PRA Health Sciences

PRA's Approach to Data Integrity – Scoring, Risks, Assessment and Implementation

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21-Nov-2019

Introduction

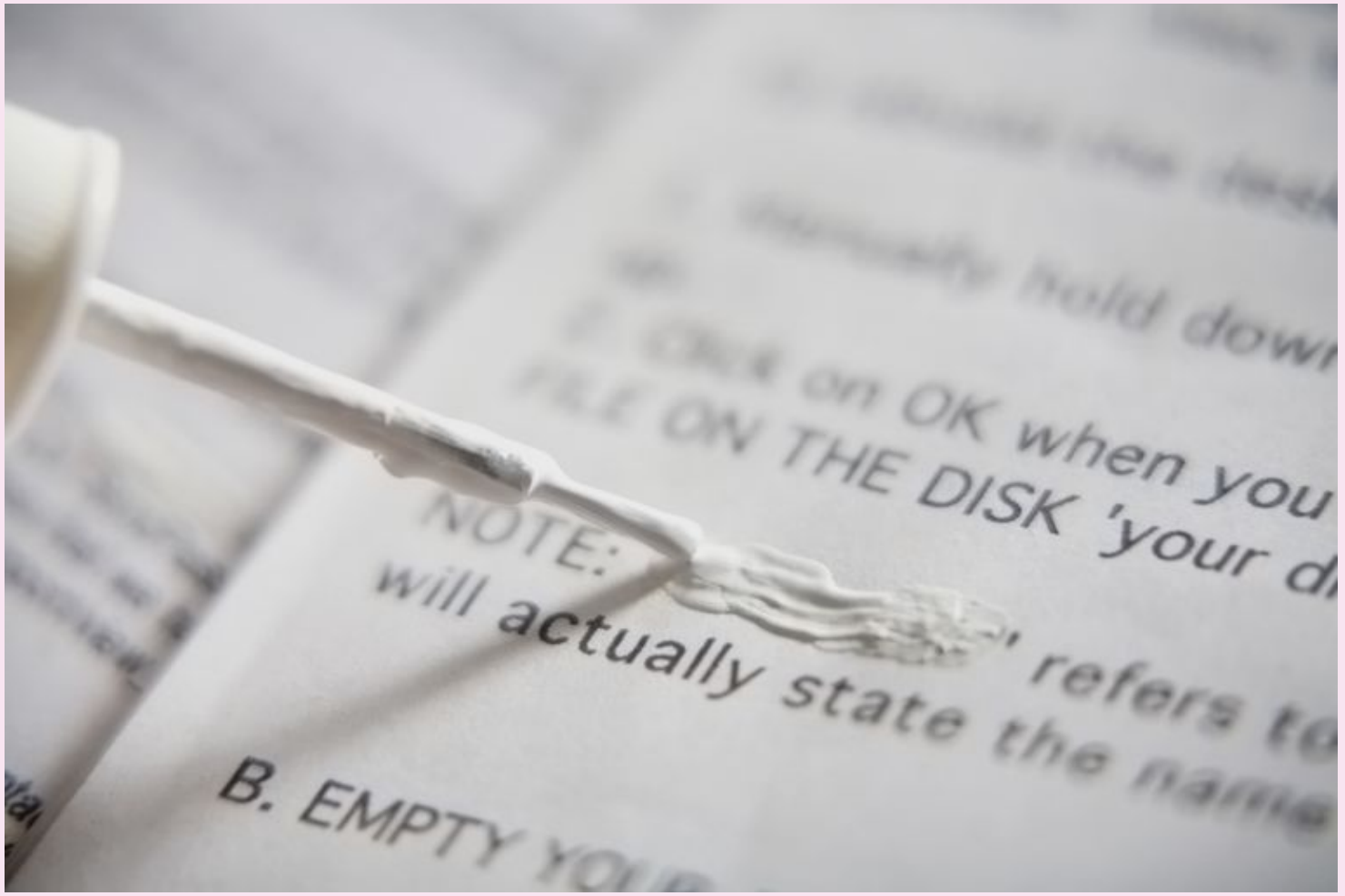
What is Data Integrity???

Complex?

