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| **Should This LITTLE Drug Go to Market?** | |
| **Introduction** | |
| The quality control team is a group of individuals, at a specific company, who are responsible for making sure all products are tested and deemed safe before release. Students will take on the role of the quality control team through this curriculum. Students will apply their knowledge of physical and chemical characteristics to test a “drug” for safety before it is released to market. After testing, students will apply their knowledge of the drug development process to create a standard operation of protocol (SOP), so others can make the drug. Through this process, students will learn the importance of communication (verbal and written), team work, collaboration, maintaining controls and documentation. Students will also develop a deeper understanding of the biotechnology industry, what it is, who works there, and how this can be part of their future. | |
| **Learning Outcomes** | |
| * Students will evaluate materials, using physical and chemical tests, to determine if the material can be used in the drug manufacturing process * Students will recommend a drug for release based on physical and chemical characteristics identified through testing * Students will explain the need for controls during the biotechnology drug development and manufacturing process through the completion of a written lab conclusion * Students will generate a scientific procedure that can be used to manufacture a new drug using the engineering design process * Students will recognize the job opportunities available in the biotech industry, and the education needed to obtain those jobs | |
| **Curriculum Alignment** | |
| **Science**   * *6.P.2*-Understand the structure, classifications and physical properties of matter * *6.P.2.3*-Compare the physical properties of pure substances that are independent of the amount of matter present including density, melting point, boiling point and solubility to properties that are dependent on the amount of matter present to include volume, mass and weight * *6.P.3-*Understand characteristics of energy transfer and interactions of matter and energy   **Math**   * *6.SP.5*-Summarize numerical data sets in relation to their context * *6.EE.9-*Use variables to represent two quantities in a real-world problem that change in relationship to one another * *6.RP.A.3*-Use ratio and rate reasoning to solve real-world and mathematical problems * *MP.1*-Make sense of problems and persevere in solving them * *MP.2*-Reason abstractly and quantitatively * *MP.5*-Use appropriate tools strategicall*y*   **Social Studies**   * *6.H.2*-Understand the political, economic and/or social significance of historical events, issues, individuals and cultural groups. * 6.E.1.2-Explain how quality of life is impacted by economic choices of civilizations, societies, and regions.   **Exploring Biotechnology**   * *EB02*-Analyze the language and math of biotechnology. * *EB04.01*-Discuss the nature of science, scientific inquiry and problem solving. * *EB06*-Analyze biotechnology in health care. * *EB9*-Analyze ethical and professional standards in health care and biotechnology. * *EB10*-Analyze careers in biotechnology, bioinformatics, biomanufacturing, agriculture and health care**.**   **Common Core Reading**   * *RST.2*-Determine the central ideas or conclusions of a text; provide an accurate summary of the text distinct from prior knowledge or opinions * *RST.3*-Follow precisely a multistep procedure when carrying out experiments, taking measurements, or performing technical tasks * *RST.4*-Determine the meaning of symbols, key terms, and other domain-specific words and phrases as they are used in a specific scientific or technical context relevant to grades 6–8 texts and topics * *RST.9*-Compare and contrast the information gained from experiments, simulations, video, or multimedia sources with that gained from reading a text on the same topic   **Common Core Writing**   * *WHST.2*-Write informative/explanatory texts, including the narration of historical events, scientific procedures/ experiments, or technical processes * *WHST.4-*Produce clear and coherent writing in which the development, organization, and style are appropriate to task, purpose, and audience * *WHST.5*-With some guidance and support from peers and adults, develop and strengthen writing as needed by planning, revising, editing, rewriting, or trying a new approach, focusing on how well purpose and audience have been addressed * *WHST.9*-Draw evidence from informational texts to support analysis, reflection, and research   **North Carolina Evaluation Standards**   * *Standard 1A-*Teachers lead in their classroom * *Standard 2A*-Teachers provide an environment in which each child has a positive, nurturing relationship with caring adults * *Standard 2B-*Teachers embrace diversity in the school community and in the world * *Standard 2C*-Teachers treat students as individuals * *Standard 3A*-Teachers align their instruction with the *North Carolina Standard Course of Study* * *Standard 3B-*Teachers know the content appropriate to their teaching specialty * *Standard 3C-*Teachers recognize the interconnectedness of content areas/disciplines * *Standard 3D* Teachers make instruction relevant to students * *Standard 4C*-Teachers use a variety of instructional methods * *Standard 4D*-Teachers integrate and utilize technology in their instruction * *Standard 4E-*Teachers help students develop critical thinking and problem‐solving skills * *Standard 4F-*Teachers help students work in teams and develop leadership qualities * *Standard 4H-*Teachers use a variety of methods to assess what each student has learned | |
