New approaches in the life sciences industry: innovative strategies for courageous companies

For many years, the pharmaceutical industry has been investing increasing amounts of money in the development of new products. The number of marketing authorisations, however, has only recently gone up. The need for innovative development strategies is obvious. However, for large corporations it is often challenging to implement such innovative approaches. In the following interview, Dr. Friedemann Taut explains how small- and mid-sized companies can stay a nose ahead of the big companies. Dr. Taut is a specialist in anaesthesia, intensive care, and clinical pharmacology. Based on extensive industry experience, he is founder and managing director of Taut Science & Service Ltd., which specializes in consulting services for Medical Device and Drug Development.

The number of new drug approvals (FDA) has only recently picked up again. Before that, we saw a decade of dramatically decreasing numbers, although R&D expenditures had nearly doubled. Do you have an explanation for this?

Effective treatments are already available for common diseases such as asthma and hypertension. So we shouldn't expect major breakthroughs for these indications. Pharmaceutical companies therefore turn to projects in niche indications, including orphan drugs, where development is relatively time-consuming and costly. In addition, regulatory requirements increase and drug safety regulations get stricter.

An even greater problem: the relatively rigid and expensive structures seen in some large companies can be prohibitive to true innovations. Executives of such companies tend to be risk-averse and sometimes prefer to stay on well-trodden paths. Admittedly, they carry a high responsibility for many jobs and the share price. Any failure, especially the failure of a high-risk project, would likely negatively impact on their career chances. Brave, innovative strategies, however, often involve greater personal risk, the kind that many people are not willing to take.

How do corporate structures need to change in order to create more room for truly innovative projects?

Dr. med. Friedemann Taut, managing director of Taut Science & Service Ltd. © private

Well, look at small companies, biotech start-ups for example, where entrepreneurial energy and constant innovation are prerequisites for market survival. Some big corporations are setting up their R&D business units empowered with a great deal of autonomy, similar to start-ups. Start-up culture (flat hierarchy, quick decision making) encourages taking responsibility for and identifying with the company's projects. Ultimately, start-up culture increases the power of innovation and productivity.

Some small- and mid-sized companies benefit from an agile company culture and are therefore well positioned for moving into interesting niches. As a matter of fact, there is currently a great deal of interest among private investors in well-positioned life science companies of this kind. However, the challenge faced by small companies is that they often lack comprehensive in-house operative, medical, and scientific expertise, which is, amongst other things, a prerequisite for making a successful transition from preclinical research into experimental clinical development.

Could these companies buy in the expertise they need? For example, could they buy the services of top medical experts to design innovative development strategies for them?

They can certainly do so. Highly paid key opinion leaders (KOLs) are gladly taken on board. However, this does not solve every problem, even if top scientists are involved. If many different companies hire the same KOLs who then give similar advice, the companies run the risk of participating in mainstream rather than finding innovative paths. Such experts also tend to be surprisingly detached from the operational necessities the core teams need to master, and the knowledge of which is essential for integrative strategy work.

Ideally, what kind of people should make up a core team to be able to design the most effective strategies?

Naturally this largely depends on the requirements of each specific project. In most pharmaceutical projects and, with slight variations, in medical device and combined projects, an experienced project manager ensures that areas such as technical development, preclinical development, regulatory affairs, intellectual property, and the various aspects of clinical development are well taken care of.

Strategies must be developed by the core team and discussions with KOLs must be conducted at eye level. This, of course, requires very capable and confident teams within the company. It is crucial that the medical and scientific expertise related to an indication is combined with comprehensive experience from operative work in clinical trials. Only controversial discussions on a high technical and scientific level will enable companies to veer off the beaten track and discover ideas with great potential. If everyone is always in agreement, nothing will happen. Mutual backslapping in times of major market success has unfortunately thwarted many development opportunities despite the multi-million budgets that would have been available.

Is the establishment of a strong core team and encouragement to conduct controversial discussions therefore essential for developing innovative life sciences products? What could go wrong if the people in charge ignore this?

There are some key elements in clinical development programmes which have unfortunately repeatedly caused costly clinical trials to fail. One can only wonder why existing and published knowledge is so often ignored.

Let's take the American NIH-NHLBI[1] ARDS[2] Network as an example. It was a research network established in 1994 to study the treatment of acute respiratory distress syndrome (ARDS). In its 20 years of existence, several pharmacological approaches were tested in critical care patients with shock lung. Unfortunately, the network basically stuck with quite similar trial concepts throughout, and repeatedly produced negative outcomes, although the weaknesses in trial design and patient selection had long been known. Huge amounts of taxpayers' money were wasted.

Some clinical studies do not recruit the subset of patients who would really benefit from the test substance. Other trials fail because it is not realised early enough that the primary endpoint, e.g. a certain degree of disease progression, occurs much less frequently than expected. Countermeasures can be taken during an ongoing trial, but only if the team is highly alert and experienced. I am sure that in the past, effective and important new therapeutic principles were discarded because the validity of the clinical trials was too poor.

How can productivity in the pharmaceutical and medical device industry be bump started?

Innovation and productivity rely on profound knowledge of the matter in hand, ranging from scientific basics to the art of operative development and the patient situation. I therefore believe that high-end networking, i.e. cooperation between the most knowledgeable experts in different disciplines, and joining forces with a common vision, is the key in this process. Nowadays, this is usually done in virtual teams; immediate geographical proximity of team members is no longer a prerequisite for effective cooperation. However, managing such teams is highly demanding.

Known errors must be avoided at all costs. Existing knowledge must be applied consistently. Senior

managment must be able to rely on and trust their teams. They need to grant them sufficient wiggle room to execute. This is the only way to leverage the full potential of the team and of the development project at stake.

You are active in the BioLAGO life sciences network in the Lake Constance region. How can networks help boost productivity in the pharmaceutical and medical device industries?

Although the pharmaceutical industry has nearly doubled its R&D investments over the last ten years, it seems to be increasingly difficult to obtain market approval and place real innovations on the market. © jarmoluk/Pixabay

A life sciences network like BioLAGO offers the opportunity of finding specialised companies and experts nearby that can then join forces to generate the best possible solutions. The result of such networks can be expected to provide far more than the sum of its parts. BioLAGO has already reached the critical mass necessary to leverage such efficiencies.

Dr. Taut, thank you very much for talking to us.

[1] NIH-NHLBI, National Institutes of Health - National Heart Lung and Blood Institute, American organisation that provides public funding to scientific projects, similar to Deutsche Forschungsgemeinschaft (DFG)
[2] ARDS, acute respiratory distress syndrome

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Biotechnology – driver of innovation in the pharmaceutical industry

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