of product stability data results reported in the Product Quality Reviews had been fabricated. Neither hard copy nor electronic records were available. In addition issues were seen with HPLC electronic data indicating unauthorized manipulation of data and incidents of unreported trial runs prior to reported analytical runs. MHRA
Wockhardt Limited	Jul 2013	WL	211.194(a)	Fail to ensure that laboratory records included complete data derived from all tests necessary to assure compliance with established specifications and standards.
Posh Chemicals Pvt Ltd	Aug 2013	WL	API	Failure to protect computerized data from unauthorized access or changes.
Agila Specialist Private Limited	Sep 2013	WL	211.68(b)	The computer system being used for HPLC did not have adequate controls to prevent unrecorded changes to data.
Smruthi Organics Ltd.'s	Oct 2013	Statement of non-compliance with GMPs.	Article 47 of 2001/83/EEC	The agency observed manipulation and falsification of documents and data in different departments. There was no raw data available in the Quality Control laboratory for the verification of compendial analytical methods. (French Health Products Safety Agency)

[1] US FDA, CPG 7356.002F, API Process Inspection, February 2006, requires the inspection of "Quality and retention of raw data (e.g., chromatograms and spectra)." Laboratory Control records in US FDA Guidance for Industry Q7 GMP Guidance for API (August 2011) indicates that "Laboratory control records should include complete data derived from all tests conducted to ensure compliance with established specifications and standards, including examinations and assays."

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Ind-Swift Limited	Oct 2013	Statement of non-compliance with GMPs.	2003/94/EC (EU GMPs)	It was not possible to confirm the validity of stability testing data. Several falsified and inaccurate results had been reported in long term stability and batch testing. Discrepancies between electronic data and those results formally reported were identified. Established processes to verify data accuracy and integrity had failed and there had been no formal investigation raised by the company. The company provided commitments to address the data integrity concerns and initiated a wider review of quality critical data. Additional discrepancies were identified in process validation and release data. During on-going communications with the licensing authority regarding the data review, the company failed to disclose data integrity issues for all products. No satisfactory explanation was given for this discrepancy. (MHRA)
Zeta Analytical Ltd	Nov 2013	Statement of non-compliance with GMPs.	European Union's GMP guideline	The computer system being used for HPLC did not have adequate controls to prevent unrecorded changes to data. (MHRA)
WOCKHARDT LIMITED	Nov 2013	Statement of Non-Compliance to GMPs	Art. 111(7) of Directive 2001/83/EC as amended.	Entries were seen to be made when personnel were not present on site, documentation was seen that was not completed contemporaneously despite appearing to be completed in this manner. (Competent authority of United Kingdom)
Wockhardt Limited	Nov 2013	Statement of non-compliance with GMPs	2003/94/EC (EU GMPs)	The deficiency related to data integrity, deleted electronic files with no explanation. MHRA
Wockhardt Limited	Nov 2013	WL	21 CFR 211.194(a), 211.68(b)	Failure to maintain complete data derived from all laboratory tests (Chikalthana facility). Inadequate control of computer systems (Waluj and Chikalthana facilities). The computer system being used for HPLC did not have adequate controls to prevent unrecorded changes to data.
Seikagaku Corporation	Dec 2013	Statement of non-compliance with GMPs.	2003/94/EC (EU GMPs)	The critical deficiency concerns systematic rewriting/manipulation of documents, including QC raw data. The company has not been able to provide acceptable investigations and explanations to the differences seen in official and non-official versions of the same documents. (Competent Authority of Sweden)
Smruthi Organics Ltd.'s	Jan 2014	Statement of non-compliance with GMPs.	Article 47 of 2001/83/EEC	There was no raw data available in the Quality Control laboratory for the verification of compendial analytical methods. (French Health Products Safety Agency)
Ranbaxy Laboratories, Inc.	Jan 2014	483	211.68(b)	The computer system being used for HPLC did not have adequate controls to prevent unrecorded changes to data.
Punjab Chemicals and Crop Corporation Limited	Jan 2014	Statement of non-compliance with GMPs.	Article 47 of 2001/83/EEC	One individual training file of an employee has been observed to be recently re-rewritten; The Batch Manufacturing record was lacking details with regards to manufacturing steps and in-process controls; The sample retention log-book for Trimethoprim had falsified entries. (French Health Products Safety Agency)
USV Limited	Feb 2014	WL	211.68(b)	The computer system being used for quality control laboratory did not have adequate controls to prevent unrecorded changes to data.
Canton Laboratories Private Limited	Feb 2014	WL	API	The computer system being used for Atomic Absorption Spectrophotometer did not have adequate controls to prevent unrecorded changes to data. Failure to maintain complete data derived from all laboratory tests.

