

Course Student Learning Outcomes Assessment

BIOL 194 Quality and Regulatory Compliance in Biosciences

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General Information (Course Student Learning Outcomes Assessment)

Standing Requirements

Course Description

This course will cover quality assurance and regulatory compliance for the biosciences industries. Topics will span quality control and Federal Drug Administration (FDA) regulations for the biotechnology, biopharmaceutical, biomedical device and food industries. Theories and application of quality assurance and quality control will be presented and several different quality systems will be discussed such as GMP (good manufacturing practices), ISO9000 (International Standards Organization), Six Sigma and Lean.

Course Student Learning Outcomes

BIOL 194 Quality and Regulatory Compliance in Biosciences Outcome Set

Outcome	
Outcome	Mapping
Outcome 1 Exhibit knowledge of regulatory compliance in the bioscience industry.	Institutional Student Learning Outcomes: Act 2, Communicate 1, Communicate 2, Communicate 3, Learn 1, Learn 2, Learn 3, Think 1, Think 2
Outcome 2 Demonstrate knowledge of quality assurance in the bioscience industry.	Institutional Student Learning Outcomes: Act 2, Communicate 1, Communicate 2, Communicate 3, Learn 1, Learn 2, Learn 3, Think 1, Think 2

2014-2015 Assessment Cycle

Measurements

Outcomes and Measures

BIOL 194 Quality and Regulatory Compliance in Biosciences Outcome Set

Outcome

Outcome 1

Exhibit knowledge of regulatory compliance in the bioscience industry.

▼ **Measure:** Meabs of assessment 194
Course level; Direct - Exam

Description of Measurement Tool: A. Several final exam questions were asked that queried students' understanding of regulatory compliance. The final exam questions are listed in the attached appendix for reference, and are referred to here by their question number. The questions are a mix of multiple answer, matching, fill-in-the-blanks, and true/false.

B. Knowledge of regulatory compliance can also be assessed by examining how meaningful/reflective the students' discussions of compliance topics are. Two discussion board assignments directed students to discuss the most common non-compliances, and the content of FDA Form 483 inspection reports and warning letters, which reveal the consequences of non-compliances / violation of regulations.

Criteria for Success: Individual & Collective Student Criterion: A. For this first-time offering of the course, success is defined as 75% or more of the students earning 75% or more on a question.

B. For this first-time offering of the course, success is defined as 75% or more of the students earning 75% or more on a discussion board assignment.

Cycle of Assessment: Spring 2015

Who is Responsible for Assessment Activity?: Biology faculty currently teaching this course

Outcome 2

Demonstrate knowledge of quality assurance in the bioscience industry.

▼ **Measure:** Meabs of assessment 194
Course level; Direct - Exam

Description of Measurement Tool:

Criteria for Success: Individual & Collective Student Criterion:

Cycle of Assessment: Spring 2016 or the next time the course is offered

Who is Responsible for Assessment Activity?: Biology faculty currently teaching the course.

Findings

Finding per Measure

BIOL 194 Quality and Regulatory Compliance in Biosciences Outcome Set

Outcome

Outcome 1

Exhibit knowledge of regulatory compliance in the bioscience industry.

▼ **Measure:** Meabs of assessment 194
Course level; Direct - Exam

Description of Measurement Tool: A. Several final exam questions were asked that queried students' understanding of regulatory compliance. The final exam questions are listed in the attached appendix for reference, and are referred to here by their question number. The questions are a mix of multiple answer, matching, fill-in-the-blanks, and true/false.

B. Knowledge of regulatory compliance can also be assessed by examining how meaningful/reflective the students' discussions of compliance topics are. Two discussion board assignments directed students to discuss the most common non-compliances, and the content of FDA Form 483 inspection reports and warning letters, which reveal the consequences of non-compliances / violation of regulations.

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B. For this first-time offering of the course, success is defined as 75% or more of the students earning 75% or more on a discussion board assignment.

Cycle of Assessment: Spring 2015

Who is Responsible for Assessment Activity?: Biology faculty currently teaching this course

Findings for Meabs of assessment 194

Summary of Findings: A. For each of the 11 Regulatory Compliance-related Final Exam Questions, the question number and percentage of students earning at least 75% on the question is specified below. The number of students in the course was 16.

