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Primary containment refers to the protection of personnel and the immediate environment from exposure to hazards. Secondary

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containment refers to the protection of the environment outside the facility.

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control in the biomanufacturing industry. After completing this chapter the student will be able to:

- Explain why microbiological control is important in a biomanufacturing facility and provide a number of examples as to how it is achieved and



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The biomanufacturing product development process is time consuming and expensive. It is estimated to take 8–15 years, at a

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cost of \$500 million–\$1 billion, to bring a biopharmaceutical to the market, with some estimates being less conservative. The sooner the product is brought

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