

Labtech Exam SS22

28 questions, 90 mins time, from 11 lectures

- 27 with SC or MC (it was known if it was one or more correct answers)
- 1 with drawing lines between correlated words

Animal Studies - Martin Schenk

1. What is the percentage of killed animals for research purposes?

1. 50 - 60 %
2. 30 - 50 %
3. 1 - 5 %
- 4. 0.1 - 0.5 %**
5. 0.05 - 0.1 %

2. Where can you find rough experimental plan of animal trials?

- 1. Internet**
2. Only after court hearing
3. Not at all for people not involved
4. Release after determination
5. University website

3. What is the meaning of the 3R principle?

1. other combinations of words starting with r
- 2. reduction, refinement, replacement**
3. Retesting, realising, rechecking

Good Laboratory Practice and Good Manufacturing Practice - Gabriella Bellavia

4. What are standard operational procedures?

- 1. lab program in chronological listing of action steps**
2. monitored, recorded, archived and reported

3. Protecting staff from toxins
 4. How to clean appliances...
 5. system to avoid mistakes
5. What is GLP?
1. **quality systems with organizational process and conditions under which non-clinical health and environmental safety studies are planned, performed,**
6. How is responsible for the quality of data?
1. Study director
 2. **Study personnel (see slide 10)**
 3. Quality assurance unit
 - 4.

ATMPs I - Introduction - Prof Helena Kelly

7. Holoclar (replaces tissue) what kind of ATMP, cells on fibrinogen scaffold?
1. somatic cell therapy
 2. Combined ATMP
 3. **Tissue engineering** (*EMA online: "Holoclar is a type of advanced therapy product called a **tissue engineered product**"*)
 4. Gene therapy
8. What is the procedure applied for dendritic cells to cure solid cancer, which is produced in a specific hospital, which is patient dependent, where the
1. **hospital examination**
 2. orphan diseases
 3. PRIME
 4. ...
9. Orphan Drugs what is true (more than 1 answer)
1. Get faster market release
 2. **reduced costs for regulatory processes**
 3. **10 yr market exclusivity**
 4. financing of clinical trials
 5. patent

Medical Information System and Economics - Jens Maschmann

10. Implementation of MIS what is NOT true

1. more in clinical intern IT than externally
2. can be implemented without ag... of clinical intern people
3. something about classical data warehouse systems
4. not that strict regulation within MIS and devices used

11. Medical information systems - what is true?

1. can be used to transfer data easily between different departments
2. is always leading to a decrease in costs
3. implement with clinical personnel and not with external persons
4. something with mere IT system

12. Medical facility planning (true statement)

1. is not important because of that old money system
2. not necessary because costs of ... cannot be changed
3. **should be performed in accordance with users/stakeholders**
4. ...

Medical devices - Regulations, Classification and Application - Robert Willy

13. FMEA, which one of those aren't FMEA type

1. UFMEA
2. PFMEA
3. **OFMEA**
4. DFMEA

14. What is the right sequence of the regulatory pathway?

1. **Intended Purpose → Classification → Conformity Route → Certification**
2. Other combinations

15. ISO Norm of design controls and development?

1. **13485**
2. 14971
3. 14835
4. 10993

Clinical Trials and Good Clinical Practice - Martin Weiss

16. Which statement is wrong?

1. Adverse events are not necessarily correlated to the drug
2. **Adverse reaction are all events except those related to the drug**
3. Serious adverse event must be treated in the hospital
4. Serious adverse event could be lethal, congenital abnormalities

17. What requirements study participants don't need to fulfill?

1. **German citizenship**
2. Full aged
3. In possession of their civic rights
4. Able to understand consequences
5. Informed consent

18. What is not part of the gold standard for clinical trials?

1. **Unicenter**
2. Randomized
3. Double-blind
4. Controlled
5. Prospective

Device Verification and Validation - Sebastian Schosteck

19. Verification and validation which is incorrect:

1. **Complete validation can be done without verification**
2. **Verification is done at the end of product development**
3. Validation must include tests on patients
4. Verification checks if output of design equals input design
5. Validation checks product fulfills intended use/user requirements

20. What is per definition aim of clinical studies? (More than one correct answer)

1. **Safety**
2. **Performance**
3. **Efficacy**
4. Value prepositions
5. Marketability

ATMPs II - Entering Clinical Phase - Thomas Gwinner

21. Connect with lines - one left word fits to one right word (4 words on left side, 8 on right side)

CMC (1)	Pharmaceutical quality (1)
API (2)	Drug substance (2)
CTA (3)	CTD (3)
ATMP (4)	Cell and gene therapy (4)
	IND
	Drug product
	Compound development

22. What do you need to be able to start the clinical trial? (more than one answer correct)

1. **Be able to show with preclinical data that the product has the necessary efficacy and will probably be safe for the use in humans & worth the risk**
2. have the needed budget
3. have completed a Scientific advice and got a positive result
4. **Have the CMC prepared in accordance with the CTD**

23....

Start up II - Shannon Layland

24. What does SWOT stand for?

1. **Strengths, weaknesses, opportunities, threats**
2. Other words with the same first letter

25. How could opportunity costs also be described (more than one answer)

1. **loss of potential gain from other alternatives**
2. **value of the next best thing you give up whenever you make a decision**
3. The money you pay to be admitted to pitch competitions
4. ...

26. What is the business model canvas?

1. **a management template for starting businesses**
2. predominantly for oil paintings
3. a 30+ page document detailing a startup
4. a marketing tool

Medical Devices - Regulations, Classifications, Applications - Christoph Kiesselbach

27. What is correct for medical devices?

1. **working principle based on physical means and not based on metabolic, immunological or ... means**
2. application of directive 2001/83 EC for medicinal products
3. classification ... ?
4. **regulation 2017:745 immediately applicable in member states**
5. conformity assessment ... ?

28. What is correct regarding medical device legislation? (more than one answer correct)

1. **Classification of medical devices into classes I, IIa, IIb, III**
2. **Classification according annex XIII of regulation 2017:475**
3. **Directives ... have been repealed in may 2021/2022 and from then on the regulations 2017:745 and 2017:746 are applied**
4. Classification into classes A, B and C
5. EU regulations need to be translated into national law by each member state