| **Critical Vocabulary\*** | |
| * **Biotechnology** - The use of living organisms to solve problems and make useful products | |
| * **Quality Control (QC)** - A system to achieve or maintain the desired level of quality in a manufacturing process by inspecting the raw materials and samples at various stages of the process, as well as monitoring the process, so problems can be solved | |
| * **Standard Operation of Protocol (SOP)** - A document that defines, in detail, every step of only one particular process so it can be performed exactly the same way every time | |
| * **Good Manufacturing Practices (GMP)** - A set of minimum standards enforced by the Food and Drug Administration to ensure the safety and purity of drug products manufactured in the United States | |
| * **Good Documentation Practices (GDP)** -The standard to which documents should be created and maintained | |
| * **Certificate of Analysis (C of A)** –A certificate that ensures the quality and purity of a drug substance | |
| * **Chromatography** - A technique that separates mixtures to identify their components | |
| * **Solubility** - The ability of a substance to dissolve | |
| * **pH** - The measure of how acidic or basic a substance is, with 0 being the most acidic and 14 the most basic | |
| * **Solution** - A mixture of solute and solvent | |
| * **Dissolve** -A solid absorbed in liquid, to make a solution | |
| * **Solute** - The substance being dissolved | |
| * **Solvent** - The substance in which the solute is dissolved | |
| * **Assay** - Method for determining the presence or quantity of a component | |
| * **Performer** -The person running the assay or following the standard operation of protocol | |
| * **Verifier** -The person observing the performer, to make sure the standard operation of protocol is followed | |
| * **Purity** - a quantitative assessment of uniformity | |
| * **Bioassay** - A method of determining the action of a compound by quantifying its effect on living organisms or their component parts | |
| * **Clinical Trial** - A research study designed to answer specific questions about vaccines or new therapies or new ways of using known treatments by testing them in humans | |
| * **Food and Drug Administration (FDA)** - The agency of the U.S. Department of Health and Human Services that regulates the testing of experimental drugs and approves new drugs and medical products based on evidence of their safety and efficacy | |
| * **Virus-** A small infectious agent that can replicate only inside the living cells of an organism | |
| * **Potency-** strength of medicine | |
| * **CV-** (ANTIVIRAL CPE ASSAY OF INTERFERON BETA-1a USING A549 CELLS )test is designed to measure how much a product is protecting the patient from the virus | |
| *\*Definitions abbreviated from:* [*http://www.ncbiotech.org/biotech-basics/what-is-biotechnology/biotech-glossary*](http://www.ncbiotech.org/biotech-basics/what-is-biotechnology/biotech-glossary) | |
| **Classroom Time Required** | |
| **Seven Days\***   * *Day One and Two:* Pre assessment, Engage and Explore * *Day Three and Four*: Explain * *Day Five and Six*: Elaborate and Evaluation, post assessment * *Day Seven*: Scientific debate (extension)   *\*Time will vary based on classroom environment and students prior knowledge* | |
| **Materials Needed** | |
| **Teacher Materials** | **Student Materials** |
| *Pre Activities* | *Pre Activities* |
| * Pre assessment answer key | * [Pre Assessment](file:///C:\Users\kctucker\AppData\Local\Curriculum%20Resources\Pre%20Test.docx) |
| * Tic Tacs | * [Mapping your future: Exploring Careers in Biomanufacturing Section II D-F Article](file:///C:\Users\kctucker\AppData\Local\Articles\careersInBiomanufacturing.pdf) |
| * Water | * Dictionary |
| * [ABC News Tylenol Recall clip](http://abcnews.go.com/WNT/video/big-tylenol-recall-bigger-9581228) | * [Discussion Group Assignments](file:///C:\Users\kctucker\AppData\Local\Discussion%20Group%20Resources\Discussion%20Group%20Assignments.docx) |
|  | * + [Word Detective](file:///C:\Users\kctucker\AppData\Local\Discussion%20Group%20Resources\Word%20Detective.docx) |
|  | * + [Illustrator](file:///C:\Users\kctucker\AppData\Local\Discussion%20Group%20Resources\Illustrator.docx) |
|  | * + [Bridge Builder](file:///C:\Users\kctucker\AppData\Local\Discussion%20Group%20Resources\Bridge%20Builder.docx) |
|  | * + [Discussion Director](file:///C:\Users\kctucker\AppData\Local\Discussion%20Group%20Resources\Discussion%20Director.docx) |
