EXAM 1st of February 2010
BME-1176 Biomedical Engineering C
NOTE! Write answers to questions 1.1, 1.2, and 2, each to separate papers, please!

Q1. (5p)
1.1 What is the difference between the concepts medical data, medical information, and medical knowledge? Describe their relationship by using an ECG as an example. (3p)
1.2 Explain term Good Manufacturing Practice. (2p)

Q2. (5p)
What information is needed for mathematical models for example FEM model of a blood flow in blood vessel?

Q3. (5p)
Mark correct answer, is the claim correct or wrong.

<table>
<thead>
<tr>
<th>Claim</th>
<th>TRUE</th>
<th>FALSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory affairs and marketing strategy have nothing in common</td>
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<td>Regulations of medical devices are equal in every country</td>
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<td>Regulatory processes with the authorities require always tons of documentation</td>
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<td>ISO 13485 is a quality system standard of medical devices</td>
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<td>Implantable devices are the subclass of the invasive devices</td>
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Q4. (5p)
Explain, why in vitro and in vivo tests are done, what kind of information they will provide.

Q5. (5p)
Explain following terms and phrases:
A) Cleaning F) Bioburden
B) Desinfection G) Clean room
C) Sterile H) Living particle
D) Antiseptic I) Laminar flow (in clean room)
E) Aseptic J) Histology