Focus Labtech 2

1. Legal aspect with a focus on medical devices

What I can say is that the questions will be general in nature and not go into very specific details. So for example a question might ask general facts about classification of medical devices but not for specific rules.

2. Clinical Trials and Good clinical practice
-Gold standard definition
→ some items
-Requirements
-Study participants to be included (slide 10)
→ fully aged, inform content, rights, need to understand impact consequences
-Adverse reactions, events, serious events
Important slides he mentioned: 22, 13 (no details)
-Examples of documentation obligations

3. MD Regulations, Classifications and Applications
-Regulatory pathway and design controls & development.

-Slides(8, 11, 12, 13, 14,15,19,20)?!

4. Intro ATMPs

5. Animal Studies
-He said in the lecture: focus on red Text in slides

6. GLP and intro GMP

7. Methodologies of devices verification and validation
- 3 MC questions from slides
- Essential aspects, not difficult
- Verification/Validation

I recommend that you look at the V-model and verification/validation. If something is asked, then basic aspects. I have many examples in the slides, these are only for illustration and are of course not asked. That should narrow down the material considerably.

8. Medical information systems and economic aspects of facility planning
-Core statements no details such as abbreviations

9. ATMPs entering clinical phase
-He said: Part 2
- nothing company specific
- developmental pathways and approval

10. Startup 1
-there is no size fits all
-Approach business model design as much as you do science through experimentation, Data collection (Revise business model), verification
-Engage with customers very early, even before building first prototype
→ customer-centric
-Not only follow your vision
-Don't stick to … (change management if needed???)
-Investigate inner why

11. Startup 2
Business Model
Business canvas
Last 2 slides about conclusion