Exam 22\textsuperscript{nd} of April, 2013
BME-1306, Commercialization of Research Results
Professor Heimo Ylänen

Basic Scientific calculator (no graphing/programmable) accepted in exam.

\textbf{Q1. (6p)}

Good Manufacturing Practice involves 10 Golden Rules. Describe 6 of them. (6p)

\textbf{Q2. (6p)}

Explain the differences between the different categories in classification of medical devices according to EU? (6p)

\textbf{Q3. (6p)}

What is the difference between Market Analysis and Market Plan? (3p)
Why should you always do a Market Analysis? (3p)

\textbf{Q4. (6p)}

Why should you make a business plan before starting a business? (6p)

\textbf{Q5. (6p)}

a) According to definition, what is haemolysis? (2p)
b) What is causing haemolysis? (2p)
c) Why is it important to apply Haemolysis test on certain Medical Devices and what kind of Medical Devices are those? (2p)