|  | * [Two Column Notes](file:///C:\Users\kctucker\AppData\Local\Curriculum%20Resources\Two%20Column%20Notes.docx) |
|  | * [Two Column Notes-Modified](file:///C:\Users\kctucker\AppData\Local\Curriculum%20Resources\Two%20Column%20Notes-modified.docx) |
| *Microbiology Lab* | *Microbiology Lab* |
| * Two packages of Grape Kool-Aid | * Prepared Kool-Aid samples and mixtures |
| * One package of Lemon Lime Kool-Aid | * Coffee Filers |
| * Small sealable containers or bottles for each Kool-Aid Sample | * Distilled Water |
| * Tap Water | * 25mL graduated cylinder\* |
| * 25mL graduated cylinder\* | * 100mL beaker\* |
| * [Chromatography SOP Teacher Guide](file:///C:\Users\kctucker\AppData\Local\Chromotography%20Experiment\Chromatography%20SOP%20Teacher%20Guide.docx) | * Ruler |
| * Labels | * Cotton swab |
|  | * Pencil |
|  | * Calculator |
|  | * [Paper Chromatography SOP](file:///C:\Users\kctucker\AppData\Local\Chromotography%20Experiment\Paper%20Chromatography%20SOP.docx) |
|  | * [Paper Chromatography Test Form](file:///C:\Users\kctucker\AppData\Local\Chromotography%20Experiment\Paper%20Chromatography%20Testing%20Form.docx) |
| *Bioassay Lab* | *Bioassay Lab* |
| * Distilled Water | * 1 Permanent marker |
| * Stirring rod | * Pipettes |
| * 200mL volumetric flask | * GrapeX prepared sample |
| * Small sealable containers for sample (2) | * [CV plate picture](file:///\\M0592sfs01\Home$\Staff\elawrence3\My%20Documents\Dropbox\Kenan%20Fellows%20Curriculum%20Project\Bioassay%20Group\CV%20Assay%20Plate%20Results.docx) |
| * [Bioassay SOP Teacher Guide](file:///C:\Users\kctucker\AppData\Local\Bioassay%20Experiment\BioAssayR%20SOP%20Teacher%20Guide.docx) | * PLA Plate Readings   + [PLA Plate 1 Analyst 1 Left](file:///C:\Users\kctucker\AppData\Local\Bioassay%20Experiment\PLA%20Plate%201%20Analyst%201%20Left.pdf)   + [PLA Plate 1 Analyst 1 Right](file:///C:\Users\kctucker\AppData\Local\Bioassay%20Experiment\PLA%20Plate%201%20Analyst%201%20Right.pdf)   + [PLA Plate 1 Analyst 2 Left](file:///C:\Users\kctucker\AppData\Local\Bioassay%20Experiment\PLA%20Plate%201%20Analyst%202%20Left.pdf)   + [PLA Plate 1 Analyst 2 Right](file:///C:\Users\kctucker\AppData\Local\Bioassay%20Experiment\PLA%20Plate%201%20Analyst%202%20Right.pdf) |
| * Labels | * [SD Bioassay SOP](file:///C:\Users\kctucker\AppData\Local\Bioassay%20Experiment\SD%20Bioassay%20SOP.docx) |
| * Grape Kool-Aid powder mix | * [CV Bioassay SOP](file:///C:\Users\kctucker\AppData\Local\Bioassay%20Experiment\CV%20Bioassay%20SOP.docx) |
|  | * [Bioassay Test Form](file:///C:\Users\kctucker\AppData\Local\Bioassay%20Experiment\BioAssay%20Test%20Form.docx) |
|  | * Calculator |
|  | * 25mL graduated cylinder |
|  | * 5 test tubes |
|  | * Test tube rack |
| *Sample Control Lab* | *Sample Control Lab* |
| * Grape Kool-Aid | * Active Ingredient #1 (Kool-Aid) |
| * Grape Jell-O | * Active Ingredient #2 (Jell-O) |
| * Water | * GrapeX Solution (Water) |
| * [Sample Control SOP Teacher Guide](file:///C:\Users\kctucker\AppData\Local\Sample%20Control%20Group\Sample%20Control%20SOP%20Teacher%20Guide.docx) | * Hot plate or crock pot (access to warm water) |
| * Labels | * Oven mit |
|  | * Ice |
|  | * 3-100mL beakers\* |
|  | * 25mL graduated cylinder\* |
|  | * Thermometer |
|  | * Stirring rod |
|  | * Stop watch or clock with a second hand |
|  | * Electronic balance or triple beam balance |
|  | * [Sample Control SOP](file:///C:\Users\kctucker\AppData\Local\Sample%20Control%20Group\Sample%20Control%20SOP.docx) |
|  | * [Sample Control Test Form](file:///C:\Users\kctucker\AppData\Local\Sample%20Control%20Group\Sample%20ControlTesting%20Form.docx) |
| *Chemistry Lab* | *Chemistry Lab* |
| * Kool-Aid Powder Mix **WITH** sugar added | * pH test strips |
| * Kool-Aid Powder Mix **WITHOUT** sugar added | * pH chart |
| * Ziploc bags | * 25mL beaker\* |
| * Electronic balance | * Petri dish or watch glass |
| * Labels | * Cotton swabs |
| * [Physical Characteristics SOP Teacher Guide](file:///C:\Users\kctucker\AppData\Local\Chemistry%20Experiment\Physical%20Characterisitc%20SOP%20Teacher%20Guide.docx) | * 10mL graduated cylinder\* |
|  | * [Glucose test strips](http://www.flinnsci.com/store/Scripts/prodView.asp?idproduct=21528) |
|  | * Glucose concentration chart |
|  | * Electronic balance |
|  | * Tap water |
|  | * Magnifying glass |
|  | * Popsicle sticks |
|  | * Thermometer |
|  | * Paper towel |
|  | * Grape Kool-Aid powder mix with sugar added |
|  | * Grape Kool-Aid powder mix without sugar added |
|  | * [pH SOP](file:///C:\Users\kctucker\AppData\Local\Chemistry%20Experiment\pH%20SOP.docx) |
|  | * [Glucose SOP](file:///C:\Users\kctucker\AppData\Local\Chemistry%20Experiment\Glucose%20SOP.docx) |
|  | * [Physical Characteristics SOP](file:///C:\Users\kctucker\AppData\Local\Chemistry%20Experiment\Physical%20Characteristic%20SOP.docx) |
|  | * [Physical Characteristics Test Form](file:///C:\Users\kctucker\AppData\Local\Chemistry%20Experiment\Physical%20Test%20Testing%20Form.docx) |
| *Post Activities* | *Post Activities* |
| * [Post assessment answer key](file:///C:\Users\kctucker\AppData\Local\Curriculum%20Resources\Post%20Assessment.docx) | * [Post assessment](file:///C:\Users\kctucker\AppData\Local\Curriculum%20Resources\Post%20Assessment.docx) |
