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Data Integrity – in Manufacturing, Laboratories, and role of the QMS

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About PDA

- The Parenteral Drug Association (PDA) is the leading global provider of science, technology, and regulatory information. The PDA creates awareness and understanding of important issues facing the pharmaceutical and biopharmaceutical community and delivers high-quality, relevant education to the industry. Since its founding in 1946 as a nonprofit organization, PDA has been committed to developing scientifically sound, practical technical information and expertise to advance pharmaceutical/ biopharmaceutical manufacturing science and regulation, so members can better serve patients.

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PDA Vision

To maximize product quality, availability, and value by connecting people, science, and regulation within the pharmaceutical and biopharmaceutical community so that PDA is:

The preferred choice for professionals who seek specialized, innovative skills and knowledge enhancing their professional development

The premier educational partner for professionals in academia, industry, and government for the advancement of manufacturing, quality, and regulatory science

An organization that aligns its practices and resources in support of its core values of a basis in science (science based), integrity, and inclusion

PDA Mission

To advance pharmaceutical/biopharmaceutical manufacturing science and regulation so members can better serve patients.

PDA's Science-Based Activities

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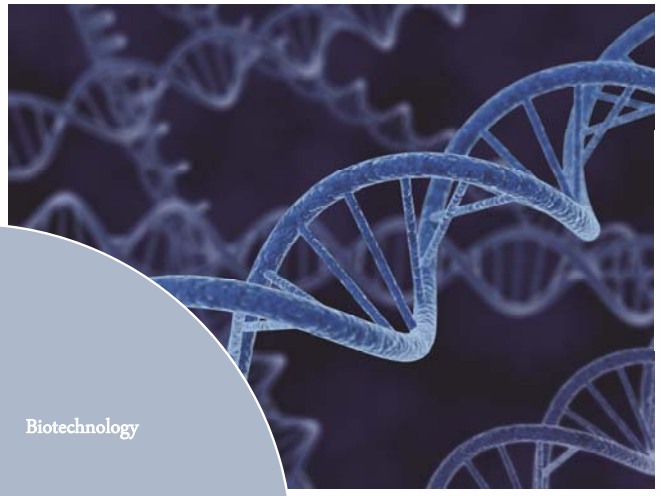

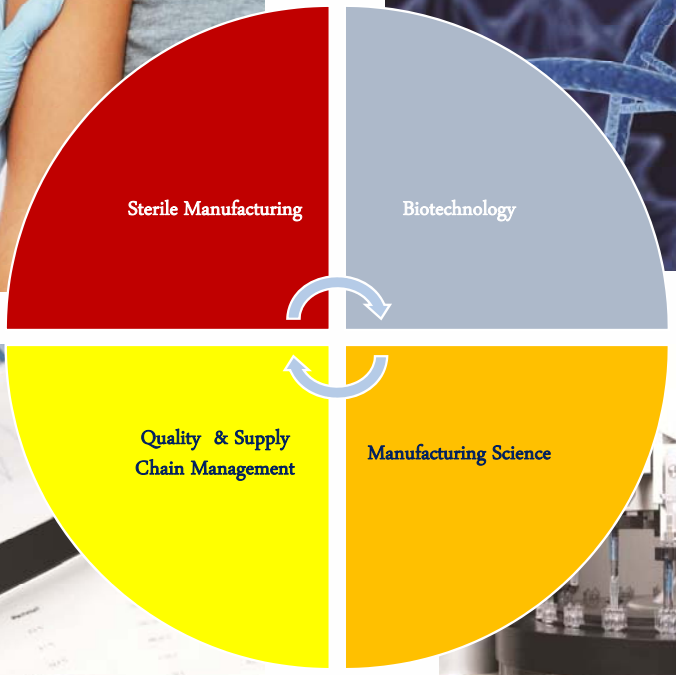

PDA Advisory Boards and their Interest Groups

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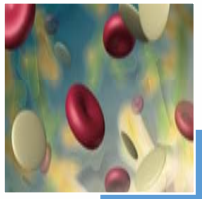

BioAB

- Advanced Virus Detection Technologies
- Biopharmaceutical Manufacturing
- Combination Products
- Vaccines
- Cell and Gene Therapy
- Biosimilar

SAB

- Applied Statistics
- Facilities and Engineering
- Filtration
- Lyophilization
- Microbiology/EM
- Packaging Science
- Pharmaceutical Cold Chain
- Pharmaceutical Water Systems
- Prefilled Syringes
- Process Validation
- Sterile Processing
- Visual Inspection

RAQAB

- **Data Integrity**
- GMP Links to Pharmacovigilance
- Inspection Trends
- Management of Outsourced Operations
- Pharmacopeial
- Quality Risk Management
- Quality Systems
- Regulatory Affairs
- Supply Chain Management
- Technology Transfer

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Today's Agenda

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- General Considerations for Data Integrity
- Integrating Data Integrity Requirements into Manufacturing and Packaging Operations
- Data Integrity Management System for Pharmaceutical Laboratories – key points from PDA Technical Report 80
- Data Integrity – role of the Quality Management System

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Link to Product Quality

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- Data integrity is the cornerstone of establishing and maintaining confidence in the reliability of data to ensure patient safety and product quality

- The reliability of manufacturing production and control data depends on the procedures, systems, processes and controls that are in place to ensure data integrity

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Key Regulatory Guidance

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- MHRA: *GxP Data Integrity Guidance and Definitions* (March 2018)
- FDA: *Data Integrity and Compliance with Drug CGMP Questions and Answers Guidance for Industry*, (December 2018)
- WHO: *Guidance on Good Data and Record Management Practices, WHO Technical Report Series, No. 996, Annex 5* (2016)
- PIC/S: *Draft PIC/S Guidance: Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments* (November 2018)
- **NEW**: WHO Draft Guideline on Data Integrity

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Data Integrity in the Context of an Inspection

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Documentation is a Key Element in the "What" of an Inspection

Key questions:

- Can past issues be documented?
- Does the scientific evidence support claims and conclusions made in reports?
- Do trending information or previous investigations point to potential concerns about the safety or efficacy of the manufactured product?

