Whitepaper 1

Redesigning biotech research regulation systems from first principles.

The importance of a careful balance between innovation and regulation in the biotechnology industry is paramount. However, due to natural forces at play, the division of resources between innovation and regulation is preventing the industry from reaching its maximum innovative capacity by large margins. In order to prevent stifling of growth of innovative power of the biotech industry, Panorama Laboratories proposes working toward a zero time investment regulation system.

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State of the industry

Pharmaceutical compounds influence our most fundamental building blocks (biology), so mistakes in designing and producing those compounds may lead to unwanted effects on our biology. For this reason, we have guidelines that require careful documentation and testing of pharmaceutical compounds before bringing them to the market. These guidelines are built on top of scientific foundations, so the more we learn, the more we are able to protect ourselves from mistakes.

For innovative organisations building these compounds, these regulations take the form of paperwork. All research, development and manufacturing in the pharmaceutical industry is subjected to rules regarding conduct and very strict documentation of that conduct. Obviously, no one is against these regulations being in place, since everyone relies on the same biological foundation. This does not mean, however, that organisations are happy spending their resources on activities that are not their core business. From an innovation point of view, most work required to abide regulation is not necessary to make a successful innovation. From this point of view, as long as it is safe and functional, no more resources need to be invested. From here on, generating paperwork for regulation purposes is only added to get market access.

Now that we have established that regulation is both fundamentally necessary and never an innovative organisation's core activity, it becomes clear that it would be preferable to
1. ***Maximize the data available*** *to guarantee the safety of new innovations*
2. ***Minimize the amount of resources*** *that an organisation spends on regulation.*

Even though this conclusion is well known throughout the biotech industry, both maximizing data and minimizing resources spent are hardly ever considered beyond what is classically available. Maximizing data is driven by stricter rules for lab technicians to write down even more details. Minimizing resources is driven by centralizing all quality control personnel and cutting as many corners as possible without sacrificing the probability of passing regulation. This has not changed in the last 30 years, with the exception of documentation being typed more than scribbled.

Road to zero time investment regulation

At Panorama Laboratories, we take maximizing data and minimizing resources to its maximum capacity. Our goal is to decrease the time investment needed to pass any regulation regarding biotech research to zero. We do this by advancing data collection in laboratories and automating reporting based on this data collection.

In order to reach this goal, we have a set of principles to maximize data availability and minimize resource allocation.

1. ***All actions in a research track need to be documented.*** *There needs to be an unbroken chain of data that can be used to completely simulate all actions that lead to a research result.*
2. ***The creation of documentation of an action and the action itself need to be integrated as one.*** *This way, there is no way that the documentation misrepresents the action. This is a huge problem with the current, human-based, documentation systems. Documentation is always subjected to human influence due to the human interpretation of an action preceding the documentation of that action.*

3. ***Documentation assessment has to be automated.*** *Because regulation is based on current knowledge, and current knowledge is ever increasing, resource allocation for passing regulation also has to keep increasing. The only way for innovation to keep happening at the rate it does now, is to make sure resource allocation to passing regulation does not scale at the same rate as growth of collective human knowledge. The logical conclusion is increased automation.*

Based on these principles, we have a 2-phase plan to decrease time allocation to regulation to zero.

1. ***Create devices that are able to integrate documentation and the action in the biotech laboratory,*** *and do this for every action that can be executed in the laboratory.*
2. ***Create algorithms that allow for automated assessment of all these actions in the laboratory****. After which reporting based on these results should be automatable.*

Panorama Laboratories starts with pipetting.

We are now in the beginning of the first phase. We are building a device that can document all pipetting actions that take place in the laboratory with a very high resolution as the action happens. Pipetting was chosen as a first action to supply a documentation system for because it satisfied three rules that we set for our first product.

1. *The action it documents has to take place very often.*
2. *The documentation resolution that currently exists is insufficient to adequately measure its effects on the final result.*
3. *Failing to properly execute the action it documents can lead to a substantially large misunderstanding of the final result.*

Micropipette use satisfies all those rules to the largest extent of identified actions in the laboratory, which is why our first product, the Panorama Beacon (name subject to change), focusses entirely on documentation and assessment of this action.

By building a new documentation and assessment system from first principles, Panorama Laboratories is working towards a zero time regulation system. Although that goal is still far away, the necessity of the goal is already clear. With the current standards of regulative efficiency, abiding regulation will encompass an ever growing percentage of resources available to bringing new innovations to the market. By generating data in a way that algorithms are able to carry the regulative workload, innovations in the future can reach the market faster, while not sacrificing quality and safety.

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