Specializing in FDA Regulatory Matters

Problems with Pharma Data Integrity

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Welcome

- No opening jokes for this presentation

- DATA INTEGRITY NEEDS TO BE TAKEN SERIOUSLY IN THE PHARMACEUTICAL INDUSTRY TODAY AND ALWAYS!

Potential Negative Consequences of not Complying with CGMP Regulations

- *If you receive a Warning Letter or you firm is placed on the Import Alert List: you may have to stop manufacturing, recall your products, train all of your employees, validate your manufacturing processes, validate your testing methods and re-qualify your equipment. You will also be required to hire consultants.*

- *This will cost you millions of dollars and could take several years to re-start your production. You will not obtain any new NDA or ANDA approvals and you will not be able to submit any changes to your already approved applications. Your stock price will go down. You may lose your customers and you may have to close your facilities.*

21 CFR Part 11 Electronic Records; Electronic Signatures

- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11

- TITLE 21- FOOD AND DRUGS

- PART 11 ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

21 CFR Part 11 Electronic Records; Electronic Signatures (II)

Subpart A--General Provisions

§ 11.1 - Scope

§ 11.2 - Implementation

§ 11.3 – Definitions

Subpart B--Electronic Records

§ 11.10 - Controls for closed systems

§ 11.30 - Controls for open systems

§ 11.50 - Signature manifestations

§ 11.70 - Signature/record linking

21 CFR Part 11 Electronic Records; Electronic Signatures (III)

Subpart C--Electronic Signatures

§ 11.100 - General requirements

§ 11.200 - Electronic signature components and controls

§ 11.300 - Controls for identification codes/passwords

Data Integrity and Compliance With CGMP Guidance for Industry: DRAFT GUIDANCE

- http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm495891.pdf
- U.S. Department of Health and Human Services
- Food Drug Administration
- Center for Drug Evaluation and Research (CDER)
- Center for Biologics Evaluation and Research (CBER)
- Center for Veterinary Medicine (CVM)
- April 2016 Pharmaceutical Quality/Manufacturing Standards (CGMP)

Data Integrity and Compliance With CGMP Guidance for Industry: DRAFT GUIDANCE (II)

- The purpose of this guidance is to clarify the role of data integrity in current good manufacturing practice (CGMP) for drugs, as required in 21 CFR parts 210, 211, and 212.
- Part 210 covers Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General
- Part 211 covers Current Good Manufacturing Practice for Finished Pharmaceuticals.
- This guidance provides the Agency's current thinking on the creation and handling of data in accordance with CGMP requirements

Data Integrity and Compliance With CGMP Guidance for Industry: DRAFT GUIDANCE (III)

- Definition used in Guidance
- Data integrity refers to the completeness, consistency, and accuracy of data. Complete, consistent, and accurate data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate

- **(ALCOA)**

Training on Data Integrity Guidance (II)

- FDA expects that data be reliable and accurate. CGMP regulations and guidance allow for flexible and risk-based strategies to prevent and detect data integrity issues. Firms should implement meaningful and effective strategies to manage their data integrity risks. This should be based upon their process understanding and knowledge management of technologies and business models

- In recent years, FDA has increasingly observed CGMP violations involving data integrity during CGMP inspections. This is troubling because ensuring data integrity is an important component of Industry's responsibility to ensure the safety, efficacy, and quality of drugs, and of FDA's ability to protect the public health

Training on Data Integrity Guidance (II)

- These data integrity-related CGMP violations have led to numerous regulatory actions, including warning letters, import alerts, and consent decrees. The underlying premise in 210.1 and 212.2 is that CGMP sets forth minimum requirements to assure that drugs meet the standards of the FD&C Act regarding Safety, Identity, Strength, Quality and Purity
- Electronic signature and record-keeping requirements are laid out in 21 CFR Part 11. They apply to certain records subject to records requirements set forth in Agency regulations, including parts 210 and 211.
- The guidance outlines FDA's current thinking regarding the narrow scope and application of Part 11 pending FDA's reexamination of part 11 as it applies to all FDA-regulated products

Training on Data Integrity Guidance (III)

- Data integrity refers to following attributes of data: Completeness, Consistency and Accuracy
- Metadata is the contextual information required to understand data. A data value is by itself meaningless without additional information about the data. Metadata is often described as data about data
- Metadata is structured information that describes, explains, or otherwise makes it easier to retrieve, use or manage data
- For example, the number “23” is meaningless without metadata, such as an indication of the unit “mg.” Among other things, metadata for a particular piece of data could include: Date/time stamp for when the data were acquired, User ID of the person who conducted the test or analysis that generated the data, Instrument ID used to acquire the data.