Warning Letters and Data Integrity

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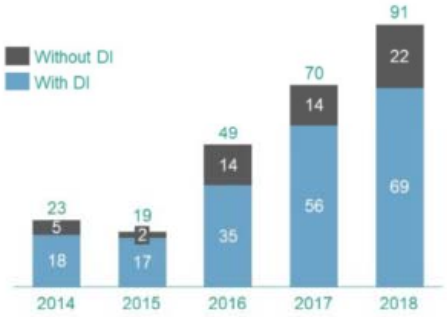
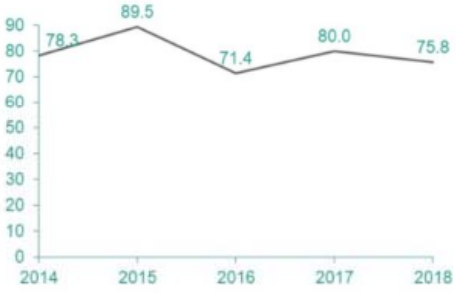
Figure 1

Govzilla

Global Drug Manufacturing Warning Letters by Data Integrity
count



Global Drug Manufacturing Warning Letters citing Data Integrity
percent



Footnotes:
1. Fiscal year used, based off Warning Letter Issuance Date
2. 264 Warning Letters analyzed (Rx and OTC)
3. ~212 unique text strings used to identify Data Integrity – 2018 Guidance, plus ALCOA plus used to generate key terms

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	TOTAL
China	1	1	3	1			2	2	14	19	15	58
U.S.	1	2	1	1	1			0	7	15	8	36
India	1	1		2		6	7	10	9	12	6	54
Europe		1					1	2	6	3	1	14
Brazil									3			3
Japan	1								2	1	3	7
Thailand								1				1
Canada			1		1					2	1	5
Mexico					2					1	1	4
UAE					1							1
Jamaica					1							1
South Korea										2	4	6
Singapore										1		1
Australia											1	1
Taiwan											1	1
Dominican Republic											1	1
TOTAL	4	5	5	4	6	6	10	15	41	56	42	194

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Examples of DI Issues Cited in Production Operations

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Example	Category
Falsification/Fabrication of Records (e.g. visual inspection data)	False Entries
Delaying, Denying, Limiting or Refusing Inspection (failure to grant access)	Delay/Deny/Limit/Refuse Inspection
Computer Access Controls (e.g. shared logins, unprotected spreadsheets, etc.)	Computer Access Controls
Lack of Contemporaneous Data Entries (e.g. pre- or backdated records, records signed by operators who did not performed the activities, etc.)	Contemporaneous data entries
Unexplained Data Discrepancies (e.g. Production equipment labeled as clean but found to be dirty, inaccurate quantities for quality defects, etc.)	Data Discrepancies
Batch data traceability (Programmable logic controllers (PLCs) and manufacturing equipment with shared login credentials, not identifying unique operators)	Data Traceability and Attributability
Data Deleted, Destroyed, or Missing/Unavailable (e.g. batch production records, cleaning records, etc.)	Data availability
Audit Trails Unavailable/Disabled (e.g. Lack of audit trail to document who accessed each of the PLC and man-machine interface equipment)	Audit trails
Inaccurate/Incomplete Data or Records (e.g. Inaccurate entries in batch records; incorrect quantities of active ingredients/raw materials	Inaccurate and Incomplete Records
Illegible Data Entries (e.g. batch records with data changes in pencil)	Legibility
Unofficial Records (e.g. use of unofficial records, rough notes or loose paper)	Unofficial Records

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Key Principle – ALCOA/ALCOA+

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ALCOA Principles require that data is:

- **Attributable** — Who acquired the data or performed an action and when?
- **Legible** — Can you read the data and any entries?
- **Contemporaneous** — Documented at the time of the activity.
- **Original** — A written printout or observation or a certified copy thereof.
- **Accurate** — No errors or editing without documented amendments.

ALCOA + adds:

- **Complete** — All data including any repeat or reanalysis performed on the sample.
- **Consistent** — All elements of the analysis such as the sequence of events follow on and are date or time stamped in the expected sequence.
- **Enduring** — Not recorded on the back of envelopes, cigarette packets, sticky notes, or the sleeves of a coat but in notebooks or electronic media in the data systems of instruments.
- **Available** — Can be accessed for review and audit or inspection over the lifetime of the record.

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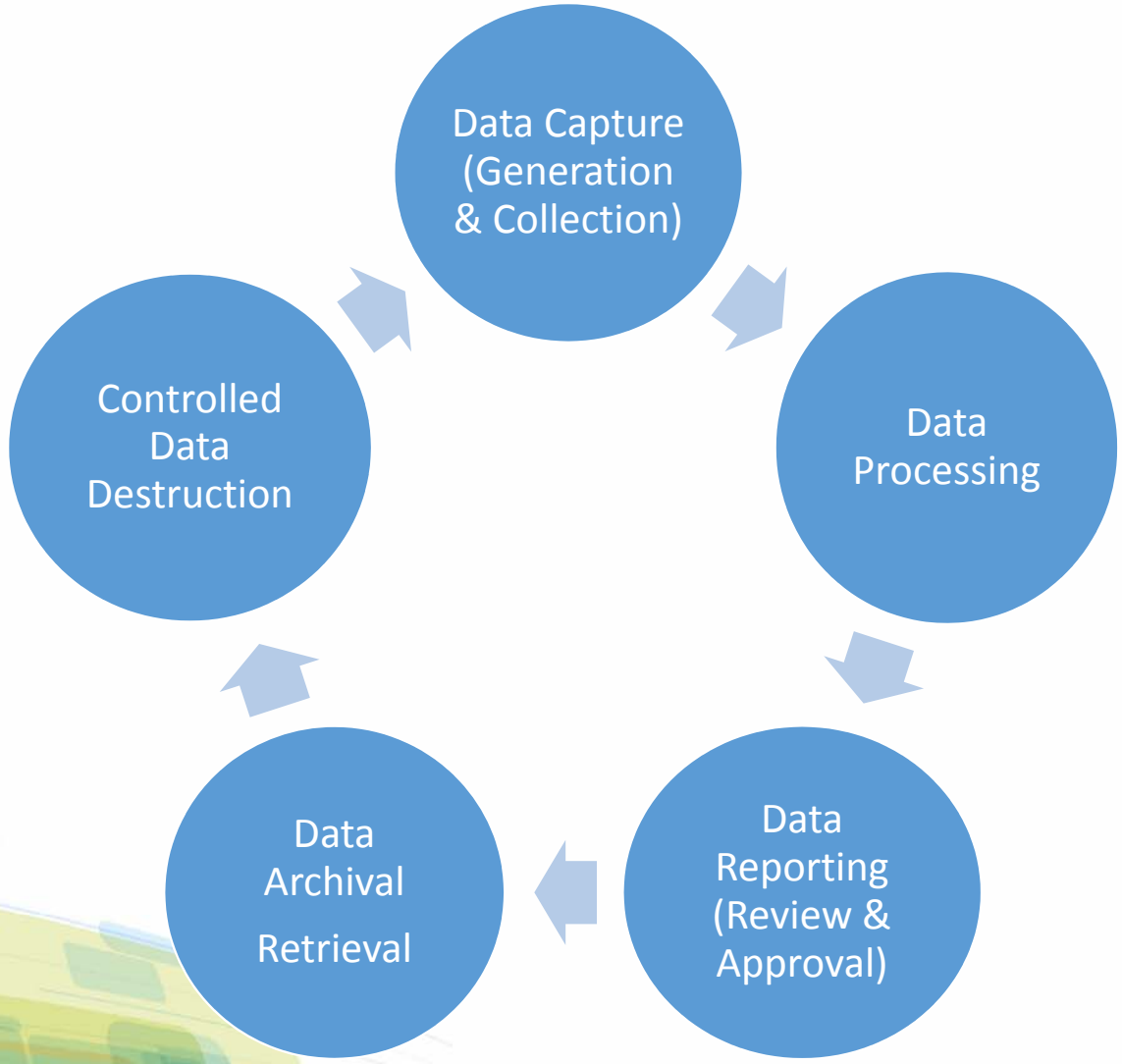
The Data Lifecycle



