

Medical Device Core Skills

CWF - MAINTAIN A SAFE AND PRODUCTIVE WORK ENVIRONMENT				
Key Activity	Performance Indicators	Underlying Knowledge	Assessments	
Recognize unsafe conditions and take corrective and/or preventive action(s)	Different types of hazards eg. (biological, chemical, physical, electrical, radiological) are identified	Meaning of safety symbols & signs; OSHA and EPA principles	Match the safety symbol to its meaning	
		Basic understanding of electricity and electrical hazards	Scenario: You walked into the storage room and see this [show picture of room with 2 very heavy boxes on top shelf, not properly secured, and overloaded circuit with daisy-chained power strips and numerous cords plugged into each strip]. Describe what unsafe condition(s) exist, if any, and what could be done to correct it/them.	
		Types of physical hazards	Scenario: You walked into the Prep Room and see a bottle had fallen off the shelf and broken on the floor, spilling most of its chemical contents. Demonstrate what you would do, and explain out loud what you are doing and why as you deal with this situation.	
		Proper identification, handling, and storage of hazardous materials (acids, bases, corrosives, oxidizers, explosive, flammable, etc.)		
	Emergency procedures are demonstrated	Location, purpose and proper use of safety equipment		On a map of the facility, indicate the type and location of all safety equipment (teaching lab)
				Explain the conditions under which specified safety equipment is used
				Don and remove PPE equipment properly
	Sources of safety information (MSDS/SDS)		Demonstrate proper procedures in response to a simulated emergency	
			Give examples of various emergency situations (e.g. earthquake, fire, tornado, active shooter) and ask for description of proper responses	
Follow relevant safety policies, guidelines, protocols and regulations (e.g. company, OSHA, EPA, CDC)	Workplace behavior/actions compliant with industrial and regulatory safety standards are demonstrated (e.g. LOTO, confined space, PPE, egress)	OSHA Hazard Communication Standard (HCS), 29 CFR 1910.1200; OSHA HCS guidance document [https://www.osha.gov/Publications/OSHA3695.pdf]; OSHA HC Program fact sheet [https://www.osha.gov/Publications/OSHA3696.pdf]	Execute the steps needed, in the correct order, to properly LOTO the piece of equipment in preparation for maintenance.	
			Demonstrate appropriate response to a given scenario where a standard should be applied	
	Appropriate resources are used to identify proper disposal/waste treatment procedures	Awareness of safety training requirements from all federal and state regulatory bodies as well as company specific policies		Choose a chemical/material and ask student to: (1) retrieve SDS, (2) identify PPE, (3) describe special handling procedures, (4) describe special hazardous waste and disposal procedures.
			How to locate and use MSDS/SDS	
Access and use MSDS (SDS) and other safety information sources	Safe material handling and storage is demonstrated	Proper use of fume hood and biosafety cabinet		
		How to locate and use MSDS/SDS		
		Function and proper use of various types of PPE	Demonstrate appropriate use of PPE for a given situation	
		How to locate and use MSDS/SDS		
	Safe use of lasers, high voltage, radiological equipment, etc. is demonstrated	How to locate and use equipment instructions and other safety information sources		Demonstrate appropriate safe use of such equipment for a given situation
Maintain a safe, clean, contamination-free, and clutter-free environment, as appropriate	Workspace is cleaned before and after use	Nature of contamination, and the principles of containment, sterilization (e.g. CIP/SIP), and disinfection	Demonstrate appropriate workspace cleaning procedure	