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Company Name	Date		Regulation	Note
SOMET	Mar 2014	Statement of non-compliance with GMPs.	Article 47 of 2001/83/EEC Article 51 of 2001/82/EC	Complete records of raw data generated during cleanliness tests by thin layer chromatography are missing. (French Health Products Safety Agency)
Smruthi Organics Ltd.'s	Mar 2014	WL	API	Failure to maintain complete and accurate laboratory test data generated in the course of establishing compliance of your APIs to established specifications and standards.
Colorado Histo-Prep	Mar 2014	WL	58.81(b)(10)	Your firm failed to establish SOPs describing the handling and retrieval of electronic data. Handling of electronic data includes the security (e.g., audit trails) and statistical analysis of raw data. Although you provided the FDA Investigator with SOP H-31, "Server" and "Data Storage and Disaster Recovery," which describes the physical storage of electronic data in a central file server, your SOP lacks details concerning how you ensure the security of data, and how changes to the files are managed and documented. Furthermore, you failed to monitor access and record changes (via an audit trail) of electronic statistical data and statistical analyses. Thus, the quality and integrity of your data and analyses cannot be ensured.
Wockhardt Limited	Mar 2014	Statement of non-compliance with GMPs	2003/94/EC (EU GMPs) Article 47 of 2001/83/EEC	A critical deficiency was cited with regards to data integrity of GMP records, entries were seen to be made when personnel were not present on site, and documentation was seen that was not completed contemporaneously despite appearing to be completed in this manner. (Competent Authority of United Kingdom)
Steris Corporation	May 2014	WL	820.70(i)	The application is set up to automatically discard any dosimeter absorbance readings outside the set operating range of **(b)(4)** to **(b)(4)** absorbance units.
Sun Pharmaceutical Industries Limited	May 2014	WL	211.68(b)	Delete raw data files on computers used for your GC instruments in your quality control laboratory. Computer systems without security controls. As an example there are several equipment with PLC controls and/or MMI. Each of the equipment access is via use of a password for each of the three levels of access i.e. operator, supervisor and administrator. There is a common password used by several individuals.
Wockhardt's Illinois	May 2014	483	211.68(b)	A general login on one computer allows data stored on the hard drives of these instruments to be changed or deleted by any user.
Micro Labs, Ltd	May 2014	Notice of Concern (WHO)	WHO references 15.9, 17.3d, 15.1	HPLCs did not have audit trails enabled, some audit trails missing when peaks were manually integrated, no SOP to describe when manual integration is acceptable. Some instruments had date and time functions unlocked and were not linked to a server, so timestamps could be manipulated. One HPLC had a shared password so actions were not attributable to an individual. In some cases, trial injections were made but were not part of the test record.
Mahendra Chemicals	May 2014	WL	API	2. Failure to prevent unauthorized access or changes to data, and to provide adequate controls to prevent omission of data. Your laboratory systems lacked access controls to prevent raw data from being deleted or altered. For example.

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				a) There is no assurance that you maintain complete electronic raw data for your Gas Chromatography (GC) instrument. FDA investigators observed multiple copies of raw data files in the recycle bin connected to the GC instrument QC-04 even in the presence of "Do Not Delete Any Data" notes posted on two laboratory workstation computer monitors. b) Employees were allowed uncontrolled access to operating systems and data acquisition software tracking residual solvent, and test and moisture content. Our investigators noted that there was no password functionality to log into the operating system or the data acquisition software for the GC, the High Performance Liquid Chromatography (HPLC) instrument QC-17, or the Karl Fischer (KF) Titrator QC-13. c) HPLC SpinChrome and GC Lab Station data acquisition software lacked active audit trail functions to record changes in data, including original results, who made changes, and when. In your response, you state that your laboratory GC, HPLC and KF systems are now password-protected and that you have begun drafting analytical software password procedures for the GC, HPLC and KF laboratory instruments. However, your response does not state whether every analyst will have their own user identification and password. You also mention plans to install a validated computer system. However, you did not provide a detailed corrective action and preventive action (CAPA) plan or conduct a review of the reliability of your historical data to ensure the quality of your products distributed to the U.S. market. Inadequate controls of your computerized analytical systems raise questions about the authenticity and reliability of your data and the quality of your APIs. It is essential that your firm implements controls to prevent data omissions or alterations. It is critical that these controls record changes to existing data, such as the individuals making changes, the dates, and the reason for changes. In response to this letter, provide your comprehensive CAPA plan for ensuring that electronic data generated in your manufacturing operations, including laboratory testing, cannot be deleted or altered. Also identify your quality control laboratory equipment and any other manufacturing-related equipment that may be affected by inadequate controls to prevent data manipulation".
Micro Labs Tamil Nadu	Not available	Not available		Data Integrity (Source: Health Canada) Regulatory Partners
Micro Labs Goa	Not available	Not available		Data Integrity (Source: Health Canada) Regulatory Partners
Micro Labs Bangalore	Not available	Not available		Data Integrity (Source: Health Canada) Regulatory Partner
Apotex, Inc.	Jun 2014	WL	API	General lack of reliability and accuracy of data generated by your firm's laboratory, which is a serious CGMP deficiency that raises concerns about the integrity of all data generated by your firm. Failure to maintain complete data derived from all laboratory tests.