Training on Data Integrity Guidance
(IV) AUDIT TRAIL

- Data should be maintained throughout the record's retention period. This should be done with all associated metadata required to reconstruct the CGMP activity (e.g., §§ 211.188 and 211.194). The relationships between data and their metadata should be preserved in a secure and traceable manner.
- Audit trail means: A secure, Computer-generated, Time-stamped Electronic Record. This record should allow for reconstruction of the course of events relating to the creation, modification or deletion of an electronic record.
- An audit trail is a chronology of the record.

"who, what, when and why"

Training on Data Integrity Guidance
(V) AUDIT TRAIL

- For example, the audit trail for a high performance liquid chromatography (HPLC) run could include: The user name, Date/time of the run, The integration parameters used, and Details of a reprocessing, if any, Change justification for the reprocessing

- Electronic audit trails include those that track creation, modification, or deletion of data (such as processing parameters and results), those that track actions at the record or system level and such as attempts to access the system or rename or delete a file

Five Things to Know About Data Integrity

- For several years now, data-integrity violations have been the main reason why the US Food and Drug Administration (FDA) has issued warning letters to pharmaceutical manufacturers and 2015 was no exception.
- Regulators continue to identify the same set of shortcomings. In fact, for the last 15 years, regulatory agencies have cited the same deficiencies – related to data integrity and data management. Yet it appears that the industry as a whole has made limited progress in self-identifying and remediating these deficiencies.
- In an effort to demonstrate the recurring pattern, FDA observations that were listed in 2015 Warning Letters were tabulated in 2015. There are five questions that the management of every pharmaceutical company needs to ask itself and take remedial action in order to consistently do well in regulatory inspections.

Five Things to Know About Data Integrity (II)

1. Are you duplicating your testing efforts?

- Our tabulation observed that companies which get warning letters are duplicating efforts. Since duplication of activities add to costs of a manufacturing unit, it is worth asking why companies need multiple testing of the same product?
- Is duplication done because there is a lack of confidence in the manufacturing process? Could this be the reason why “test” or “trial” injections are performed to ensure the “actual” result will pass when GMP documents have to be completed?
- Or could it be that there is a big gap between the commitments made to regulatory authorities and the actual process being performed on the shop floor?
- If your company is making these mistakes, look at how to reduce duplication of activities. Elimination of duplication improves compliance and also brings about cost efficiencies.

Five Things to Know About Data Integrity (III)

2. Does your company lack real-time documentation?

- Several companies that faced regulatory action last year did not document operations in real-time. Why go through the added effort to duplicate documentation once the activity has been completed?
- Are the questions which need to be answered the same as those for duplicate testing? Is it also a possibility that companies are not manufacturing the product but only manufacturing paper?

Five Things to Know About Data Integrity (IV)

3. Do you have problems configuring audit trails?

- Problems with audit trail configuration was the most frequent observation made by the FDA. Interestingly, the observation was made across brands of software and equipment, reinforcing the fact that the problem had more to do with improper set-up than access to the appropriate solution.
- The right configuration is important to track audit history, especially in organizations with multiple operators and administrators. How should companies configure audit trail functions in any software used to acquire data that can impact product quality?

- This is definitely an area that companies need to address

Five Things to Know About Data Integrity (V)

4. Are you getting to the root of quality failures?

- In many cases, where products routinely failed quality standards, the FDA inspectors found the firms had not conducted thorough investigations to get to the root-cause of the problem.
- Do companies differentiate between a one-off product quality problem coming from the manufacturing line and a recurring process failure with the potential of dispatching a contaminated product to the market? Without a thorough investigation that gets to the root cause of failing a quality standard, no company can hope to be GMP compliant.

