The Covid-19 Pandemic – A Global Pharmaceutical Manufacturing Challenge




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Abstract

In the current environment, of the global COVID-19 pandemic, it is necessary to take a hard look at the manufacturing capacity and response capabilities of the global pharmaceutical sector. Given the current known infection rates, and current efforts to limit infections, it is reasonable to suggest that by the end of 2020 about 200 million people may be infected by Covid-19. However, the other 6,800 million people present the challenge. Both immediately, and in preparation for the next such occurrence (consider our recent history of SARS, Ebola, MERS, Swine Flu/A(H1N1) etc.), the world, and the pharmaceutical industry in conjunction with the WHO as a global coordination body, should come up with an appropriate response. Therefore, it is incumbent on the industry, with its significant resources, financial and intellectual, to find a pathway through the 'regulatory expectation' and typical industry approach to deliver a facility design and proven manufacturing platform which, with global co-operation, could be raised out of the ground and qualified, within a shorter period of time than ever before. We aim, in a series of articles to lay out a potential pathway forward on this manufacturing topic, with a particular focus on the vaccination element. This article gives an introduction to the various treatment options that may require manufacture.

Keywords: Covid-19, pharmaceutical, biopharmaceutical, capacity, vaccine, treatment, manufacturing

1. Introduction

The Covid-19 pandemic has not been transparently brought under robust control in any country. The current strategies of public space and service closures, social distancing and personal hygiene has successfully flattened the infection curve in some countries. But, this has not removed the basic threat posed by the SARS-CoV-2 virus. Further global cycles of rebounding infection waves accompanied by the re-imposition of restrictive practices on daily life by national and local governments in response to the immediate public health threats is forecasted, the so called 'hammer and dance'[i]. The

question becomes how do we emerge from the current pandemic situation and safely shed the current restrictive control measures.

As with any significant threat to public health, the solution lies not only in treating the existing situation, but also developing preventive measures. Specifically, it is important to take stock of short and intermediate term treatments that may be employed as an immediate medical response for those currently infected, as well as the intermediate to long-term development of treatments to better reduce the death rate. In addition to the intermediate and long-term development of treatments, vaccines must also be developed within this same time frame to prevent those not infected from becoming ill or further transmitting the virus.

While the response to these needs has been a massive and unprecedented collaborative effort undertaken by the pharmaceutical industry, aimed at developing as many possible answers to the 'treatment' and 'vaccine' question as possible, there are many technologies that must be entertained and evaluated. This article will discuss the technologies underlying many of the proposed treatments and vaccines. Follow-on articles will discuss the potential to scale-up these technologies, build/modify, commission and start up sufficient manufacturing capacity to address the scale of the pandemic, and do all of this on a timescale that is acceptable.

2. How Do We Combat Covid-19

There are multiple options for treatment and vaccines for Covid-19. Some treatment options may be based on previously approved pharmacueticals with other indications. Treatments can reduce the severity and impact of the symptoms, or clear the patient of the virus completely. Treatments can provide relief to people with severe responses, who are at risk of dying from the infection. However, treatments don't prevent people from becoming infected, and the disease will continue to spread.

A vaccine provides active acquired immunity to a virus and typically contains an agent that resembles a disease-causing virus. The agent stimulates the body's immune system to recognize and destroy the virus. The immune system retains this agent in its 'memory' so that it will be able to combat future infections. By providing different levels of immune readiness and effectiveness, vaccines can stop outbreaks before they happen, or prevent them from rapidly propagating through a vulnerable population. Examples of this are the measles and mumps vaccines administered globally to young children, or the widespread distribution of the annual flu vaccine. The efficacy of vaccines is continually demonstrated on a local and global basis. There is more than two centuries of history using this medical technology, which began by using inoculations of the cowpox virus to prevent death and serious illness by the far more serious smallpox virus. An ongoing vaccination programme against SARS-CoV-2 is the best option to provide us with some level of normalcy in our lives.

3. First Line of Defence: Immunoglobin

One of the first protection options available, with limited risk, is to collect plasma from people who have been infected by the virus and have been certified as recovered. Once infected with the virus, our immune systems will start developing anti-bodies of Immunoglobins to fight off the intruding virus. By collecting this immunoglobin (IG), and administering it to other people, the anti-bodies will provide temporary protection from the virus. This immunoglobin would ideally be provided to people at elevated risk, such as healthcare professionals working on the front lines with Covid-19 patients, as well those populations who may have severe complications from Covid-19.