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	Good housekeeping practices using tools such as 5S (sort, straighten, shine, standardize, sustain) and visual workplace philosophy are correctly applied	Tools used for good housekeeping such as 5S and visual workplace	During each lab period, maintain an organized work space to minimize clutter and remove unessential objects
	Line clearance prior to activity is demonstrated	Principles and purpose of line clearance	Pre-clean as appropriate and remove/ put back all materials, supplies, equipment, etc. not needed for the production run
	Environmental monitoring activities are performed	Use of particle counter, air sampler, basic microbiology monitoring/test methods, etc	Demonstrate basic environmental monitoring techniques: 1 Perform air sampling and particulate counting in the clean area/ room; 2 Perform surface swab of cleaned spaces (e.g. work bench), and identify microbial contaminant(s) [simulated scenario]; 3 Describe appropriate response(s) if contamination (particles and/or microbes) are discovered
		Actions to take when nonconformances are identified	
		ISO, US, and European standards for clean room settings	
Appropriate gowning procedure and clean room behavior	Demonstrate proper gowning procedure in a simulated ante and clean rooms layout Identify desirable and undesirable behaviors in a video of people working in a clean room/area, and explain why		
Select appropriate PPE to use to protect self from biological, chemical, and/or physical hazards	Different types of PPE are identified and their functions are described	Function and proper use of various types of PPE	Select appropriate PPE for given scenarios
Participate in appropriate business philosophies as defined and established	Business philosophy principles and concepts (lean, six sigma, Kaizen, etc) are applied correctly	Lean, Six Sigma, and Kaizen concepts	Based on a scenario, use business philosophies to identify where they can be applied
Conduct job functions appropriately, consistently and accurately		Importance of procedures and underlying regulatory ramifications	Follow a given procedure (ex. SOP)
		Consequences of non-compliances	Follow a given procedure (ex. SOP)
Recognize inappropriate work environment and take corrective and/or preventive actions	Different types of inappropriate work environments (temperature, humidity, lighting, noise level, particulates, etc) are identified	ISO, US, and European standards for work environments	Recognize inappropriate work environments based on given scenarios (eg. data, picture of leak, etc)

CWF - PROVIDE ROUTINE FACILITY SUPPORT

Key Activity	Performance Indicators	Underlying Knowledge	Assessments
Monitor, maintain, troubleshoot/repair equipment	Preventive maintenance is performed as specified	Maintenance requirements of different pieces of equipment	Assign equipment to students to monitor, maintain, and troubleshoot, and to properly document such efforts in the equipment log book
	Monitoring activities are performed and documented according to established procedures	Proper data collection and documentation procedures (Equipment logbook, SOP's, process specifications, and other technical documents)	Scenario: Describe a specific piece of equipment that is not working. Have students access users manual and list reasons why equipment is not working.
	Basic equipment troubleshooting is performed	How to use equipment user manuals and/or how to contact manufacturer for help	
Use equipment correctly according to manufacturer's guidelines	Equipment performance is verified prior to use	Calibration, qualification, verification, and validation and the differences among them	Describe/show what must be considered or done prior to use of a particular piece of equipment
	Recommended operating conditions of the equipment is used	General principles of metrology	Select appropriate measurement or calibration device for required process
	Initialization and shutdown of equipment is performed correctly	Use of (inter)national calibration standards and traceability	Properly perform calibration on a piece of equipment
Maintain inventory of raw materials, parts, components and/or equipment	Periodic inventory of stock/supplies taken in compliance with established procedures	Inventory control principles and rules for ordering, e.g. first in first out (FIFO)	Answer real-world questions about reordering based on a materials database and inventory procedure set up for a mock company
	Materials, parts, and equipment are stored appropriately	Storage considerations of materials, interpretation of the MSDS/ SDS	Demonstrate materials storage per MSDS/SDS
	Expired materials, parts, and equipment are discarded according to established procedures		Perform an inventory of materials, parts, and equipment, and explain what the next steps should be (e.g. (re)ordering, obsoleting, discarding expired, etc.) based on the inventory results
	Materials are identified to ensure traceability	Lot traceability, Bar coding, QR, and labeling systems	Apply traceability techniques using the system available in the lab
Prepare materials/supplies/equipment for use	Correct selection and quantity of necessary materials/supplies/equipment for the activity is gathered and prepared for use	Proper preparation procedures for materials/supplies/equipment	Demonstrate the necessary set-up to run a particular test/assay, or use of a piece of equipment.
Conduct root cause analysis	Minor equipment failures are identified and corrected	Troubleshooting techniques	Scenario: Given a particular product or process that has failed, investigate to determine possible causes (or the root cause, if possible)
		Conditions that cause equipment to go out of calibration	Given a scenario, identify conditions that caused equipment to go out of calibration
		Root cause analysis tools (fishbone, 5 Why's,)	Given a scenario, conduct root cause analysis using appropriate tool
Use proper cleaning procedure for work areas	Work area maintenance is performed appropriately and documented, including clean rooms if appropriate	Proper gowning procedures	Demonstrate clean room gowning
		Disinfectants, cleaning methods, environmental monitoring methods	Demonstrate cleaning procedures appropriate for the work area
		Documentation of cleaning inspection	Use check-off list to demonstrate proper cleaning
Follow waste management procedures	Materials are discarded according to established procedures	Classification of materials and proper disposal including toxic/ hazardous waste	Demonstrate safe disposal procedures for given scenarios and materials

