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Job Market

The Other Life-Sciences Industry

By [Cliff Mintz](#)

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"There is a growing need for molecular biologists, biomaterials scientists, and biomedical and software engineers who understand the science that goes into device design." --Jules Mitchel, Target Health Inc.

Mention medical devices and diagnostics (MD&D) and most life scientists think of surgical instruments, catheters, prosthetic limbs, artificial joints, and imaging machines. Yet, recent advances in genomics and bioinformatics, coupled with nanotechnology and innovations in the biomaterials field, are transforming the MD&D industry. "The medical device and diagnostics business is one of the best kept secrets of the life sciences industry," says Tom Ippolito, Ph.D., vice president of regulatory affairs and quality assurance at Chembio, a Medford, New York–based medical device and molecular diagnostics manufacturer.

"Sequencing the human genome, device miniaturization, and the advent of combination devices have shifted the focus from engineering to the life sciences in the device industry," adds Jules Mitchel, president of Target Health Inc. in New York City, a company that conducts clinical trials for MD&D companies.

The secret is well-kept among job seekers, too. Focused on the prospect of jobs at biotech and pharma companies, many life scientists overlook MD&D--a field that, though perhaps currently less lucrative than those better known industries, is also easier to enter for early-career life scientists.

Growth



Jules Mitchel

In 2007, the worldwide market capitalization for MD&D companies was roughly \$240 billion. That's less than biotechnology (at \$365 billion) and pharmaceuticals (at \$1094 billion), but it's a big industry--according to a report by the consulting firm Frost & Sullivan, it's projected to grow over the next 3 to 5 years at an annual rate of 9%, a growth rate comparable to big pharma.

The recent growth is driven, experts say, by aging populations and increased life expectancy in the developed world; combination products that couple a medical device with a drug, the device usually acting as a drug-delivery vehicle; miniaturization (via nanotechnology), making medical devices less invasive; and the use of molecular diagnostics to customize therapeutic regimens and to assess individual disease risk. In 2007, the industry received about \$4.1 billion in new investment, mostly in neurology, cosmetics and aesthetics, orthopedics, cardiovascular devices, and diagnostics. That's enough investment to create as many as 2000 new jobs for life scientists.

Medical devices and the FDA

Medical devices range from the simple, such as Band-Aids, to the high-tech, such as imaging machines and the BRCA1 and BRCA2 molecular diagnostic tests for breast cancer (see sidebar).

Examples of medical devices

1. Coronary stents
2. Pacemakers
3. Prosthetic limbs
4. Medical lasers
5. Biosensors
6. CT scanners
7. Magnetic resonance imaging machines

8. Catheters
9. Artificial hips/knees/disks
10. Surgical instruments
11. Diagnostic tests (serological and molecular)

Like drugs, medical devices must receive regulatory approval before they can be marketed and sold--but the regulatory hurdles and costs are much lower for devices than they are for drugs. The U.S. Food and Drug Administration (FDA) classifies medical devices and diagnostic tests as Class I, II, or III. In general, Class I and Class II devices don't require clinical testing. Most Class III devices do require clinical testing, but the clinical trials are typically smaller, much less costly, and shorter in duration than those required for pharmaceuticals.

Career opportunities in MD&D

Until the late 1990s, most MD&D jobs were in engineering, manufacturing, quality control, and marketing and sales. Degree requirements typically ranged from a high school diploma to an undergraduate degree in science or engineering. Since then, the increasing complexity of many devices, coupled with clinical and regulatory requirements, has created opportunities for scientists with graduate degrees. "Because of the increasing design complexity and regulatory requirements for these devices, there is a growing demand for Ph.D.-level employees with ... problem-solving skills who can address scientific issues that may arise regarding the design, safety, and efficacy of devices," says Ippolito.

New disciplines are also coming into play. Ippolito adds that demand is increasing for scientists with expertise in clinical research, regulatory affairs, and quality control and assurance. "There is a growing need for molecular biologists, biomaterials scientists, and biomedical and software engineers who understand the science that goes into device design," adds Mitchel. Neurology, biochemistry, pharmacology, and physiology are also disciplines of interest. Geographically, many of the larger and more established device manufacturers are located in the Midwest and the Northeast (Table 1), but smaller MD&D start-up companies have begun to appear in most states in the United States.