| * [SOP Rubric](file:///C:\Users\kctucker\AppData\Local\Curriculum%20Resources\Writing%20an%20SOP%20Rubric.docx) | * [C of A worksheet](file:///C:\Users\kctucker\AppData\Local\Curriculum%20Resources\Certificate%20of%20Analysis.docx) |
| * Sugar-divide between groups | * [SOP handout](file:///C:\Users\kctucker\AppData\Local\Curriculum%20Resources\Writing%20an%20SOP.docx) |
|  | * Kool-Aid mix(not presweetened) |
|  | * Sugar |
|  | * Gallon container |
|  | * Large spoon |
|  | * Electronic balance |
|  | * Volumetric glassware (600mL beaker)\* |
| *\*Beaker and graduated cylinder sizes are a suggestion. If you have comparable volumetric glassware or measuring devices, substitutions can be made* | |
| **Pre Activities** | |
| Teacher Preparation | |
| * Please view each Teacher Guide, with the corresponding lab, for instructions on how to prepare for the lab * Copy/laminate [science cards](file:///C:\Users\kctucker\AppData\Local\Scientist%20Cards), which are used for grouping students during lab activities * The following documents need to be copied, one per student\*   + Biotechnology Pre Assessment   + Biotechnology Post Assessment   + Mapping your future: Exploring Careers in Biomanufacturing Section II C-F   + Writing a scientific argument (extension)   + Discussion Group Responsibilities * The following documents need to be copied, one per pair of students\*   + Paper Chromatography SOP   + Bioassay SOP   + Sample Control SOP   + Glucose SOP   + pH SOP   + Physical Characteristics SOP   + Chromatography Test Form   + Bioassay Test Form   + Sample Control Test Form   **\*NOTE**: How documents should be copied will change, based on grouping strategies. The recommendations included in the lesson are based on the grouping strategy mentioned in the **EXPLAIN** section of the lab.   * + Physical Characteristics Test Form * The following documents need to be copied, one per group of students\*   + Set of discussion group activities (word detective, bridge builder, illustrator, discussion director) * The following needs to be copied ONLY for the Bioassay group   + CV picture and set of PLA readings * Before completing the labs in the EXPLAIN section, please arrange your classroom to maximize students’ ability to work in groups of four (*i.e. for my classroom this would involve pushing two lab tables together to make a pod*). * Label each lab table as follows (total eight tables):   + Two tables with “Bioassay Group”   + Two tables with “Microbiology Group”   + Two tables with “Chemistry Group”   + Two tables with “Sample Control Group” * Place all items needed to complete the lab on a tray. Prepare one tray for each lab group, containing the appropriate materials to complete the lab. Having all materials on a tray makes it easier for students to obtain materials and clean up after the lab is complete | |
| Student Preparation/Prior Knowledge | |
| * Prior to completing this activity, students should understand the following concepts:   + Solubility   + Physical and chemical properties of matter   + Density   + How heat affects the motion of molecules   + Plug numbers into a formula and solve   + Metric units of measure (i.e. grams, liters, Celsius, meters) * Students should be able to perform the following tasks:   + Use an electronic balance   + Read a thermometer   + Use a calculator   + Use a stop watch   + Use and read volumetric glassware   + Known the science safety rules   + Use a disposable pipette   + Use a ruler | |
| **Warm Ups:** | |
| * Below are suggested warm up questions student can answer, before the class begins * Warm ups should take five minutes to answer   + *Day One:* Dig deep into that brain and pull out any knowledge you have on medicine. How is it made? Who makes it? What is its purpose? Record any other details you know about medicine.   + *Day Two*: In twelve words or less, summarize what you learned from yesterday’s activities.   + *Day Three*: Biotechnology is a big word. How would you explain its meaning to a second grader? Use words or pictures.   + *Day Four*: What was one big “aha” moment you had while working for the quality control department at The Shark Science Group?   + *Day Five*: Look back at your Two Column notes from our discussion, what do you remember about SOPs? What are they? What is their purpose? How are they written?   + *Day Six*: Explain the following statement, “If it is not written, it never happened”   + *Day Seven*: Think back to a time when you had an argument with a parent, sibling or friend. Did you win the argument? What made it a successful argument? Is there something you would have said differently? | |
| **Engage: Day One** | |