CWF - PERFORM MEASUREMENTS/ TESTS/ ASSAYS

Key Activity	Performance Indicators	Underlying Knowledge	Assessments
Collect samples according to established procedures and applicable sampling plans	Samples are collected according to established procedures for testing purpose	Sampling procedures for material/product	Scenario: You are responsible for in-process (or raw material or final product) testing for a production run. The run has been simulated for you. Demonstrate collection, preparation, labeling and storage of samples for testing according to the in-process (or raw material or final product) testing procedure (provided).
		Statistical sampling plans to be followed for testing	
		Chain of custody requirements for samples	
Prepare samples according to established procedures	Samples are prepared (if required) according to established procedures for testing purpose	Sample preparation procedures	
Label samples properly for identification and traceability, including raw materials, inprocess samples and finished goods	Samples are labeled according to established procedures for testing purpose	Labeling procedures	
Store samples properly, including raw materials, inprocess samples and finished goods	Samples are stored according to established procedures for testing purpose	Storage procedures and conditions appropriate for the sample	
Follow appropriate test procedures/instructions	Test(s) are performed according to established procedures	Relevant measurement range and sensitivity of different tools	Given specification and tolerance, select correct tool
		Recognize and distinguish between types and causes of measurement error	Demonstrate use of selected tool to make measurement
			Identify abnormal results; identify source of the abnormal results
		Distinction between accuracy and precision	Use class data to determine accuracy and precision
		Reflect on accuracy and precision of each tool choice available	
	Appropriate measurement/test tool(s) is(are) chosen for the application	Relevant measurement range and resolution of different tools	
	Uncertainty in measurement		
Measurement/test tool(s) is(are) used correctly			
Document data & results according to established procedures	Documentation is maintained properly	Format and function of different document types (eg. lab notebooks, batch records, SOP's, protocols, forms, etc.)	Create portfolio of documentation examples including lab notebooks, batch records, SOP's, protocols, forms, etc.
	Batch records and forms are completed properly	Good documentation practices including electronic records	Create portfolio of documentation examples including lab notebooks, batch records, SOP's, protocols, forms, etc.
	Information is entered and verified correctly in final format (lab notebook, electronic database, etc)	Data entry methods acceptable for document type	Demonstrate entering and verification of collected data set
Interpret and/or analyze data & results as appropriate	Test-specific mathematical calculations are performed	Principles of descriptive statistics (mean, median, mode, standard deviation, range, linear regression)	Demonstrate data processing and presentation through a laboratory activity.
	Data & results are presented in an appropriate manner	Creation and interpretation of graphs, tables, etc.; Familiarity with graphing software	Develop a report from a given set of data