Five Things to Know About Data Integrity (VI)

5. Have your employees been adequately trained for inspections?

- When inspectors arrive on site, panic creeps in. That's a common observation and employees definitely need training to handle regulatory inspections.
- However, before you begin training employees for rigorous interviews from inspectors, check if your training procedures are effective, whether or not your GMP procedures are overly complicated and if employees are following common unwritten practices?
- Lack of proper employee training can be detrimental to the image of your company, as employees often end up giving ill-informed answers to inspectors. Remember – regulators are just doing their job. They have a governing body to answer to. They will report issues they find weighty and incompliant to GMP and quality norms.

Current Regulatory Agencies Focus

- There is an increase in Health Authorities Observations and Actions pertaining to Data integrity
- Data Integrity denotes the quality and accuracy of data over the entire lifecycle
- FDA Warning Letters and Import Alerts
- EU Non Compliance Reports
- WHO De-Certification

Data Integrity

- The current culture can influence the understanding or meaning of integrity
- Noble quality culture can compensate for weak systems
- Poor Data Integrity can be considered an illness. A comprehensive plan could recommend the necessary corrections
- Data Integrity can be considered as a design problem. Fear or the desire to ”make” a batch pass can lead to Data Integrity difficulties. These difficulties can be a lifecycle problem
- All personnel in an organization must understand the importance of Data Integrity and the significance of their specific roles. Supervisors, Managers, Directors, Vice Presidents and Presidents must understand the importance of supervising the entire manufacturing process

Data Integrity (II)

- Many people may consider that the root cause of a problem is equipment malfunction or human error
- A comprehensive root cause analysis should be conducted before incorrect assumptions are made
- You must also consider that there could be multiple root causes for a problem

Data Integrity as Defined by MHRA

- In July 2016, the MHRA released a draft document titled MHRA GxP Data Integrity Definitions and Guidance for Industry. It is a glossary of DI terms where the definitions are further explained with some context to aid in applying the existing regulations available. This is an update to their guidance released in March 2015. While they have not re-defined data integrity, there are some differences to note.
- The guidance relates heavily to building your DI environment with a practical risk-based approach to the data collected, whether electronically or manually. It refers frequently to ICH Q9 Quality Risk Management as a practical approach to determining the effort required in applying data governance restrictions.

Data Integrity as Defined by MHRA (II)

- There is also an emphasis on the design of the controls to support data quality and integrity. The idea of ‘data integrity/quality by design’ is something that aligns with the ISPE GAMP® 5 system validation process and PIC/S PE 009 Annex 15 Qualification and Validation. In order to apply the regulations appropriately, the organization must understand the:
- ▪data required
- ▪collection system and processing
- ▪criticality to the patient
- ▪risk of data tampering
- ▪controls required
- Each of the requirements should be documented and risk assessed before implementing a system. The validation process provides an ideal framework for documenting the data integrity lifecycle.

Data Integrity as Defined by MHRA (III)

- GMP facility deadline
- The guidance places a lot of emphasis on metadata integrity and two sections highlight the importance of user identification and data change controls/restrictions:

- Computerized system user access / system administrator roles
- While hybrid systems are accepted if they provide the adequate level of control, it is expected that GMP facilities, whose hybrid system does not meet the requirements for DI, should update their system by the end of 2017

Data Integrity as Defined by MHRA (IV)

- Current thinking
- The guidance does not report any major revelations or changes to DI or its definitions, that have not already been discussed in recent times
- The simple matter is that DI is still a hot topic because the regulators are still discussing it. It is still the cause of an increasing number of regulatory citations over the last 5 years:
- 2 in 2010 to 10 in 2014
- 17% of warning letters in 2014
- 30% of warning letters in 2015
- Failures were predominantly in almost all API warning letters in 2015

Warning Letter 1

1. Failure to maintain complete data derived from all laboratory tests conducted to ensure compliance with established specifications and standards.