Q1: 81.3%, Q2: 56.3%, Q3: 62.5%, Q4: 93.8%, Q5: 68.8%, Q6: 87.5%, Q7: 87.5%, Q8: 81.3%, Q9: 87.5%, Q10: 75.0%, Q11: 87.5%

B. For the most common non-compliance discussion, 75% of the students earned at least 75% on this discussion board assignment. For the FDA Form 483 inspection report and warning letter content discussion, 81.3% of students earned at least 75% on this discussion board assignment. For each of the 11 Quality Assurance-related Final Exam Questions, the question number and percentage of students earning at least 75% on the question is specified below. The number of students in the course was 16.

Q1: 75.0%, Q2: 50.0%, Q3: 75.0%, Q4: 62.5%, Q5: 87.5%, Q6: 6.25%, Q7: 93.8%, Q8: 81.3%, Q9: 68.8%, Q10: 81.3%, Q11: 12.5%

Results: Criteria for Success Achievement Status: Met

Analysis of Findings: A. Out of 11 final exam questions, 8 questions (Q1, Q4, Q6, Q7, Q8, Q9, Q10, and Q11) were answered by at least 75% of the students (n=16) who earned at least 75%. Of the remaining 3 questions, (Q2, Q3, and Q5), the percentage of students who earned at least 75% ranged from 56.3% to 68.8%.

B. The outcomes of these two discussion board assignments demonstrate that students gained an understanding of regulatory compliance and are able to engage in meaningful and reflective dialog about compliance and the consequences of non-compliance. The ability to discuss regulatory compliance is a valuable skill for workers in the biosciences. Out of 11 final exam questions, 6 questions (Q1, Q3, Q5, Q7, Q8, and Q10) were answered by at least 75% of the students (n=16) who earned at least 75%. Of the remaining 5 questions, (Q2, Q4, Q6, Q9, and Q11), the percentage of students who earned at least 75% ranged from 6.3% to 68.8%. Students performed worst on Q6 and Q11, with only 6.3% and 12.5% of students, respectively, earning 75%. Both of these questions were short answer type, and hence represented authentic testing. Q6 tested students' ability to identify documentation errors, which represent violations of good documentation practices. Q11 tested students' ability to make connections among the different topics and subtopics covered in the course and be able to discuss identified relationships.

Recommendations: A. This set of questions seems to represent a rigorous method for assessing knowledge of regulatory compliance. These questions will be used again with the next cohort to increase the sample size and further evaluate their valuable for this assessment purpose. Additionally, more emphasis will be put on the information/concepts relating to those questions that did not meet the criterion for success.

B. These two discussion board assignments seem to be a good method for assessing knowledge

of regulatory compliance. These discussion board assignments will be used again with the next cohort to increase the sample size and further evaluate their valuable for this assessment purpose. Additionally, these discussion board assignments will be modified, and possibly complemented by the addition of new activities, to increase the richness of the dialog, which should deepen the understanding of regulatory compliance. This set of questions seems to represent a rigorous method for assessing knowledge of quality assurance. These questions will be used again with the next cohort to increase the sample size and further evaluate their valuable for this assessment purpose. Additionally, more emphasis will be put on the information/concepts relating to those questions that did not meet the criterion for success, in particular Q6 (identification of documentation errors) and Q11 (synthesis of the course material).

Outcome 2

Demonstrate knowledge of quality assurance in the bioscience industry.

▼ **Measure:** Meabs of assessment 194
Course level; Direct - Exam

Description of Measurement Tool:

Criteria for Success: Individual & Collective Student Criterion:

Cycle of Assessment: Spring 2016 or the next time the course is offered

Who is Responsible for Assessment Activity?: Biology faculty currently teaching the course.

Findings for Meabs of assessment 194

No Findings Added

Overall Recommendations

No text specified

◆ **Plans of Action**

◆ **Status Reports**

2013-2014 Assessment Cycle

 **Measurements**

 **Findings**

 **Plans of Action**

 **Status Reports**

2012-2013 Assessment Cycle

 **Measurements**

 **Findings**

 **Plans of Action**

 **Status Reports**