The process of producing this immunoglobin starts with collecting plasma from patients who have recovered from the virus and have been symptom free for 14 days. The convalescent plasma is then transported to existing plasma fractionation facilities for viral inactivation, fractionation and purification. This purified plasma, also referred to as hyperimmune immunoglobin, can then be administered as a temporary preventative and protective measure.

Some initial trials in China have indicated that this approach can be successful to protect people from Covid-19. The approach is a proven technology and has also been shown to be successful on other types of corona viruses. It has been reported that eight SARS patients were successfully treated with convalescent plasma during the last major outbreak with no immediate adverse events[ii]. During the MERS outbreak, this approach failed due to insufficiently high titer plasma from recovered patients.

As a treatment, administered immunoglobin is expected to start being effective within a few weeks and can be effective for up to a few months. The treatment, however, is costly and many indications require it to be given regularly. As the immunoglobin is only available from recovered patients, both sources and quantities are limited and require the cooperation of recovered patients in order for it to be harvested. This treatment may provide a welcome initial response, but other treatments are required to alleviate the risks of people who may get infected in the coming months until vaccines will be available.

4. Treatment: The Medium-Term Response

In parallel to the development of a workable vaccine against SARS-CoV-2, we need to develop treatment agents for the most critically ill patients. With the medical system currently flooded with patients, the usual decade long struggle to develop a treatment regimen is not a luxury we can afford. So any immediate treatment option is likely to be the re-purposing of an existing treatment for another indication, or the use of an existing platform to develop a bespoke agent.

The study of the Covid-19 illness is only a few months old, so our understanding of the clinical progress of the disease are still sketchy. But it appears that there are multiple pathways that are causing mortality in the most critically ill. The three pathways that have been identified are severe damage to the lungs and other organs by the virus itself, being overwhelmed by secondary infections due to a suppressed immune system and being overwhelmed by a cytokine storm caused by an over-activated immune system.

These pathways are likely to require different modes of treatment and it is unlikely that one pharmaceutical agent will address all of the mortality pathways. Indeed, even if one agent is found to have a significant effect there will be substantial unintended consequences or ancillary impacts; already there are worldwide shortages of chloroquine and hydroxychloroquine for patients who require them to treat lupus, malaria and rheumatoid arthritis as public demand increases for a drug that has, at best, questionable positive effects and proven detrimental effects[iii].

4.1. Anti-Malarial Small Molecules

Chloroquine, Hydroxychlorquine and their derivatives have been suggested as treatment agents for Covid-19. These agents have been used as anti-malarial drugs and immune-suppresents for autoimmune disorders (such as lupus). Their mode of action in the anti-malarial indication involves interference in the transport of infective agents into the cell. In addition, hydroxychloriquine suppresses the formation of cytokines and has been used to modulate over-active immune systems as an immune-suppressant. While the modes of action and *ex-vivo* testing appear promising, early clinical results against Covid-19 are mixed[iv,v,vi].

Like most antiviral compounds, the identification and development of an effective small molecule or small molecule cocktail is likely to be a time consuming challenge. But since these compounds have been used as anti-malarial drugs they have been produced in large quantities by established manufacturing processes.

4.2. Other Small Molecules

Laboratories around the world have been screening all possible small molecule compounds for activity against Covid-19. If any of these compounds are effective, they can generally be made via (relatively) straight forward chemical syntheses. But the pharmaceutical industry is continually striving to develop small molecule antiviral agents, often with limited success, and those successes have taken decades to identify and develop.

4.3. Existing Anti-Viral Cocktails

There has already been a significant amount of chatter around possible existing anti-viral treatments that work specifically to inhibit viral replication. These are particularly interesting as they may prevent infected patients from developing severe symptoms by limiting the depth and severity of the viral spread within affected respiratory systems, allowing the immune system to respond better to the virus. There are several antiviral cocktails that have been approved against, for example, HIV and Hepatitis C. These compounds interfere in the replication of the virus within the cell. A cocktail of compounds is typically used which renders it difficult for the virus to mutate around the effect of the compounds. While these cocktails have been developed to specifically target a particular virus of interest, there is potential that a cocktail of these antiviral compounds may have some effect against the replication of the SARS-CoV-2 virus. These compounds are currently made in relatively large amounts – to cover millions of patients. But they are relatively difficult small molecules to make and scaling up to cover 100s of millions of patients will be a challenge.

