



*By: CQA Team*



## ◆ What is Data Integrity?

The *extent to which all data are **complete, consistent and accurate**....*

*.....throughout the data **lifecycle***

*.....From initial data generation and recording through processing (including transformation or migration), use, retention, archiving, retrieval and destruction.*

## Raw Data

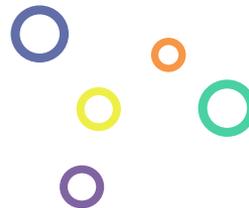
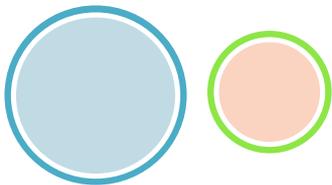
Original records, retained in the format in which they were **originally generated** (i.e. paper or electronic), or as a 'true copy'.

## Meta Data

**Data about data** that provide the contextual information required to understand structure, elements, interrelationships and other characteristics of data.  
E.g. 28 mg

## Data

**All records**, including raw data and metadata and all subsequent transformations and reports.



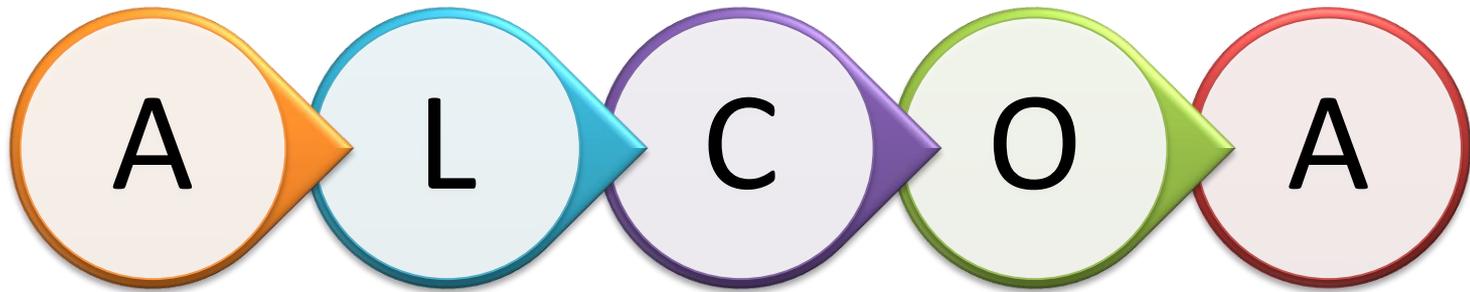
# DATA INTEGRITY

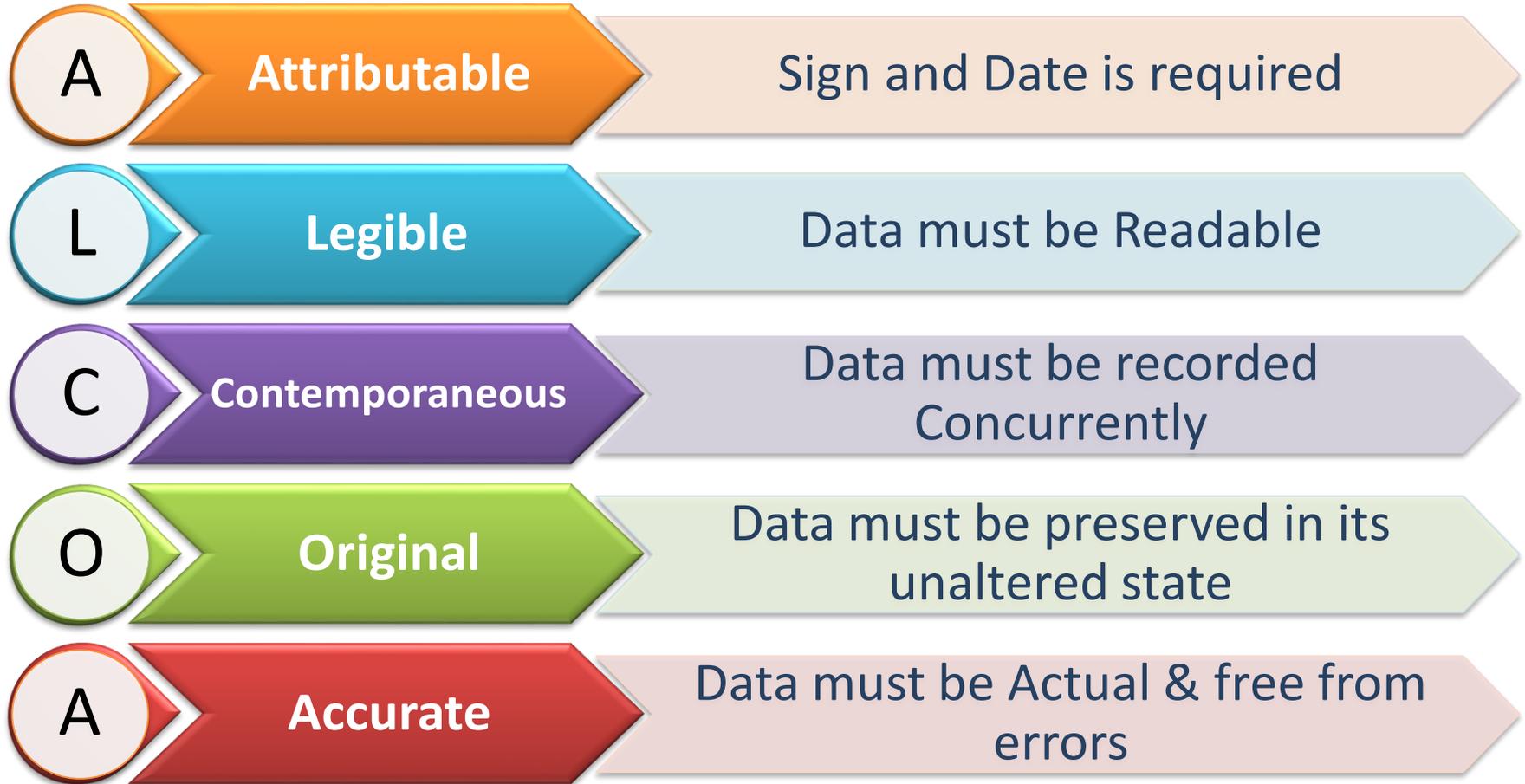
## Paper Data

BMR/BPR  
Logbook  
Label / Printouts  
Formats

## Electronic Data

Software  
SCADA  
HMI/ PLC  
Computer System





# DATA INTEGRITY

DOs

DON'Ts

**Attributable**

**GMP DATA SHOULD BE RECORDED WITH SIGN, NAME, DATE AND TIME AT THE TIME OF ACTIVITY PERFORMED. THIS DATA SHOULD BE LEGIBLE**

<b>Product Name</b>	A B C		
<b>Batch No.</b>	1 2 3 4 5		
<b>Description</b>	<b>Observation</b>	<b>Done by</b>	<b>Checked by</b>
White to off white tablet with one side break line	white to off white tablet with one side break line		XYZ 06/09/16