Data Integrity Risk Assessment

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- Basic approach to DIRA based on WHO Guideline

	Severity			
OCCURRENCE		LOW	MEDIUM	HIGH
	LOW			
	MEDIUM			
	HIGH			
		HIGH	MEDIUM	LOW
	Detection			

Example:

1. During weighing of a sample, the date entry was not contemporaneously recorded, but the date is available on a print-out from the balance and log book for the balance.
2. Risk assessment:
    1. Data is available
    2. Occurrence is LOW
    3. Detectability is HIGH
3. Overall risk may be considered LOW

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Data Criticality Assessment

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Data Criticality	Definition
High	**When the intended use of the data directly impacts product quality and/or product safety–** – Product quality monitoring and control of processes that may be responsible for causing variability during manufacturing, release, or distribution impacting critical quality attributes, critical material attributes, critical process parameters, or critical process controls, including those that may be linked with the product registration dossier – Product safety monitoring and control of processes that ensure effective management of field alerts, recalls, complaints, or adverse events
Medium	When the intended use of data relates to quality attributes, material attributes, process parameters, key process parameters, or process controls that are not CQAs/CPs/CPPs and may or may not be in the product registration dossier; this includes parameters of the manufacturing process "may not be directly linked to critical product quality attributes but need to be tightly controlled to assure process consistency"
Low	When the intended use of data is to provide evidence of routine GMP compliance relating to monitoring and control of processes that do not fall into the High or Medium category.

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DATA CRITICALITY LEVELS	DATA CONTROL LEVELS: High	DATA CONTROL LEVELS: Medium	DATA CONTROL LEVELS: Low
H	**Criticality** CQA/CP/CPP impacting quality & safety Data Controls Validated & effective automated or hybrid data capture & analysis system in place	**Criticality** CQA/CP/CPP impacting quality & safety Data Controls Hybrid systems or manual data capture, limited automated data analysis, manual data transcription	**Criticality** CQA/CP/CPP impacting quality & safety Data Controls Manual data capture, no automated data analysis, manual data transcription, heavy reliance on second-person witnessing of data entries
M	**Criticality** Noncritical processes & process parameters Data Controls Validated & effective automated data capture & analysis system in place More controls than may be required based on data criticality	**Criticality** Noncritical processes & process parameters Data Controls Hybrid systems or manual data capture, limited automated data analysis, manual data transcription	**Criticality** Noncritical processes & process parameters Data Controls Manual data capture, no automated data analysis, manual data transcription, heavy reliance on second-person witnessing of data entries
L	**Criticality** Monitoring noncritical environmental conditions, utilities, noncritical equipment calibration & maintenance Data Controls Validated & effective automated data capture & analysis system in place More controls than may be required based on data criticality	**Criticality** Monitoring noncritical environmental conditions, utilities, noncritical equipment calibration & maintenance Data Controls Hybrid systems or manual data capture, limited automated data analysis, manual data transcription More controls than may be required based on data criticality	**Criticality** Monitoring noncritical environmental conditions, utilities, noncritical equipment calibration & maintenance Data Controls Manual data capture, no automated data analysis, manual data transcription, heavy reliance on second-person witnessing of data entries

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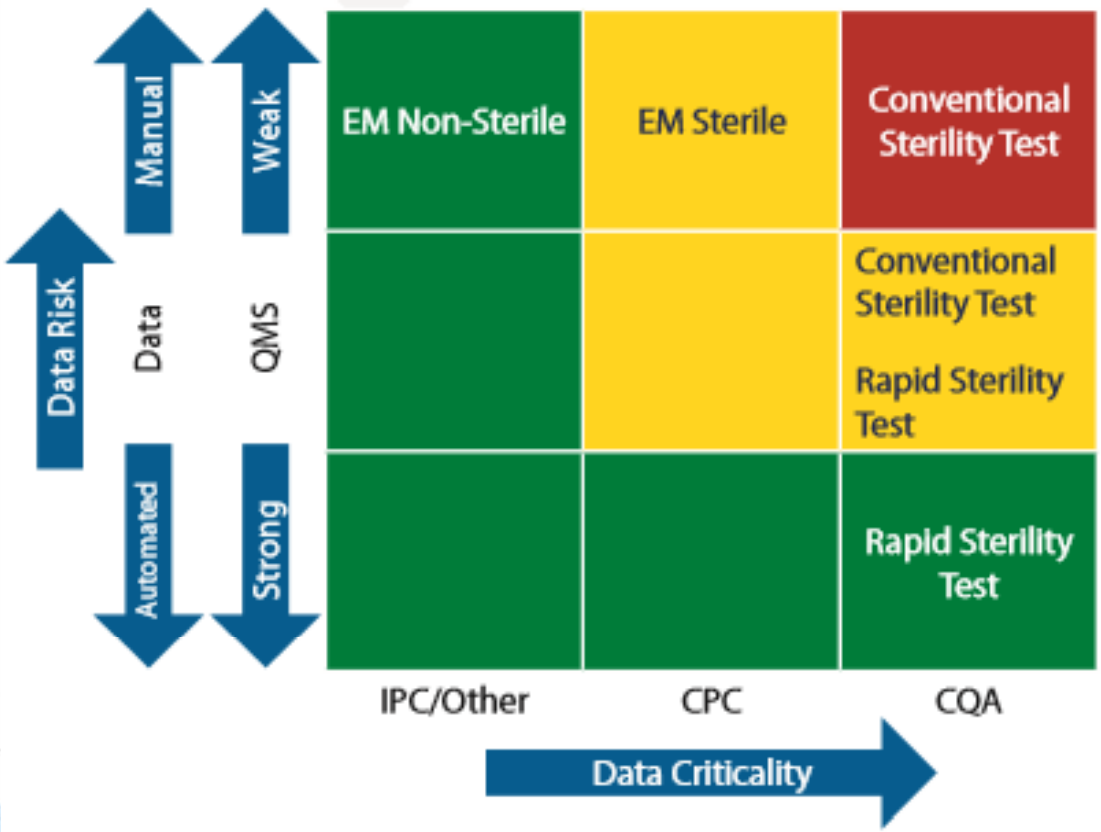
Potential Data Integrity Risk Matrix for Microbiological Testing



Legend	
CQA	Critical Quality Attribute
CPC	Critical Process Control
IPC/ Other	In-Process Control
Auto/ Elec	Automated/ Electronic
QMS	Quality Management System

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Potential Categories of Data Integrity Vulnerability

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- **Data Management Technology**
  - Data transcription
  - Frequency of periodic reviews and change management based on intended use
  - Hybrid systems (e.g., discrepancies between paper printout and corresponding electronic record, data duplication)
  - New or complex manufacturing technology (causing repeat errors)
  - Overwriting existing electronic data
  - System validation age and adequacy related to data export, calculation, reporting, and transfer
  - Appropriate access level
  - Technologies with inadequate data integrity elements such as unique access, audit trail, data backup & restore, electronic data review, date & time stamp, among others (e.g., spreadsheets, LIMS)
  - Unexplained discrepancies between electronic raw data and reported data