Several pharmaceutical companies are rapidly undertaking studies in these areas, and some have shown promise. For instance, Ivermectin has been shown to inhibit replication *in-vitro*, but issues arise when the dosages required are considered in addition to complications from possible resulting neurotoxicity[vii]. Similarly, Remdesivir is being touted as a possible replication inhibitor even though it did not receive approval as a treatment for SARS or MERS, despite that it showed promise both *in vitro* and *in vivo*[viii].

4.4. Antibody to the SARS-CoV-2 Virus

The genetic sequence of the SARS-CoV-2 virus was quickly determined, and the three-dimensional structure of the virus soon followed. The key feature of the virus structure is the surface S protein which gives the corona virus its spikey structure. The S protein appears to be the key protein for the entry of the virus into an uninfected cell. Multiple groups around the world have taken both the shape of the S protein

and the shape of the ACE-2 receptor on the target cell and are developing antibodies to these. The antibody to the S protein would inactivate the virus particle and an antibody to the ACE-2 receptor would block the attachment of the virus.

Both approaches could be used to minimize the reproduction of the virus in an infected patient. Once an effective antibody is identified, the expression, production and purification of the antibody in the existing mAb manufacturing platforms is relatively straight forward. The first generation of anti- SARS-CoV-2 antibodies will not be optimized for activity, lack of side-effects and high manufacturing titre.

4.5. Immuno-Suppresion Using mAbs

A number of existing commercial mAbs are used to suppress overactive immune systems for diseases such as rheumatoid arthritis. There is evidence that some of these compounds may be effective at modulating cytokine storms. One of these compounds is already in a Phase III trial for the prevention of cytokine storms in the treatment of Covid-19[ix]. This type of compound could be quickly produced in the existing mAbs manufacturing platforms around the world.

4.6. Immuno-Stimulation Using mAbs

There are existing mAbs which act to stimulate a suppressed immune system. To deal with the clinical path showing suppressed immune function, it may be possible to use existing immuno-supportive mAbs to treat the co-morbidities. Since these are already commercial compounds, they can also be quickly produced using the existing mAbs manufacturing platforms.

5. Vaccines: Long-Term Prevention

5.1. Traditional Vaccines: Live or Inactivated

Traditional vaccines consist of either live attenuated or inactivated vaccines. Live attenuated vaccines rely on administering a weakened form of the virus to a healthy individual. The dose is formulated so that it is not strong enough to cause the patient to get sick, but sufficient to elicit a biochemical response and for the patient to boost and train their own immune system. This type of vaccine can be provided at low cost and provides a durable immunity, requiring less frequent, or no, booster shots. The downside of this vaccine is that attenuated virus can continue to evolve in the host if it is not overcome completely and the virus may reacquire some of its virulence. This type of vaccine can also cause severe complications in immunocompromised patients.

Inactivated vaccines administer an inactivated form of the virus or specific components, including toxoids, to boost the patients' immune system. This type of vaccine can provide protection to people with compromised immune systems, as there are fewer risks compared to live attenuated vaccines. However, because the virus or the specific components are inactivated, a higher dose or more frequent repeated doses are required to achieve ongoing protection.

Both vaccine types are typically produced by taking a host cell or organism and providing the right environment to stimulate the virus to replicate. Inactivation, if required, is performed by physical process such as heat, or chemicals such as formaldehyde or β-propiolactone. The viruses or specific components are then isolated, purified and filled in vials or syringes for administration. The equipment and facilities that process live virus require higher containment procedures to protect the manufacturing staff. Generally, the large-scale manufacturing equipment involved, coupled with facilities designed for a particular vaccine process, makes sharing or switching over between vaccines a challenge.

Flu vaccines predominantly use embryonic chicken cells in eggs as the host cells. Due to having different receptors and other characteristics, the SARS-CoV-2 virus can't replicate in embryonic chicken cells[x,xi]. Other cell lines will need to be used to develop the production of traditional vaccines. This also means that common flu manufacturing facilities using an egg-based process cannot support production of Covid-19 vaccines without significant modifications. Immediately this removes the manufacturing and supply chain for the largest by volume, biologically produced, drug product produced globally from the list of potential options for manufacturing a vaccine for Covid-19.

It should be noted that a vaccine may never be developed as has been the case of AIDS. To date, there have been no successful vaccines fully developed and licenced for a coronavirus. Treatment and herd immunity could be the only options.