**Legible**

**Data recorded is not legible**

**Checked by sign done before Done by**

**Attributable**

**DON'T DO SIGNATURE OF OTHER PERSON OR  
DON'T RECORD THE GMP DATA ON BEHALF OF OTHER PERSON**

**In-process Test (Frequency : 30 ± 5 minutes)**

Time	Sealing Temperature (°C)	Done by Sign/Date
10:00	141	ABC 07/09/16
10:30	143	ABC 07/09/16
11:00	140	ABC 07/09/16
11:30	142	ABC 07/09/16
12:00	140	ABC 07/09/16
12:30	142	XYZ 07/09/16
13:00	145	XYZ 07/09/16
13:30	146	XYZ 07/09/16

**Person XYZ recorded entry ,  
Sign/Date on behalf of ABC**

**Time of recording should be  
actual, as per defined  
frequency and accurate.**

**Recording exactly at half an  
hour, which is not practical.**

**Attributable**

**DON'T SHARE USER NAME AND PASSWORD TO ANY ONE.  
USE INDIVIDUAL USER NAME & PASSWORD ONLY.  
DON'T USE GENERIC USERNAME/PASSWORD.**



**Tell me your  
password**

**Sorry, I cannot  
share it with  
anybody**



# Contemporaneous

## DON'T PERFORM ACTIVITY IN BACK DATE

Date: 07/09/16			
Product Name	A B C D		
Batch No.	1 2 3 4		
Test	Observation	Done by	Checked by
pH (Limit: 4.0 to 6.0)	5.2	ABC 07/09/16	XYZ 07/09/16

Attendance Record				
Date	Name	Emp ID	In Time	Out Time
01-09-16	ABC	0001	09:03	17:22
02-09-16	ABC	0001	09:00	17:23
03-09-16	ABC	0001	09:01	17:24
04-09-16	ABC	0001	Week Off	
05-09-16	ABC	0001	08:57	17:20
06-09-16	ABC	0001	09:00	17:25
07-09-16	ABC	0001	Absent	