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Human Factors Matrix

	Unintentional Act	Intentional Act	
Thinking Errors	**Procedure Gap** Error caused by gaps in rules stating what tasks should be performed and by whom, e.g., lack of or inadequate SOPs **Knowledge Gap** Error caused by knowledge gaps in how to perform a task, e.g., lack of or inadequate training	**Fraud** Violations caused by malicious intent to perform a fraudulent act, e.g., falsifying data for personal gain or avoid personal pain	Exceptional Violations
Action Errors	**Attention Failure** Error caused by taking the wrong action, e.g., unfocused state of mind or a frequently performed action goes wrong or multitasking or aggressive deadlines **Memory Failure** Error caused by taking no action, e.g., omit to perform a routine task due to forgetting its place in the sequence	**Misconduct** Violations caused by knowingly ignoring procedures or controls due to misplaced priority, e.g., ignoring established controls to compensate for aggressive target/time pressure	Situational Violations

Potential Categories of Data Integrity Vulnerability

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- **Human Factors**
  - Lack of supervisory review
  - Manual observations or measurements (e.g., weighing)
  - Repeat human errors (e.g., due to multitasking, high personnel turnover, inadequate training, time pressures)
  - Training and procedures (complex, long, unclear, incomplete, or difficult-to-access instructions)
  - Unclear role definition or segregation of duties
  - Culture (fear, frustration, intent, unacceptable local documentation practices)

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Data Control Levels

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Control Level	Definition/Examples
High	High degree of validated process automation; electronic data lifecycle (e.g., capture, analysis, reporting); minimal human intervention
Medium	Hybrid—some manual processes; semi-automated data lifecycle processes; partial or lack of system interfaces
Low	Manual data lifecycle (e.g., capture, transcription, second person witnessing); manual process measurements and testing; manual processes with a high degree of human intervention

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Control Grid for Issuance and Reconciliation of Paper Records

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Generation and Reconciliation of Documents		High Data Criticality	Medium Data Criticality	Low Data Criticality
Prevention Control	Controlled issuance – How	Unique identification for each record (including additional pages/sheets needed to complete the activity)	No unique identification needed	No unique identification needed
	Controlled issuance – Who	Designated unit with concurrence of the quality unit	Designated unit with concurrence of the quality unit	Anyone
	Reconciliation	Full reconciliation of records and pages based on unique identifier	Full reconciliation of records and pages based on quantity issued	No reconciliation
	Controlled Print	Required	Required	Not required
	Bulk printing allowed?	No	Yes, with process in place to avoid misuse	Yes
	Destruction of blank forms	With the quality unit present	Performed by the operating unit, quality unit oversight required	By the individual, quality unit oversight required

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Control Grid for Data Accuracy when Manual Recording without Controlled Second Format

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Data Accuracy when Manually Recording Data without a Controlled Second Format		High Data Criticality	Medium Data Criticality	Low Data Criticality
Prevention Control	Second check for data recording – What action?	Four-eyes and downstream quality unit review to ensure requirements are met	Downstream verification that raw data meets requirements	General check of adherence to good documentation practices, but no check for accuracy required
	Second check for data recording – Who?	Peer and downstream quality unit review	Peer review	Peer review
	Second check for data recording – When?	Real-time by peer. Quality unit review before batch release	Before the next critical process step or before batch release, as appropriate	Before batch release or within timeframe specified in procedures

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Control Grid for Data Accuracy when Transcribing Manually Recorded Data into an Electronic System

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Transcription of Manually Recorded Data into an Electronic System		High Data Criticality	Medium Data Criticality	Low Data Criticality
Prevention Control	Second review required for data transcription – Who?	Quality Unit	Peer	None

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Control Grid for True Copy (Paper to Electronic)

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True Copy (Paper to Electronic)		High Data Criticality	Medium Data Criticality	Low Data Criticality
Prevention Control	Review requirements	Documented review by second person from the quality unit for legibility, accuracy, and completeness	Documented review by second person (not necessarily from the quality unit) for legibility, accuracy, and completeness	Documented verification by person performing the scan for legibility, accuracy, and completeness
	Discard of original allowed	Yes, unless there is a seal, watermark, or other identifier that can't be accurately reproduced electronically. Quality unit must be present	Yes, performed by the operating unit, unless there is a seal, watermark, or other identifier that can't be accurately reproduced electronically. Quality unit oversight required	Yes, individual can discard original Quality unit oversight required

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Control Grid for Access to Electronic Systems

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Access Controls for Electronic Systems		High Data Criticality	Medium Data Criticality	Low Data Criticality
Prevention Control	Access to Electronic systems – HOW	Identification and authentication (User ID + Password)	Identification and authentication (User ID + Password)	Passcode/group account based on role & information access
	Access to Electronic Systems – Time-out frequency	If within the area, after 15 min of inactivity; manual log-out when leaving the area	If within the area, after 30 min of inactivity; manual log-out when leaving the area	Never for operators; manual log-out after completion of activities for engineers/operators
	Password change frequency	Every 90 days	Every 180 days	Annually
	Periodic user account access review	Annually	Annually	Every 2 years
	Account lock-out after repeated incorrect password entries	5 incorrect password entries	10 incorrect password entries	Never
	Password recycling – Reuse of previously used passwords	10 cycles	5 cycles	N/A

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Potential Categories of Data Integrity Vulnerability

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- **GMP process**
  - Aborted runs (e.g., due to lack of planning, understanding system operation, suitability of equipment and process)
  - Complex process (e.g., many interfaces, high level of human intervention, high levels of manual data entry)
  - Data flows and ownership not well defined
  - Inadequate line clearance checks
  - Negative trends related to changes, deviations, out of specification, alarms, out of calibration
  - New or complex processes (causing repeat errors)
  - Operation switching (GxP vs. non-GxP)
  - Unavailability of quality-related data requested during regulatory inspections

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Data Flow in Hybrid Analytical Systems

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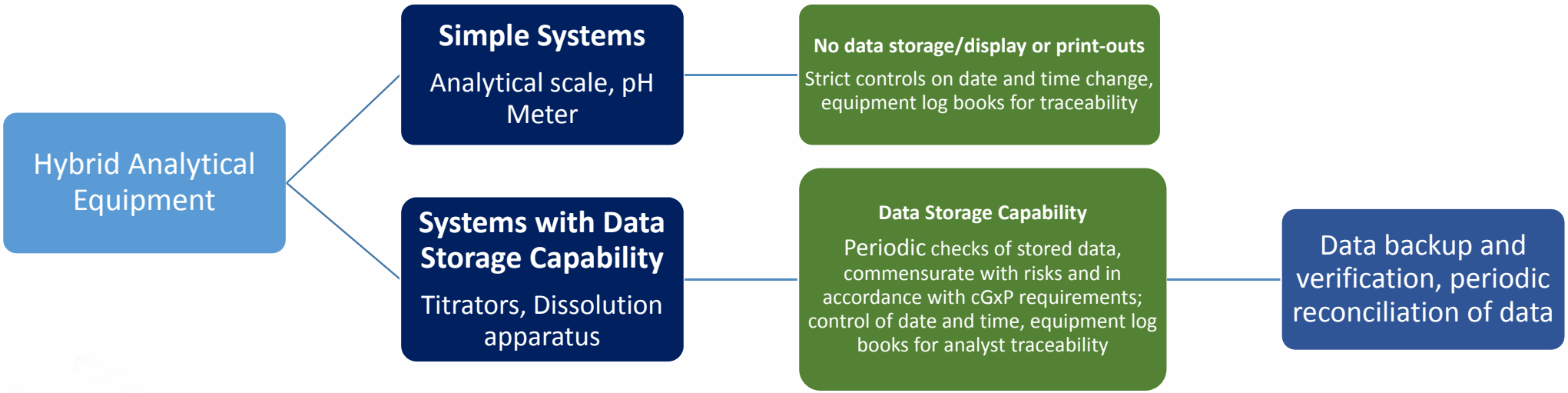