2. Failure to investigate and document out-of-specification results.

3. Failure to include adequate documentation during complaint investigation.

4. Failure to record activities at the time they are performed.

Warning Letter 1 (II)

- Our inspection revealed that your firm selectively omitted CGMP records directly related to the testing and manufacturing of your products. You are responsible for the accuracy and integrity of the data generated by your firm. A firm must maintain all raw data generated during each testing and manufacturing operation, including graphs, charts, and spectra from laboratory instrumentation. You must properly identify these records to demonstrate that each released batch was manufactured in accordance with validated parameters, was tested appropriately, and met release specifications. Your firm's executive management is responsible for ensuring the quality and safety of your products. Implementing adequate controls and systems to prevent omission and manipulation of laboratory data is at the foundation of fulfilling this critical responsibility.

Warning Letter 1 (III)

- The above examples raise serious concerns regarding the integrity, reliability and accuracy of the data generated and available at your facility. In your response to this letter, provide a comprehensive evaluation of the extent of the omission, deletion and destruction of records, a risk assessment regarding the potential impact on the quality of products, and a comprehensive corrective and preventive action plan. Your response should include a summary of your investigation into missing, inaccurate or unreliable tests results with a description the findings. Your investigation should assess the impact of these and any similar incidents on the quality of the drug products produced with your APIs, and should describe the steps that will be taken to prevent these fundamental breaches of data integrity and management oversight in the future.

Warning Letter 1 (IV)

- Your plan should also ensure that controls are put in place that are sufficient to prevent omissions of data and prevent unauthorized changes to existing data. Any changes to data should only occur in strict accordance with approved established procedures, and the date of change, identity of person who made the change, and an explanation or reason for the change should always be recorded. Your firm also needs to improve its procedures for analyzing complaints, handling OOS results, and assuring effectiveness of corrections following investigations into deviations and OOS results.
- Accordingly, you should include a detailed description of your plan to implement a robust quality system in your response to this letter. This remediation plan should describe the broader steps taken to ensure direct and effective corporate oversight of the quality and operation functions of this facility. This system should ensure sustainable compliance with CGMP, including the basic capability to prevent data manipulation and destruction or deletion of records.

Warning Letter 1 (V)

- Your plan should also describe your commitment, procedures, actions, and controls to ensure data integrity generally. This plan should describe the corrective actions implemented to ensure that all managers, supervisors, and quality unit personnel are properly trained in detecting a lack of data integrity and data manipulation. The investigation should provide detailed descriptions of any other incidents where your quality unit failed to ensure proper testing of any materials and should include a retrospective review of all test results generated by your laboratory personnel.
- We acknowledge that you committed to hiring a third party auditor with experience in detecting data integrity problems to assist you with this evaluation and to assist with your overall compliance with CGMP. Your data integrity consultant should:

Warning Letter 1 (VI)

- Finally, in response to this letter, you should also provide a list of all the batches of APIs in distribution and those intended to be shipped to the U.S. market that relied upon missing, inaccurate, or unreliable test data.

- The deviations cited in this letter are not intended to be an all-inclusive list of deviations that exist at your facility. You are responsible for investigating and determining the causes of the deviations identified above and for preventing their recurrence and the occurrence of other deviations.

Warning Letter 2

Our investigators observed specific violations during the inspection, including, but not limited to, the following:

1. Your firm failed to ensure that laboratory records included complete data derived from all tests necessary to assure compliance with established specifications and standards (21 CFR 211.194(a)).

The inspection of your facility documented multiple incidents of performing "trial" testing of samples, disregarding test results, and reporting only those results from additional tests conducted. For example,

a. The official release data for … Tablets for unknown impurities was reported to be within specification (NMT… (%). However, the chromatographic data showed that the "trial" injection data for this batch failed the unknown impurities specification with a result of … %.

b. The official High Performance Liquid Chromatography (HPLC) impurity data for … Tablets batch … 3-month stability time-point @ 25oC/60% RH only included the most favorable result obtained from multiple test results without any justification. The data from this batch was submitted to the U.S. FDA as an exhibit batch.

In addition to the examples above, **our inspection found that 2,803 of 44,643 injection results were not processed or reported in the official data folder for dissolution analysis via HPLC for … Tablets**. Our inspection identified numerous examples of “trial” injections for various drug products (U.S. and non-U.S. markets), which suggests that this is a common practice.