5.2. Advanced Vaccines: Sub-Unit Vaccines

After the first wave of traditional whole-virus-derived vaccines, a new approach was used to create vaccines as it was discovered that for robust immune response the whole virus was not required. Instead, the full virus molecule could be substituted by a single protein or subunit to generate a robust immune response. These protein-based vaccines are easy and relatively cheap to make and have become the most common variety outside of egg-based influenza vaccines. These vaccines can either be based on recombinant proteins, synthetic peptides, virus-like-particles, or viral vectors.

Subunit vaccines do have limitations with respect to immunogenicity. They typically require multiple immunizations to achieve similar levels of immune response

achievable with traditional vaccines. They can require an adjuvant to be included, in a complex formulation process, in order to increase the immunogenic effect. These formulations often confer substantial stability, shelf-life and storage benefits, although they can be complicated to develop and are particular to each sub-unit. For some platforms, adjuvants could enhance immunogenicity and make lower doses viable, thereby enabling vaccination of more people, for the same manufacturing capacity, without compromising protection. Vaccines can be enhanced with licensed adjuvants already produced, or with novel adjuvants specifically designed for a Covid-19 vaccine. So far, at least 10 developers have indicated plans to develop adjuvanted vaccines against Covid-19, and some vaccine developers have committed to making licensed adjuvants available for use with novel Covid-19 vaccines developed by others.

Recombinant protein vaccines are developed by inserting a gene (coding for a vaccine protein) into a host cell. The host cell will then produce the protein that can generate immune system response. The immune system will recognize the expressed protein and provide future protection against the target virus. Recombinant protein vaccines are manufactured by culturing the host cells or expression system; bacteria, insect, yeast, plant, mammalian, and cell-free. The recombinant protein is then purified and injected into the patient for vaccination. There are licensed vaccines based on recombinant proteins for other diseases, and so such candidates could take advantage of existing large-scale biopharmaceutical production capacity.

Virus-Like-Particle (VLP) vaccines are particles that closely resemble viruses but are non-infectious. VLPs contain no genetic material, potentially yielding safer and cheaper vaccine candidates. A handful of VLP-based vaccines have been commercialized for protection against viruses such as hepatitis B virus and human papillomavirus. Like recombinant protein vaccines, VLPs are produced in large scale fermenters using cell lines such as bacterial, mammalian, insect, yeast, and plant cell lines.

Viral vector vaccines use a modified virus that creates an immune response, akin to the unmodified virus, and thereby produces the required antigens. The vectors designed for measles retain the ability to replicate (replicating viral vector), whereas the viral vectors for adeno-associated virus and herpesvirus are modified to so they cannot replicate (non-replicating viral vector)[xii]. The vector plasmid is transfected into specially designed cell lines. The viral vector propagates in the infected cells in a production scale fermenter. After this, the vector is collected from infected cells and purified by ultracentrifugation. Generally, viral vectors achieve high immunogenicity without an adjuvant.

Synthetic peptide-based vaccines are ”chemically defined”, small-peptide antigens that have been engineered to induce the desired immune response. Unlike recombinant proteins, viral particle and viral vector vaccines, peptide-based vaccines are synthetically prepared in chemical reactors. Peptide antigens can be fully and precisely characterized as a chemical entity and this avoids problems associated with biological contaminations and storage. Production of peptides has become simple, easily reproducible, fast and cost-effective due to recent developments in solid phase peptide synthesis (SPPS) using automatic synthesizers and the application of microwave techniques[xiii]. The peptides though are poorly immunogenic and need to be delivered with additional immune-stimulating agents such as adjuvants or particulate delivery systems/carriers. Delivery systems are usually physically entrap the vaccine components in/on the carrier - typically liposomes and virosomes are used. However, chemical conjugation can be also applied to build more stable delivery platforms.

5.3 Cutting Edge Vaccines

The last group of vaccines are the DNA and RNA vaccines. These types of vaccines deliver a specific nucleotide sequence that cells inside a patient use to produce the proteins that pathogens use to cause disease. Those proteins will act as antigens that the immune system will recognize, thereby creating resistivity to viral infection.