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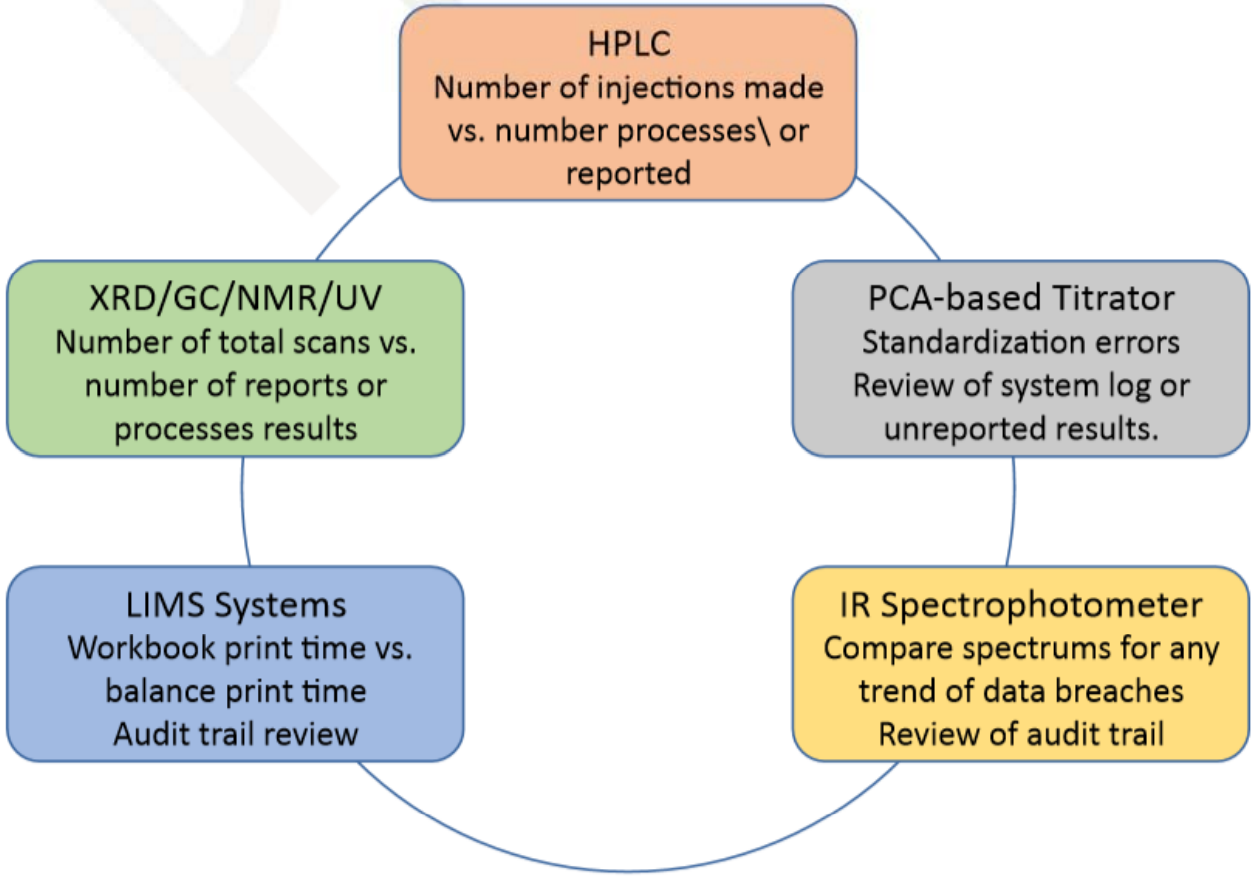
Routine Checks of Typical Data Sets in the Laboratory



Spreadsheet Protection and Controls

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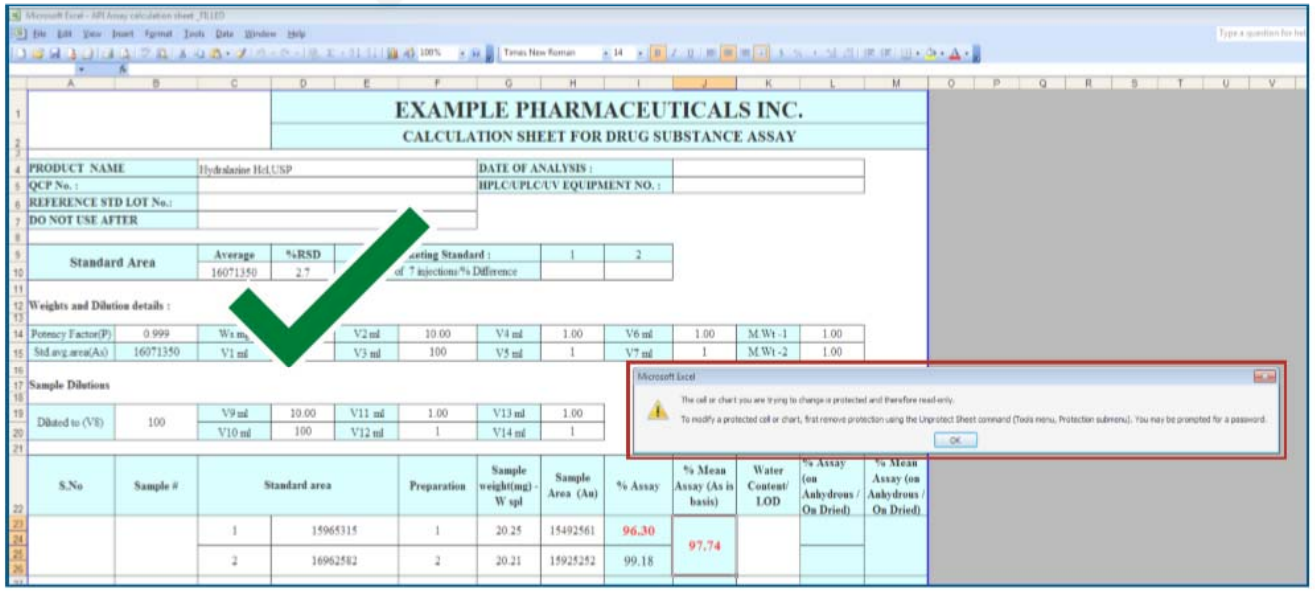

- Encrypt with password protection
- Restrict editing (set to “Read only”) so previous data is not retained in the template
- Save spreadsheets to a designated location on the server and capture the file location on each spreadsheet Change passwords and revalidate customized spreadsheets periodically per established SOPs