| * Have students complete the “Biotechnology Pre Assessment”   + *Make sure students know this assessment is not for a grade, but to measure comprehension*   + *Collect when students are completed* * Tell students: “I have a headache. *What do you recommend I do to cure my headache?”*    + Write student recommendations on the board   + Possible responses include: *Take pain reliever, take a nap, eat soup, drink soda, put a cold washcloth on your head, take Motrin, head to the doctor, etc.* * After listening to student responses, tell the students you like the suggestion of taking a pain reliever. Ask students *“How do you recommend I obtain and take the pain releiver?”*   + Write student recommendations on the board   + Possible responses include: *go to the medicine cabinet, head to the store to buy the pain releiver, take two tablets with water, swallow the liquid pain releiver, chew the chewable pain releiver tablets, etc.* * Using “a candy resembling a pain releiver, simulate taking themedicine per the student recommendation you select * Hand back the pre-assessments and have students grade each other’s pre assessments * Appear alarmed, tell students you remember hearing something on the news last night, regarding pain relievers * SHOWVIDEOCLIP: <http://abcnews.go.com/WNT/video/big-tylenol-recall-bigger-9581228>   + After watching the clip, ask the students “Do you think I just took bad Tylenol?” * State: Do you ever think the medicine or food you eat will be harmful to you?” Companies must ensure quality safety and integrity of their products; the group that does this is called the Quality Control department. Quality Control Departments are most known in Biotechnology companies, like Johnson and Johnson, who are responsible for developing drugs that help us when we are sick * Explaintostudents that later in the week you will take on the role of the Quality Control Department. You will have to test a drug for quality and impurities. | |
| **Explore: Day One to Two** | |
| * Hand out, “*Mapping your future: Exploring Careers in Biomanufacturing Section II D-F*” * Beforereading:   + Have students skim the article, focusing on pictures, titles, headings and highlighting key vocabulary they might not understand   + Ask students, “What do you think this article is about?”     - *Students should identify that this article is about the manufacturing process in biotechnology. The process is regulated to make sure patients and consumers stay safe. Reviews what is involved in the manufacturing process. Why does quality matter? The rules for maintaining quality. SOPs*   + Ask students, “What words stick out to you and could make this article confusing?”     - *Possible words include: Regulations, biopharmaceutical, pharmaceuticals, biotechnology, validation, predefined, specifications, synthesis, purification, and formulation*     - Take time to explain the meaning of the words students list. Have students write the meaning of the word in the margin of the article   + Ask students, “How has the author organized this article to make it easier for you to read?”     - *Headings, titles, pictures, bullets, font size, capital letters, indenting, numbering, bold lettering* * **During reading**:   + Have students read the article, as a class, through popcorn reading (or students can silently read).   + While reading have students highlight or mark areas that are confusing or require additional clarification * **After reading**:   + Answer any lingering questions students have developed from reading the article (the areas they highlighted)   + Complete the [Discussion Group Activity](file:///C:\Users\kctucker\AppData\Local\Discussion%20Group%20Assignments.docx)     - Students will work in groups of four     - Students should be grouped heterogeneously. For example:       * [*Bridge Builder*](file:///C:\Users\elawrenc\Dropbox\Kenan%20Fellows%20Curriculum%20Project\Discussion%20Group%20Resources\Bridge%20Builder.docx)*:* AIG Level Student       * [*Discussion Director*](file:///C:\Users\elawrenc\Dropbox\Kenan%20Fellows%20Curriculum%20Project\Discussion%20Group%20Resources\Discussion%20Director.docx): High performing student, not identified       * [*Word Detective*](file:///C:\Users\elawrenc\Dropbox\Kenan%20Fellows%20Curriculum%20Project\Discussion%20Group%20Resources\Word%20Detective.docx): Middle/Low performing student       * [*Illustrator*](file:///C:\Users\elawrenc\Dropbox\Kenan%20Fellows%20Curriculum%20Project\Discussion%20Group%20Resources\Illustrator.docx)*:* Low performing student     - Have students complete their individual assignment, then get together with their group and share their answers and discuss their role * After reading the article, lead a classroomdiscussion around the question *“what are biotechnology and the quality control process?”* (Have students record the discussion in two column note format, as this information is important for the successful completion of the lab). Discussion topics should include:   + Can you summarize biotechnology in your own words?     - *Biotechnology affects so much of our lives, but what exactly is it? In its broadest sense, biotechnology is the use of living organisms and biological processes to solve problems or make useful products. If you break biotechnology into its root words, you have:*     - *bio — “living systems,”*     - *technology — “the use of scientific knowledge and tools to solve problems or make useful products.”*   + What is the Food and Drug Administration and what is their job?     - *FDA is responsible for maintaining quality and making sure each company is following the correct procedures and keeping the consumer safe*   + Why do companies have a quality control department?     - *Responsible for testing and sampling all products involved in the manufacturing process and the final drug*     - *Without the quality control department, we would not know if the products we use/consume are safe*   + What happens if there are problems found by the Quality Control department? What could happen if these problems are not solved?     - *When quality is poor, companies pay: damaged company reputation, lost customers, injured, ill or deceased customers, expensive lawsuits, high product costs, loss of profit, company shutdowns and lost jobs*   + Summarize the steps of Biomanufacturing     - *Synthesis, preparing the materials; purification, separating the leftover chemicals; formulation, making the drug into the form it will be administered (tables, liquids, creamed, etc); final dosage form, put drug into its final dosage and dispense into containers, label and package*   + What are the five rules of quality?     - *Understand the customers’ needs, say what you do, do what you say, prove it, improve it*   + What is a SOP? And why might this be useful?     - *SOPs guide every task in the manufacturing process by defining each procedure in detail so it can be performed exactly the same way every time to ensure that the product meets specifications*   + What is included in a SOP?     - *Effective date, purpose, scope, responsibility, references, materials and equipment, procedures, and approval* | |
| **Explain: Day Three to Four** | |
| * Prior to class, **arrange your classroom** so students can work in a group of four to maximize productivity and collaboration   + There should be eight groups of four or eight groups with students equally distributed   + Lab set up will differ based on number of students * Label each lab table as follows:   + Two tables with the name “Bioassay Group”   + Two tables with the name “Microbiology Group”   + Two tables with the name “Chemistry Group”   + Two tables with the name “Sample Control Group” * Before class, standatthedoor and give each student a scientist trading card * When the bell rings, instructstudents to find the table that matches the area where their scientist works, as indicated on their trading card   + Students with microbiologist cards will sit at the microbiologist table, etc.   + Give students a few minutes to review their cards and become acquainted with the scientist * After students arrange themselves in their groups, please review the following prezi:   + [**Pre Lab Discussion**](http://prezi.com/n21swht15zk7/?utm_campaign=share&utm_medium=copy&rc=ex0share) * Handout to each group the appropriate SOP and student guide   + Have students review the SOPs and student guide with their group * REMIND STUDENTS you MUST adhere to the SOP. You NEED to document any questions you have BEFORE you start the lab. The Shark Science Group cannot afford any deviations, which means not following the procedure. Deviations result in invalid data, significant financial retributions and harming the health of the patients. * While studentsreviewtheirSOP, walk around the room and addressanyquestions. If students do not have questions, ask the following questions:   + *What materials do you need?*   + *Does time matter?*   + *Who are the performer and verifier?*   + *What does a pass look like? A fail?*   + *How does your test work?*   + *What are you testing for?*   + *Any steps unclear?*   + *Do you understand how to use the equipment needed?*   + *Do you know where that equipment is located around the room?*   + *Are there any words that you need to define before starting?*   + *What potential problems do you think you might encounter?* * Before issuing thelabmaterials, check for understanding.   + *Thumbs up (I am ready to go), Thumbs down (SOS! HELP!), Thumbs to the middle (I need more time and clarification).*   + REMIND STUDENTS TO REPORT ANY DEVIATION FROM THE SOP, IMMEDIATELY TO THE QUALITY CONTROL OFFICE (aka the teacher) * Hand out the materials * Students shouldbegintesting according to the SOP. *Please see the specific Teacher**SOP**guides for additional information on each assay* * While students are testing, monitorprogress and address any questions that arise   + During experiments, guide student thinking asking*: “What are you doing, why are you doing that, how did you do that, and how do you know?”* * After each group has collected the data, and filled out the test form correctly, students will need to completethe[Certificate of Analysis (C of A)](file:///C:\Users\kctucker\AppData\Local\Curriculum%20Resources\Certificate%20of%20Analysis.docx) for each sample   + Students will know their group based on the number on their scientist trading cards (one through eight)   + Ones will be a group, twos will be a group, etc   + Make sure each group has a Chemist, Sample Control, Bioassay and Microbiologist scientist * **Completing the C of A**   + C of A will need to be completed for each sample.   + Drug Identification Information:     - Name: GrapeX     - Origin: Shark Science Group LSM Site     - Chemical Classification: Liquid     - Identification: (the lot number written on label)     - Manufactured date: (found on sample label)     - Expiration date: (found on sample label)   + Results     - Report the findings from the lab   + Test     - What was done to find the results     - Color, visual     - Taste, taste     - Odor, smelling     - pH, pH paper     - Temperature, thermometer     - Glucose, Glucose strips     - Virus Protection, CV Assay     - Impurity, Paper Chromatography     - Solubility, Solubility   + Storage     - Identify the sample has been stored appropriately, and not contaminated during testing * After the C of A is complete, lead a class discussion:   + Which sample passed the test? How did you know?     - *only sample one should pass the test, as it is GrapeX, compared data to the standard*   + *What sample did not pass the test? How did you know?*     - *Sample two should not pass any tests, as in each assay is has been designed to fail the test*   + What might cause a drug to pass or fail a quality test?     - *Manufacturing, contaminated chemical, not following SOP, etc*   + How can The Shark Science Group make sure another sample does not fail? Remember failed drugs equal money lost     - *Regulate what happens in the lab. Make sure the proper SOP is being followed. Make sure there is an SOP to follow* | |
| **Elaborate: Day Five** | |
| * State**:** After thorough investigation and reviewing your C of A, the CEO of the Shark Science Group has decided that our SOPs are not updated, and therefore have caused several drugs to fail. We are losing a significant amount of money! It is now your job, as the quality control department, to re-write the SOP for manufacturing GrapeX and try to save the company money. * Review how to write an SOP using the [SOP guidelines handout](file:///C:\Users\kctucker\AppData\Local\Curriculum%20Resources\Writing%20an%20SOP.docx) * State the followins from the SOP guideline handout “If it is not written, it never happened.” Askstudents to explain the meaning of this phrase * Handoutmaterials and start writing SOPs   + If teacher has access to tablets or laptops, have students type their SOP, in Microsoft word or other word processing application | |
| **Evaluate: Day Five -Six (Assessment)** | |
| * After students write their SOP, have the studentstradethe SOP with another group * Handout testing materials * Have students follow, word for word, the other group’s SOP, making suggestions to improvethe clarity of their classmates’ SOP   + If teacher has access to tablets or laptops, have students [share their SOP via Google Drive](https://support.google.com/drive/answer/2494822?hl=en)   + Students can open the word document [and track suggested changes](http://office.microsoft.com/en-us/word-help/track-changes-while-you-edit-HA001218690.aspx)   + Students should check to make sure ALL parts of the SOP are present * When testing finishes, have students return the SOP to the original group * The group should review the suggestions for improvement * Students should create a final draft of the SOP to turn in for a grade (see [SOP Rubric](file:///C:\Users\kctucker\AppData\Local\Curriculum%20Resources\Writing%20an%20SOP%20Rubric.docx))   + Grades on the SOP will identify if students understand Good documentation, Good manufacturing practices, SOPs, and quality control   + A grade of an 80% or higher shows proficiency * Review the Two Column notes the students took at the beginning of the unit * Pause for any questions students might have regarding biotechnology and quality control * Have students complete the Post Assessment * Have students exchange papers and grade the assessments | |
| **Extend: Day Seven (digging deeper)** | |
| * Hand out “[writing a scientific argument](file:///C:\Users\kctucker\AppData\Local\Curriculum%20Resources\Writing%20a%20Scientific%20Argument.docx)”   + Review the writing prompt and requirements for writing an argument with your students   + Pause for questions * After students have outlined their argument and classroom guidelines have been shared, allow time for students to share their viewson the prompt.   + *Classroom guidelines should include, but are not limited to: all students’ views will be accepted. If you disagree, it needs to be respectfully and backed by evidence. Listen while others are talking. Wait until a presenter has finished talking, before you ask to share your views.* | |
| **Community Engagement** | |
| * Field trip to the Community lab on Biogen Idec’s RTP campus or other local biotechnology company * Invite members of the community, who are employed by the biotech industry, to share their knowledge and give students an idea of jobs they can hold in the future * When dividing up groups, use the scientist trading cards. Change the cards provided in the lesson to match companies in your area | |
| **Modifications** | |