Warning Letter 2 (II)

- Your response to our findings of “trial” injections attempts to explain the rationale for retesting … and … (1a above). You state that “the unknown were intermittent spikes resulting in aberrant chromatography caused by electronic disturbance or pressure fluctuation.” Your subsequent investigation into the observation concluded that “the unknown impurity peak…is not characteristic of the product and was not observed in the analysis of all commercial and exhibit batches.” **The fact that you did not observe the peak in commercial and exhibit batches does not justify disregarding the test run or failing to follow up with appropriate corrective actions and preventive actions.**
- 2. 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)).

Warning Letter 2 (III)

3. Your firm failed to establish and follow appropriate written procedures, designed to prevent objectionable microorganisms in drug products not required to be sterile (21 CFR 211.113(a)).
4. Your firm failed to follow written procedures applicable to the quality control unit (21 CFR 211.22(d)) and your quality control unit failed to review and approve all drug product production and control records to determine compliance with all established, approved written procedures before a batch is released or distributed (21 CFR 211.192).

Warning Letter 2 (IV)

- The foregoing examples are of serious CGMP violations demonstrating that your quality system does not adequately ensure the accuracy and integrity of the data generated at your facility to ensure the safety, effectiveness, and quality of the drug products you manufacture. We found that your quality system failed to ensure the adequate investigation and resolution of quality failures. ARPL failed to investigate OOS results, failed to contemporaneously document failures and report failures, and selected only passing results without the oversight of a quality unit. In your response and in subsequent communications with the agency, you indicated that you interviewed employees and found no evidence of data manipulation or deletion. In focusing on the issues of deletion and alteration of data, you have not sufficiently addressed or resolved other substantial CGMP issues as discussed above. In response to this letter and including the specific requests noted above, provide the following to the Agency:
- **We also recommend that you contact …@fda.hhs.gov, or 301-796-3284, within five days of receipt of this letter to schedule a regulatory meeting with …**

Warning Letter 3

- Mailed in June 2016. This warning letter summarizes significant deviations from current good manufacturing practice (CGMP) for active pharmaceutical ingredients (API).
- Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your API are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

1. Failure to prevent unauthorized access or changes to data and failure to provide adequate controls to prevent manipulation and omission of data.

1a. Our investigator's review of the audit trail for the residual solvent stability testing indicated that an analyst manipulated your computerized gas chromatography (GC) system to falsify residual solvent stability results for multiple batches of (b)(4) API distributed to the U.S.

Warning Letter 3 (II)

- During the inspection, FDA's investigator discovered a lack of basic laboratory controls to prevent changes to and deletions from your firm's electronically-stored data. Your firm relied on incomplete and falsified records to evaluate the quality of your drugs and to determine whether your drugs conformed with established specifications and standards.
- Our investigator found that your firm failed to prevent data manipulation on multiple computerized analytical systems. Your firm re-tested samples without justification and deleted raw analytical data from computerized systems. You are responsible for determining the causes of these deviations, for preventing their recurrence, and for preventing other deviations from CGMP.

1b. Our investigator's review of the audit trails for the high performance liquid chromatography (HPLC) system indicated that, just prior to the completion of certain stability analyses for (b)(4) API, analysts routinely aborted the ongoing tests to prevent your HPLC system from recording some assay and impurities test data.

Warning Letters 3 (III)

2. Failure to document manufacturing operations at the time they are performed.

Your response was inadequate. Neither revised templates and procedures nor retraining your staff alone can prevent operators from continuing to falsify batch manufacturing records

Conclusion

Deviations cited in this letter are not intended as an all-inclusive list. You are responsible for investigating these deviations, for determining the causes, for preventing their recurrence, and for preventing other deviations in all your facilities.

Warning Letters 3 (IV)

- Conclusion continued
- After you receive this letter, you have 15 working days to respond to this office in writing. Specify what you have done since our inspection to correct your deviations and to prevent their recurrence.

