## Stakeholder: Large Medical Device Company

### Roles BME students take in their organizations?

<table>
<thead>
<tr>
<th>Job Title</th>
<th>Description</th>
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<tbody>
<tr>
<td>Technical Development Program (Intern, Co-op, + Full-time)</td>
<td>Two-year training program focused on developing high-potential, entry-level technical professionals. This program combines hands-on experiences and career mentoring with technical training classes to accelerate associates' development. Associates will graduate with the confidence and technical ability to create and produce the company's next generation of products designed with the customer in mind. It is a two-year technical training program focused on growing high-potential, entry-level professionals who are passionate about science, technology and saving lives, and who have the desire to strive to create innovative, quality products and processes. This rotational program is designed to accelerate professional development by exposing the associate to the technical businesses through a variety of critical assignments and targeted training. Professionals will graduate with the confidence and technical ability to create and produce the company's next generation of products and therapies designed with the customer experience in mind. The TDP professionals will have the opportunity to experience a range of engineering and science roles such as designing and improving products and processes, and improving quality. These roles may be in areas such as new product design, formulation development, modeling, material selection, pilot plant operations, quality, design for reliability, product testing, manufacturing and supply chain. Program professionals will also learn the company's design methodologies such as critical thinking, data-driven decision-making and design control utilizing our therapeutic or device product design processes. TDP professionals will learn to work closely with other functions to integrate product designs for manufacturability, reliability and serviceability, providing optimal customer-centric products for the company. Training classes and projects will help the professionals enhance their core competencies. TDP professionals will combine their hands-on experiences and in-depth training with career mentoring, so they have all the tools necessary for a successful career at the company. The company also has a Technical Development Program internship (12 weeks) and co-op (8 months), which have similar roles as a TDP full-time but over a shorter time period and with fewer responsibilities.</td>
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| Direct hire (positions vary)                            | • **Most common for BME’s right out of school:**  
  o Systems engineers: integrating different systems within a design; integrating how a pump works with an administration set; ensuring function as a group  
  o Verification and validation engineers: doing protocol writings and execution; writing verification reports; quality checks on verification reports |
What technical skills do they look for in BME students?

Overall, they BME’s as lead integrator in systems engineer role and be able to interface with multiple people/different functions. **Doesn’t typically put in solely technical role (i.e. CAD/FEA, etc); those are usually for traditional engineering disciplines (ME, EE, CE, CHEME, etc.)**

- Base skills that make BME valuable:
  - Systems thinking: how do you integrate a bunch of different components – expects as baseline
  - **V-diagram: needs to be in curriculum**
    - Systems, risk management & reliability
  - Verification and validation:
    - How do you write verification protocols and reports
  - User needs assessment to user requirements and specifications
  - Device reliability

- Others that would be added bonuses:
  - Stability: how stable is device over time
    - Sterility: how do we maintain sterility
    - Environmental aging
  - Any basic CAD software – agnostic, doesn’t matter which one it is
    - SolidWorks, Autocad, ProE
  - IBM Doors – requirement management software
  - JIRA
  - Clearquest
  - Product life cycle management → Siemens TCU (just visibility / basic familiarity with software)
  - Be able to interface with manufacturers – design for manufacturability
  - Human factors; being able to communicate with doctors and clinicians; maybe some exposure to marketing
  - Project management – Microsoft Project would be good to know

- For this company’s devices, in general, students would also need:
  - Basic general understanding of: - thinks BME curriculum does well
    - Mechanical statics
    - Polymers
Stakeholder: Large Medical Device Company

- Electronics and hardware and software
  - Arduino control, maybe raspberry pi (but typically don’t put biomed’s in that role)

For Master’s:
- Understand how the medical industry operates would be very helpful: regulatory (FDA pathways), risk, quality (21 CFR 820.30 design control)

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<thead>
<tr>
<th>Job Title</th>
<th>Skill</th>
<th>Expectation Level</th>
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<tbody>
<tr>
<td>Freshman</td>
<td>Should be able to contribute something technically</td>
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<td></td>
<td>Text execution role</td>
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<td></td>
<td>Good documentation practices</td>
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<td></td>
<td>Good laboratory practices</td>
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<tr>
<td>Sophomore</td>
<td>Some level of understanding of what a systems role looks like</td>
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<td></td>
<td>Basic mechanical and electrical skills, able to program</td>
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<td></td>
<td>Probably used for protocol drafting role (authors of protocols, not study director)</td>
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<td></td>
<td>Project management (Microsoft Project)</td>
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<tr>
<td>Junior</td>
<td>Writing protocols; do the bulk of the writing and executing; deal with issues that arise; come up with own protocols</td>
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<tr>
<td>Senior</td>
<td>Full fledged integrator</td>
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<td></td>
<td>Understand QFD – requirements</td>
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<tr>
<td></td>
<td>Good understanding of verification and validation</td>
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<td></td>
<td>Cursory understanding of risk, reliability, user needs assessment, validation</td>
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What soft skills do they look for in BME students?
- Ability to work in a team
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- Very clear communication
- Very concise organization
- Ability to lead a team
- Ability to work cross-functionally
- Conflict resolution – resolving conflicts between technical experts
- Strong work ethic & “grit”
- Ability to take initiative – for systems role typically the only systems engineer in group

Notes (Note any additional points that were discussed, but not covered above):
- **His concern is that BME is that they're a jack-of-all-trades but master of none.** Never take more than a few classes in a particular discipline. To him, there’s no core skill-set. That’s why he doesn’t hire as many biomedical as chemical, electrical, mechanical, etc.. In addition, the extra master’s is only really helpful when undergrad was different (i.e. a core major and then get a BME to apply the concepts from that major). Universities are degrading value of master’s degree with no thesis-based master’s (extra year of classes not a huge value-add).
- Everything above is how he uses BME’s in current state (i.e. for systems roles); guesses that’s okay because there’s a need for that
- **His disappointment with BME’s is that is all he uses them for (systems roles, not purely technical roles)**
  - It would be great to have a BME that could in a CAD role – could do hard-core CAD work and solve tough mechanical problems and design something elegant enough that could fit into higher level system
    - Same for electrical, computer science, etc.
  - Doesn’t see BME’s graduate with that level of expertise to trust them to put into those types of roles
- **Would be helpful to get concentrations earlier on – because seems to be a long time out**
- Would prefer to see mechanical engineer, chemical engineer with bio-focus
  - For mechanically-oriented jobs
    - Not enough technical depth in BME’s for them to succeed in their role (in-depth knowledge of particular subject-matter) – usually can figure it out, but want someone who can hit the ground running
Stakeholder: Large Medical Device Company

- Doesn’t find that there’s much desire to go do mechanical role, seems BME’s want to do verification and validation, etc. (doesn’t seem like they want to do a core discipline engineering role)
- Same is true for electrical, chemical, and computer engineering