| * Two column notes with pictures (SIOP Strategy, for ELL students) * Before, during and after reading strategies (Project CRISS reading strategies)   + See explore section for suggestions regarding strategies * Discussion groups: Assign tasks based on ability and student interest. For example:   + *Bridge Builder*-students who can think deeply and have prior knowledge to connect to the story   + *Discussion Director*-students who can lead a group   + *Word Detective*-students who needs a little challenge, but would not be up to the task of the previous two jobs   + *Illustrator*-students who have artistic talents or struggle with expressing ideas in writing * Group Assignments   + Group your students heterogeneously (each group should have a variety of students representing different academic levels)   + Allow for higher level thinkers to go beyond what they know and encourage them to explain   + Allow for the struggling thinkers to receive assistance from classmates who are well versed in the material. * This lesson was designed for the 6th grade middle school classroom. The simple lab procedures in the "explore” section can easily be modified for a high school biology or biotechnology course. Changes can include running an ELISA, Gel Electrophoresis, PCR, absorption spectroscopy, etc. The techniques used will depend on available lab material and developmental level of your students. * If orchestrating multiple activities at the same time is too difficult to manage, pick one or two activities for the students to complete. * To have every student complete every lab, expand the length of the lesson as follows:   + Day One and Two: Engage and Explore   + Day Three: Introduce lab and complete chemistry experiment   + Day Four: Solubility Experiment   + Day Five Chromatography   + Day Six: Immunology   + Day Seven: Certificate of Analysis   + Day Eight: SOP writing   + Day Nine: SOP Testing   + Day Ten: Post Test | |
| **Alternative Assessments** | |
| * Two column notes: when appropriate, students who have IEPs, 504s or are ELL should use the modified two column notes to direct their thinking | |
| **Supplemental Information** | |
| * Embedded throughout the lesson, modifications section, and each teachers guide for the specific lab SOPs | |
| **Websites** | |
| * **ABC News Tylenol Recall Coverage:** <http://abcnews.go.com/WNT/video/big-tylenol-recall-bigger-9581228> * **Link to Biomanufacturing article:** <http://www.ncabr.org/downloads/curricula/careersInBiomanufacturing.pdf> * **North Carolina Association for Biomedical research:** <http://www.ncabr.org/> * **Biotechnology in the middle school:** <http://www.occc.edu/bbdiscovery/msprebiot.html> * **Project CRISS:** <http://www.projectcriss.com/> * **SIOP Model:** <http://siop.pearson.com/about-siop/index.html> * **Sharing on Google Drive:** <https://support.google.com/drive/answer/2494822?hl=en> * **Tracking changes in Microsoft Word:** <http://office.microsoft.com/en-us/word-help/track-changes-while-you-edit-HA001218690.aspx> * **Quality Control Microbiologist interview:** <http://www.teachersdomain.org/resource/biot09.biotech.car.qcbiot/> * **Biotechnology in North Carolina:** <http://www.ncbiotech.org/sites/default/files/new_tools.pdf> * **Quality Control Associate:** <http://www.aboutbioscience.org/careers/qualitycontrolassociate> | |
| **Comments** | |
| This set of lessons is designed to mimic the day to day operations of the Quality Control department in the Biotech Industry, specifically a Biopharmaceutical company. I had the privilege of spending five weeks in a cutting edge Quality Control lab. I designed this lesson to share my experience with educators and students, across the country. Also, this lesson was designed to teach the North Carolina Science Essential Standards, while providing students with a real world application of what they are learning in the 6th grade (yes, scientists still use what they learned in the 6th grade). Integrating the curriculum through real world scenarios answers the age old question, “Teacher, why do I need to know this?” Finally, this lesson will allow educators and students to see the link across subject areas. It will challenge you to dig deeper into the relationships of math, science, reading, writing, and social studies. | |
| **Author Information** | |
| Erin Marie Lawrence is a teacher at Wake Forest Middle School, Wake Forest, NC. This school is part of the Wake County Public School system, the largest in the state. She earned her Bachelor of Science degree in biology and chemistry from Slippery Rock University. She went on to earn her Master of Education degree, with a concentration in Secondary Education, also from Slippery Rock University, Pennsylvania. Erin was nominated as a Wake County Beginning Teacher of the Year (2010). She was named a National Science Teacher Association (NSTA) New Teacher Fellow (2011-2012) and a Kenan Fellow (2013-2014). Erin has led several professional development classes on “Flippin’ the Classroom” and was on a panel for the Siemens Stem Academy Webinar called “Flipping the Classroom with FIZZ.” Erin has also done work for her county science department to align the North Carolina Essential Standards to the Common Core Literacy Standards. When Erin is not teaching, she enjoys running, eating local, swing dancing, and baking cupcakes. | |