DNA vaccines usually consist of synthetic DNA containing the gene that encodes the disease-agent protein. Usually, the plasmid DNA used as vaccine is propagated in bacteria such as E. coli and they are isolated and purified for injection. The manufacturing process for DNA plasmid vaccines is performed in fermenters and is well-established, allowing experimental vaccines to be quickly developed. The plasmid DNA is usually injected intramuscularly or intradermally[xiv]. The principle behind a DNA vaccine is that the antigen can be expressed directly by host cells in a way that simulates viral infection and invokes an immune response from the host. DNA immunization techniques allow antigen production to occur *in vivo*, by-passing the need to produce and purify protein antigen *in vitro*. They have been shown to induce broadly protective and improved antibody responses in ‘prime-boost’ regimens in combination with other sub-unit treatments[xv]. However, DNA vaccines carry the risk of permanently changing a person’s DNA, or triggering unintended signalling and biochemical pathways, requiring extensive clinal testing and potentially long-term follow up.

RNA vaccines use messenger nucleic acid RNA (mRNA), which are blueprints for a cell to reproduce a particular protein, to produce the protein that mimics the virus. mRNA

can be produced in a process involving the enzymatic transcription of the target RNA. This process uses RNA polymerases from a linearized plasmid DNA template, followed by enzymatic destruction of the DNA template by DNases[xvi]. The purification of the resulting mRNA can be performed by precipitation and chromatographic methods according to size. Finally, the mRNA particle needs to be embedded in a delivery vehicle such as lipid nanoparticles. mRNA vaccines have several advantages over DNA vaccines, in that they do not carry the risk of DNA integration and require smaller dosage forms, and therefore smaller manufacturing facilities.

Some DNA and mRNA vaccines use a harmless virus or bacterium as a vector or carrier, to introduce the genetic material into cells. Several such recombinant vector vaccines are approved to protect animals from infectious diseases.

DNA and mRNA vaccines have many advantages. They are fast to develop once an investigator has the published genome of a virus. For example, the time from selection of the viral genes to be included in DNA vaccine to initiation of clinical studies in humans has been dramatically reduced over the last decade and was reduced to just three months for the Zika virus[xvii]. They are easier to adjust and to fine-tune for a particular beneficial immune response. They may also eliminate the need for cold chain storage of the product, which is typically required for biologically prepared vaccines. The cost to make these vaccines can be substantially lower at full-scale up to an estimated factor of 10[xviii]. However, these types of vaccines are still considered experimental for human use. Research in DNA vaccines started 30 years ago, but most remain in clinical trial phase 1 testing and there are no approved DNA or mRNA vaccines on the market for human use.

6. How Fast Can We Produce Vaccines?

Is development, approval, and manufacturing of novel vaccines feasible in 18 months?

By offering a perspective on how we have historically dealt with pandemic outbreaks and development of vaccines, we can provide important context to the challenges we will face currently.

One of the first examples that may provide some insight is the vaccination against Rubulavirus that causes the mumps. A vaccine against the Rubulavirus was developed in 1967, but it took over 4 years between collecting vial samples and an approved vaccine in 1967[xix].

On the other hand, development of the new yearly flu vaccine takes only up to 5 or 6 months. But, the flu virus has been extensively characterized for decades and there are immense records of strains currently and historically active around the globe and years of practiced technological transfer of 'this year's' flu' into a safe-for-market product. Indeed, the formulation of the influenza vaccine often changes between August, when the first annual batches for the northern hemisphere are released, and November, when a different picture emerges in September and early October of a different strain being in circulation. Even in this year's flu season this speed of reaction was not sufficient, as the most virulent and prevalent flu strain circulating in the U.S.A. was an influenza B strain, whereas the seasonal vaccine was set up to target primarily influenza A. As a result, the hospitalization rate of children was even greater than that caused by the A(H1N1) pandemic in 2009, which primarily affected babies and children, not older populations.

The swine flu or A(N1H1) pandemic outbreak in 2009 is an example of a success story, in relation to vaccine manufacturing response, and was somewhat of a success story when it came to an overall pandemic response[xx]. The disease was first detected around April of 2009. Within a couple of weeks, test methods were developed and rolled out. Historical experience of flu strain manipulation meant that new vaccines were developed rapidly. The first clinical trials were started 4 months after the first detection of the novel influenza strains. Three months after that, no fewer than 4 different vaccines were approved. The initial target was to produce up to 159 million doses for the initial target group, but by December 2009 sufficient doses were available for anyone who wished to be vaccinated. These vaccines were produced in manufacturing facilities for influenza vaccines, using the same manufacturing process. As already outlined however, these manufacturing platforms are not suitable for Covid-19.

