

Name: **Lieu & Co**Date: **05/10/2016**Quiz name: **GDP part 1 (chapter 1-3)**Score: **92%**

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- ✓ 1. One of this chapter is NOT part of the GDP
- ☐ A Quality Management
  - ☐ B Personnel
  - ☐ C Operations
  - ☐ D Outsources activities
  - ☒ E Manufacturing and control
  - ☐ F Self-inspection
  - ☐ G Transportation
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- ✓ 2. Who is responsible for the quality system ?
- ☐ A The local Quality unit
  - ☒ B The local organisation's management
  - ☐ C MBQ (Merck Biopharma Quality) Leadership team
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- ✓ 3. Shall the Quality System also control and review the outsourced activity ?
- ☒ A True
  - ☐ B False
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- ✗ 4. Is it the responsibility of the contracted outsourced company to identify and implement potential improvements ?
- ☒ A True
  - ☐ B False
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- ✓ 5. How should be monitored the effectiveness of the quality system ?
- ☒ A Periodic Management Review
  - ☐ B Self-inspection
  - ☐ C KPIs
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- ✓ 6. What is the ultimate goal of a risk management ?
- ☐ A To improve the KPIs
  - ☐ B To work with other departments
  - ☒ C To protect the patient
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- ✓ 7. Who should be trained on GDP?
- ☒ A All personnel involved in wholesale distribution activities.
  - ☐ B The Quality unit
  - ☐ C SNO

☐ D Warehouse personnel

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- ✓ 8. The Responsible person...
- ☐ A decides on the final disposition of returned, rejected, recalled or falsified products
  - ☐ B approves return of goods to saleable stock
  - ☐ C ensures that initial and continuous training programmes are implemented and maintained
  - ☐ D is responsible to ensure coordination and promptly performing any recall operations for medicinal products
  - ☐ E ensures that customer complaints are dealt with effectively
  - ☐ F ensures that suppliers and customers are approved
  - ☐ G approves any subcontracted activities that might impact GDP
  - ☒ H All of the above
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- ✓ 9. The roles and responsibilities of employees working in key positions are defined in a written Job Description
- ☒ A True
  - ☐ B False
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- ✓ 10. What should be in place if the buildings are not operated directly by the wholesale distributor?
- ☐ A Self-inspection
  - ☐ B A Quality Manual
  - ☐ C A Quality Organisation
  - ☒ D A contract
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- ✓ 11. Alarm systems to provide alerts when there are temperature excursion from 2°C-8°C area must be in place. Is it the same for ambient temperature storage of medicinal product ?
- ☒ A True
  - ☐ B False
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- ✓ 12. The receiving and dispatch and storage areas don't need to be separated
- ☐ A True
  - ☒ B False