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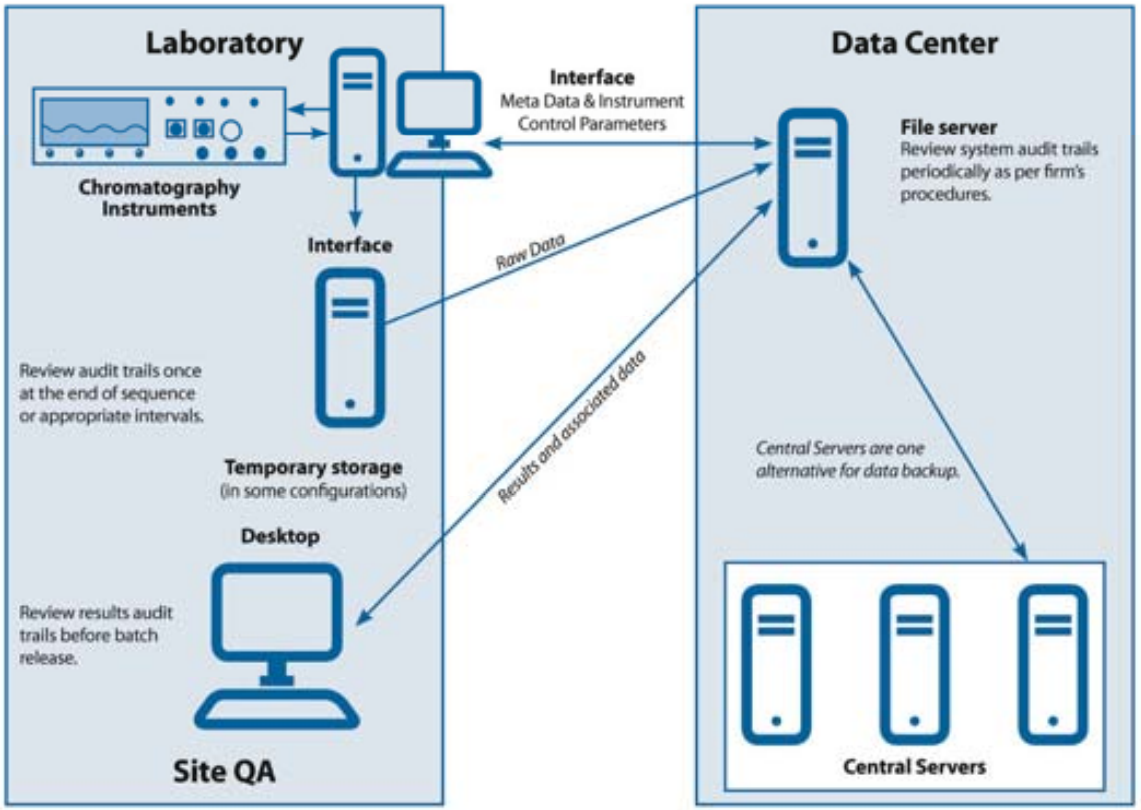
Analytical Laboratory Computerized Systems (ALCS)



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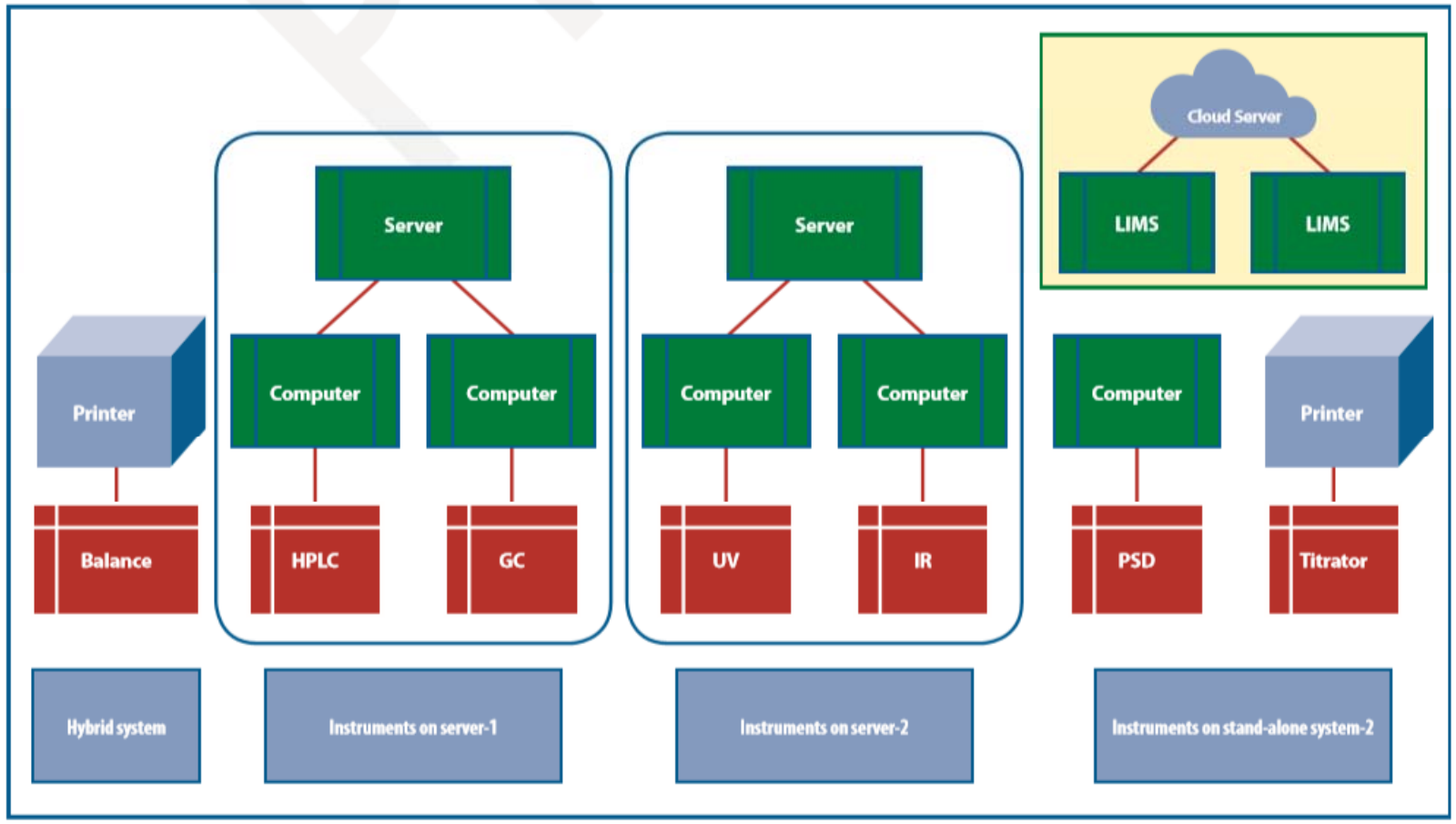
Typical Analytical Laboratory Data Mapping



