

Hackathon Problem Statement

Summer 2020

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Background

In October 2019 you presented to a group of investors about your new Company, Xis, and the novel gene therapy product it was going to make...AND YOU WON! They granted you the funding and you started right away building and hiring. You are one year in and right on target with your project timeline!

You have submitted your novel gene therapy product to the FDA and you have an inspection for your newly designed & built facility that is coming up in Year 3.

Your investors want updates and to know that you are on track and they will see a solid ROI!

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But wait, there is more

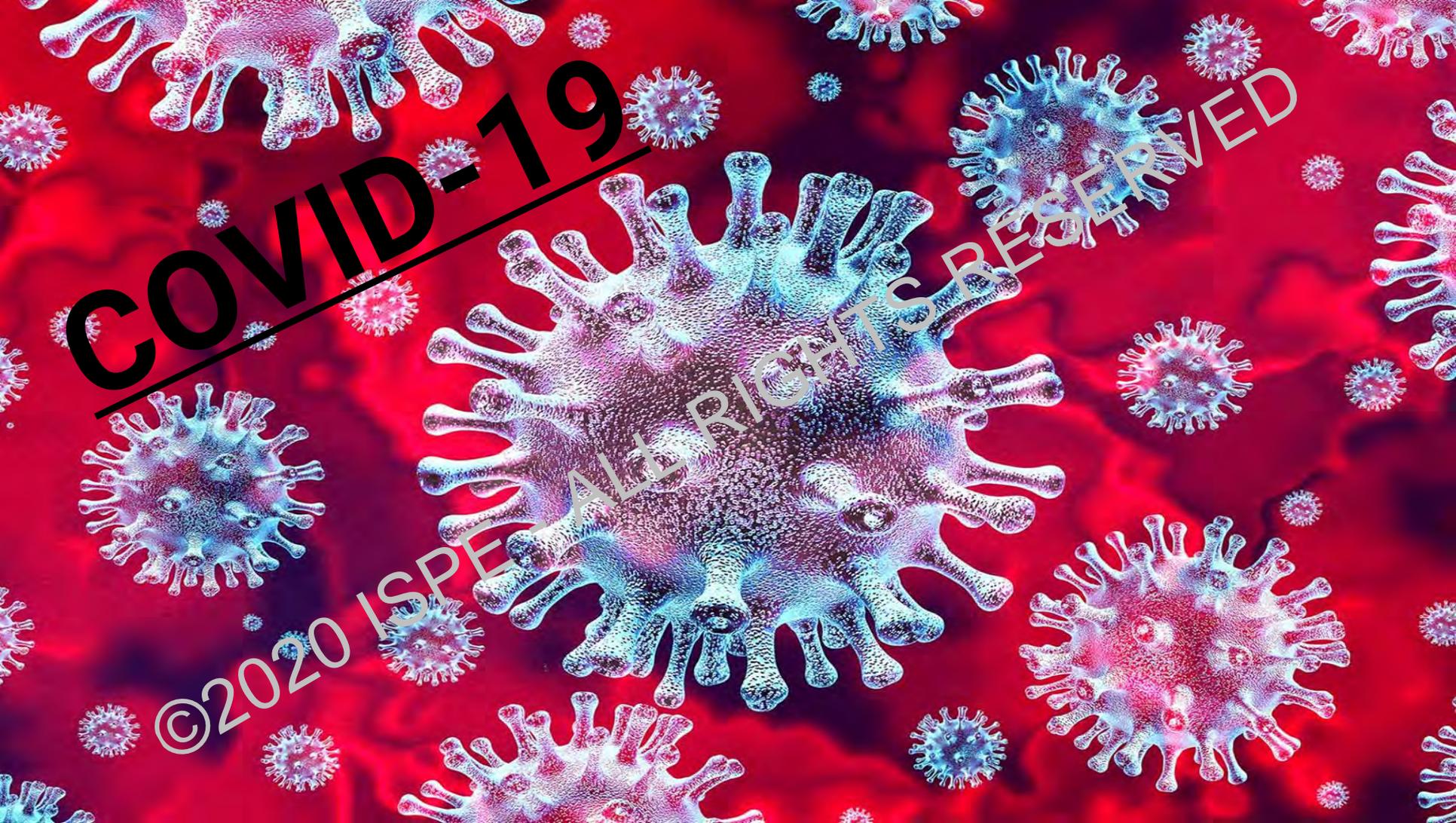
You have been seeing news articles about a novel virus outbreak in China, then it has spread to Europe.

Oh No, the US now has reported cases and just like that we are in a pandemic unlike anything we have seen in many generations!

What will happen to your project and timeline.....

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COVID-19

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A Bump in the Road!

2019				2020				2021				2022				
Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
			Technical Readiness													
		Non GMP Engineering/Tech Transfer Runs														
					GMP Readiness											
		Travel Restrictions and Shelter-In-Place Orders Begin			Today					Mock Audit Begins			FDA Audit - 01APR2022			

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Problem Statement

You are 3 months out from your first Engineering and Tech Transfer Runs, **and your Mock Audit and FDA Audit target dates have NOT changed!**

- You still have equipment being qualified but the SMEs now cannot travel.
- Manufacturing staff was completing Tech Transfer and Training but with travel now halted you are trying to re-group.
- Supply chains from around the world are impacted and you do not have a full stock of materials.

How do you pivot and keep the timeline moving, while re-grouping lost time and preparing for a new VIRTUAL Mock Audit of your facility!?

What now?

- Using your group's Hackathon timeline, break up the problem statement into the sections you feel are most important and can be successfully tackled.
- Each Sub-Team **select one area-of-focus**:
 - Tech Transfer
 - Process Performance Qualification (PPQ)
 - Good Manufacturing Practice (GMP) & Pre-Approval Inspection (PAI) Readiness.
- Make sure you state your area of focus clearly in your presentation.
- *Hint - Check out your Resource page for more details on what each area-of-focus consists of, including what regulatory bodies are now calling for under COVID19.*



Food For Thought

Use the following Key Ideas as a jumping-off point, to facilitate your team's research and discussion. Note that not all of these will be relevant to your Sub-Team's chosen area.

Key Ideas	
Personnel	What are the critical roles for this effort, and how do these roles and responsibilities change given circumstances? What roles can be done remotely, and how can we improve effectiveness of remote staff? How can we protect those who are required to be on-site?
Facility	What are the constraints due to the equipment and procedures already in place, and how can they be mitigated? What workarounds are possible for equipment that cannot be installed / qualified in time?
Supply Chain	How can the team address shortages? How can existing stock be used more efficiently?
Audit Procedure	How can an internal or 3rd party auditor ensure a rigorous mock inspection when executed virtually? What measures can be taken to enable rapid and effective follow up on any mock inspection findings in time for the FDA Audit Date?
Technology	How can new or underutilized technology help address new challenges around: <ul style="list-style-type: none">- Technical team collaboration- Impacted business processes- Safety- Security and Data Integrity

Presentation Guidance

- Elements you may want to include in your discussion and presentation:
 - A clear statement of the basis for your presentation, including the specific Area-of-Focus of each of your Sub-Teams. This will determine our judges' focus during final presentation.
 - A new timeline if required
 - What resources your "Company" needs under the new circumstances (people, time, money)
 - Novel ideas to move forward (this is where the out of the box thinking really comes into play).
 - Do not forget to include how new processes are implemented in practice - this will be technically challenging so have creative and cost-effective solutions.
 - Don't forget to take advantage of the expertise that your coaches (and any other SMEs you can identify) bring to the table!
- **BE CREATIVE!**

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