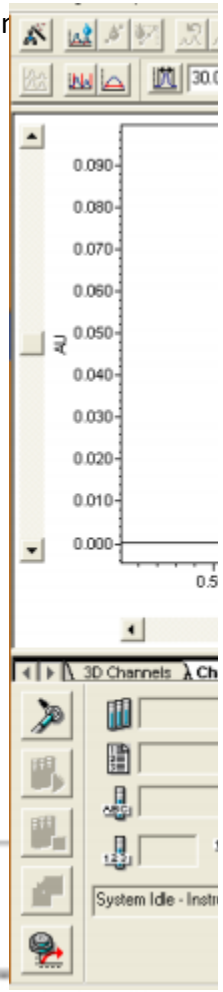
Difficult?

Boring?

Early 90's University Hospital



Mid 90's - 2005
GMP QC Lab



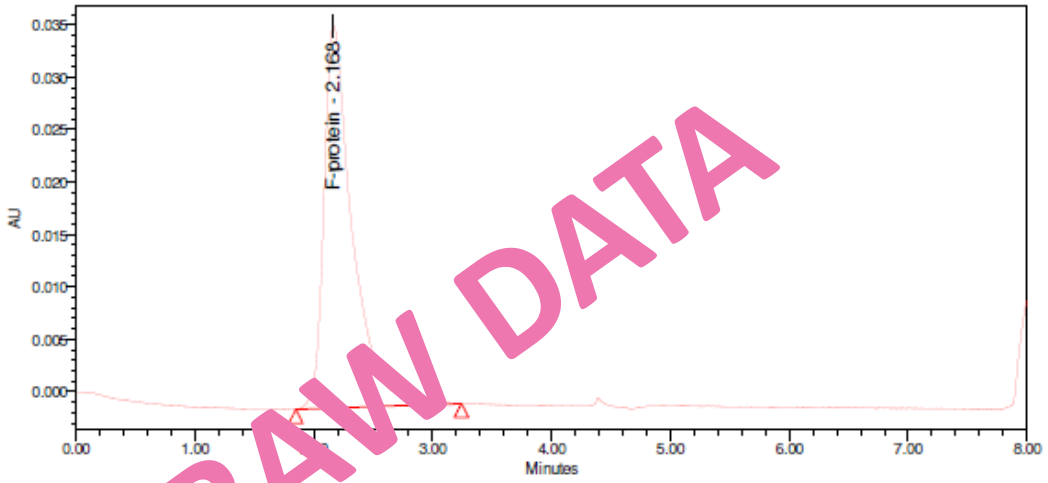
13	19:44	010771	UMK	
14	19:49	008342 ~~004342~~	SAS	yes

SAMPLE INFORMATION

Sample Name:	F-strep	Acquired By:	System
Sample Type:	Unknown	Sample Set Name:	HPSEC Fprotein run3
Vial:	1:A,3	Acq. Method Set:	HPSEC_BEH200
Injection #:	1	Processing Method	HPSEC_BEH200_Fprotein_2
Injection Volume:	20.00 ul	Channel Name:	PDA Ch1 280nm@4.8nm
Run Time:	8.0 Minutes	Proc. Chnl. Descr.:	PDA Ch1 280nm@4.8nm

Date Acquired: 1/12/2002 3:44:42 PM CET
Date Processed: 2/7/2002 4:26:30 PM CET

Auto-Scaled Chromatogram



RAW DATA

Peak Results

	Nam	RT	Area	Height	% Area	Amount	Units
1	F-protein	2.168	608413	36453	100.00		
2	HA strep	2.470					

Reported by User: System
Report Method: HPSEC report
Report Method ft 2495
Page: 1 of 1

Project Name:
Date Printed:
2/7/2002
4:30:24 PM Europe/Amsterdam

CURRENT EXPECTATIONS:
DATA INTEGRITY REFERS TO THE COMPLETENESS, CONSISTENCY, AND ACCURACY OF DATA

- Attributable
- Legible
- Contemporaneous
- Original
- Accurate
- Complete
- Consistent
- Enduring
- Available

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ALCOA +

ALCOA+	Paper record	Present?	Electronic record	Present?
Attributable	Paper sign off	✓	Personal login	✓
Legible	Readability checked during review	✓	Readable data format	?
Contempora-neous	Labjournals completed during execution	✓	Date stamps; log files; audit trail	?
Original	Wet ink	✓	Raw data defined	?
Accurate	Checked during review	✓	Validated software	✓
Complete	Checked during review	✓	Complete data, incl metadata	?
Consistent	GDocP	✓	All changes logged	?
Enduring	Paper archive	✓	Electronic archive	?
Available	Paper binders	✓	Backwards compatibility	✓

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Legible	Readability checked during	✓	Readable data format	?
Enduring	Paper archive	✓	Electronic archive	?
Available	Paper binders	✓	Backwards compatibility	✓

How can we establish the same level of control for electronic records????