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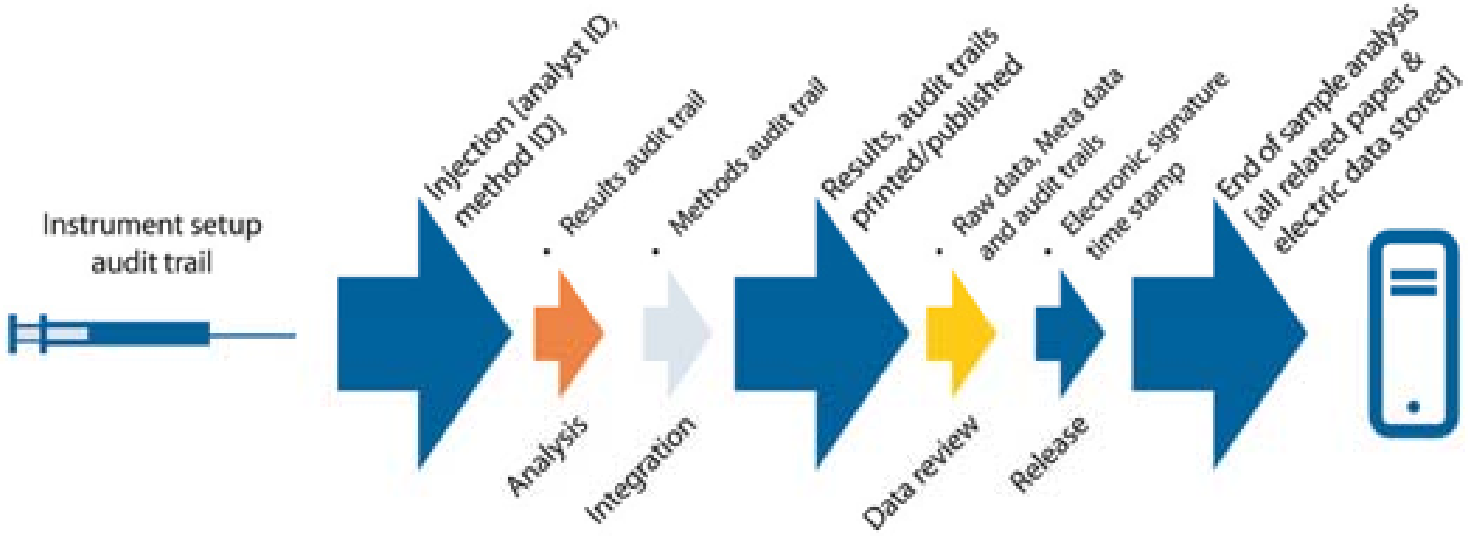
Typical Data Flow in Chromatographic Analysis



Example Audit Trail Summary

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System Level

User Activity (login/logoff/failure login attempts/privilege changes)

Application Level

User activities (login/logoff/failure login attempts/privilege changes)

Data creation/modification/deletion/publishing/restoring

Methods creating/modification/deletion

Product/Molecule Folder Level

Summary of sequence, methods, result audit trails

Data acquired system details

Method

Creation/modified details

Each modification identified by version number

Sequence

Sequence modification during and after execution

Result

Calculated Value

Processing history (Integration type, result number, calibration curves and modification of sample details), publishing details

Logged in as QA Reviewer

File Edit View Records Help

	Action	Change Date	User
1	Successfully Logged On	3/22/2018 10:41:17 AM EDT	Groupleader
2	Unsuccessful Logon Attempt	3/22/2018 10:42:52 AM EDT	Analyst A
3	Successfully Logged On	3/22/2018 10:42:56 AM EDT	Chemist
4	Unsuccessful Attempt to Confirm Identity	3/22/2018 10:45:02 AM EDT	Groupleader
5	Unsuccessful Logon Attempt	3/22/2018 11:05:03 AM EDT	Analyst A
6	Unsuccessful Logon Attempt	3/22/2018 11:05:15 AM EDT	Analyst A
7	Unsuccessful Logon Attempt	3/22/2018 11:05:38 AM EDT	Analyst A
8	Successfully Logged On	3/22/2018 11:20:28 AM EDT	Chemist
9	Successfully Logged On	3/22/2018 11:31:03 AM EDT	Chemist
10	Unsuccessful Attempt to Confirm Identity	3/22/2018 11:31:58 AM EDT	Chemist
11	Successfully Logged On	3/22/2017 11:34:02 AM EDT	Groupleader

Sample Set Method Report Summary

Sample Set Name QCE_680_007_Inj Linearity_SSM Sample Set Id 3784

Peak Results

	SampleName	Vial	Date Acquired	Instrument Method Id	User
1	Blank (Mobile Phase)	1	2/3/2017 11:22:34 AM EST	1003	Chemist
2	Caffeine (0.06 mg/mL)_5µL	2	2/3/2017 11:26:13 AM EST	1003	Chemist
3	Caffeine (0.06 mg/mL)_20µL	2	2/3/2017 11:29:56 AM EST	1003	Chemist
4	Caffeine (0.06 mg/mL)_40µL	2	2/3/2017 11:33:51 AM EST	1003	Chemist
5	Caffeine (0.06 mg/mL)_80µL	2	2/3/2017 11:38:00 AM EST	1003	Chemist
6	Caffeine (0.06 mg/mL)_100µL	2	2/3/2017 11:42:21 AM EST	1003	Chemist

Peak Results

	Result Comments	Altered	Result #	Injection ID	Date Acquired	Result ID
1	Process Injection	No	1	3786	2/3/2017 12:15:39 PM EST	3821
2	Process Injection	No	1	3792	2/3/2017 12:15:40 PM EST	3822
3	Process Injection	No	1	3798	2/3/2017 12:15:40 PM EST	3823
4	Process Injection	No	1	3804	2/3/2017 12:15:41 PM EST	3824
5	Process Injection	No	1	3810	2/3/2017 12:15:41 PM EST	3825
6	Process Injection	No	1	3816	2/3/2017 12:15:42 PM EST	3826

Specific Result number

Denotes sample name alteration ("Yes" if name altered)

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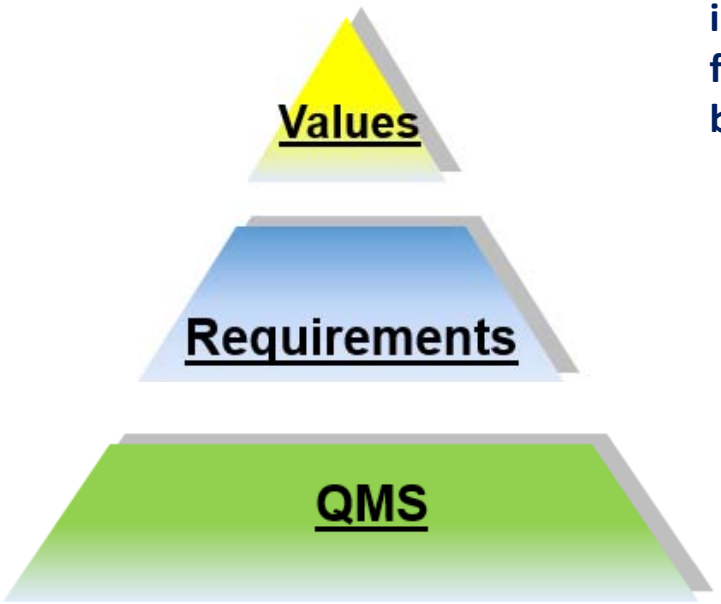
Role of the Quality Management System



Values: Integrity and honesty are at the core of data integrity. A company code of conduct (or equivalent) that captures the values of integrity and honesty related to data integrity will lay a solid foundation in support of procedural controls and fosters quality behavior.

