



Letter to the Editor

Skunkworks project for Big Pharma



Teaming with just 50 people, Steve Jobs developed the Macintosh computer, making a major impact on the computer industry and the lives of people around the world [1]. This achievement dramatically illustrates what a small and loosely structured group of highly trained and creative individuals with different skills can accomplish when they work closely together to achieve a common goal. But this is just one example. In the 1950's and 60s, Lockheed employed a strategy known as *Skunk Works* to produce airplanes (U2 and SR-71 Blackbird) that were decades ahead of similar products developed by others. Moreover, these planes were manufactured under budget and more rapidly than those produced by competitors (see the fascinating account of this engineering approach [2] (Fig. 1). This concept got traction now even in the way students are thought and evaluated (e.g. [3]).

Large projects like introducing medicines to the market to combat common and rare diseases are complex and expensive. Big participating teams require time-consuming self-education and hierarchical structures. Moreover, the process itself can often be characterized by a “lack of ownership”, risk avoidance, and complex regulatory protocols (not only to fulfill federal guidelines but

also to overcome internal barriers). Clearly more complex decision making is partly responsible for the significant cost, duration of time and opportunities lost to competition. Several small start-up companies succeed in shortening this process and for a fraction of the cost. But to their detriment, both large and small team processes also can become uncoupled from ever changing science, with resulting obsolescence of the involved project.

A skunkworks strategy for a large pharmacological (biotechnology) company makes sense as significant talent and experience already exist. Oversight of the whole project from beginning to end by a specifically created team could introduce the necessary competitiveness and commitment to a common goal, along with a true sense of ownership. Clear lines of responsibility, “*in situ*” intersection of ideas between personnel with different expertise, and accountability would foster creativity and cooperation among smaller team members. As a consequence, the time and cost of achieving a common goal could be reduced. Once active molecules are identified, a holistic view of the science, safety, clinical trials, and a team of potential physicians established with their input and commitment to success of the project in subsequent human testing and regulatory issues could be entirely conceived from day one. In this iterative skunkworks process, more rapid imple-

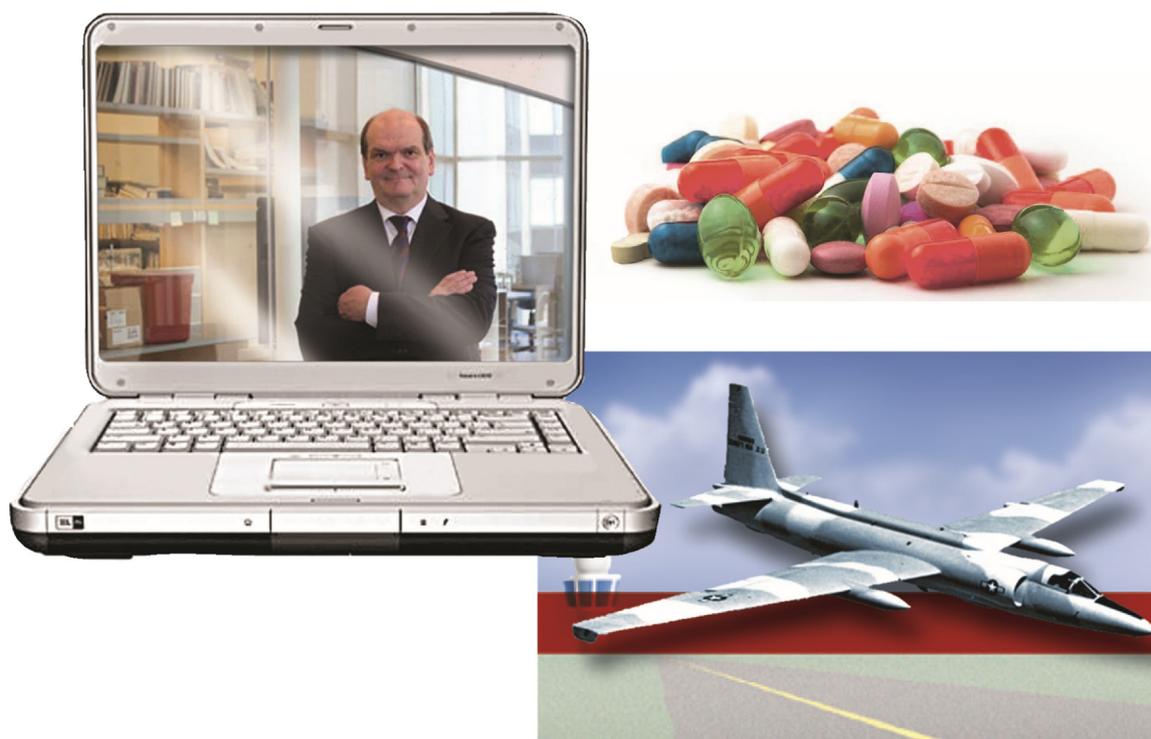


Fig. 1. Proven *Skunk Works* for engineering should be extended to drug development.

mentation of new developments from scientific fields, as well as imaging/testing of affected patients could be implemented without significant delay. Handing over the project from one group to another with only a minor interconnection as drug development proceeds is unlikely to be optimal. Another major impediment is lack of continuity on the project imposed by moving from one focus to another. Science simply does not work this way.

Such a skunkworks-implemented project could significantly reduce the cost/time for drug development, retain the most talented and committed personnel and surely be competitive with the current approaches of Big Pharma and small biotech companies. Even as we do experiments daily, learn from our observations and correct our mistakes, we rarely introduce an interactive structural organization into our therapeutic teams. Implementation of new ideas is limited or seldom practiced at the organizational level. New audacious approaches must be attempted that have ground-breaking potential as to how new medicines are conceived and developed. Successes of Lockheed Corp. and Apple Inc. with a skunkwork approach paved the way for transformative engineering advances (Fig. 1). So now when drug development has matured, perhaps a skunkworks project could be adopted not only by small Biotech companies, but also by Big Pharma as well. Such proposals have already been written and evaluated for biotech companies and large Pharma (samples can be found in Refs. [4–6]). Thus, considering the secrecy in the industry, the open question is whether Big Pharma would adopt this approach? Is it simply that the experiment has not been tried, that only a truncated version of “skunkwork” has been implemented, or that the current

organizational structure simply does not allow such a far reaching experiment. Perhaps we will hear from Big Pharma at some point.

References

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Krzysztof Palczewski
*Department of Pharmacology, School of Medicine,
Case Western Reserve University, Cleveland, OH
44106, USA*
E-mail address: kxp65@case.edu

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