Table 1. **Location of medical device and diagnostics companies**

| Company | State | Device Area |
|-------------------------------|----------------------|--|
| Abbott Labs | Illinois | Diagnostics, hospital/orthopedic/cardiovascular products |
| Baxter | Illinois | Hospital and surgical products |
| Becton, Dickinson and Company | New Jersey | Diagnostics |
| Boston Scientific | Massachusetts | Cardiovascular products |
| Dade Behring | Illinois | Diagnostics |
| GE Healthcare | Wisconsin/New Jersey | Diagnostic imaging |
| Johnson and Johnson | New Jersey | Hospital and surgical products, orthopedic/cardiovascular products |
| Medtronic | Minnesota | Hospital products, cardiovascular devices |
| 3M | Minnesota | Tissue repair |
| Myriad Genetics | Utah | Genetic testing |
| Perlegen Sciences | California | Genomics/Diagnostics |
| Roche | Indiana | Diagnostics |
| Stryker | Michigan | Orthopedic, surgical devices |
| Zimmer | Indiana | Orthopedic devices, biomaterials |

The salaries of MD&D scientists tend to be lower than those of their pharmaceutical and biotechnology counterparts. Typically, employee-benefits packages are less comprehensive, annual bonuses are smaller, and there is less opportunity for career advancement in MD&D. But those gaps are likely to close, Ippolito says, as MD&D companies seek top talent to design and manufacture more sophisticated and complex devices.



Mark Citron

On the plus side, Mark Citron, vice president of clinical and regulatory affairs at TyRx Pharma in Monmouth Junction, New Jersey, a combination cardiac device manufacturer, says it's much easier for entry-level scientists to find jobs at MD&D companies. "Having a Ph.D. is an advantage, not a requirement for a job, in the device industry," says Citron. Extended postdoc training and prior industrial

experience--absolute musts for pharmaceutical and biotechnology jobs--may not be necessary for entry-level MD&D jobs.

Louise Sigismondi, a neuroscientist, landed a job as a regulatory affairs specialist at ChemBio after a year of postdoctoral training. "After 1 year of postdoctoral training, I realized that I didn't want to do basic research for the rest of my life. So, I applied for a job at ChemBio, and, much to my surprise, I got it." Although postdoc training is not essential, it can help job seekers find work at larger and more established MD&D companies, Citron and Ippolito agree. However, these days, much of the cutting-edge science and innovation takes place at start-up and mid-size MD&D companies.

Job requirements, skill sets, and the nature of the work



Louise Sigismondi

Experts say that research in the MD&D industry--like most industry research--is focused on the market. "The research that we do is rapidly paced, extremely applied, and product-driven," Ippolito says. "There is virtually no time to pursue basic research problems in this business. I hire self-motivated, team-oriented individuals who are comfortable working in constantly changing research and regulatory environments." Citron likes to hire "technically competent 'big picture' scientists who are comfortable working on multiple projects at the same time. If you don't like doing applied research, then the device and diagnostics industry may not be for you." Sigismondi, who has worked at both pharma and device companies, prefers the latter. "My salary is lower, but I enjoy doing applied research because there is a greater likelihood [than in pharma] that the products that I work on will make it to market."

What does the future hold?

Right now, molecular biologists, immunologists, and quality control and assurance and regulatory scientists are in high demand, especially at diagnostic and biomaterials companies. Most industry experts agree that personalized medicine and theranostics--diagnostic tests bundled with therapeutic agents to

treat a specific disease--point to a bright future for the industry. However, as the sophistication and complexity of newer devices increases, so will the costs and regulatory requirements for device approval. This, coupled with rising health care costs and lower reimbursements from insurance companies, may slow the predicted rapid growth of the MD&D industry--and job opportunities--even as the demand for scientists with more advanced training increases.

Another thing to consider before jumping into M&D is the notion that because the industry has a lower status than academia, pharma, or biotech, a ticket to the MD&D industry tends to be one-way. "I think it is much easier for a person with a pharma or biotechnology background to get a job in the device industry than it is for a person with device experience to break into the pharma or biotech business," says Ippolito, who spent more than 15 years in the biotechnology field before moving into the MD&D field.

Nevertheless, in light of the fierce competition and a slumping market for life sciences jobs in academia, biotechnology, and the pharmaceutical industry, it may be worth considering a career in the MD&D industry. "The salaries may be higher in pharma and biotech," says Sigismondi, "but my current salary is considerably higher than what I would be making as a postdoc or if I was unemployed."

Images, top to bottom: PhotoDisc, courtesy of Jules Mitchel, Cliff Mintz, courtesy of Mark Citron, courtesy of Louise Sigismondi

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