Stanford eCorner

Drug Development Process

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Richard Scheller lays out the complex steps involved in the early research and subsequent development of drug products. As Genentech's Executive Vice President of Research and Early Development, Scheller directs the early stages of the process before handing off produced molecules for further development by the company. Scheller admits that while research is his clear focus, he respects the incredible logistical challenges of trying to bring a product to market.

Transcript

I'm in charge of discovering medicines that will make a real difference in people's lives. So, as you may know Genentech is now an incorporated company in the United States but 100 percent owned by a large Swiss drug company called Roche. But our group is completely independent and our job is to discover medicines that make a difference. We don't make any generic drugs. We don't make any copies of other drugs. Innovation is our... We're going to live or die based on innovation. We also believe very strongly in the view of personalized medicine. That is, making medicines that are tailored to individuals. The Roche group owns two businesses: a pharmaceutical business and a diagnostic business.

So, very large, I don't know, maybe fourth, fifth largest pharmaceutical company in the world and the largest diagnostic company in the world. So the idea is to make medicines that really, really deliver benefit-tangible, terrific benefit-for people. So if we make a medicine for somebody with cancer, we have to show that they actually live longer when they take the medicine, for example. So I oversee research. So our research group is about 1,300 folks. We have about 150 other people who are post docs. Now, why would we have a post-doc program? People come through. They come from all over the world. They stay for four five years. They bring in new techniques and ideas.

They're not cynical yet. They work at night and in the weekends and it just energizes the place. Then we have scientists at various levels. And the job of the scientist is two-fold, to do basic science. We'd like to give each of our scientists somewhere, some what we call discretionary time. Maybe that's somewhere between 10 and 30 percent of their time, so it depends on the individuals. Some people are, frankly, it's a 100 percent but that's a different topic. And with their discretionary time, they're supposed to just do interesting things. Do whatever you want; make a discovery, publish a paper. We published 20 papers in science, nature and cell last year; hundreds of papers overall from the company.

But the other real tangible deliverable of the scientist is to come up with a medicine and move that medicine into what we call early development. And in early development, the compound goes through various further stages of testing to make sure that it's safe. We do all the work to file in I&D That's a new drug application with the FDA and we file the I&Dand then we do the clinical studies Phase I and Phase II. In Phase I, you usually just treat patients. Then, make sure that the drug is safe. You start at a very, very low dose. I mean, imagine, putting something into a human that's never been in a human before. Slowly, escalate the dose. It depends on the disease.

Sometimes it will be in patients with the disease, sometimes not. But then, usually in Phase II, you do a relatively small number of patients but enough patients so that you have statistical power to see that you're making a difference in the disease.

And what we then do would be, if their Phase II trial works, to hand the medicine to them, the Global Development Group, to do the final clinical testing. And the final clinical testing would then be done in 80 countries around the world. It's a logistical absolute nightmare. It's done in many, many more patients so that the statistical power increases dramatically. And then, work with the regulatory authorities to get permission, if you will-so the FDA, in case of the United States-permission to market the drug. So my job is to deliver molecules that we say have gone through proof of concept. We believe that they work. We have the chemical entity.

We know that it can be manufactured and to hand this to the Global Group where there's a lot of science involved but there's a huge amount of logistics and regulatory involvement. And that's when the commercial people get involved and so on. Frankly, I'm less interested in that. I then go back and try to discover a new medicine and show that it works.