CWF - COMPLY WITH APPLICABLE REGULATIONS AND STANDARDS

Key Activity	Performance Indicators	Underlying Knowledge	Assessments	
Follow established policies and procedures	GXP's (Good Manufacturing, Laboratory, and Documentation Practices) are executed correctly and completely	Knowledge of applicable sections of 21 CFR 820 and ISO 13485; Familiarity with applicable current federal, state, local and industry regulations and standards, Quality Management Systems (QMS), key elements of QS, roles of mgmt and workers in a quality system, role of procedures	Exam questions around What is the basic structure of the quality system and what are the responsibilities of the individuals in the company	
		Applicable websites containing current industry regulations and standards	Navigate applicable medical device related databases to find 510 K's, adverse event reports, etc. in response to a case study	
		Consequences of noncompliance (impacts on operations, company customers, FDA - 483s, warning letters, field actions, and other enforcement actions)	Research 483s, warning letters, etc. in response to a case study	
	Deviations are handled appropriately	Policy/procedures for deviations	Given a scenario in which a technician executing an established procedure encounters a need for a deviation from the procedure, describe what must be done in order for the deviation to be allowed and executed	
	Necessity for and fundamentals of regulations are understood	FDA - history including enacted laws/promulgated regulations, organizational structure, premarket approvals	FDA organizational structure	Identify landmark events that brought about regulatory laws
			Regulatory submissions (premarket approvals (PMA), premarket notifications (510k))	Draw an organizational chart showing the divisions of the FDA and how they are related
		Classifications of Medical Devices (Class I, Class II and Class III)	Given a scenario, identify which submission is appropriate	
		Classifications of Medical Devices (Class I, Class II and Class III)	Given a variety of devices, research and determine the classification of each	
	Knowledge of appropriate regulatory expectations is demonstrated	Quality manual, including the quality policy, standard operating procedures, work instructions	Given a regulation (ISO 1345 and 21 CFR 820), highlight the key pieces that would need to be in our quality manual; what procedures would you then need?	
		Industry Standard Operations (ISO): ISO 14971 (Environmental Management and ISO 13485 (Medical Device Quality Management), ISO 15189 (GLP's) 21 CFR 820, MDD (ISO 9001: 2015 TBD)	Create outline of applicable regulations (see underlying knowledge) and Identify when apply & scope	
Record information according to established procedures	Good documentation practices are demonstrated	Types of records [lab notebooks, batch records, logs, Design History Files (DHF), Device History Record (DHR), Device Master Record (DMR), production records, etc.], their purposes and how to properly complete each type	Correctly and completely fill out various types of records, including making corrections correctly (crossing out error with a single line through, writing the correct entry adjacent to the error, and adding initials and date)	
Exercise proper document control	Documents are managed according to proper document control, including using proper change control systems to make changes in documents	Knowledge of applicable sections of 21 CFR 820 and ISO 13485	Demonstrate, using a revised controlled document and change control procedures [provided as props], how the document becomes effective, and once it does, describe what must be done to ensure the previous version does not get used inadvertently.	
		Concepts related to document changes, approvals, and distribution of documents		
Participate in required training	Required training is completed by the specified deadline and competencies are demonstrated	Formal training process (training matrix; training policies in effect; re-training frequencies; consequences of missed (re)training deadlines) and mandatory requirements in regulations/standards	Give student assignment to "attend" an on-line training then test over that training topic; describe why training is important	
Respond to audit-related activities	Knowledge of position-specific role in the audit process is demonstrated	Types of audits	Test question: Describe different types of audits	
		The audit process	Participate in mock audit (Demonstrate appropriate behaviors during a mock audit with role playing)	
		Role of various positions during audits		
		What to include and not include in a response during an audit interview, Appropriate responses		
Adhere to control principles in accordance with the established quality system	Knowledge of change control is demonstrated	General change control philosophy; potential consequences that may arise when change is not controlled	Explain what is meant by change control. In your explanation, describe the key benefits as well as the consequences of not following change control	
	Knowledge of design control is demonstrated	Design control philosophy; relationships among customer requirements, company specifications, design inputs and outputs, design reviews, design verification, and design validation Applicable sections of 21CFR820 and ISO 13485 covering design control including Design History File (DHF);	Scenario: Your company is approached by its best customer about designing an improved version of the product that you currently manufacture. Describe what design control steps an engineer would take the customer's requirements and design a new and improved product that meets the requirements and fulfills its intended use.	