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Apotex Pharmachem India Private Limited (APIPL)	Not available	Not available		Data Integrity (Source: Health Canada) Health Canada / Regulatory Partner
Apotex Research Private Limited (ARPL)	Not available	Not available		Data Integrity (Source: Health Canada) Health Canada / Regulatory Partner
Trifarma S.p.A.	Jul 2014	WL	API	Failure to maintain complete data derived from all laboratory tests. The firm deleted all electronic raw data supporting the company's high performance liquid chromatography (HPLC) testing. Failure to prevent unauthorized access or changes to data. The computer system grants all laboratory personnel full privileges to delete or alter raw data on the laboratory systems. At the time of the inspection, the company's HPLC and gas chromatograph software had no audit trails to show when raw data was changed and who changed it.
Impax	Jul 2014	483	211.68(b)	The plant has two spectrophotometers that don't have adequate controls to ensure analysts can't rewrite or delete analytical data. The systems are used in testing raw materials, stability and release." Source: Quality Management Network Vol 6, No 33 (August 15, 2014).
Renown Pharmaceuticals PVT.LTD	Aug 2014	Statement of non-compliance with GMPs.	2003/94/EC (EU GMPs)	Record integrity and veracity: some records were made up or altered. Lack of mechanisms to ensure integrity of analytical data. (Spanish Agency of Medicines and Medical Devices)
Hebei Dongfeng Pharmaceutical Co., Ltd	Aug 2014	Statement of non-compliance with GMPs.	Article 47 of 2001/83/EEC	Data recording and integrity in the QC laboratory. (Competent authority of Romania)
Fujian South Pharmaceutical	Sep 2014	Statement of non-compliance to GMPs.	Art. 111(7) of Directive 2001/83/EC	The computerized systems in the quality control department could not show whether approval of raw materials and final API was based on valid and accurate data. (Italian Medicines Agency)
Taishan City Chemical Pharmaceutical Co. LTD.	Sep 2014	Statement of Non-Compliance to GMPs	Article 47 of Directive 2001/83/EC	Insufficient securisation of the electronic raw data in the Quality Control laboratory (No limitation of access levels, no restriction on the deleting of data, no audit trail, inadequate traceability and archiving practises) (French Health Products Safety Agency)
Cadila Pharmaceuticals Limited	Oct 2014	WL	API	Failure to prevent unauthorized access or changes to data and to provide adequate controls to prevent omission of data. Source: Quality Management Network Vol 6, No 46 (November 14, 2014).
Sharp Global Limited	Oct 2014	WL	API	Printing batch records from personal computers over which the company lacked adequate controls. Gas chromatographs didn't prevent the deletion or altering of raw data files, and lacked audit trails that record any changes to data. Sharp management told investigators that the company's practice was to delete raw data files once the chromatograms were printed. Source: Quality Management Network Vol 6, No 46 (November 14, 2014). Failure to prevent unauthorized access or changes to data and to provide adequate controls to prevent omission of data.
Zhejiang Apeloa Kangyu Bio-Pharmaceutical Co. Ltd.	Oct 2014	Statement of Non-Compliance to GMPs	Art. 80(7) of Directive 2001/82/EC	The company failed to establish a procedure to identify and validate GMP-relevant computerized systems in general. Two batch analysis reports for Colistin Sulfate proved to be manipulated. HPLC chromatograms had been copied from previous batches and renamed with different batch and file