Two other corona-virus outbreaks were significant early warning alarms to the situation we are now in with the SARS-CoV-2 virus. SARS (caused by SARS-CoV-1 virus) broke out in 2003 but was contained to 2 dozen countries. MERS broke out in 2012 and spread to several countries, including the US. MERS had a much higher fatality rate, with 3 or 4 out of every 10 patients reported with MERS to have died. Both strains of the corona-virus had different transmission rates and methods, limiting the spread and making it easier to contain. Many studies were initiated to develop vaccines for these corona viruses. But because these viruses were contained relatively quickly (SARS) or few cases developed (MERS), the development programmes were stopped or reduced, and no vaccine was ever approved.

The Ebola outbreak started in 2014 and lasted until 2016. It was mostly contained to west Africa, with a few cases reported in Europe and the United States. The outbreak resulted in more than 28,600 people reported to be infected and 11,325 deaths[xxi]. Since then, treatments as well as vaccines have been

developed and approved by international consortia, but it took more than 3 years after the outbreak was contained. Indeed, the manufacturing site for the Ebola vaccine only received regulatory approval for producing the vaccine in 2019.

7. Summary and Conclusions

The sections above have given a brief survey of the manufacturing technologies behind many of the proposed treatment and vaccine candidates being developed in labs and clinics across the world. There is a wide range of technologies being investigated, and these technologies range in maturity from established commercial platforms to cutting edge laboratory developments. Once the treatments and vaccines are identified and demonstrated in the clinic, it will be necessary to manufacture them, and manufacture them on a truly world scale.

In the current environment of the global Covid-19 pandemic, it is necessary to take a hard look at the manufacturing capacity and response capabilities of the global pharmaceutical sector. It is apparent that even if there were a treatment and or vaccine discovered and approved within the next 3-9 months, that the current global capacity for manufacture of all vaccines is probably in the order of 1 billion doses in the first year (based on CDC figures of an annual flu vaccine doses in the US produced in 2019/2020 of 174.5 million[xxii]). Even this would require a significant cut-back in existing treatment and vaccine manufacture which could have significant impact in other areas – potentially creating an epidemic or pandemic risk in seasonal flu due to shortages or lack of ability to react to an unexpected strain emergence as has occurred in the very recent past[xxiii]. This reduction of production capacity in other vaccines or treatments would not be a viable option on the scale required for this global emergency.

Given the current known infection rates, and current efforts to limit infections, it is reasonable to assume that by the end of 2020 less than 200 million people may be infected by this disease. But the other 6,800 million people present the challenge. Sheltering in place for 5 years while the world slowly builds immunity (if that is even physiologically possible) or waits for the pharma industry to gradually deliver a working solution is not ideal. This becomes particularly challenging to imagine when, hundreds of mutations of COVID-19 have already been identified[xxiv] and continued modification of a development vaccine may be required.

The scientific community is in overdrive, there are currently at least 600 studies relating to Covid-19 registered with the NIH in the US[xxv]. It is time for the engineering and facility qualification industry to step up and deliver our expertise to the effort.

8. Where to Next?

We aim, in a series of articles, to layout a potential pathway forward on this manufacturing topic, with a particular focus on the vaccination element. The articles will deal with the following topics:

i. Where are we now? A review of current manufacturing technologies for the potential vaccine and treatment platforms.

ii. Where do we go next? A discussion of how to ensure sufficient manufacturing capacity. Can we utilize existing facilities and what is required in that case? Do we need to build new facilities and how can we do so as quickly as possible? How many new facilities may be required? Do we need new collaborations with non-traditional partners?

iii. How do we build it? Looking at an approach to deliver a manufacturing facility of significant scale in a quick timeframe in an environment where facility lead times are typically 3 years from inception to first batch for qualification.

iv. How do we continue to produce it? A view of qualification and continued manufacturing for a vaccine in this environment.

v. Who and how much? Financing and ownership of these facilities in the near and long-term will eventually become hot topics, but it is imperative on us to rise above this for the greater good. We will suggest methods for how this may be achievable in the immediate and long-term.

About Hyde Engineering + Consulting

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Global capabilities and offices throughout the United States, Europe and Asia gives Hyde clients the convenience of a single worldwide partner. Our staff of over 200 professionals are dedicated to understanding client needs and exceeding their expectations.

Regardless of the size of the facility or complexity of the project, Hyde provides peace of mind through global expertise.

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