- Your quality system does not adequately ensure the accuracy and integrity of data to support the safety, effectiveness, and quality of the drugs you manufacture. In your firm's … response, you admitted that personnel were not properly trained and that you planned to hire a consultant to perform comprehensive CGMP training. You committed to recall your API in …2016, correspondence to the Agency. We have since received confirmation from your (b)(4) sales agent that you did initiate a voluntarily recall of … API from your U.S. customers. **We strongly recommend that you retain a qualified consultant to assist in your remediation. In response to this letter, provide the following.**

Warning Letters 3 (V)

- Because of the findings of the FDA inspection described in this letter, your firm was placed on Import Alert ..-.. on .. 2016.

- Until you completely correct all deviations and we confirm your compliance with CGMP, **FDA may withhold approval of any new applications or supplements listing your firm as an API manufacturer. Failure to correct these deviations may also result in FDA continuing to refuse admission of articles manufactured at …., into the United States** under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Under the same authority, **articles may be subject to refusal of admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B).**

Updates on WL 1

- ? back on FDA's import alert list

- Just when it seemed ? was getting its compliance act together and putting its problems behind it, its bulk drug facility got placed on the FDA's Red List.
- The bulk drug division in ? is the latest to join FDA's import alert list, with ?? units already on the list.
- While ? recently said it had received establishment inspection reports (EIR) for the facilities with observations, it also mentioned that the "receipt of EIR does not materially change the status of import alert for the concerned manufacturing units for the US market."
- The bulk drug (API) facility in ? had received a EU Written Confirmation from the Indian Central Drug Authority for the following ?

Update

- Recent News About ? FDA-483 Observations
- The observations listed on the form, highlight concerns, which had not previously been reported. ? not only failed to mention the presence of an analytical laboratory, which was “only discovered” later, they deleted analytical raw data and the inspectors found many original documents in the company’s waste area.
- Multiple instances where samples were failing specifications and reported as passing have also been cited.

Update

- Aug 21, 2016, Making ? units cGMP compliant time consuming: ?
- ? Thinks remediation process at facilities as a "time consuming" process even as it aims to bring at least one of the plants to conform to current good manufacturing practice regulations (cGMP) in the current fiscal year
- On ? plant, which is under the USFDA scanner for violations of cGMP, the company faced anticipated supply constraints and delays in product approvals driven by the cGMP compliance remediation efforts
- This impacted our US revenues for the year. We expect to eventually resolve this in future. However, this did not deter us from continuing to invest heavily in building the specialty business in the US
- The drug major continues to invest significant time and resources in ensuring that it remains committed to 24x7 cGMP compliance

Mitigating the Risks of Error

- These are not errors. The are intentional changes to the data.
- The use of an electronic data system that is adequately validated according to 21 CFR Part 1!, will prevent workers from being able to make these changes through the audit trail function of a compliant system
- The importance of following good data integrity procedures needs to be instilled into everyone involved with manufacturing at each of your facilities
- This should be done with training, which conveys the strongly worded message regarding the negative consequences regarding falsifying data

Increasing Reporting Efficiency

- It is only through adequate training on well written SOPs and the threat of termination, that will teach workers of the serious consequences of data falsification
- Many laboratory are afraid to report OOS results due to the fear of termination. You must instruct your laboratory, QA and operating staff that they will not be punished for reporting OOS results.
- Manufacturing and testing personnel should be taught to report these OOS results to their direct supervisor.

How Automation Can Help in Structured Reporting

- The use of fully electronic document systems, which are compliant with 21 CFR Part 11, will prevent your personnel from changing results because of the required audit trail functions
- If you need assistance, FDA's enactment of Part 11 (Electronic Records; Electronic Signatures, has created an entirely new business. This new business are all of these new companies whose consultants specialize in compliance with 21 CFR Part 11

How Automation Can Help in Structured Reporting(ii)

- Please be careful about companies who sell hardware and software that “Claim to be in compliance with 21 CFR Part 11”
- These claims may simply be marketing tools
- These electronic systems must be validated at your facility with your computers.

Reduction in Human Error

- A reduction in human errors could be taught by continuous quality improvement procedures such a “Right First Time or First Time Right”
- Since there is not enough time for these continuous quality improvement programs in today’s presentation, pleas enquire about these at another time

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