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				names. Several electronically stored HPLC runs had not been entered into the equipment logbooks. The nature of these data could not finally been clarified. Neither the individual workstation nor the central server had been adequately protected against uncontrolled deletion or change of data. The transfer of data between workstations and server showed to be incomplete. No audit trail and no consistency checks had been implemented to prevent misuse of data.
Apotex Pharmachem (Canada)	Nov 2014	483	211.68(b)	5 cases of failure to prevent unauthorized access or changes to data.
Dr Reddy	Nov 2014	483	211.68(b)	Computerized systems don't have proper controls in place to prevent unauthorized access or changes to data.
North China Pharmaceutical Group Semisyntech Co., Ltd	Nov 2014	Statement of Non-Compliance to GMPs	Article 47 of Directive 2001/83/EC and Article 51 of Directive 2001/82/EC	Manipulation and falsification of GMP documents (rewriting of records with change of content, an inconsistency of signatures and date in many records, etc.) were observed in different department. Lack of data integrity in the QC laboratory (No access control, inadequate traceability and archiving practices, no audit trail, no restriction on the deleting of data, etc.) and falsification of the analytical results for residual solvents. (Competent authority of France)
North China Pharmaceutical Group Semisyntech Co., Ltd	Not available	Not available		Data Integrity (Source: Health Canada) Regulatory Partner
GVK Biosciences	Dec 2014	–	–	Concerns over the quality of data from clinical trials conducted by GVK, regulators in France, Germany, Belgium and Luxembourg suspended the marketing approval of 25 generic drugs. http://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/france-germany-suspend-some-drug-approvals-over-data-by-gvk-biosciences/articleshow/45392105.cms http://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/four-european-union-countries-suspend-authorisation-of-25-drugs-studied-at-gvk-biosciences/articleshow/45396530.cms
Novacyl Wuxi Pharmaceutical Co., Ltd.	Dec 2014	WL	API	Failure to manage laboratory systems with sufficient controls to ensure conformance to established specifications and prevent omission of data. Other significant deficiencies noted in your laboratory system include failure to use separate passwords for each analyst's access to the laboratory systems.
SRI KRISHNA Pharmaceuticals Ltd.	Dec 2014	Statement of Non-Compliance to GMPs	Art. 111(7) of Directive 2001/83/EC as amended.	1. The company did not have a proper system in place to make sure that electronic raw data cannot be adulterated or deleted. Analysts routinely use the PC administrator privileges to set the controlling time and date settings back to over-write previously collected failing and/or undesirable sample results. This practice is performed until passing and/or desirable results are achieved. 2. Established laboratory control mechanisms are

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Company Name	Date		Regulation	Note
				not followed. Electronic records are used, but they do not meet systems validation requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records. (Italian Medicines Agency)
SRI KRISHNA Pharmaceuticals Ltd.	Not available	Not available		Data Integrity (Source: Health Canada) Regulatory Partners
North China Pharmaceutical Group Semisyntech Co., Ltd	Jan 2015	Statement of Non-Compliance to GMPs	Article 47 of Directive 2001/83/EC and Article 51 of Directive 2001/82/EC	No access control, inadequate traceability and archiving practices, no audit trail, and no restriction on the deleting of data. French National Agency for Medicines and Health Products Safety
Micro Labs Limited	Jan 2015	WL	21 CFR 211.68(b)	Failed to EXERCISE appropriate controls over computer or related systems to assure that only authorized personnel institute changes in master production and control records, or other records.
Novacyl (Thailand) Ltd	Feb 2015	WL	API	Not retaining "complete raw data from testing performed to ensure the quality of your APIs. Lack of proper controls in place to prevent the unauthorized manipulation of your laboratory's raw electronic data. The gas chromatograph (GC) computer software lacked password protection allowing uncontrolled full access to all employees.
Cadila Pharmaceuticals Limited	Feb 2015	WL	API	Failure to prevent unauthorized access or changes to data and to provide adequate controls to prevent omission of data. a. The inspection found that the audit trail feature for your gas chromatography (GC) instruments was not used until October 2013, even though your 2009 GC software validation included a satisfactory evaluation of the audit trail capability. b. There is no assurance that you maintain complete electronic raw data for the **(b)(4)** GC instruments, the Malvern particle size analyzer, and the ultraviolet (UV) spectrophotometer. Our inspection found that these instruments were connected to stand-alone computers that stored the data and that the data could be deleted. c. Prior to our inspection, your firm failed to have a back-up system for the data generated by one of the **(b)(4)** Fourier transform infrared pectrometers, the polarimeter, the UV spectrophotometer and the Malvern particle size analyzer.
Dr. Reddy's Laboratories	Not available	Not available		Data Integrity (Source: Health Canada) Regulatory Partner
IPCA Laboratories Ltd.	Not available	Not available		Data Integrity (Source: Health Canada) Regulatory Partner
IPCA	Not available	Not available		Data Integrity (Source: Health Canada) Regulatory Partner