Requirements: Requirements for data quality and integrity attribute should be incorporated into policies, standards, and user requirements. Management engagement and sponsorship is key to data integrity.

QMS: The quality management system for pharmaceuticals is described in the international harmonized standard ICH Q10. It is important to

- Ensure the integrity of the data in the QMS for decision making
- Use the QMS to manage data integrity

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Role of the QMS in Data Integrity and Data Controls

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QMS Element	Role in Data Integrity Management
Standards/requirements	Define the expectations that must be adhered to/met. These must be incorporated into SOPs, business process, and monitoring mechanisms.
Documentation	Provides requirements, SOPs and doc mgt to mitigate risk of DI
Deviation & CAPA	Provides process to investigate DI, develop and implement CAPAs
Change mgt	Provides formal process to manage change to minimize risk of DI
Training	Provides process to develop and deploy systematic training on DI
Auditing	Provides structured program to assess / identify DI issues
Management review	Provides mechanisms to monitor, review that controls are appropriate and effective
User requirements and validation	Provide the mechanism to identify the attributes that must be met and demonstrated capability.

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Detection of Data Integrity Issues

IPA Innovation, Quality and Global Reach

- Document & Data Review
- Trending
- Corporate Level Controls
- Management and Supervisory activities
- Audits & Assessments
- Surveillance & Oversight
- Manual & Computerized Modes of Detection
- Specialized Training to detect

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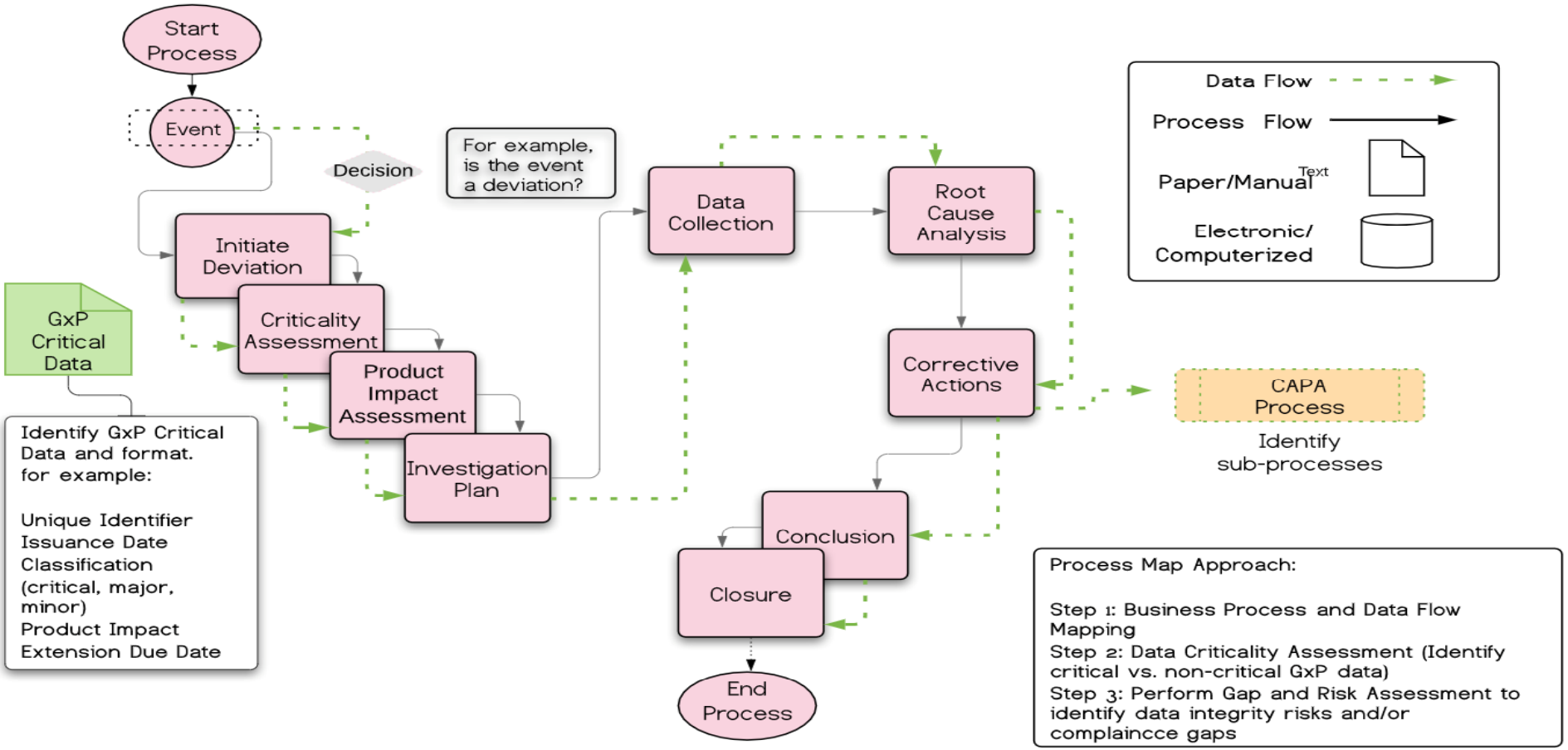
Process Mapping
Deviation Management Process



Resources

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IPA
Innovation, Quality and Global Reach


PDA Journal of Pharmaceutical Science and Technology

PDA Points to Consider: Best Practices for Document/Data Management and Control and Preparing for Data Integrity Inspections

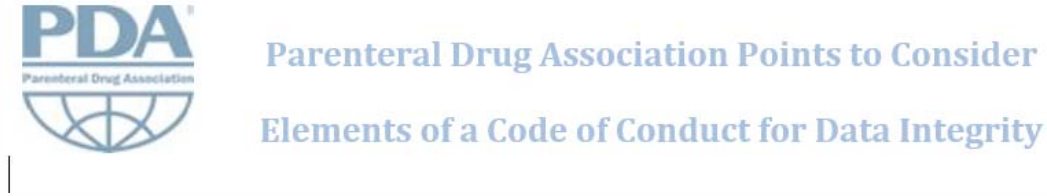
Deborah M. Autor, Zena Kaufman, Ron Tetzlaff, et al.

PDA Journal of Pharmaceutical Science and Technology **2018**.
Access the most recent version at doi:10.5731/pdajpst.2018.008573


PDA

Technical Report No. 80

Data Integrity Management System for Pharmaceutical Laboratories


PDA Parenteral Drug Association

Parenteral Drug Association Points to Consider

Elements of a Code of Conduct for Data Integrity

Coming Soon: Technical Reports on DI in Manufacturing and QMS. Expected Publication is Q1 of 2020