Sign done in back date,

Doer was absent on that day



## DATA SHOULD BE ONLINE RECORDED (CONTEMPORANEOUS)

Sr. No	Name of Ingredient	Quantity Dispensed (Net Wt.)	Material Batch No.	UOM	Time		Dispensing/Weighing process	
					Start	End	Done by Sign/Date	Checked by Sign/Date
1	CCC	125.00	A789	Kg	15:20	15:50	XYZ 05/09/16	EFG 05/09/16
2	RRR	12.89	B234	Kg	15:55	16:04	XYZ 05/09/16	EFG 05/09/16

### TRAINING ATTENDANCE SHEET

Training Topic	Data Integrity
Date	05/09/16
Time Duration	From : 15:10 (hrs) - To : 15:48 (hrs)
Name of the Faculty	ZZZ
Faculty's sign & date	ZZZ 05/09/16

Same person is involved in two different activities at the same time/date.

Following participants attended the training program on the above mentioned topic

Sr. No.	Name	Employee No.	Department	Signature
01	XYZ	123	Production	XYZ 05/09/16
02	ABC	678	QC	ABC 05/09/16

**Original**

**DON'T RECORD GMP DATA ON UNAUTHORIZED MEDIA**



**Recording on Unauthorized paper, Blank pages, back of labels, Excel / Word file in computer is not acceptable**

**GMP Document**

	123

XYZ  
06/09/16

**Authorised Copy**

**Transcription from unauthorized formats to GMP documents is not right practice**



**Original**

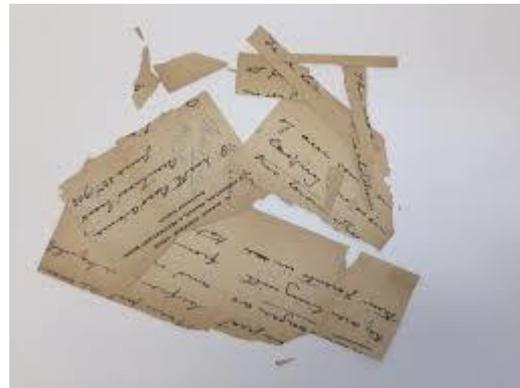
**DO NOT TEAR AUTHORISED PAPER- THESE ARE ORIGINAL DATA**



**Don't Tear  
GMP  
documents**



[www.alamy.com](http://www.alamy.com) - DF3X95



**Original**

**DON'T RECORD FALSE DATA**

Logbook				
Date	Time	Temperature (°C)	% RH	Sign/Date
01/08/16	07:38	24.3	48	DEF 01/08/16
02/08/16	07:40	24.6	43	DEF 02/08/16
03/08/16	07:35	23.8	45	DEF 03/08/16
04/08/16	07:43	24.0	47	DEF 04/08/16
05/08/16	07:36	23.5	44	DEF 05/08/16
06/08/16	07:50	22.9	49	DEF 06/08/16

**Data doesn't match with electronic data.**

**Recording done without performing the activity**

BMS Alarms			
Date	Time	Temperature (°C)	Alarm
02-08-16	07:40	30.1	Temp. High
02-08-16	10:17	29.4	Temp. High
02-08-16	15:22	28.7	Temp. High
02-08-16	16:04	30.2	Temp. High