CWF - COMPLY WITH APPLICABLE REGULATIONS AND STANDARDS

Key Activity	Performance Indicators	Underlying Knowledge	Assessments
	Knowledge of purchasing control is demonstrated	Supplier relationships; supplier agreements; supplier qualifications; supplier management; supply chain management; purchasing documentation, traceability, and approvals Applicable sections of 21CFR820 and ISO 13485 covering supplier approval, raw material specifications, purchase orders	Scenario: Personnel in the purchasing department reports that supplier for raw material X will discontinue production as of later date. An alternate source for X has been identified. What steps need to be taken with regard to purchasing in order to comply with the company's quality system?
	Knowledge of production & process control is demonstrated	General philosophy with consideration of materials, methods, machine, man, and environment; monitoring program; material control and traceability; established procedures and compliance with them; equipment monitoring, inspection, maintenance, and repair; personnel with appropriate and current training; facility and environmental control for product/process quality/consistency Applicable sections of 21CFR820 and ISO 13485 covering control of production and production-related processes	Design a cGMP facility that enables appropriate work flow
	Knowledge of labeling & packaging control is demonstrated	Label integrity, appropriate label information content, inspection of labeling, storage and controlled issuance for use, packaging selection considerations Applicable sections of 21CFR820 and ISO 13485 covering key elements of labeling and packaging control	Scenario: You are assigned to execute a production run for a batch of 5,000. Materials has issued you 5,050 labels (per labeling policy). At the conclusion of the production run, you have made 5,003 units and you have 39 labels remaining. What are your obligations to close out this production run?
	Knowledge of environmental control is demonstrated	Work environment requirements for product consistency, how to enter and work in special work environments, safety concerns Applicable sections of 21CFR820 and ISO 13485 covering controlled environments, PPE, Hazmat, clean room gowning, clean room behavior, gowning verification	Students participate in gowning training; verification via plating if possible; while gowned, students perform cleaning and verification of cleaning activity as well as environmental monitoring activities
	Knowledge of management controls is demonstrated	Management responsibility for operations, including production, quality, continuous improvement, resources, and customer satisfaction Applicable sections of 21CFR820 and ISO 13485 covering management review, authority, delegation, quality management representative, provision of resources	Students are given a scenario in which a manager is facing an issue within the company. Students will be asked to write a paragraph indicating how the manager should respond and act to the issue in accordance with applicable regulations
	Knowledge of materials management / control is demonstrated	Incoming raw materials handling (quarantine, acceptance or rejection after inspection/QC testing, storage for use or disposition of rejected material), FIFO (first in first out), inventory, purchasing Applicable sections of 21CFR820 and ISO 13485 covering control of materials	According to 21CFR820 and ISO 13485, what should be done to properly manage materials (raw materials, in-process materials, and finished goods)?
Adhere to traceability principles	Items (e.g. raw materials, in-process product, final product, samples, etc.) are labeled appropriately and lot numbers are recorded	Concept and importance of traceability within the medical device workplace; traceability of materials, documentation, and training Device History Record (DHR), Device Master Record (DMR), Manufacturing Process--BOM (Bill of Materials); Product status, label elements, key items on the label, minimum label requirements, lot # part #, status, equipment identification	Compliance review a completed batch record for lot numbers and equipment ID numbers (record can be a prop, or one filled out by another student). Describe the information that must be tracked in order to trace a material from receiving all the way through to delivery to the customer
Participate in validation activities	Draft procedure is tested according to validation protocol and feedback to author is provided	Types of validation: equipment (Installation Qualification, Operational Qualification, Process Qualification), methods, validation protocol, protocol deviations, documentation	Students test simple devices while following validation protocols (PQ), or students set up a small device (microwave) and see if works (IQ), or set equipment across range to see where get best results (OQ) or describe the IQ, OQ, and PQ of a new piece of equipment purchased for manufacturing

CWF - COMPLY WITH APPLICABLE REGULATIONS AND STANDARDS

Key Activity	Performance Indicators	Underlying Knowledge	Assessments
Recognize and address nonconformances	Appropriate corrective and/or preventive action(s) is(are) taken and documented	Investigating a nonconformance, risk review, material review board, containment, correction, CAPA, root cause	Scenario: Manufacture of device [use given procedure] Part 1: Does this device pass or fail QC check? [provide props; fail due to not meeting spec = nonconformance] Part 2: You have been assigned to investigate. Describe the process for your investigation, including all possible causes. [intent is root cause analysis] Part 3: How would you go about eliminating each of the possible causes? Part 4: The root cause was determined to be a raw material. [Specifically, the raw material was released without proper review/testing. This event triggered an internal audit.]
Understand risk management principles	Patient risk factors associated with the employee's work are understood Unforeseen risks are identified and communicated appropriately Risk mitigation activities are supported as requested	ISO 14971 (Medical Device Risk Management), different risk assessment tools, FMEA (Failure Mode Effects Analysis), and 3x3 matrix (acceptability criteria)	Consider an insulin pump. Identify and describe/assess risks related to: the materials used to manufacture it; the production processes used; the equipment used in manufacturing; the end user? For each risk identified, provide ways that the risk can be mitigated.
Understand the principles of post market surveillance	Recalls, complaints, and MDR's are supported as requested	Purpose and requirements of the post market surveillance system Applicable standards and regulations 21 CFR 7, 803, 806 and 820 and ISO 13485	Describe the benefits of participating in post market surveillance. Provide specific examples of surveillance-related benefits.

