

Biogen Specific Teaching Material

Quality – Importance of Making Quality Products





Questions & Answers

Quality – Importance of Making Quality Products

1. When it comes to the batch record and the release procedure, most pharmaceutical companies have a high first-time-right rate. (true or false?)

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1. False. A first-time-right rate is close to zero when it comes to the batch record and the release procedure.

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2. The average percentage of deviations due to human error in current manufacturing processes is at _____ percent.

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2. The average percentage of deviations due to human error in current manufacturing processes is at 75%.

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3. What can result when existing errors remain undetected and resolved?

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3. If errors go undetected, it can result in performance losses (e.g. fewer batch releases, further deviations, human error)

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4. In the end, an effective quality system is predominantly (according to operators) oral. (true or false?)

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4. False. An effective quality system is predominantly a written one.

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5. Name at least three (3) consequences of deviations of the quality system.

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5. Some consequences are increased scrap, more deviations, fewer batch releases, delivery bottlenecks, etc.

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6. What does Quality Costs means?

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6. Quality Costs relates to preventing, detecting and remediating product issues.

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7. Quality costs make up close to _____ of total costs in the pharmaceutical industry.

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7. Quality costs make up close to 30% of total costs in the pharmaceutical industry.

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8. The pharmaceutical industry is one of the biggest spenders in R&D and in quality costs. (true or false?)

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8. True.

Thank you for your attention!

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