### Instructor information

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### **Course Coordinator**

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#### Course overview

The course will address, among others, the following topics:

- Ensuring Validity and Reliability
- Laboratory Procedures
- Quality Assurance: Procedures, Tools & Methods
- Laboratory Management

After completing this course, participants will:

- Gain practical knowledge of standard laboratory practices and quality systems required to oversee a scientific laboratory's quality management program;
- Acquire the breadth of knowledge needed to obtain laboratory results that are reliable, accurate, interpretable, repeatable, defensible and timely; and
- Be able to successfully participate on a laboratory management team including budgeting and developing a technology strategy.

Participants will receive a certificate upon successful completion of the course. (See Grading Policy Below for more information)

### Time commitment

Approximately 8 – 10 hours per week

## **Technology requirements**

- A computer that is less than 4 years old;
- Reliable high-speed Internet connection (cable/DSL or better) with an updated browser;
- For optimal viewing of course presentations, please use Mozilla Firefox
- Software such as Microsoft Word, PowerPoint & Excel 2003-2013 or equivalent;
- Common plug-ins (e.g., Adobe Reader, Flash Player, virus protection, etc.); and
- Microphone and speakers.

## **Course tools**

All course materials and activities will be presented on the course website (http://) Details will be provided to participants before the start of the course. All readings can be accessed from the course website. All course communication will take place using e-mail.





### **Course content**

Weekly materials are presented using a variety of formats, including online narrated power point slide presentations and videos. Weekly course assignments, conducted as a discussion or homework assignment, will assist in the participant's understanding of concepts. These include but are not limited to: statistical process controls, developing standard operating procedures (SOPs), corrective/preventive actions, and methods of validation.

### Grading

Grades will be determined as follows:

Discussions (6)	30 pts
Homework (6)	70 pts

Note: Each discussion is worth 5 pts each. Each Homework is worth 10 pts each, except for HW # 5 which is worth 20 pts.

## **Grading policy**

Due to the participatory nature of this web-based class, regular log-in to the learning management system is expected. Completion of the course assignments and a Total Score ≥70% on all course assignments is required to receive a certificate.





Week (Dates)	Topics	Assignments/Due Dates		
Unit I – Laboratory Quality System Structure				
<b>1</b> Sept 7 – 13, 2020	Laboratory Quality Systems-Overview; Laboratory Standards	Self-Introduction;		
<b>2</b> Sept 14 - 20, 2020	ISO 17025 Requirements; Laboratory Accreditation	Homework #1 – Due Sept 21, 2020 Discussion #1 – Due Sept 21, 2020		
Unit II – Laboratory Quality Control Techniques				
<b>3</b> Sept 21 - 27, 2020	Statistical Process Control	Homework #2 – Due Sept 28, 2020		
	Quality Control Techniques			
4	The Big Three	Discussion # 2 – Due Oct 5, 2020		
Sept 28 – Oct 4, 2020	<ul><li>Traceability</li><li>Proficiency Testing Uncertainty</li></ul>	Homework #3 – Due Oct 5, 2020		
_	Quality Control Procedures	Homework #4 – Due Oct 12, 2020		
5 Oct 5 - 11, 2020	<ul> <li>Chain of Custody</li> <li>Control of Non-conforming work</li> <li>Recording and Reporting for Quality Assurance</li> </ul>	Discussion # 3 – Due October 12, 2020		
Unit III – Method Validation				
6 Oct 12 – 18, 2020	Validation of Analytical Procedures	Discussion # 4 – Due October 19, 2020		
7	Validation of Microbiological Procedures &			
Oct 19 – 25, 2020	Chemical Procedures, Spectroscopic Procedures and Rapid Methods	Homework #5 –Due Oct 26, 2020		
8 Oct 26 - Nov 1, 2020	Validation of Spectroscopic Procedures and Rapid Methods	Discussion #5 – Due Nov 2, 2020		
Unit IV – Laboratory Quality Management				





9 Nov 2 – Nov 8, 2020	Concept of Quality Management; Technology Strategy; Budgeting; Benchmarking	Homework #6 – Due Nov 9, 2020
<b>10</b> Nov 9 – 13 2020	Laboratory Networks ; Laboratory Safety; Risk Assessment	Discussion #6 – Due Nov 13, 2020