CWF - MANAGE AND COMMUNICATE INFORMATION

Key Activity	Performance Indicators	Underlying Knowledge	Assessments
Comply with company communication policies	Consequence of noncompliance with communication policies are explained	Purpose of nondisclosure agreements, Sunshine act, interactions with healthcare professionals	Given a scenario (e.g. production run that spans two shifts and several days; or a set of lab tests that span two shifts and multiple days) and a necessary change in workflow, students shall take the role of a shift leader and draft an e-mail communicating the appropriate details about the workflow change and a proposal to the other shift and leader regarding how the two shifts can work together to accomplish the newly assigned task.
		Typical company specific communication policies (e.g. nondisclosure agreements, quality policies, mission/vision statements, HR policies, EH&S policies, etc.)	
		Social, legal and ethical issues relating to information and its use and labeling	
Communicate information in an appropriate manner	Proper communication method is chosen and used (e.g. formal reports, memos, e-mail, etc.)	Types of communication methods (e-mail, word processing, etc) and their best uses	Give students information they need to communicate and tell with whom they need to share the information. Students must then identify the best way to communicate that information and develop a mock communication (e-mail, word processing, etc)
		Safety and security of communication; permanent nature of documented communication; need for accurate and complete records in permanent communication	Early in the semester, teach students a procedure and have them write down how to complete that procedure. At the end of the semester, have them perform the same procedure only using their notes.
		Appropriate and inappropriate styles and content for all correspondence	Given an example of internal communication, have students respond appropriately and/or critique it
Assist in reviewing/commenting, revising, and writing technical documents	Errors in technical documents are recognized and appropriate changes are suggested	Required components and format of technical documents	Students each write a technical document (SOP, report, WID, or other document) and exchange within the class for peer review and revision
Suggest continuous improvements	Inefficiencies are recognized and appropriate action is taken	5S, mistake proofing	Peer review technical documents or, when given an inefficient document, identify where improvements can be made
		Appropriate applications of technical documents	
Use computer tools effectively	Basic word processing tasks are performed	Basic features of word processing applications	Choose any type of assignment and have students match the required specifications (e.g. margins, page layout, headers/footers, font type, font size, acceptable use of bold/italic, etc)
		Spreadsheet software is used	Given data from a test/production run, use spreadsheet software to create a table to display the data in a clear and understandable manner, plot the data using an appropriate graphing method, and calculate average, standard deviation, and CV for the data set as directed
	Different types of graphs and the scope of use of each type		
	Different functions available for formulas		
	Presentations are created	Basic features of presentation applications	
		Characteristics of effective presentations	
	Access online information		Use of search engines with effective search criteria
Other workplace-relevant software applications are navigated proficiently		Usage and purpose of <hub-specific> or position-specific applications	

CWF - PERFORM MATHEMATICAL MANIPULATIONS

Key Activity	Performance Indicators	Underlying Knowledge	Assessments
Perform calculations relating to work function	Basic manipulations involving exponents are performed correctly	Basic mathematical concepts involving exponents	Perform calculations involving exponents
	Significant figures, when taking and rounding measurements, are used correctly	Proficiency in the concept of significant figures	Identify significant figures with measurements and record correctly according to measurement requirements
	Conversions between standard and scientific notation are performed correctly	Expression of values in different formats and why	Convert data between standard form and scientific-notation correctly.
	Calculations of logs and antilogs for powers of ten are performed correctly	Difference between logs and antilogs for power of ten	Can perform sample problems
	Conversions between proportions, decimals, percentages, fractions, and ratios (including dilutions) (e.g. $C_1V_1 = C_2V_2$ equation) are applied correctly	Basic mathematical concepts involving proportions, decimals, percentages, fractions, and ratios	Perform calculations involving conversions
		Relationship between variables in an equation	Predict the change correctly based on the relationship between variables in an equation
	Conversions between units of measure (e.g. within the metric system and between metric and US systems) are performed correctly	Metric system and common prefixes, US system, and conversion factors between related units of measure	Convert measurements between metric and US systems correctly
Perform data analysis	Data is correctly analyzed using descriptive statistical functions	Purpose of various statistical functions, such as mean, mode, standard deviation, coefficient of variation, chi squared tests and r^2 values	For measurements of samples taken from a variety of production lots, calculate the mean and standard deviation for the samples from each lot.
	Data is graphed using the appropriate graphing method	Appropriate application of graphs and charts	Graph data using appropriate chart
		Standard curve principles	
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