Data Integrity program

Most important for a successful Data Integrity program?

AWARENESS!!!

- 12 minutes Data Integrity awareness video for all PRA employees based on ALCOA+ principles
- Training program tailored to different roles (creators, supervisors, reviewers, approvers, archivists, etc.)

Procedural controls (the boring stuff)

Data Lifecycle SOP

Planning phase for new systems and upgrades of existing systems

- Scoring the system for potential data integrity risks
- Assessing data integrity risks
- Creating data flow schemes
- Data definitions (raw data, meta data, processed data, etc.)

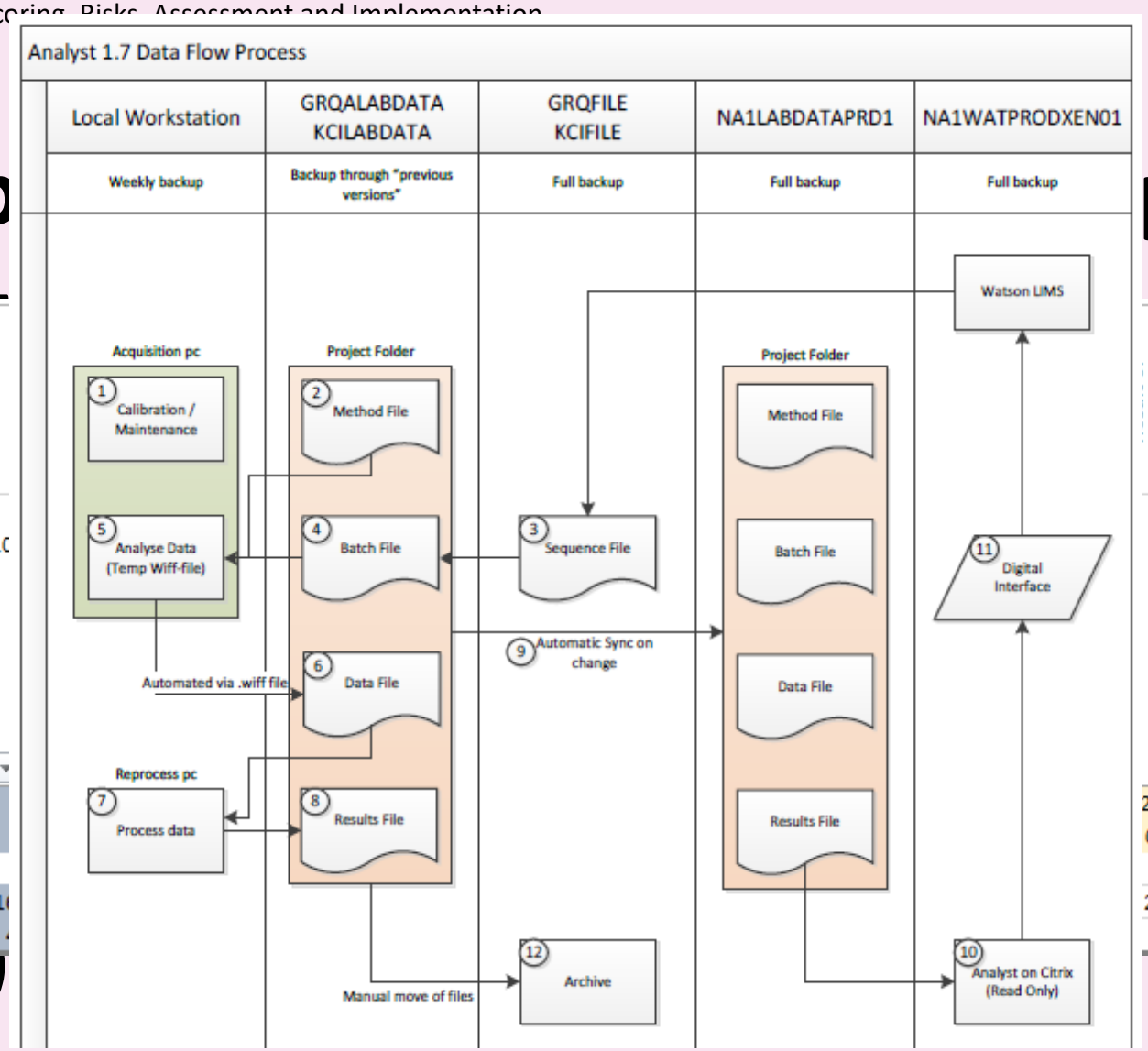
Planning phase for new systems and upgrades of existing systems

