

BTN 1120 - Laboratory Safety & Regulatory Compliance  
Credit Type – Proficiency



MIAMI VALLEY  
**TECHPREP**  
CONSORTIUM

<b>Course Description and Learning Outcomes:</b>
<a href="https://www.sinclair.edu/course/params/subject/BTN/courseNo/1120/">https://www.sinclair.edu/course/params/subject/BTN/courseNo/1120/</a>
<b>Faculty Pathway Specialist(s)</b> (Please include name, email and office hours):
<b>Susan Luken</b> , <a href="mailto:susan.luken@sinclair.edu">susan.luken@sinclair.edu</a> , office hours available through email
<b>Resources Needed to Offer Course</b> (software, equipment, books [include ISBN and edition], etc. – please include any associated costs):
<b>Textbook needed:</b> <i>Basic Laboratory Methods for Biotechnology</i> 3rd Edition - By Lisa Seidman and Cynthia Moore ISBN 978-036-7244-903 (print) or 978-1000-480801 (ebook). If class copies are not possible, faculty must at least have a copy to teach from.  <b>Equipment needed:</b> chemical spill kit, various examples of PPE, various glassware and sink, equipment for fire extinguisher training.
<b>How is the final grade for the course determined?</b> (Please list all required assignments, assessments, etc.)
Final grade is determined by the lecture exams and the cGLP exam. Other homework assignments are suggested but may be modified as long as the points are the same for the course.
<b>Who is responsible for grading the required assignments and/or assessments?</b> (faculty or instructor?)
If the final exam is given on paper, the high school instructor is required to grade and post grades. If the class takes the assessment online, the faculty will assist with grading, and instructor will post grades to eLearn. Scoring or rubric for grading and answer key is provided.
<b>What is the grading scale for the course?</b>
Grading scale: A is 100-90%, B is 89-80%, C is 79-70%, D is 69 – 60%, F is 59% and below. Yes, borderline grades can be rounded up (89.5 can be an A).
<b>Must students access the eLearn shell regularly to complete requirements?</b>
Not required, the teacher can print assignments and tests out an input the grades. Activities can be printed and completed by hand.
<b>Does the course require access to YouTube, GoogleDrive, etc.?</b>
There are helpful videos as well as a GoogleDrive available as a resource for instructors.
<b>Additional course details or requirements important for instructors not covered above:</b>
This course will cover: <ul style="list-style-type: none"><li>- Chapter 3: The Business of Biotechnology</li><li>- Chapter 35: Biotechnology and the Regulation of Medical and Food Products</li><li>- Chapter 36: The Lifecycle and Regulation of Pharmaceutical Products</li><li>- Chapter 4: Introduction to Product Quality Systems</li><li>- Chapter 5: Quality in Research Laboratories</li><li>- Chapter 6: Documentation: The Foundation of Quality</li><li>- Chapter 38: Quality Systems in a Regulated Production Facility</li></ul>

- Chapter 7: Introduction to a Safe Workplace
- Chapter 8: Working Safely in the Laboratory: General Considerations and Physical Hazards
- Chapter 9: Working Safely with Chemicals
- Chapter 10: Working Safely with Biological Materials
- Unit Covering cGLPs
- Unit Cover cGMPs
- Fire Extinguisher training (fits into Chapter 8)

Tests can be done via eLearn or a paper version. Other homework or activities can be found on eLearn and through a google drive. Please email Faculty, Susan Luken ([susan.luken@sinclair.edu](mailto:susan.luken@sinclair.edu))

**Most common (or popular) degrees this course is in?**

Biotechnology AAS  
Bioscience Lab Skills CRT