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Polydrug Laboratories PVT. LTD	Mar 2015	Statement of Non-Compliance to GMPs	Art. 111(7) of Directive 2001/83/EC as amended Art. 80(7) of Directive 2001/82/EC as amended	Deficient management of the computerized system. Agency for medicinal products and medical devices of the Republic of Slovenia
Hospira	Mar 2015	WL	211.68(b) and 21CFR 211.194(a)	Your firm failed to exercise appropriate controls over computer or related systems to assure that only authorized personnel institute changes in master production and control records, or other records (21 CFR 211.68(b)). Your firm failed to ensure that laboratory records included complete data derived from all tests necessary to assure compliance with established specifications and standards (21CFR 211.194(a)). In addition to lists the violations (211.68(b) and 21CFR 211.194(a)), discussing similar documented violations in Hospira India, and stating that the violation is a systemic violation at Hospira, it orders Hospira specific global remediation action items.
Nosch Labs	April 2015	483	API	Nosch also lacked controls to ensure electronic records are equivalent to paper records and to prevent personnel from modifying or deleting information. The company did not return a request for comment by press time. QMN 04SEP15, Vol. 7, No. 35
Yunnan Hande Bio-Tech. Co. Ltd.	Apr 2015	WL	API	Failure to prevent unauthorized access or changes to data and to provide adequate controls to prevent omission of data" in a laboratory infrared (IR) spectrometer. It requests a “comprehensive evaluation of the extent of the inaccuracy of the reported data. As part of your comprehensive evaluation, provide a detailed action plan to investigate the extent of the deficient documentation practices noted above”
Nosch Labs	April 2015	483	API	Nosch also lacked controls to ensure electronic records are equivalent to paper records and to prevent personnel from modifying or deleting information. The company did not return a request for comment by press time.
VUAB Pharma	May 2015	WL	API	The 2nd observation in the May 27, 21015 WL states that "Failure to prevent unauthorized access or changes to data and to provide adequate controls preventing data omissions." (In ICH Q7 GMP for API (10 nov 2000) this observation is related with section 5.43.) Your firm did not properly maintain a back-up of HPLC chromatograms that form the basis of your product release decisions.
Zhejiang Hisun Pharma Company Ltd.	Jun 2015	Not available		Data Integrity (Source: Health Canada) Regulatory Partner
Quest Life Science	Jun 2015	Notice of Concern (WHO)	Not available in the Notice	The observation is related with the installation of Adobe Acrobat Editor in a QA station and the possibility of overwriting records using this software.
WUXI JIDA PHARMACEUTI	Jun 2015	Statement of Non-	Art. 111(7) of Directive 2001/83/EC as	Laboratory testing (deviation 28): some deviations were found for the IR instrument, in particular the IR software had not a controlled access via ID and

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CAL		Compliance to GMPs	amended	password and it was not forbidden to copy and rename a file. Italian Medicine Agency
Parabolic Drugs Limited	Jun 2015	Statement of Non-Compliance to GMPs	Art. 111(7) of Directive 2001/83/EC as amended	Falsification and Security and integrity data. Italian Medicine Agency
JINAN JINDA Pharmaceutical	Jun 2015	Statement of Non-Compliance to GMPs	Art. 111(7) of Directive 2001/83/EC as amended	Breaches of data integrity in the context of HPLC analysis. Italian Medicine Agency
Mahendra Chemicals	Jul 2015	WL	API	The laboratory system lacked access controls to prevent raw data for being deleted or altered and employees had uncontrolled access to operating systems and data acquisition software.
Agila Specialties Pvt Ltd (Specialty Formulations Facility) (Maylan)	Aug 2015	WL	211.68(b)	Your firm failed to exercise appropriate controls over computer or related systems to assure that only authorized personnel can change master production and control records, or other records (21 CFR 211.68(b)). Your Siemens computer-based BMS and NVPMS do not require passwords to access the network and servers. Your contractors' access is uncontrolled. Responsibilities for system administrators are undefined. This violation is recurrent (See above). On September 9, 2013, we cited your firm in Warning Letter 320-13-26 for failure to exercise appropriate controls over computer or related systems.
Svizara Labs Private Limited	Sep 2015	Notice of Concern (WHO)	GMP or GCP	The company performed several analyses, e.g. with HPLC. However, there were no records and data. These were found to be deleted for several test runs. Moreover, the company was not able to restore data that were archived or backed-up for HPLC equipment.