System	Product quality Impact	Application Usage	No. of Users	Gamp	Electronic Raw data	Storage of files	Interfacing (incl data transfer)	Audit Trail Available	Esignature Approval	Data manipulation by (includes deletion)	Detection of failure	Result of Manipulation	Account management	Account Type	Result of Account	Sum	Priority
	5 = QC 4 = GxP 1 = Other	5 = Daily 3 = Weekly 1 = Monthly or less	3 = > 50 2 = 50-10 1 = <10	3 = Cat.5 2 = Cat.4 1 = Cat.3	10 = Flat 5 = DB/Flat 1 = DB	9 = Local, open 6 = Local, secured 3 = Server/Study file, open 1 = Server/Study file, secured	10 = Manual (readable file) 7 = Manual (non-read. file) 4 = custom (e.g. scripts) 2 = API Push 1 = API Auto	10 = no 3 = partly 1 = full 0 = n/a static data	5 = no 1 = yes 0 = n/a static data	10 = All Users 5 = Selected User 3 = Admin/user 2 = Admin 0 = None	5 = Difficult 3 = Medium 1 = Easy		10 = None 5= Operational 1 = IT/Non operational 0 = n/a	5=None 3=Application 1= LDAP/ windows			1= 71-100 2 = 51-70 3 = 8-50
MAX SCORING	5	5	3	3	10	9	10	10	5	10	5	25	10	5	25	100	
MIN SCORING	1	1	1	1	1	1	0	0	0	0	1	0	1	1	1	8	
Category	"General"				"Data flow and audit trail"					"Manipulation"			"Accounts"				
	Sum category MAX		16	16.0 %				44	44.0 %		25	25.0 %		25	25.0 %		
	Sum category MIN		4	50.0 %				2	25.0 %		0	0.0 %		1	6.3 %		

data, etc.)

Planning p pgrades of existing data, etc.)

System	Product quality Impact	Application Usage	No. of Users
	5 = QC 4 = GxP 1 = Other	5 = Daily 3 = Weekly 1 = Monthly or less	3 = > 50 2 = 50-10 1 = <10
MAX SCORING	5	5	3
MIN SCORING	1	1	1
Category		"General"	
	Sum category MAX		1
	Sum category MIN		



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25	10	5	25	100	
0	1	1	1	8	
		"Accounts"			
25.0 %		25	25.0 %		
0.0 %		1	6.3 %		

Important: Initial assessment for Data Integrity for all new exciting systems requested by the Science department

Best System we can get

The Whole world is using this

The Best System for many years

What about "User Accounts"??

"Audit Trails"??

"Secured data storage"??

Important: Initial assessment for Data Integrity for all new exciting systems requested by the Science

The best system for science is not always the best system to be used in a GLP environment

The Whole world is using this

many years

"Audit Trails"??

"Secured data storage"??

Maintenance phase

- Identity and access management
- Data Storage: local, server, flat files, database
- Back-up control: local, server, datacentre
- Data transfer: how is it controlled?
- Audit Trail review: system audit trail, project audit trail
- Archiving

Maintenance phase

This process describes the lifecycle for identity and access management, which includes activities for creating and disabling Digital Identities, setting up and retiring User Accounts, and maintaining System Access.

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Evaluation of all present computerized systems

- Schedule data integrity evaluations for all present systems based on priority (scoring system)
- Identify any gaps
- Upgrade systems when possible
- Retire legacy systems and replace

What is needed for a successful implementation of a Data Integrity program??

- Dedicated team
- Knowledge
- Time
- Commitment from executive management

Planning

- Training: General training on going, role-based training Q1-2020
- Data Lifecycle SOP: Q4-2019 draft version available
- Evaluation of all present computerized systems: Through whole 2020

Finally:

Do you enjoy working in (GLP) regulated environments?

Do you love quality data?

Then:

- Data Integrity is not a threat, but a new exciting chapter for our modern-world labs.
- Where paper was our output in the old days, electronic data is our biggest assets these days
- It deserves the same level of control (or better) as we have for paper

Thank you!!!

Questions???