**Accurate**

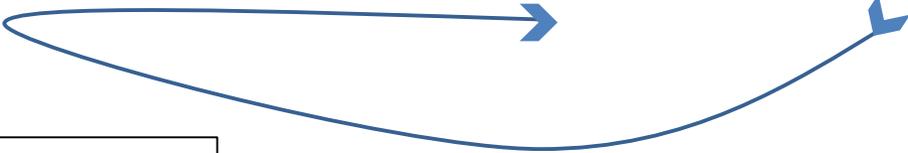
**DO NOT RECORD DATA ON THE BEHALF OF OTHER EMPLOYEE**

**Person AAA : Performing activity**  
**Person BBB: Checker**

Person doing Actual Recording	Done by	Checked by
AAA	AAA	BBB



Person doing Actual Recording	Done by	Checked by
BBB	AAA	BBB



**Recording should be done by Actual "DOER" only**

**Checker should be different person who is not participating in activity but Check each and every part of activity**

Accurate

GMP DATA SHOULD BE ACCURATELY RECORDED IN DOCUMENTS

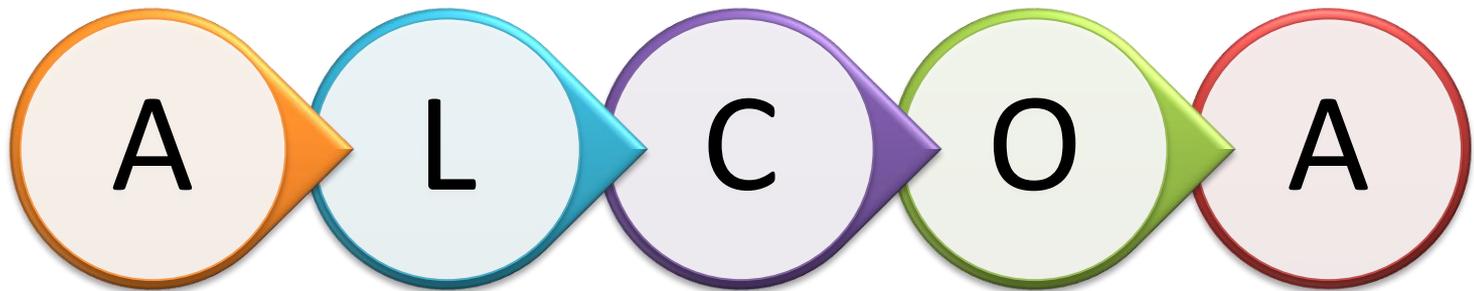
Date: 06/09/16			
Product Name	A B C D		
Batch No.	1 2 3 4		
Test	Observation	Done by	Checked by
pH (Limit: 4.0 to 6.0)	5.8	Y Y Y 06/09/16	X Y Z 06/09/16



Display Shows 6.4

Record the correct readings as observed.  
Don't manipulate the reading to pass the batch

CADILA HEALTHCARE LTD.  
Corporate Quality



**Consistent**

Data must be recorded in Consistent manner

**Complete**

All data must be recorded/ attached and reported

**Enduring**

Data must be recorded on authorized media

**Available**

Data must be available throughout lifecycle

**RECORD GMP DATA BY PERMENENT INK ONLY  
DON'T USE PENCIL, ERASER, CORRECTION FLUID**



## LEGIBLE DOCUMENTATION

Clearly Record the Data:

29

What's that number?  
Is it 27? 28? 24? 25?  
Hmmm... What do we do now?



**How you read this number?**

1. 27
2. 24
3. 29

27

**Always record the data  
that can be easily  
readable.**

**ORIGINAL DATA SHOULD BE RECORDED ACCURATELY ON AUTHORISED  
FORMAT**



Authorized format



Unauthorized format



**RESULT FOUND OUT OF SPECIFICATION:  
HOW TO RECORD AND WHAT TO DO ?**



**Don't manipulate the  
data for passing result .**

**Record as it is and go  
through QMS tools to  
address the OOS.**

**DOCUMENTATION PRACTICE**

GMP Document			
Sr.no.	Date	observation	sign
1	1/6/2015	complies	ABC
2	1/6/2015		
3	1/6/2015	complies	ABC
4	1/6/2015	complies	ABC
5	1/6/2015	complies	ABC
6	1/6/2015		
7	1/6/2015		
8	1/6/2015	complies	ABC
9	1/6/2015	complies	ABC
10	1/6/2015	complies	ABC

GMP Document			
Sr.no.	Date	observation	sign
1	1/6/2015	complies	ABC
2	1/6/2015	complies	ABC
3	1/6/2015	complies	ABC
4	1/6/2015	complies	ABC
5	1/6/2015	complies	ABC
6	1/6/2015	complies	ABC
		NA	



Put Sign  
and Date



## WRONGLY RECORDED DATA. HOW TO CORRECT?



**If any recording error occurred, don't overwrite.**

**Don't use fluid ink.**

**Use good documentation practice**

**DOCUMENT SHOULD BE COMPLETE AND AVAILABLE**



**Document should be always available for Audit/Review.**

**We never deny to auditor for any document**

## IDENTIFICATION OF DUPLICATE DOCUMENT



**Duplicity of any document is easily identifiable don't make duplicate document.**

## DI Coordinators

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-  Arati - [Arati.Dube@zydusmail.com](mailto:Arati.Dube@zydusmail.com)
-  Sadanand - [Sadanand.Kausadikar@zydusmail.com](mailto:Sadanand.Kausadikar@zydusmail.com)
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THANK  
YOU