

Stakeholder: Small Biotechnology Company

Roles BME students take in their organizations? BME students can be hired in many roles, from hands on engineering and design to marketing and sales.

What technical skills do they look for in BME students? Technical skills are very low on priority. This is because medical device design is so varied with skills a single design class can't cover them all with useful depth.

Job Title	Skill	Expectation Level			
		Freshman	Sophomore	Junior	Senior
	Basic Mechanics		X	X	X
	and Materials				
	Properties				
	Basic statistical		X	X	X
	analysis				
	Technical Writing			X	X

What soft skills do they look for in BME students?

Soft Skill	Description	
Team work	Everything will be done in teams, so being able to work in one effectively is important	
Design Control	Understand the general process of designing a product. Understand the laws that regulate design but they	
	don't need to know the company's specific procedures right away	
Aware of the	The average engineer or manager doesn't want to spend much time explaining concepts to a new hire.	
terminology		

Notes (Note any additional points that were discussed, but not covered above):

Terminology includes:

FDA

FDA clearance: 510(k) and PMA

ISO, particularly ISO13485

Design Controls

Waterfall, Agile, and other methodologies of Design Control



Product lifecycle management

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Risk and risk analysis
Market requirements (MRD, Market Requirements Document)
Traceability Matrix
Design Inputs
Design Outputs
Verification
Validation
Usability
Root cause analysis